

Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances

**U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics
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Pursuant to section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Environmental Protection Agency (EPA) has prepared this initial regulatory flexibility analysis (IRFA) for the “TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances” proposed rule. The IRFA must include a discussion of the reason the agency is considering the proposed rule, as well as the objectives and legal basis for the proposal. It must also include a description and estimate of the number of small businesses that will be affected. It must describe the reporting, recordkeeping, and other compliance requirements of the proposed rule and must identify any federal rules that may duplicate, overlap, or conflict with the proposed rule. Finally, the IRFA must describe any significant regulatory alternatives to the rule that would accomplish the stated objectives of the applicable statutes and would minimize impacts to small businesses.

Section 607 of the RFA further notes that to comply with the IRFA requirements, the Agency must “provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.”

Based on the information available to EPA at the time the Notice of Proposed Rulemaking (NPRM) for this action published (86 FR 33926), EPA certified the proposed rule as not having a significant economic impact on a substantial number of small entities (No SISNOSE).¹ This certification under the RFA must have a factual basis for the claim, addressing both the number of small entities affected by the rule and the impact the rule will have on small entities. Since the NPRM published, EPA found additional data and received feedback via public comments to update its economic analysis, including estimating the number of PFAS article importers. EPA has since accounted for the burden that the rule would impose on article importers, including the burden on the number of article importers who will be required to report as well as the number of entities that will have to assess their previously manufactured (including imported) articles and products to determine whether they must submit reports. This updated information does not support a No SISNOSE certification for the previously proposed rule, therefore, EPA convened a Small Business Advocacy Review Panel. EPA is publishing this IRFA for public comment prior to issuing a final rule.

EPA has updated its estimate of costs for the proposed rule as proposed from approximately \$10.8 million to \$876 million in industry costs, as well as from \$948,078 to \$1.6 million in agency costs. As discussed further below, in the Summary of Impacts for Small Entities, the affected small businesses subject to the rule are expected to incur \$863,483,965 in costs for this one-time reporting. The distribution of per-firm costs for manufacturers are estimated to range from \$6,553 to \$1,800,068. Per-firm costs for article importers are estimated to range from \$4,046 to \$224,734.

In this IRFA, EPA first presents updates to the draft Economic Analysis that was published with the proposed rule, in response to SER interest. The remainder of the document then follows the more typical organization of an IRFA and includes the requisite discussions under the RFA.

1. Updates to the Economic Analysis

Since publishing the draft Economic Analysis, EPA has updated the industry estimates to include article importers as well as adjust certain cost estimates based on public and SER comments. Given the changes to the estimates and the SER recommendation to include updated burden, cost, and benefit discussions in the IRFA, this section of the IRFA discusses the cost estimates for all affected entities. For information specifically regarding small entities, see sections 4 (Description and Number of Small Entities Affected) and 7 (Small Business Impact Analysis).

A. INDUSTRY COSTS

Under the proposed rule, affected firms, including small entities, may perform the following activities:

- Rule Familiarization
- Article Importer Compliance Determination
- Form Completion
- CBI Claim Substantiation
- Recordkeeping
- Central Data Exchange (CDX) Registration and Electronic Signature

Note that certain information that is requested in the CDR that falls under TSCA section 8(a)(2)(A) through (G) would be required by this rule, such as information on specific chemical identity, categories of use, production volume, byproducts, and number of persons exposed and duration of exposure. In instances where PFAS manufacturers under this rule have already reported the requested information to EPA for that same year, they would not be required to re-report. As a conservative estimate that does not overstate costs to industry, EPA does not account for this duplicative reporting. However, EPA expects that most firms will need to submit some information under the rule, even if they have previously reported to CDR because the rule requests different information from CDR. Additionally, this rule requires reporting for each year since 2011 in which a PFAS was manufactured, whereas reporting is not required annually for CDR. In addition, firms that have not previously submitted information to CDR will need to submit data under the rule.

Rule Familiarization

The proposed rule requires reporting businesses and their staff to become familiar with the TSCA section 8(a)(7) rule and its various requirements. In the draft Economic Analysis, EPA estimated that the cost associated with rule familiarization would be approximately \$70 per firm with an associated 0.82 burden hours. Since publishing the draft Economic Analysis, EPA has updated the rule familiarization costs. Updated rule familiarization costs for this rule consist of two major components: (1) understanding the rule and its various requirements and (2) understanding the structural definition of PFAS.

For reporting firms, EPA assumes firms will spend 17 hours of technical labor and 7 hours of managerial labor to familiarize themselves with the reporting form (EPA 2020b). EPA recognizes that article importers have varying levels of knowledge about the chemical content of the articles they import and may not immediately know if they are subject to the rule. EPA anticipates that importers of articles that *may* contain PFAS will spend some time familiarizing themselves with the rule and then take steps to determine if they are subject to the rule's requirements (i.e., that they have manufactured a PFAS). EPA assumes that the importers of articles will spend 6.4 hours of technical labor and 2.85 hours of

managerial labor to familiarize themselves with the rule enough to perform compliance determination (see Article Importer Compliance Determination section for more information on this activity). If the article importers determine that they are subject to the rule's reporting requirements, EPA assumes article importers will spend an additional 10.6 hours of technical labor and 4.15 hours of managerial labor to fully complete rule familiarization (thus a total of 17 hours of technical labor and 7 hours of managerial labor).

In addition, firms need to familiarize themselves with the structural definition of PFAS. EPA assumes that manufacturing and importing firms and large article importers will have staff with the technical knowledge to understand a structural definition more easily. Therefore, manufacturing firms and large article importers are assumed to spend 4 hours of technical labor on familiarization with the structural definition of PFAS. Small article importers are assumed to spend 7 hours on familiarization with the structural definition of PFAS. EPA also assumes 10 percent of these small article importer firms will rely on consultant attorneys for help understanding the structural definition. The remaining 90 percent of firms are assumed to rely on in-house technical staff. To simplify the analysis, the burdens and costs of structural definition familiarization presented in Table 1 represent a weighted average of labor types. Several SERs commented that they may rely on outside help, ranging from chemists, accountants, to attorneys. Using Bureau of Labor Statistics' National Industry-Specific Occupational Employment and Wage Estimates to compare the annual hourly wages of these occupations, EPA uses attorney wages in this analysis as it provides a comparatively conservative estimate. EPA is soliciting public comment on the number of burden hours firms, particularly small firms, will spend on understanding the structural definition and if firms will contract any outside help.

It is expected that all firms in the potentially affected universe will undertake structural definition familiarization activity and some rule familiarization activity, including article importers that do not report under this rule.

Table 1: Per-Firm Industry Burden and Cost: Rule Familiarization (2021\$)

Reporting Activity	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Attorney	Technical	Managerial	Total	Attorney (\$121.28/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
Rule Familiarization: Non-Reporting Firms	0	6.4	2.85	9.25	\$0.00	\$521.25	\$265.20	\$786
Rule Familiarization: Reporting Firms	0	17	7	24	\$0.00	\$1,383.73	\$652.26	\$2,036
Structural Definition Familiarization for Manufacturing Firms and Large Article Importers	0	4	0	4	\$0.00	\$325.58	\$0.00	\$326
Structural Definition Familiarization for Small Article Importers	0.7	6.3	0	7	\$84.90	\$512.79	\$0.00	\$598

Note: Values may not sum due to rounding

Source: EPA 2009; BLS 2022a

Article Importer Compliance Determination

Importers may have varying levels of knowledge about the chemical content of the articles they import. The reporting standard would require reporting entities to evaluate their current level of knowledge of their imported articles, 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 requires that submitters conduct a reasonable inquiry within the full scope of their organization and may also entail inquiries outside the organization to fill gaps in the submitter’s knowledge. Therefore, this analysis estimates unit costs for article importers to perform the following activities to determine whether any articles they import contain PFAS:

- **Identify the type of imported articles that potentially contain PFAS.** This step involves reviewing the inventory of articles imported by the company and developing a list of the type of articles that are likely to be subject to the rule. This determination may be done based on an understanding of the uses of PFAS and the application of any *a priori* knowledge of the material and its manufacture to assess the probability of whether PFAS may be present. Costs will likely vary based on the number of articles imported and the complexity of those articles.
- **Identify suppliers involved.** The importer may choose to identify the suppliers from whom the articles identified in the previous step are imported. This involves examining the company’s existing records, and potentially contacting the suppliers to make them aware of the reporting requirements and the importer’s preferred data collection method. Costs will likely vary based on the number of articles imported, number of suppliers, and frequency of supplier changes.
- **Collect data from suppliers.** Importers may choose to obtain verification from identified suppliers that PFAS is or is not found in the article. There is currently no single, widely accepted standard procedure to identify regulated chemicals in supply chains. However, there are a number of organizations that help provide information on the content of articles, organize

declarations from suppliers, or certify suppliers based on materials or processes used¹. EPA does not expect companies to perform chemical testing on articles to determine if they contain PFAS, as this falls outside of the known or reasonably ascertainable standard. A range of activities may be involved depending on the level of experience of the importer. Companies may use a database system such as the Global Data Synchronization Network or BOMcheck or reach out to a trade association for support and guidance on supply chain management. Importers may also use individual agreements/certifications or questionnaires with their suppliers to ensure compliance with the rule. Costs will likely vary widely depending on the data collection method, number of articles, number of suppliers, and frequency of supplier changes.

- **Recordkeeping.** The importer may choose to keep records confirming the activities completed to determine if PFAS is present in articles.

EPA recognizes that there is a range of factors that make obtaining data on substances in articles from suppliers easier or more difficult and thus per-firm costs can vary significantly among entities (EPA 2014). EPA received several SER comments reinforcing how these factors could affect the ease and ability of entities in obtaining information. For example, one SER commented that proprietary information, long supply chains, and changing suppliers make obtaining information more difficult. They also mentioned that given their lack of leverage within the supply chain, small businesses may face more difficulties requesting information from suppliers. Additionally, another SER commented that the frequent changes in products make obtaining information more difficult.

Table 2: Factors Affecting the Ease of Obtaining Information on Substances

Factors Making Data-Gathering Easier	Factors Making Data-Gathering Harder
The importation of the product occurred recently	The importation of the product occurred years ago
The organization has well-maintained, electronic records	The organization has paper records and/or cannot readily locate records for the whole reporting timeframe
The organization requesting information is a major/important customer of the supplier	The requesting organization is not a key customer

¹ Note, the following are included as examples and do not necessarily reflect EPA’s endorsement:

- The Japan Green Procurement Survey Standardization Initiative (JSPSSI) developed the Joint Industry Guide (JIG) for Material Composition Declaration for Electronic Products, which is a standardized survey used to communicate the composition of chemicals in electronic products between suppliers and customers.
- The Global Data Synchronization Network (GDSN) is a customizable data management platform that enables companies to share information about their products with their trading partners.
- The International Material Data System (IMDS) is an online database that suppliers use to provide information on substances in the parts they sell to auto manufacturers.
- BOMcheck provides a resource for importers and product manufacturers to gather substance declarations from their suppliers.
- Green Seal is a global nonprofit organization that develops sustainability standards for products, services, and companies and offers third-party certification for those that meet the criteria in the standard.

The requesting organization has close or longstanding links with the supplier	The requesting organization switches suppliers frequently and/or the supplier is non-responsive
The supplier is a large, multinational company	The supplier is a small company
The supply chain is short and simple	The supply chain is long and/or complex
Products and processes remain unchanged for long periods	Product and process development is rapid, with frequent changes in substances used
There is no secrecy about production composition	The substance content of products is commercially valuable information and/or secret for other reasons
Source: Swedish Monitoring Board (2002) as cited in Risk and Policy Analysts Limited (2003) and several SER comments	

Any person required to report under this rule, as proposed, would supply the information to the extent it is known to or reasonably ascertainable by them, or a reasonable estimate when actual data are not available (i.e., known or reasonably ascertainable). Per SER recommendations, the scenarios below are intended to serve as a general guide of what EPA assumes article importers may or may not do as part of the compliance determination activities. These scenarios will not necessarily account for all the relevant circumstances of a particular entity.

General Scenarios Involving Company Changes

1. If a supplier is out of business (i.e., has not simply been spun off, merged, or acquired by another company; see discussion below), submitters would not need to contact them as the company no longer exists.
2. If a supplier has split into multiple companies, merged, or been acquired by another company, submitters may need to contact multiple entities to determine who has the relevant information.
 - a. One company becomes two companies (e.g., a division of Company X is separated from Company X to become Company Y)
 - i. Submitters may need to determine whether Company Y was created as the continuation of the part of Company X that previously supplied the pertinent article(s).
 - ii. If Company Y is the continuation of the part of Company X that supplied the pertinent article(s), then submitters should contact Company Y for information on all the supplying that Company X did during the calendar years of the reporting period, including the supplying that it did while it was a unit of Company X.
 - iii. If Company Y is not the continuation of the part of Company X that supplied the pertinent article(s), then submitters should contact Company Y only for information based on the supplying that it did during the calendar years of the reporting period and after it was created and contact Company X separately for information based on its own supplying.
3. Two companies become one company (e.g., (1) one company ceases to have a separate identity, because it has been combined into another company; or (2) two companies cease to have their separate identities, because they have combined to form a new company)

- a. The submitter may need to contact the resulting company about the combination of the supplying conducted by the original companies during the calendar years of the reporting period.
4. One company takes ownership of another company; the two companies maintain their separate identities (e.g., acquiring company buys at least 50% of the voting shares of an acquired company. The acquired company continues to exist as a separate legal entity.)
 - a. The submitter may need to contact the acquired company.
5. A part of one company becomes a part of a different company; two companies continue to exist (e.g., Company X combines with a part of Company Y, acquiring all of the assets of that unit of Company Y and assuming all of its liabilities. The remainder of Company Y continues to exist as a separate legal entity.)
 - a. The submitter may need to contact Company X about the supplying subject to the rule that it did during the calendar years of the reporting period including the supplying that the newly combined unit did before it combined with Company X.
 - b. The submitter may need to contact Company Y about any supplying subject to the rule that it did during the calendar years of the reporting period excluding the supplying that the divested unit did between those same calendar years.

General Scenario Involving Record Retention

6. EPA acknowledges that there may be submitters who do not have records going back to January 1, 2011, and for whom certain information (e.g., imported article inventory records, supplier records, etc.) is not known or reasonably ascertainable. If that is the case, reporting is not required under this rule as proposed. EPA recommends documenting why records do not exist for the full reporting period.

General Scenarios About Conducting Inquiry Within and Outside of an Organization

7. Submitters need not conduct extensive supply chain surveys. That is, they need not conduct a new survey of their suppliers by sending out a comprehensive set of identical questions to multiple suppliers for a given article type to fulfill the rule's reporting standard. However, fulfilling the reporting standard may entail inquiries outside the organization (e.g., contacting first tier/immediate suppliers, major suppliers, examining a supplier's public website) to fill in the gaps in the submitter's knowledge, where the submitter's current knowledge is less than what a "reasonable person similarly situated might be expected to possess, control, or know."
8. Stock Keeping Units (SKUs) are numbers that retailers assign to products to track inventory. If a product is available in different colors or sizes, each variation has a unique SKU number. When there are multiple like items with different SKUs (e.g., textiles made of the same fabric, but of different colors, sizes, and/or shapes), contacting each supplier and collecting requested data on each individual SKU may be beyond the scope of known to or reasonably ascertainable information. Note, if an importer has reason to believe that different items are made from different PFAS (e.g., if their supplier has indicated different PFAS were used in different products through different trade names), they are not considered like items for the purpose of this rule, as the items may be comprised of different reportable substances that each require reporting under section 8(a)(7).

9. Under the “known to” portion of the standard, a submitter must ascertain what it knows without confining its inquiry to what is known to managerial and supervisory employees. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (e.g., considering employees in research and development (R&D) or sales, and not limited to the information known to managerial or supervisory employees). The standard does not necessarily require that the submitter conduct an exhaustive survey of all employees. Additionally, it does not require submitters to contact former employees.
10. Submitters may collect information by checking third-party certifications and declarations through databases. Generally, these databases do not include chemical content information below certain de minimis levels. For example, the International Material Data System (IMDS) database has a default de minimis 0.1% reporting threshold, unless otherwise specified. Therefore, submitters may still attempt to contact suppliers to determine whether PFAS are present.

Other General Scenarios

11. As proposed, this rule does not require submitters to perform chemical analyses on articles or products to determine if they contain PFAS, nor does it require the generation of any other data that are not currently known to or reasonably ascertainable by the submitter.
12. EPA recognizes that some covered substances may not yet have CASRNs, and that other chemical identifiers (e.g., TSCA Accession Numbers, Low Volume Exemption numbers) may be more readily available than a CASRN in some cases. Reporters under this proposed rule need not apply for a CASRN or other identifier if one is not known or reasonably ascertainable. EPA notes that, although registering for a CASRN or other identifier is not a requirement of the proposed rule and therefore is not included in the Economic Analysis, multiple SERs discussed the cost and time associated with obtaining a CASRN, including manufacturers of R&D substances. EPA intends to provide such clarification in guidance accompanying the final rule. As noted in the notice of proposed rulemaking, EPA is interested in comments on whether the final rule should include a data field allowing reporters to provide generic names or descriptions in the event a manufacturer is aware they have produced or imported a PFAS but are not able to reasonably ascertain the specific PFAS identity.

In the draft Economic Analysis, EPA was not able to provide average per-firm cost estimates associated with identifying the type of imported articles that potentially contain PFAS and collecting data from suppliers as these activities are dependent on the number of PFAS these firms will report. Since publishing the draft Economic Analysis, EPA has estimated the number of article importers affected by the rule and the number of PFAS these firms will report. Table 3 presents updated estimates of the per-firm industry burden and cost of article importer compliance determination. EPA estimates each firm will spend an average of approximately \$3,916 on these activities. EPA is assuming that new reporters, including importers of articles, will not obtain attorneys to comply with the due diligence standard of known or reasonably ascertainable to determine potential reporting obligations. Though several SERs, specifically those representing importers of articles, identified that they will most likely obtain an attorney to determine their compliance obligation under EPA's reporting standard for this rule. The activities and cost derivations are discussed in more detail in *Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs* (EPA 2014). Note that several TSCA section 8 rules, including the Chemical Data Reporting (CDR) rule, and related guidance documents do not apply to importers of articles.

Firm: Per-Firm Industry Burden and Cost: Article Importer Compliance Determination (2021\$)

Activity	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
Identify the type of imported articles that potentially use PFAS ¹	0	13	0	13	\$0.00	\$1,058.15	\$0.00	\$1,058.15
Identify suppliers involved ²	17	7	0	24	\$631.99	\$569.77	\$0.00	\$1,201.76
Collect data from suppliers ³	0	20.2	0	20.2	\$0.00	\$1,644.20	\$0.00	\$1,644.20
Recordkeeping ⁴	0	0.15	0	0.15	\$0.00	\$12.21	\$0.00	\$12.21
Total	17	40	0	57	\$631.99	\$3,284.33	\$0.00	\$3,916.32

Sources: EPA 2014; BLS 2022a

¹ Actual costs may vary based on number of articles imported and the complexity of the article itself (number of components). Average of a range of 2 to 24 hours technical labor.

² Actual costs may vary depending on the number of articles imported, number of suppliers, and frequency of supplier changes.

³ Actual costs only apply to those companies that choose to collect data from suppliers. They will vary depending on the specific data collection method chosen. Total costs depend on considerations including the number of articles imported, number of suppliers, and frequency of supplier changes. Average of a range of 0.08 to 8 hours per article.

⁴ Actual costs may vary depending on recordkeeping system already in place.

If an importer determines that any article contains PFAS, they will be subject to the same reporting requirements as the PFAS manufacturers and are expected to incur compliance costs associated with form completion, CBI claim substantiation, recordkeeping, and CDX registration.

Article importers have varying levels of knowledge about the chemical content of the articles they import. The reporting standard would require reporting entities to evaluate their current level of knowledge of their imported articles, as well as conduct a reasonable inquiry within the full scope of their organization and may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. On the other hand, EPA believes that chemical manufacturers and bulk importers know which chemicals they are manufacturing. Therefore, they are not expected to take the same steps article importers will in order to assess if they need to report. EPA is soliciting public comment on whether there are compliance determination costs beyond those presented here for non-article importers.

Form Completion

The proposed rule requires one-time reporting of certain information, including specific chemical identity, categories of use, production volume, byproducts, environmental and health effects, number of persons exposed and duration of exposure, and disposal. All affected firms are required only to submit information that is known or reasonably ascertainable to them.

EPA estimates form completion burden and costs separately for manufacturers and article importers. Table 4 presents a summary of the estimated per-firm burden and costs associated with form completion. EPA estimates each manufacturing firm who reports will incur an average of approximately 507 burden

hours and \$41,152 in costs per firm. Note, this burden estimate for manufacturing firms has not changed since the draft economic analysis was published, although EPA is now able to estimate the per-firm form completion costs for article importers. Table 5 presents estimated per-firm burden and costs for article importers. EPA estimates that each article importer who reports will incur an average of approximately 138 burden hours and \$11,003 in costs per firm. Note that the proposed rule requires some reporting elements to be reported for each chemical, site, and/or year subject to the rule. Table 4 and Table 5 aggregate all burden and cost estimates to the firm level using the average number of reports per firm (average of 5.85 PFAS per-firm for manufacturers and average of 5 PFAS per-firm for article importers).

Table 4: Per-Firm Industry Burden and Cost: Manufacturer Form Completion (2021\$)

Reporting Element	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
1 Company and plant site information	0.00	0.024	0.009	0.0330	\$0.00	\$1.95	\$0.84	\$2.79
2 Common or trade name, chemical identity, and molecular structure	10.24	26.33	5.85	42.41	\$380.59	\$2,142.75	\$545.10	\$3,068.44
3 Byproducts	0.00	2.93	0.00	2.93	\$0.00	\$238.08	\$0.00	\$238.08
4 Categories of use	0.00	26.00	10.65	36.65	\$0.00	\$2,116.56	\$992.09	\$3,108.65
5 Total production volume	0.00	50.19	12.69	62.89	\$0.00	\$4,085.51	\$1,182.87	\$5,268.38
6 Occupational exposure	0.00	78.98	0.00	78.98	\$0.00	\$6,428.25	\$0.00	\$6,428.25
7 Environmental release and disposal	0.00	55.58	0.00	55.58	\$0.00	\$4,523.58	\$0.00	\$4,523.58
8 Environmental and health effects data	0.00	227.45	0.00	227.45	\$0.00	\$18,513.36	\$0.00	\$18,513.36
Total	10.2	467.5	29.2	506.9	\$380.59	\$38,050.05	\$2,720.90	\$41,151.54

Note: Estimates may not sum due to rounding
Sources: EPA 1994; EPA 2018a; EPA 2018b; BLS 2022a

Table 5: Per-Firm Industry Burden and Cost: Article Importer Form Completion (2021\$)

Reporting Element	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
1 Company and plant site information	0.00	0.016	0.006	0.0220	\$0.00	\$1.30	\$0.56	\$1.86
2 Common or trade name, chemical identity, and molecular structure	8.75	22.50	5.00	36.25	\$325.29	\$1,831.41	\$465.90	\$2,622.60
3 Byproducts	0.00	0.00	0.00	0.00	\$0.00	\$0.00	\$0.00	\$0.00
4 Conditions of use	0.00	22.23	9.10	31.33	\$0.00	\$1,809.03	\$847.94	\$2,656.96
5 Total production volume	0.00	2.15	0.54	2.69	\$0.00	\$174.59	\$50.55	\$225.14

6	Occupational exposure	0.00	67.50	0.00	67.50	\$0.00	\$5,494.23	\$0.00	\$5,494.23
7	Environmental release and disposal	0.00	0.00	0.00	0.00	\$0.00	\$0.00	\$0.00	\$0.00
8	Environmental and health effects data	0.00	0.03	0.00	0.03	\$0.00	\$2.03	\$0.00	\$2.03
	Total	8.8	114.4	14.6	137.8	\$325.29	\$9,312.60	\$1,364.95	\$11,002.83

Note: Estimates may not sum due to rounding

Sources: EPA 1994; EPA 2018a; EPA 2018b; BLS 2022a

1. Company and plant site information

Each reporting site would need to provide the following information:

- Site information (e.g., site name, site address, technical contact name)
- Parent company information (e.g., company name, company address)

EPA estimates a total of 0.006 hours of managerial burden and 0.016 hours of technical burden per site to report parent company and site identification information (EPA 2018a).

Manufacturers: Assuming an average of 1.5 sites per manufacturing firm, EPA estimates firms will require approximately 0.10 hours of managerial burden and 0.024 hours of technical burden to report company and plant site information.

Article importers: EPA assumes each article importer will require 0.006 hours of managerial burden and 0.016 hours of technical burden to report parent company and site identification information.

2. Common or trade name, chemical identity, and molecular structure

The proposed rule requires submitters to report the following information for each chemical they manufacture or import that is subject to the rule's reporting requirements:

- Chemical or generic name
- Chemical ID
- Trade name or common name
- Molecular structure
- Physical state of chemical or mixture that contains the chemical substance

EPA estimates firms will require 1.5 to 2 hours of clerical labor, 3 to 6 hours of technical labor, and one hour of managerial labor to report chemical identity and molecular structure information (EPA 1994).

Manufacturers: Using the midpoint of these estimates and assuming an average of 5.85 reports per firm results in estimated burdens of 10.24 hours of clerical labor, 26.33 hours of technical labor, and 5.85 hours of managerial labor per firm.

Article importers: Using the midpoint of these estimates and assuming an average of 5 reports per firm results in estimated burdens of 8.75 hours of clerical labor, 22.5 hours of technical labor, and 5.0 hours of managerial labor per firm.

3. Byproducts

For each chemical at each reporting site, the proposed rule requires the following information:

- Byproduct chemical or generic name

- Byproduct chemical ID
- Indicate if byproduct is from manufacture, process, use, or disposal
- Indicate if byproduct is released to the environment; if yes, indicate the environmental media they are released to
- Byproduct volume released

EPA estimates that a description of byproducts will require 0.5 hours of technical labor per report per site (EPA 1994).

Manufacturers: Assuming 3.9 reports per site and 1.5 sites per firm, EPA estimates approximately 2.93 hours of technical burden for reporting byproducts.

Article importers: EPA does not expect that this reporting element will be applicable to article importers, and thus assumes that article importers will not incur any burden to report byproducts.

4. Categories of use

The proposed rule will require submitters to report the following information on categories of use for each chemical at each reporting site:

- Industrial processing and use – Type of process or use
- Industrial processing and use – Sector(s)
- Industrial processing and use – Function category
- Consumer and commercial use – Product category
- Consumer and commercial use – Function category
- Consumer and commercial use – Consumer or commercial
- Consumer and commercial use – Used in products intended for children
- Consumer and commercial use – Maximum concentration

The burden estimates differ for industrial uses and consumer and commercial uses (EPA 2018a). To estimate a single average burden estimate for reporting categories of use across all types of uses, this analysis therefore weights the industrial use and consumer and commercial use burdens by the percentage of each type of use observed in the 2016 CDR for PFAS manufacturers. The 2016 CDR indicates that approximately 25 percent of firms manufacture PFAS for use in consumer products (EPA 2020a). This analysis therefore further weights burdens by either 75 percent (Industrial use) or 25 percent (Consumer and Commercial use) to derive a weighted average burden per chemical.

EPA is not able to determine the average number of years per chemical for which firms will submit data under the rule. In the absence of these data, EPA (2018a)'s estimate for four reporting years is assumed to be a reasonable approximation for the number of years for which a firm will report data under the rule.

Manufacturers: EPA estimates an average of 26.00 hours of technical burden and an average of 10.65 hours of managerial burden per firm for reporting categories of use.

Article importers: EPA estimates an average of 22.23 hours of technical burden and an average of 9.1 hours of managerial burden per firm for reporting categories of use.

5. Total production volume

Each reporting site would be required to report the following elements, to the extent known or reasonably ascertainable:

- Production volume domestically manufactured at each site

- Production volume imported at each site
- Indication if imported but never physically at site
- Volume directly exported
- Industrial processing and use - % production volume
- Consumer and commercial use - % production volume
- Maximum first 12 months production volume
- Maximum yearly production volume in any 3 years

EPA is not able to determine the average number of years per chemical since 2011 for which firms will submit data under the rule's one-time reporting requirement. Several SERs commented that based on their current recordkeeping, they would not be able to report on older information. Many commented that their records span back seven years at the most and that much of the reportable information will not be known to or reasonably ascertainable. In the absence of data and based on industry comments, EPA (2018a)'s estimates for four reporting years is assumed to be a reasonable approximation for the number of years for which a firm will report data under the rule.

Manufacturers: EPA estimates 50.19 hours of technical burden and 12.69 hours of managerial burden per firm for reporting production volume.

Article importers: EPA estimates an average of 2.15 hours of technical burden and 0.54 hours of managerial burden per firm for reporting production volume. EPA anticipates that only the subset of importers who know the concentration of PFAS in their imported articles will be able to report production volume information. These estimates therefore reflect EPA's assumption that only 5% of importers will submit production volume information.

6. Occupational exposure

Each reporting site would be required to report the following elements, to the extent known or reasonably ascertainable:

- Worker activity descriptions at manufacturing site
- Number of workers reasonably likely to be exposed at the manufacturing site, for each worker activity
- Maximum duration of exposure for any worker, for each worker activity
- Number of workers reasonably likely to be exposed for each industrial process and use
- Maximum duration of exposure for any worker for each industrial process and use
- Number of workers reasonably likely to be exposed for each commercial use
- Maximum duration of exposure for any worker for each commercial use

EPA estimates this activity will require 13 to 14 hours of technical labor per report per site (EPA 1994).

Manufacturers: Using the midpoint of 13.5 hours per report and assuming 3.9 reports per site and 1.5 sites per firm, EPA estimates approximately 78.98 hours of technical burden per firm to report occupational exposure information.

Article importers: Using the midpoint of 13.5 hours per report and assuming 5 reports per firm, EPA estimates approximately 67.5 hours of technical burden per firm to report occupational exposure information.

7. Environmental release and disposal

Each reporting site would be required to report the following elements, to the extent known or reasonably ascertainable:

- Description of disposal process(es)
- Description of any changes to the disposal process or methods since 2011
- Total volume released (land disposal)
- Total volume released (water)
- Total volume released (air)
- Total volume incinerated (on-site)
- If incineration occurs: the temperature at which the chemical was incinerated
- Total volume recycled (on-site)
- Maximum quantity stored on-site at any time

EPA estimates this activity will require 9 to 10 hours of technical labor per chemical per site (EPA 1994).

Manufacturers: Using the midpoint of 9.5 hours per report and assuming 3.9 reports per site and 1.5 sites per firm, EPA estimates approximately 55.58 hours of technical burden per firm to report environmental release and disposal information.

Article importers: EPA does not expect that this reporting element will be applicable to article importers, and thus assumes that article importers will not incur any burden to report environmental release and disposal information.

8. Environmental and health effects data

Each reporting site would be required to report the following elements for each chemical with a consumer use, to the extent known or reasonably ascertainable:

- All existing information concerning the environmental and health effects of such substance or mixture.

For this proposed rule, EPA proposed requiring firms to report data using the Organisation for Economic Co-operation and Development's Harmonised Templates (OHTs; or "templates"). The OHTs are standardized formats for reporting information on chemicals, including physical properties, production and use, and effects on human health and the environment (OECD 2018). In addition to allowing reporting for a particular endpoint value (e.g., pH, biodegradation, aquatic toxicity), the OHTs are intended to summarize administrative data about the quality of the studies and publications associated with those endpoints (e.g., test materials, study design, study period).

This analysis assumes that firms will submit environmental and health effects data using templates under the Biotic Systems group (19 templates) and the Health Effects group (31 templates). Each template contains a range of fields for the submitter to report, such as endpoint value, study period, test materials, descriptions of materials and methods, descriptions of test organisms, study design, analytical monitoring, test conditions, and results and discussion.

This analysis assumes that 12 hours of technical time will be required to complete each template, which is equivalent to the burden time needed to complete a robust summary for a TSCA section 8(d) health and safety study (EPA 2018b). A robust summary for a TSCA section 8(d) health and safety data rule typically includes a description of the test substance, methods, results, conclusions, data quality descriptions, and references associated with a full study, which is similar to the data fields required for the Biotic Systems and Health Effects templates. Based on historic rates of environmental and health studies submitted to EPA under TSCA section 8(d), each firm that submits

a report is assumed to submit an average of 18 studies (templates) per chemical (9 in the Biotic Systems group and 9 in the Health Effects group). Thus, the burden per chemical is estimated at 216 hours of technical labor.

EPA expects that only a small subset of reporting firms will have these data available to submit. This analysis therefore assumes that 18 percent of firms will submit data, which is derived from the historic percentage of firms that have submitted health and safety studies to EPA under TSCA section 8(d) rules (EPA 2018b).

Manufacturers: Assuming 18 percent of firms will submit data and 5.85 chemicals per firm, EPA estimates an average of approximately 227.5 hours of technical burden per firm to report environmental and health effects data.

Article importers: EPA does not expect article importers to possess any environmental and health effects study data, and thus assumes that article importers will not incur the same burden as manufacturers for this reporting element. However, a small percentage of article importers may have existing information on health and environmental effects from product Safety Data Sheets or similar statements from third-party databases. EPA therefore assumes that 1% of article importers will spend 0.5 hours of technical burden per report. This results in an average of 0.03 hours per firm (1% x 0.5 hours x 5 reports per firm) to report environmental and health effects data.

CBI Claim Substantiation

TSCA requires that anyone seeking protection of confidential business information under TSCA must assert a claim and, for certain information, may be required to substantiate that claim. As described in the accompanying Notice of Data Availability for this IRFA, any CBI claim for a PFAS' identity must comply with CBI requirements under section 14(c)(1)(C), including by providing a sufficient generic name. For the purposes of this proposed rule, a generic name for a PFAS should note that it is a fluorinated chemical (i.e., should include "fluor" in its generic name). The Act lists information that is generally not subject to substantiation requirements. Furthermore, the Act states that health and safety data submitted for substances in commercial distribution or for which testing or notification is required under TSCA are not protected as CBI. Based on this, the reporting elements of this proposed rule for which a submitter might need to substantiate a claim of CBI, if a claim is made, include but are not limited to:

- Submitter information
- Chemical identity²
- Physical properties
- Production volumes and product concentrations
- Byproducts
- Environmental release
- Worker exposure information

² Under TSCA, claims regarding chemical identity are subject to specific substantiation requirements, and the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—(i) be consistent with guidance developed by EPA; and (ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure. A confidentiality claim cannot be asserted for chemical identities listed on the public portion of the TSCA Inventory.

- Description of disposal process(es)

In the draft Economic Analysis, EPA assumed that 25% of submissions include a CBI claim that requires substantiation and estimated that labor cost associated with CBI claim substantiation was approximately \$561 per firm. Since publishing the draft Economic Analysis, EPA has updated the CBI claim substantiation cost methodology to provide more accurate estimates. The previous analysis assumed that the information that is required for a submitter to substantiate a CBI claim is similar to the information described at 40 CFR 2.204(e)(4). EPA ICR No.1665.14 (OMB Control No. 2020-0003), Renewal of Existing Information Collection Request for Confidentiality Rules describes EPA’s process for requesting substantiation of CBI claims from submitters to make a final confidential determination in response to a FOIA request or in the course of rulemaking or litigation and provides estimates of burden associated with completing substantiations based on information identified at 40 CFR 2.204(e)(4). After reviewing the estimates, EPA determined that using the burden estimates from EPA’s (2011) Inventory Update Reporting (IUR) Economic Analysis would be a more accurate method to estimate CBI substantiation for this rule as it is a more similar activity. According to the economic analysis, submitters spent 4.38 hours on each substantiation type reviewing the information, preparing the response, and submitting the response to the Agency (assumed to be 0.36 clerical hours, 2.49 technical hours, and 1.53 managerial hours). EPA assumes that assertion is accomplished via checking a box when completing the form, so the burden is included in the form completion estimate.

According to CDR data (EPA 2020a), 10% of the reports claim the company, site, technical contact, or authorized official as CBI, and 6% of reports claim other data as CBI that requires upfront substantiation. Thus, EPA estimates that 16% of submissions include a CBI claim that requires substantiation. The average per-report burden as described above is adjusted accordingly (e.g., 4.38 hours x 16% = 0.7 hours).

Table 6: Per-Firm Industry Burden and Cost: CBI Claim Substantiation (2021\$)

Reporting Activity	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
Manufacturers								
CBI Claim Substantiation	0.34	2.33	1.43	4.10	\$12.53	\$189.70	\$133.44	\$335.67
Article importers								
CBI Claim Substantiation	0.29	1.99	1.22	3.50	\$10.71	\$162.14	\$114.05	\$286.90
Note: Values may not sum due to rounding								
Source: EPA 2020a; EPA 2011; BLS 2022a								

Recordkeeping

The proposed rule requires manufacturers (including importers) subject to the reporting requirements to retain documentation of information contained in their reports for five years from the date of submission. EPA estimates that each report will require 0.5 hours of clerical labor and 0.5 hours of technical labor per report to maintain records (EPA 1994). Note, this burden estimate has not changed since the draft economic analysis. However, EPA has since estimated the average number of reports per article importer and is now able to include the per-firm recordkeeping costs for importers of articles.

EPA acknowledges that there may be submitters who do not have records going back to January 1, 2011, and for whom certain information (e.g., imported article inventory records, supplier records, etc.) is not known or reasonably ascertainable. If that is the case, reporting is not required under this rule. EPA recommends documenting why records do not exist for the full reporting period.

Table 7: Per-Firm Industry Burden and Cost: Recordkeeping (2021\$)

Reporting Activity	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
Manufacturers								
Recordkeeping	2.93	2.93	0	5.86	\$108.93	\$238.49	\$0.00	\$347.42
Article importers								
Recordkeeping	2.50	2.50	0	5.00	\$92.94	\$203.49	\$0.00	\$296.43
Note: Values may not sum due to rounding								
Source: EPA 1994; BLS 2022a								

CDX Registration and Electronic Signature

Firms that submit a report to EPA will incur a one-time cost associated with registering with EPA’s Central Data Exchange (CDX) in order to comply with electronic reporting requirements. Respondents will incur electronic reporting costs to register with CDX and provide an electronic signature. These activities occur only once for each submitter.

The one-time burden associated with CDX registration and e-signature is estimated at approximately 2.67 hours per firm (EPA 2009). Note, this burden estimate has not changed since the draft economic analysis. These activities are estimated to require the following burden hours:

- **CDX registration.** EPA estimates that a firm will spend approximately 11 minutes per employee to register with CDX, and that an average of four technical staff members and one manager would need to register for each firm, totaling approximately 0.92 hours per firm.
- **CDX electronic signature.** EPA estimates that a firm would spend 0.25 hours preparing, submitting, and filing an electronic signature agreement (Authentication of Identity) form to EPA per employee. This burden would apply to four technical staff members and one manager per firm, totaling 1.25 hours per company. In addition, EPA estimates that a manager would spend an additional 0.50 hours accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by a firm submitting and then verifying electronic signature agreements is 1.75 hours. Note that this burden does not include any additional time required to contact EPA’s CDX help desk to notify a change of submitter status, should one occur. Filing the electronic signature agreement requires an additional mailing cost of \$3.15 per company (including five \$0.58 stamps³ and five \$0.07 business envelopes⁴).

As shown in Table 8, the estimated cost of CDX registration, electronic signature, and mailing activities is approximately \$231 per firm.

³ Price for a stamp was taken from the U.S. Postal Service website on April 8, 2022. (See USPS 2022).

⁴ Price for an envelope was determined based on the per unit price of a regular business envelope. See “Staples® #10, Self-Sealing Envelopes, 500/Box.” Available at: <http://www.staples.com/> (Accessed 4/8/2022).

As a conservative estimate, it is expected that each firm that submits a report will undertake this activity. Some submitters may already have registered to use the e-TSCA web reporting tool in CDX (and obtained an accompanying electronic signature) to comply with the mandatory electronic reporting requirements of EPA’s e-PMN rule and/or IUR/CDR rule. Those submitters will not need to repeat the CDX registration and e-signature process to file their reports. While there may be some overlap in the specific individuals that have already completed CDX activities, EPA is conservatively expecting that all firms that submit a report under this rule will need to register with CDX. Therefore, this economic analysis may overestimate the burden and cost associated with this activity.

Table 8: Per-Firm Industry Burden and Cost: CDX Registration and Electronic Signature (2021\$)

Reporting Activity	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total
CDX Registration	0	0.73	0.18	0.92	\$0.00	\$59.69	\$17.08	\$76.77
Electronic Signature	0	1.00	0.75	1.75	\$0.00	\$81.40	\$69.89	\$151.28
Mailing cost (non-labor)	-	-	-	-	-	-	-	\$3.25
Total	0	1.73	0.93	2.67	\$0.00	\$141.09	\$86.97	\$231.30

Note: Values may not sum due to rounding
Source: EPA 2009; USPS 2022; BLS 2022a

Summary of Impacts

Table 9 presents the total estimated industry burden and costs for all affected entities. As shown in the table, affected firms subject to the rule are estimated to incur approximately 11,917,931 burden hours and \$875,994,972 in costs for this one-time reporting.

EPA notes that there is a high degree of uncertainty related to article importers. Due to a lack of data on the number of articles that contain PFAS, this analysis made a number of assumptions to quantify the universe of affected article importers. This includes assumptions regarding the number of firms undertaking compliance determination activities, the type of compliance determination activities, the number of firms importing articles that contain PFAS, the number of articles per firm, and the level of knowledge of each firm about the PFAS content of their imports. Each of these assumptions introduces additional uncertainty into the industry burden and cost estimates of the rule. EPA conducted a sensitivity analysis related to the number of PFAS reported on under the proposed rule, the number of affected article importers, and the number of article importers expected to report under the proposed rule in Appendix D.

Table 9: Total Industry Burden and Costs (2021\$)

Activity	Number of Affected Firms	Average Burden per Firm (hours)	Total Burden (hours)	Average Cost per Firm (2021\$)	Total Cost (2021\$)
Manufacturers					
Rule Familiarization and Structural Definition Familiarization	234	28	6,552	\$2,362	\$552,609
Form Completion	234	507	118,616	\$41,152	\$9,629,460
CBI Claim Substantiation	234	4	959	\$336	\$78,547
Recordkeeping	234	6	1,371	\$347	\$81,295
CDX Registration and Electronic Signature	234	3	624	\$231	\$54,125
<i>Manufacturer Total</i>	<i>234</i>	<i>548</i>	<i>128,123</i>	<i>\$44,428</i>	<i>\$10,396,037</i>
Article Importers					
Rule Familiarization: Non-Reporting Firms	118,041	9	1,091,878	\$786	\$92,833,513
Structural Definition Familiarization for Large Article Importers	1,839	4	14,323	\$326	\$1,165,854
Structural Definition Familiarization for Small Article Importers	129,318	7	893,030	\$598	\$76,251,208
Rule Familiarization: Reporting Firms	13,116	24	314,776	\$2,036	\$26,703,370
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	13,116	138	1,807,462	\$11,003	\$144,309,397
CBI Claim Substantiation	13,116	4	45,957	\$287	\$3,762,880

Recordkeeping	13,116	5	65,578	\$296	\$3,887,874
CDX Registration and Electronic Signature	13,116	3	34,975	\$231	\$3,033,709
<i>Article Importer Total</i>	131,157	90	11,789,809	\$6,600	\$865,598,935
Industry Total	131,391	-	11,917,931	-	\$875,994,972

B. AGENCY COSTS

Since publishing the draft Economic Analysis, EPA has updated the agency estimates, which were previously estimated to be approximately \$948,078 for this one-time reporting. EPA assumes that the collection and administrative activities (technical labor) associated with Agency responses to the rule will be accomplished by a GS-13, Step 5 federal employee in the Washington-Baltimore-Northern Virginia area. See appendix A for agency wage rates.

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 (IT) infrastructure. EPA expects that two full-time equivalents (FTEs) of technical Agency staff time will be needed for data processing, including time to gather report format requirements, programmatic time to quality check the data, and time to review CBI chemical identity and other CBI claims. In addition, EPA estimates \$10,000 of contractor support will be required to create reports from the data. EPA further estimates that one FTE of technical staff time will be needed for analysis and data use for different programs throughout the Agency. EPA proposed requiring firms to report environmental and health effects data by attaching the relevant OECD template to their submission in CDX. EPA estimates a cost of approximately \$880,000 to the Agency for completing IT infrastructure startup tasks to allow for all the reporting under this rule in CDX.

Table 10 summarizes the total Agency hours and costs associated with administering the rule. As shown in the table, Agency hours and cost are estimated to total approximately 6,240 hours and \$1,581,083 for this one-time reporting.

Table 10: Total Agency Burden and Costs (2021\$)

EPA Activity	Burden (hours)	Cost (2021\$)
Data Processing	4,160	\$460,722
Data Analysis	2,080	\$230,361
Contractor Data Processing Support	-	\$10,000
IT Infrastructure	-	\$880,000
Total Agency Burden and Cost	6,240	\$1,581,083

C. TOTAL SOCIAL BURDEN AND COST

The total burden and cost to society includes the burden and cost to industry and the cost to the Agency. As shown in Table 11, the estimated total cost to society associated with this rule is \$877,576,055, with an associated burden of 11,917,931 hours.

Table 11: Total Social Burden and Cost (2021\$)

Type	Burden (hours)	Cost (2021\$)
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Industry	11,917,931	\$875,994,972
Agency	N/A	\$1,581,083
Total Social Burden and Cost	11,917,931	\$877,576,055

D. BENEFITS

Since publishing the draft Economic Analysis, EPA has updated the description of the benefits of the proposed rule to include more detail on how various offices within EPA will use the data collected under this rule, as well as how external stakeholders such as state and local governments, non-governmental organizations, and private-sector organizations, will utilize this data. The proposed rule is an information-collecting rule and does not attempt to reduce risks related to PFAS. This benefits analysis does not seek to quantitatively measure the associated benefits and does not formally identify or define the universe of recipients of those benefits.

The proposed rule will provide information on PFAS to which the Agency (or the public) does not currently have access. Several SERs and commenters raised concerns that information sought under this rule lacks practical utility, particularly for articles that are no longer in commerce or for information on PFAS at de minimis concentrations, present as by-products or impurities, or used for research and development purposes. Nonetheless, EPA believes that this information has value and aims to better understand the scope of existing information on manufactured PFAS and would not otherwise have knowledge of PFAS that have been manufactured as byproducts, impurities, or below de minimis levels due to multiple reporting exemptions in other rules such as CDR and TRI.

The formation of PFAS byproducts is not well understood but is expected to occur during manufacturing, including when manufacturers are not directly using PFAS in the manufacturing process. Understanding the types of manufacturing processes and reactions that can form PFAS, or transform certain PFAS into different chemicals, may provide useful insights for characterizing exposure and risk for PFAS. While byproducts may, or may not, in themselves have commercial value, they are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose. (40 CFR 704.3 and 40 CFR 720.3). EPA understands that certain waste management activities (e.g., incineration) may manufacture PFAS coincidentally, and the Agency would not otherwise have information related to their manufacture without this data gathering rule. Additionally, there may be byproducts of particular concern to the environment and human health. Some PFAS that have been linked to adverse health effects have been coincidentally manufactured as byproducts. For example, some long-chain PFAS are byproducts of the manufacturing process for fluorinated polyolefins (EPA 2022) and GenX chemicals hexafluoropropylene oxide dimer acid and its ammonium salt can be produced as a byproduct of some manufacturing processes (EPA 2021).

EPA has both the authority and the interest in receiving any existing or reasonably ascertainable data on PFAS, even in de minimis levels. Due to the strong carbon-fluorine bonds of PFAS, they are stable in the environment and resistant to biodegradation, photooxidation, direct photolysis, and hydrolysis. Some PFAS have been detected at high levels in wildlife, including higher trophic organisms, indicating that at least some PFAS have the ability to bioaccumulate (ATSDR 2021). Historical PFAS information, even below the de minimis level, is still important and relevant given that PFAS are resistant to environmental and metabolic degradation and this high persistence may mean that their continual release will result in accumulating environmental concentrations. Given the highly persistent nature of PFAS, EPA believes that it is important to understand the uses and universe of PFAS in a current and historical context to fully characterize exposure and risk associated with PFAS. By enhancing the data supplied to Agency risk-screening programs, EPA expects to more effectively and expeditiously evaluate any

potential risks 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, EPA believes that enhancing the risk screening process will have positive consequences for human and environmental health and may enable a more efficient allocation of EPA's and society's resources.

Market Failure

When buyers or sellers do not have perfect information, rational decision making cannot occur, and a market failure exists. Information regarding the hazards or exposures associated with a chemical substance may not be widely known for several reasons. In one case, known as asymmetric information, consumers and producers do not have the same level of information regarding the aggregate production, uses, and hazards of a chemical substance. Because information is a public good, producers are reluctant to provide information (that is, businesses may perceive the high costs of collecting and disclosing information to be greater than the benefits from increased access to chemical information). Individual consumers are simultaneously unlikely to be willing to pay the cost of collecting and reporting information if they can use information developed and paid for by others.

In addition to concerns about these direct costs, industry may have a disincentive to disclose data due to the possibility of liability or regulation (Applegate 1991). For example, some firms releasing TRI data saw a negative response in financial markets, indicating further reasons why businesses may be reluctant to disclose information (Konar and Cohen 1997). As a result, data on the chemicals subject to the rule may not be available in a manner that is optimal for society.

Benefits of Information-Based Policies

Increased and improved data on the production and use of PFAS in the U.S. would allow EPA and other federal agencies to use the data more effectively as part of screening and prioritization programs. Screening chemicals for potential risks is an essential step in developing and prioritizing risk management activities. Effective risk-screening by EPA depends on the ability to characterize chemical uses accurately and to predict potential exposures. Current screening activities are greatly hampered by the incomplete and inconsistent nature of available data. In addition, EPA's current screening activities are further hampered by the fact that EPA must rely on relatively limited public sources of information. This rule may benefit EPA by filling in these information gaps and contributing to better assessments of potential risks and risk management decisions. It may also help identify information gaps that may be filled using other EPA authorities.

The proposed rule will increase EPA's knowledge by providing the agency with significant exposure-related data on PFAS, as well as certain existing health and environmental effects information, and consequently is likely to result in (a) a reduction in the cost of risk-based decision making about a PFAS, and (b) an improvement in the expected outcome of the decisions.

- **Reduced cost of risk-based decision making.** By making new information about PFAS available to EPA and other government agencies, this rule may be able to replace other information-gathering, management, and dissemination activities related to PFAS.
- **Improved outcome of decisions.** Information-based policies contribute to better decisions by redirecting resources toward their most highly valued uses. With incomplete information regarding toxic chemicals, federal decision makers are not able to assess adequately the benefits and costs of actions that involve these substances. EPA decisions regarding whether, when, and how to target PFAS for further risk assessment could be misdirected if basic risk-screening information is unavailable or inadequate. With more information to fill gaps in the current understanding of the benefits and risks of PFAS,

EPA can better direct its limited resources toward high-priority risks. Improved information can therefore help lead to more socially optimal reductions in risks to humans and the environment.

The proposed rule may generate both types of benefits. First, it could provide existing data that are otherwise unavailable to EPA and reduce EPA's reliance on databases and information sources that are inadequate for accurately characterizing the risks associated with the PFAS in commerce that need to be evaluated and potentially regulated. EPA will bear the cost of processing and managing the data; however, by providing more data on PFAS uses and exposures, the proposed rule will also allow EPA to save time and resources in screening chemicals and in developing risk management priorities. Additionally, the information received under this rule may help EPA better understand the landscape of existing information on PFAS in commerce and could reduce the need for additional activities to provide necessary data for prioritization, risk evaluation, and risk management.

Secondly, the proposed rule might allow EPA to better identify candidates for its prioritization, risk evaluation, and risk management activities—to move more quickly in addressing PFAS that pose relatively high risks (and/or relatively low risk-management costs). For example, potential problems from incomplete information may include the initiation of prioritization for a relatively lower risk or higher risk-management cost PFAS, resulting in unnecessary effort and resource expenditures for both regulated parties and EPA in cases where adequate data would have led the Agency to act differently. Similarly, if a business cannot provide adequate data for its product, that product may be subject to regulations which are unsuitable for its true hazard level (Applegate 1991). In these cases, it is in the best interest of the business to disclose information about its chemical production. Reporting through TSCA ensures the public that the chemical information provided by firms is credible, and thus is more likely to be utilized efficiently (Cohen and Santhakumar 2007). As described by Konar and Cohen (1997), information provision can also serve as informal regulation, providing financial incentives for reducing behaviors which may lead to negative externalities. However, some commenters have expressed concern that the utility of data reported under this rule may be limited by poor historical record keeping and low data quality.

Potential Users of Information Generated by the Proposed Rule

As EPA learns more about the family of PFAS, the Agency can do more to protect public health and the environment. A growing body of scientific evidence shows that exposure at certain levels to specific PFAS can adversely impact human health and other living things. But while the universe of PFAS has rapidly expanded over the years, significant gaps remain related to the impacts of many PFAS on human health and in the environment as well as the understanding of the universe of PFAS. Each of these chemicals has different properties and may be used for different purposes or may simply be present as unintended byproducts of certain manufacturing or other processes. The toxicity of PFAS varies, and people may be exposed to each chemical in different ways and in varying amounts. Robust information about PFAS is needed to better understand the risks they pose, and the data gathered from the proposed rule may help EPA fill some gaps and may inform future Agency regulations and actions. EPA is expected to be the primary user of the information generated by the rule and will evaluate the data quality and robustness of information received as part of its consideration of potential uses. Depending on the type of information submitted and for which PFAS under this rule, data submitted may be applied and disseminated by EPA and other federal agencies in several ways; however it will primarily serve to reduce the costs of screening and managing chemical risks and to improve risk management decisions. If information received under this rule can be used to improve risk management decisions, then the rule could help to better target risk management activities to the areas where the net benefits (i.e., risk reductions net of control costs) are expected to be the largest.

EPA anticipates the following potential uses for the data collected from the proposed rule. EPA seeks comment on these potential uses of data collected under this rule. EPA's future use of data collected under this rule is contingent on ensuring that data quality is adequate and fit for the intended purpose.

Office of Pollution Prevention and Toxics (OPPT) Programs

EPA's OPPT would be able to use information collected on production volumes, categories of use, disposal, byproducts, and worker-related information in future screening-level assessments of potential exposure to these PFAS. OPPT's New Chemicals program ensures the safety of new chemicals, including new PFAS, prior to their entry in US commerce. Where unreasonable risks are identified during the review process, EPA must mitigate those risks before any manufacturing activity can begin. Given the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, EPA is looking at PFAS that it has previously reviewed through the TSCA New Chemicals program as well as revisiting past PFAS regulatory decisions and addressing those that may be insufficiently protective. The data gathered from this rule will help the Agency review previous actions and ensure existing PFAS are being used in ways that do not present concerns.

Additionally, OPPT screens existing chemicals on the TSCA Inventory to identify potential risks and determine whether more detailed assessments should be undertaken. With the data currently available, EPA does not have the information needed to effectively and systematically screen most PFAS, some of which may not even be included in the TSCA Inventory. This rule would supply exposure-related information that the Agency does not currently have, recognizing that industry has a greater knowledge than EPA about its own operations and the uses of chemicals it manufactures and/or sells. Without this information, EPA may: (1) not screen these chemicals, (2) screen them using outdated or anecdotal exposure information, or (3) screen them but rely on exposure estimates using modeling data. Therefore, data collected as a result of this rule may improve the Agency's ability to screen PFAS in commerce, allowing the Agency to better focus its chemical screening programs and to identify potentially risky situations earlier than otherwise possible.

OPPT may also be able to use information collected from this rule to improve the Agency's modeling data for other chemicals undergoing review. In the absence of sufficient measured data for a chemical undergoing review, chemical analogs may be used to predict environmental and human health effects. Depending on the type of information submitted and for which PFAS under this rule, data submitted may serve as analogs for other chemicals undergoing prioritization and improve the Agency's modeling data.

PFAS continue to be released into the environment throughout the lifecycle of manufacturing, processing, distribution in commerce, use, and disposal. Each action in this cycle creates environmental contamination and the potential for human and ecological exposure. PFAS-containing articles play a role in the contribution of PFAS to the environment through their use, degradation, and disposal. However, the extent of those exposures as well as the prevalence of PFAS is poorly understood because there is no comprehensive source of information on many of the PFAS that are used in different types of articles. By including article importers in this rule, EPA would have more historical information about PFAS than the Agency would not have otherwise. Data gathered from this rule would help the Agency better understand the sources and quantities of PFAS, the universe of PFAS and the firms involved, and better account for the full lifecycle of PFAS. Additionally, to the extent the requested information is not known to or reasonably ascertainable by a manufacturer or importer of PFAS (including articles), EPA may have a greater understanding of existing data gaps concerning the presence of PFAS in commerce, which would help inform the Agency's work going forward under the PFAS Strategic Roadmap.

Additionally, the gathered data could be used to inform development of future existing chemical Significant New Use Rules (SNURS) and complement EPA's testing authority under TSCA section 4 to improve EPA's knowledge of environmental and health effects information and inform EPA's Testing Strategy, if data quality is sufficient. The data gathered under this rule will also complement PFAS data submitted under other reporting rules (TSCA Chemical Data Reporting; the Toxics Release Inventory) and may improve EPA's ability to conduct data quality checks on those datasets.

Other EPA Programs

Additionally, other EPA offices' regulatory and non-regulatory programs could benefit from information collected, such as data on the manufacturing, processing, use, disposal, releases, and other waste management methods of PFAS as well as the environment and health effects data. Many offices across EPA are fulfilling directives under the Agency's PFAS Strategic Roadmap and this first nationwide dataset on PFAS, production, use, disposal, and exposure-related information could complement these activities and provide necessary screening-level data.

The collected data could help the Office of Land and Emergency Management understand the level of contamination and current risks posed by PFAS to surrounding communities and inform future regulatory and non-regulatory actions. Under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), EPA can designate a substance as "hazardous", which enhances the Agency's ability to add sites containing such substances to the Superfund National Priorities List and provides the Agency the authority to compel parties responsible for the pollution to pay for the cleanup of the site or pursue cost recovery. The data collected could also help EPA list certain PFAS as hazardous waste under RCRA, where they would become subject to the RCRA regulations – a "cradle-to-grave" management system from the point of generation through transportation to treatment and disposal at a RCRA facility. RCRA treatment, storage, and disposal facilities are subject to permit and corrective action.

The Office of Air and Radiation (OAR) could use the collected data to potentially identify sources of PFAS air emissions and increase understanding of the hazards associated with certain PFAS. More specifically, the collected data would increase OAR's ability to 1) characterize the magnitude of various PFAS species being released from various sources in the U.S., 2) estimate the transport, deposition, and fate of PFAS air emissions, resulting exposure pathways, and health impacts, 3) site monitors to collect ambient and deposition data, 4) evaluate technologies that are effective at mitigating PFAS air emissions, 5) identify and prioritize office needs for hazard and dose-response assessments to characterize risk for both inhalation and ingestion exposures. The Clean Air Act requires EPA to regulate emissions of hazardous air pollutants (HAPs), which are pollutants that are known or suspected to cause cancer or other serious health effects. The Office of Air and Radiation uses data from other ongoing EPA activities, such as field tests and TRI submissions to better understand the sources and releases of chemicals and inform decisions on designating certain chemicals as HAPs. Unfortunately, data collected under the TRI program is limited and does not provide all the necessary emissions data. The TRI program does not provide the level of detail needed for the EPA to fully characterize inhalation risks for these pollutants and only a small subset of the PFAS subject to this rule are also subject to TRI reporting. The collected data could help build the technical foundation of PFAS air emissions to inform future decisions on designating certain PFAS as HAPs.

PFAS air emissions from various chemical plants, industrial sources, and other sectors are not well characterized. How and the extent to which PFAS-containing waste material in the United States is disposed is not fully documented or understood as many PFAS are not listed as hazardous wastes under

RCRA or HAPs under Clean Air Act regulations, so they are not subject to the tracking systems associated with these regulations. Products known to contain PFAS are regularly disposed of in landfills and by incineration, which can lead to the release of PFAS. The information collected from this rule could help EPA better understand the destruction and disposal of certain PFAS-containing materials.

The Office of Water (OW) could use the collected data to inform decision making on various actions. Information related to chemical use and disposal; sources and quantities; and data on environmental and health effects can inform the listing of contaminants under the Contaminant Candidate List (CCL) under the Safe Drinking Water Act (SDWA). Contaminants under the CCL are currently not subject to any proposed or promulgated National Primary Drinking Water Regulation (NPDWR) but are known or anticipated to occur in public water systems. These data may help OW identify contaminants that may present the greatest public health concern related to exposure from drinking water. Additionally, these data can support OW in identifying priority contaminants for regulatory decision making (through the regulatory determinations process) and information collection (through the Unregulated Contaminant Monitoring Rule or UCMR). Data generated by the Rule can specifically inform the regulatory determinations process under SDWA by supporting the Agency's evaluation on whether a contaminant meets certain criteria for regulation: whether a contaminant may have adverse effects on the health of persons; whether the contaminant is known to occur or there is a substantial likelihood the contaminant will occur in public water systems with a frequency and at levels of public health concern; and finally, in the sole judgment of the Administrator, whether regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. If EPA makes a decision to regulate a particular contaminant, the data generated by the rule may also support the Agency's rulemaking process to establish a NPDWR. The collected health effects data would also inform EPA toxicity assessments for drinking water health advisories, which are developed to help Tribes, states, and local governments inform the public and determine whether local actions are needed to address public health impacts in these communities. The data collected by the Rule may also inform a variety of Clean Water Act actions to include: implementation of infrastructure funding to address emerging contaminant challenges; assessment of National Pollution Discharge Elimination System (NPDES) discharges on downstream drinking water sources or effluent toxicity; NPDES pretreatment standards for industrial users; informing the understanding of optimal options for ensuring influent quality and treatment technology selection for potable reuse treatment; States' implementation of surface water contaminant screening levels or standards; equity and environmental justice studies and assistance to disadvantaged communities negatively impacted by PFAS pollution; and development of additional standard methods for PFAS compounds.

EPA's Office of Research and Development (ORD) is the scientific research arm of the EPA. ORD conducts research for EPA that informs Agency decisions and supports the emerging needs of EPA stakeholders. The collected data could be used as inputs to ORD's assessment, research, and data compilation activities, such as Integrated Risk Information System (IRIS) assessments and other research and assessment activities, if data quality is adequate. To accelerate EPA's ability to address PFAS, EPA is working to break the large, diverse class of PFAS into smaller categories based on similarities across defined parameters, such as chemical structure, physical and chemical properties, and toxicological properties. Data collected from the rule could provide data to help EPA develop these smaller categories for further hazard assessment and to inform hazard- or risk-based decisions. Additionally, EPA will continue to develop human health toxicity assessments for individual PFAS under EPA's IRIS Program, and, if needed, other fit-for-purpose toxicity values. When combined with exposure information and other important considerations, EPA can use IRIS toxicity assessments to assess potential human health risks to determine if, and when, it is appropriate to address these

chemicals. Most PFAS, however, have limited or no toxicity data to inform human health or ecological toxicity assessments. Data from the rule could help ORD better understand human health and ecological toxicity across a wider variety of PFAS by potentially providing additional existing, relevant scientific information on PFAS environmental and health effects.

Data from the rule may also potentially inform priorities for targeted development of analytical methods for detection and measurement of PFAS in the environment and might potentially increase scientific understanding of exposure pathways by providing information on PFAS releases to the environment or other potential routes of human and environmental exposure. Such release information may also inform Agency research on PFAS management and release control practices. Data submitted on disposal practices may also be used to help prioritize efforts to evaluate the effectiveness of different treatment, destruction, and disposal technologies.

The collected data may also benefit cross-program efforts, such as helping EPA establish a voluntary stewardship program challenging industry to reduce overall releases of PFAS into the environment. From the data gathered from this rule, EPA could identify potential participants for a voluntary stewardship program and streamline industry outreach for this type of endeavor. EPA is initiating actions under multiple environmental authorities—RCRA, TSCA, CWA, SDWA and CERCLA—to identify past and ongoing releases of PFAS into the environment at facilities where PFAS has been used, manufactured, discharged, disposed of, released, and/or spilled. The collected data from this rule could also help EPA identify these facilities for compliance and enforcement follow-up under these environmental authorities. This may also help the Agency quality check its various public databases, such as CDR, TRI, and NEI, that collect information on certain PFAS.

This information may also improve EPA's ability to conduct assessments of contamination, including analyses of potential environmental justice impacts. Many known and potential sources of PFAS contamination are near low-income communities and communities of color. EPA may be able to use information collected from this rule to better understand PFAS exposure pathways in disadvantaged communities and help the Agency determine to what extent PFAS pollution contributes to the cumulative burden of exposures from multiple sources in these communities.

External Stakeholders

Addressing PFAS contamination is an important part of EPA's mission to protect human health and the environment, as evidenced by the PFAS Strategic Roadmap. EPA cannot achieve its goals of preventing and mitigating potential health and environmental concerns of PFAS exposure without better understanding the lifecycle of PFAS in the United States and communicating with communities, individuals, businesses, the media, and tribal, state, and local partners about the known and potential health risks associated with exposure to these chemicals. The Agency plans to publish non-CBI information collected from this rule. EPA may update its online analytical tools with exposure and hazard information and could also provide the CompTox Chemistry Dashboard with toxicity information. The historical and more recent data collected from this rule may enhance the public's understanding of the potential risks associated with PFAS exposure, the amount of PFAS manufactured and imported to the US, and the variety of uses of PFAS.

Comments received during this proposed rule's public comment period and in other stakeholder outreach activities indicate that there is significant interest among external stakeholders to use data that will be submitted through this rule. State and local governments plan to use information on the volumes, types, uses, and disposal of manufactured PFAS to inform their own actions addressing PFAS exposures and potential contamination. States across the country are working to increase their understanding of

PFAS and address the public health and environmental challenge of PFAS contamination and exposure. The publicly available information collected under the proposed rule would assist states' evaluations of PFAS manufactured, imported, used, and released into the environment. The New Jersey Department of Environmental Protection commented that without this rule, states would need to expend substantial resources to obtain the information that will be collected through this rule (EPA-HQ-OPPT-2020-0549-0062-A1). The Attorneys General of several states also commented that states have begun to regulate PFAS-containing products, and the collected information about PFAS in articles could help states understand the extent of potential exposures and improve their knowledge of various products that may contain PFAS, their categories of use, and production volumes (EPA-HQ-OPPT-2020-0549-0086). Despite the prevalence of PFAS in commerce, there are currently no federal standards for tracking and managing the disposal of articles containing PFAS. Additionally, there are no readily available estimates of the quantities of PFAS discarded in waste or the method of their disposal. The collected disposal data from this rule could help states better understand the disposal of PFAS and aid in their efforts protect public health. According to a study by the Tishman Environment and Design Center at the New School in New York City, the vast majority of municipal solid waste incinerators in the United States are located in communities with environmental justice concerns (Baptista 2019). Collected disposal data could also help states better understand the cumulative burden of pollution in communities with environmental justice concerns within their respective states.

Additionally, EPA is required under TSCA section 9(e) to provide information related to certain exposures or releases of a chemical substance or mixture to other EPA offices and other federal agencies upon request if such information may help prevent or reduce exposures to or releases of a chemical substance or mixture under another federal law. Information related to exposures or releases, as well as any health and safety information, could be useful for other federal agencies currently working to address various health and environmental concerns from PFAS (such as the Department of Defense, the Centers for Disease Control and Prevention, and the National Institute for Occupational Safety and Health).

Many private-sector organizations have a strong interest in reducing risks and providing leadership in preventing pollution while still maintaining productive economic enterprises. Comments received during this rule's public comment period indicate that there is interest among industry to reduce the use of certain PFAS substances that have the largest environmental and health impacts (EPA-HQ-OPPT-2020-0549-0113). These organizations may be able to better meet these objectives by developing a better understanding of PFAS exposure, hazard, and toxicity information in general. The publicly available collected data may allow them to manage risks and participate in community, regional, and national priority setting for chemicals more effectively.

The publicly available information collected under the proposed rule could also support activities typically undertaken by non-governmental organizations (NGOs), such as organizing grassroots involvement in risk-based decision-making and conducting outreach and educational programs. If data quality is sufficient, these organizations may be able to use the new data to identify and establish priorities for risks; to evaluate chemicals and chemical use patterns to determine areas of concern; to identify and promote pollution prevention opportunities; and to focus pollution prevention, public outreach, and education initiatives and activities.

The EPA is hopeful that the information collected under the reporting rule may allow for improved understanding of releases and potential contributors to water systems. The effect of the reporting rule on understanding impacts to water systems will depend on the nature of information that companies have collected in the past. The utilities sector may also use this collected data to better understand upstream

industrial sources of PFAS entering the treatment works. The American Water Works Association, the Association of Metropolitan Water Agencies, and the National Association of Clean Water Agencies commented that this one-time reporting rule has the potential to alleviate costly state-wide sampling programs to determine industrial sources of PFAS as well as burdensome industrial pretreatment investigations to identify these same industries potentially sending PFAS to publicly owned wastewater treatment works (POTWs) (EPA-HQ-OPPT-2020-0549-0046-A1).

2. Need for the Rule

Section 7351 of the FY2020 National Defense Authorization Act (NDAA) amended the Toxic Substances Control Act (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 perfluoroalkyl and polyfluoroalkyl substances (PFAS) in any year since 2011 to report and maintain records, for each year, information described in TSCA 8(a)(2). 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.

In the *Federal Register* of June 28, 2021 (86 FR 33926 (FRL-10017-78)), EPA proposed a rule pursuant to TSCA section 8(a)(7). EPA's proposed rule would require all manufacturers of PFAS in any year since 2011 to report certain information to EPA related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal (i.e., the section 8(a)(2) requirements). EPA also proposed a five-year retention period for all relevant records following the submission period.

3. Objectives and Legal Basis for the Rule

EPA proposed this rule pursuant to its authority in TSCA section 8(a)(7) (15 USC 2607(a)(7)). The National Defense Authorization Act for Fiscal Year 2020 (Pub. L. No. 116-92 7351) amended TSCA section 8(a) on December 19, 2019, by adding section 8(a)(7), titled *PFAS Data*. Section 8(a)(7) requires EPA to promulgate a rule “in accordance with this subsection requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance 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).” 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 to fulfilling statutory obligations under TSCA, this proposed rule will enable EPA to better characterize the sources, quantities, and uses of manufactured PFAS in the United States, for which no comprehensive dataset exists.

TSCA section 8(a)(5) requires EPA, to the extent feasible, not to require reporting which is unnecessary or duplicative; minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and apply any reporting obligations to those persons likely to have information relevant to the effective implementation. TSCA section 14 imposes requirements for the assertion, substantiation, and review of information that is claimed as confidential (also known as confidential business information (CBI)).

4. Description and Number of Small Entities Affected

The RFA defines small entities as including “small businesses,” “small governments,” and “small organizations” (5 USC 601). The regulatory provisions proposed by EPA for this rulemaking are expected to affect a variety of small businesses but would not affect any small governments or small organizations. The RFA references the definition of “small business” found in the Small Business Act, which authorizes the Small Business Administration to further define “small business” by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201.

The proposed rule would affect firms, including small businesses, that currently or have previously manufactured (defined by statute at 15 U.S.C. 2602(9) to include import) PFAS in any year since January 1, 2011, including in imported articles. For the purpose of this rule, EPA proposed to define “PFAS” using a structural definition: any per- and polyfluorinated substances that structurally contain the unit R-(CF₂)-C(F)(R')R”. Both the CF₂ and CF moieties are saturated carbons. None of the R groups (R, R' or R'') can be hydrogen. EPA identified at least 1,364 chemical substances and mixtures that are PFAS and would be subject to reporting under the rule, using chemicals listed as active on the TSCA Inventory (i.e., known to be in United States commerce after June 2006) and new chemicals that were submitted as TSCA Section 5 Low-Volume Exemptions (including those withdrawn). The active TSCA Inventory includes PFAS that are identified by Chemical Abstracts Service (CAS) number, confidential chemicals whose generic names contain “fluor” and are identified by Accession number, and confidential chemicals whose generic names do not contain “fluor” and therefore are not listed by CAS or Accession numbers. Of the 1,364 identified PFAS subject to reporting under the rule, EPA has identified 203 PFAS whose generic names do not contain “fluor.” EPA is separately soliciting comment on whether generic names must be sufficiently detailed to identify the reported chemical as a PFAS. Specifically, on whether 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). Note that EPA has required the submission of generic names for the public list of the confidential chemical substances manufactured or processed for a commercial purpose in the United States since the initial TSCA Inventory, *see* 42 FR 64572, 64574 (Dec. 23, 1977), and the Agency recently updated guidance⁵ on this requirement due to the Lautenberg amendments in TSCA section 14 (EPA 2018c). Submitting generic names in accordance with TSCA section 14 has no connection to, nor does it impose any requirements regarding, rebranding or changes to the composition of the chemical substance or mixture.

The scope of the rule would still include any other PFAS that meets the proposed structural definition.

TSCA requires EPA to compile, keep current and publish a list of each chemical substance that is manufactured or processed, including imports, in the United States for uses under TSCA. EPA designates chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. Manufacturers and processors are required to notify EPA before reintroducing inactive substances into U.S. commerce. If a chemical substance is not on the TSCA Inventory, then it is not manufactured or imported in the US for uses under TSCA, though it is possible it could be in an article imported into the US. Therefore, EPA believes that PFAS not on the Inventory or with an LVE are less likely to be in US commerce and reported on as the primary way they enter US commerce is through article importation, if at all. EPA conducted a sensitivity analysis related to the

⁵ See <https://www.epa.gov/tscainventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting>

number of PFAS expected to be reported on in Appendix D. EPA is soliciting public comment on the number of identified PFAS that EPA expects would be reported under this rule.

Under TSCA section 8(f), this rule is limited to manufacturing (including importing) TSCA chemical substances for commercial purposes. Unlike some other section 8(a) reporting rules, such as the Chemical Data Reporting (CDR) rule, EPA proposed this rule to include all PFAS manufacturers, with no exceptions or reporting exemption including those provided for small manufacturers. EPA expects that this rule will affect small business manufacturers (including importers, such as importers of articles) in the following North American Industry Classification System (NAICS) categories:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities could also be affected. For a detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, please, see Appendix C.

Since publishing the draft Economic Analysis (EA), EPA has since updated the estimates of affected firms to include article importers. In the proposed rule, EPA estimated that 25% of the firms covered by the proposed rule would be small businesses, or a total of 59 small businesses would be potentially subject to the rule. However, EPA also clarified that these estimates did not include article importers, given limited data available at the time of the proposed rule's publication. Based on EPA's updates to the Economic Analysis, EPA now estimates that 93% of manufacturers and 97% of article importers affected by the rule are small businesses for a total of 129, 544 affected small firms. Specifically, 218 small PFAS manufacturers and 127,576 small article importers may be affected.

Although article importers are, by virtue of the inclusion of "import" in the definition of "manufacture" under TSCA section 3, inherently a subset of manufacturers and would be covered by the proposed rule, EPA is distinguishing the estimated burden, costs, and reporting universes for article importers and non-article importers in the following discussions. For the sake of brevity, EPA will denote non-article importers (e.g., domestic producers, bulk importers) as simply "manufacturers," unless otherwise stated.

Small Business Manufacturers

EPA estimates that 234 manufacturing firms will report under this proposed rule. Using employment and revenue distribution data from the Census' Statistics of U.S. Businesses (SUSB) to estimate the percentage of firms that are small, EPA estimates that 93% of manufacturers affected by the rule are small businesses. The percentage of businesses that are small for NAICS with employment-based small business definitions are calculated using the 2019 SUSB by detailed employment size (U.S. Census Bureau 2022), while the percentage of businesses that are small for NAICS with revenue-based small business definitions are calculated using the 2017 SUSB by revenue, with revenues inflated to 2021\$. Thus, 218 small manufacturers are expected to be affected by this proposed rule.

To estimate the number of small manufacturers impacted, EPA first estimates the total regulated manufacturing firms using the subset of manufacturers reporting to the 2016 CDR rule. A total of 115 affected chemicals were reported in the 2016 Chemical Data Reporting (CDR) data (EPA 2020a). The

firms manufacturing or importing these 115 chemicals do not represent the complete universe of affected firms because they do not include firms that:

- Manufacture or import a PFAS that is not on the TSCA Inventory
- Manufacture or import a PFAS in volumes below the CDR reporting threshold of 25,000 lbs. (or 2,500 lbs. for chemicals that are the subject of certain TSCA actions)”
- Are considered “small manufacturers” and exempt from CDR⁶
- Commenced manufacture or import of the PFAS after the 2016 CDR reporting cycle
- Ceased manufacture or import of the PFAS before the 2016 CDR reporting cycle

The CDR data also does not represent the complete universe of affected substances because the database generally does not include substances that are:

- Certain byproducts, including byproducts:
 - not used for commercial purposes;
 - If its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes;
- listed at 40 CFR 711.10(d)(1)(i) and recycled or otherwise used within a site-limited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was generated, and when the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or manufactured in the same overall manufacturing process; or
- byproducts manufactured solely in either pollution control equipment or boilers use for on-site heat or electricity generation)
- Impurities
- Non-isolated intermediates
- Manufactured solely in small quantities for research and development

This analysis uses the subset of manufacturers reporting to the 2016 CDR rule to estimate the average number of sites per firm and the average number of PFAS per site. EPA estimates an average of 1.5 sites per firm and an average of 3.9 PFAS per site for the non-CBI firms reporting to CDR, resulting in an average of 5.85 PFAS per firm. In the absence of information about the non-represented firms identified above, EPA makes the simplifying assumption that these averages for the manufacturers reporting to CDR are representative of those that do not report to CDR. EPA solicits public comment on this simplifying assumption, and welcomes submission of information that could support a more informed estimate.

Consistent with the draft Economic Assessment published with the proposed rule, an estimated 234 manufacturing firms and 351 sites are expected to be subject to this rule’s reporting requirements. See Table 12 for calculations of these estimates. Of these 234 manufacturing firms, 218 firms are small. EPA notes that there are some uncertainties regarding the estimates for affected manufacturing firms.

⁶ A manufacturer (including importer) of a substance is considered a “small manufacturer” under CDR if it meets one of two standards: (1) Its total annual sales during the principal reporting year, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer); (2) Total sales during the principal reporting year, combined with those of the parent company, are less than \$120 million and the annual production volume of that chemical substance does not exceed 100,000 pounds at any individual plant site (40 CFR 704.3). Firms who meet this standard would be considered “small manufacturers” under the existing section 8(a)(1) definition, and these firms are generally exempt from CDR (except for substances that are the subject of certain TSCA actions, which are not eligible for the CDR small manufacturer exemption).

Given the lack of data on PFAS manufactured, including by small manufacturers, as byproducts, impurities, research and development substances, and other chemical substances not on the TSCA Inventory, it is possible that the number of PFAS per firm could be higher than 5.85 and that more than 218 small business firms would be impacted. That being said, EPA received public comments that many companies would not have information on byproducts and impurities without testing, which is beyond the known to or reasonably ascertainable standard. Additionally, EPA believes that PFAS not on the TSCA Inventory are less likely to be in U.S. commerce and therefore less likely to be reported. EPA is also estimating that all 1,364 identified PFAS will be reported, which may not be the case.

As shown in Table 12, of the 1,364 identified PFAS on the TSCA Inventory and with LVEs, 115 PFAS were reported under the 2016 CDR rule. As previously discussed, EPA makes the simplifying assumption that the averages for the manufacturers reporting to CDR are representative of those that do not report to CDR. Therefore, to estimate the number of affected manufacturing firms that did not report to CDR, EPA takes the remaining chemicals (1,249) and divides them by the average number of PFAS per firm (5.85) to get 214 affected firms. Note, based on how the number of affected manufacturing firms was estimated, the average PFAS per firm directly influences the estimate. EPA conducted a sensitivity analysis related to the number of PFAS expected to be reported on in Appendix D.

If the number of PFAS per firm is higher than 5.85, then EPA's estimate for number of affected manufacturing firms could potentially be an overestimate based on the calculations shown in Table 12. For example, if the average number of PFAS per firm is 10, then the estimated number of affected manufacturing firms decreases to 125 firms ($1,249/10 = 125$). Conversely, if the number of known or reasonably ascertainable PFAS per firm is lower than 5.85, then EPA's estimate for the number of affected manufacturing firms could potentially be an underestimate. For example, if the average number of PFAS per firm is 4, then the estimated number of affected manufacturing firms increases to 312 firms ($1,249/4 = 312$).

Table 12: Estimated Number of Affected PFAS, Manufacturing Firms, and Manufacturing Sites

CDR Reporting Status	Number of Chemical Substances	Number of Affected Manufacturing Firms	Number of Affected Manufacturing Sites
	A	$B = A \div 5.85$	$C = B \times 1.5$
PFAS reporting to CDR	115	20	30
PFAS not reporting to CDR	1,249	214	321
Total	1,364	234	351
Source: EPA 2020a			

Note that certain information that is requested in CDR and TSCA section 5 Premanufacture Notices (PMN) is similar to the information that would be required by this rule, such as information on specific chemical identity, categories of use, production volume, byproducts, and number of persons exposed and duration of exposure. Note that all new chemical substances, whether or not a PFAS, must be submitted as a PMN (or LVE) unless otherwise exempt. Therefore, EPA has been receiving PFAS PMNS since the 1980s if the substance is not already on the TSCA Inventory. In instances where PFAS manufacturers under this rule have already reported the requested information to EPA under CDR for that same year, they will not be required to re-report. However, EPA expects that most firms who previously reported to CDR or through section 5 will need to submit additional information under the rule, even if they have previously reported to CDR or submitted a PMN because the proposed rule

requests different information than either CDR or PMN forms. Additionally, this rule requires reporting for each year since 2011 in which a PFAS was ⁷~~used~~. In addition, firms that have not previously submitted information to CDR or through a PMN form will need to submit data under the proposed rule.

Small Business Importers of Articles

The proposed rule would also apply to importers of articles that contain PFAS (including articles containing PFAS as part of surface coatings). Article importers may have varying levels of knowledge about the chemical content of the articles they import. Therefore, it is reasonable that some importers would not know or ascertain that there is reportable PFAS in their imported articles and would therefore not be subject to report. However, there are some importers in a wide range of sectors that would be affected by this proposed rule because they would know the products or articles contain PFAS, including manufacturers, wholesalers, retailers, and recyclers. EPA anticipates that importers of articles that *may* contain PFAS will spend time familiarizing themselves with the rule and take steps to determine if they are subject to the rule’s requirements. Only a subset of these firms will determine that they are importing PFAS in articles and thus need to report information under the rule. During the panel, SERs provided additional input on the types of entities that will likely be considered as importers of PFAS to include product distributors such as those importing replacement parts and entities importing PFAS waste such as recyclers. One SER representing small businesses that process, broker, and consume recyclable commodities commented that recyclers will likely not be able to identify PFAS associated with recyclable material imported since January 1, 2011. SERs also provided feedback on a broad range of industries that may import articles containing PFAs spanning electronics and electric utility equipment, textiles and footwear, toys, vehicles, plastic containers, foams, household and commercial cleaning products, refrigeration equipment, heavy machinery and equipment, and heating and ventilation equipment.

Since publishing the draft Economic Analysis, EPA has updated its burden and cost estimates to include article importers, including entities who are non-reporters but nevertheless spend time determining whether they have manufactured a PFAS and are subject to reporting. EPA now estimates that 131,157 firms import articles potentially containing PFAS, but only 13,116 firms import articles containing PFAS and are subject to the rule’s reporting requirements. As indicated in Table 13 below, 127,615 small article importers may be affected by the rule, and 12,762 small firms are expected to import reportable article containing PFAS. Due to the lack of data on the number of articles containing PFAS and number of importers associated with these articles, EPA notes that there is a high degree of uncertainty related to article importers. EPA is soliciting public comment on the number of potential importers of articles, particularly small article importers, that may be subject to the rule.

Table 13: Estimated Number of Importers of Articles Potentially Containing PFAS

Parameter	Value	Calculation
Total value of imports, all imports (billions) ¹	\$2,494	A
Estimated value of imports, articles potentially containing PFAS (billions)	\$1,456	B
Percentage of total imports	58%	C = B/A
Total importers, all imports ²	224,699	D

⁷ CDR reporting is required every four years (2012, 2016, 2020, and 2024). For each reporting cycle, total production volume (i.e., total domestically produced and total imported) is required for all of the years covered reporting cycle, and additional information for manufacturing and processing and use is required for every 4th year (2011, 2015, 2019, and 2023).

Estimated importers of articles potentially containing PFAS	131,157	E = C x D
Estimated small importers of articles potentially containing PFAS	127,615	F = E x 97.3%
Percentage of firms importing PFAS in articles ³	10%	G
Estimated number of reporting firms	13,116	H = E x F
Estimated number of small reporting firms	12,762	I = H x 97.3%
¹ U.S. Census Bureau 2021b		
² U.S. Census Bureau 2021a		
³ EPA best professional judgement		

To estimate the number of importers of articles potentially containing PFAS in the table above, EPA first created a list of likely uses of PFAS in articles based on Glüge et al. (2020). A list of these uses crosswalked to Harmonised Tariff System (HTS) codes is presented in Appendix B. Glüge et al. (2020) compiled their inventory of PFAS uses based on risk profiles, reports and books, databases, patents, information from PFAS manufacturers, and studies that measured PFAS in products. EPA used best professional judgment to determine which uses of PFAS as described by Glüge et al. (2020) would include PFAS in articles that are covered by TSCA⁸ (e.g., not including pesticides or pharmaceuticals).

To estimate the number of importers affected by the rule, EPA used the U.S. Census Bureau’s 2019 Profile of Importing and Exporting Companies (U.S. Census Bureau 2021a), which includes the total number of importers for all commodities (Table 13, row D). EPA assumed that the number of these firms importing articles that *may* contain PFAS is proportional to the total customs value of commodities that may contain PFAS (Table 13, row C). This proportion is estimated using the U.S. Census Bureau’s USA Trade Online (U.S. Census Bureau 2021b) report for customs value of imports by HTS code, and the list of HTS codes that may contain PFAS (Table 13, rows A and B). EPA could not identify any data sources with information on the number of firms importing PFAS in articles. Using best professional judgement, EPA assumes 10 percent of firms importing articles that *may* contain PFAS will determine they are importing PFAS in articles and submit reports under the rule (Table 13, row G). EPA developed this assumption based on various public comments and SER comments regarding article importers and their lack of historical records and information on chemical content of their articles, and

⁸ Under TSCA §3 (15 U.S.C. §2602) a “chemical substance” means: any organic or inorganic substance of a particular molecular identity, including—

- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
- (ii) any element or uncombined radical.

Such term does not include—

any mixture,

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

tobacco or any tobacco product,

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

any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986

(determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges),

and any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug,

cosmetic, or device. The term “food” as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act, meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

the various challenges companies expect from contacting suppliers (e.g., foreign suppliers not responding or refusing to give information, suppliers going out of business, etc.). Additionally, EPA considered that, based on EPA's understanding of the PFAS industry, many PFAS are used in such a way that their use is a trade secret or there is no requirement that their use be stated in a specific application. EPA also recognized that article supply chains are complex, and for certain instances testing would be needed to determine the presence of PFAS, which is beyond the reasonably known to or ascertainable standards. All these factors were considered when developing the assumption that 10 percent of firms importing articles that may contain PFAS will determine they are importing PFAS in articles. EPA solicits comment on these estimates and assumptions.

EPA acknowledges there is a high degree of uncertainty regarding the number of importers of articles potentially containing PFAS and how much they are importing. With a total value of imported commodities of \$1,456 billion, the number of firms importing PFAS is going to depend on the amount imported by each firm. Lacking data on PFAS article importers, EPA assumed that the number of firms importing articles that may contain PFAS is proportional to the total customs value of commodities that may contain PFAS. But EPA recognizes that this assumption could result in an overestimate or underestimate of affected firms depending on the amount imported by each firm. For example, suppose we use the extreme assumption that firms are importing every possible commodity that may contain PFAS. This could be one firm that is importing 100% of all commodities, or this could be 200,000 firms that are importing a 1/200,000 portion of each commodity. In this example, assuming that firms are importing the entire range of commodities could result in an underestimate or an overestimate of the number of firms. EPA is soliciting public comment on the number of importers of articles potentially containing PFAS and the number of article importers that may submit reports for under this rule, particularly regarding small entities. Additionally, EPA conducted a sensitivity analysis related to the number of affected article importers as well as the number of article importers expected to report under the proposed rule in Appendix D.

Total per-firm costs are dependent on the number of imported chemicals each firm will need to report. EPA could not identify any data sources with information on the number of PFAS imported per firm. Using best professional judgment, EPA assumes that firms with knowledge of importing PFAS will report an average of 5 PFAS each. Based on CDR data, EPA estimated an average of 5.85 PFAS per firm for manufacturing firms. EPA received public comments regarding article importers and their lack of data compared to manufacturers. Given this, EPA believes the average PFAS per firm estimate would be less than 5.85 and therefore assumes 5 PFAS per reporting article importer. EPA expects that, generally, the number of PFAS imported by each firm will be dependent on the size of the firm. Thus, per-firm costs may be higher or lower than the estimated averages presented in this analysis. Furthermore, as previously discussed, EPA acknowledges that importers have varying levels of knowledge about the chemical content of the articles they import. Many SERs described the complexities of different industries' supply chains in determining whether a specific chemical substance may be present in a product or article. Therefore, the assumption that article importers will submit reports for an average of 5 PFAS reflects the expectation that some importers would not know or have access to all information on a chemical and/or article and would therefore not be subject to reporting. See section 8 Small Business Impact Analysis for more information on the estimated distribution of PFAS per firm.

Total Small Businesses

The small entities that are potentially affected by this proposed action are small businesses that currently or have previously manufactured (defined by statute at 15 U.S.C. 2602(9) to include import) PFAS or imported PFAS containing articles between January 1, 2011 and the effective date of the final

rule as well as those that have potentially imported articles containing PFAS between January 1, 2011 and the effective date of the final rule. The manufacture of PFAS as a byproduct is not exempt under the proposed rule. Unlike TSCA section 8(a)(1) rules, this proposed rule under TSCA section 8(a)(7) did not exempt small manufacturers from reporting and recordkeeping requirements.

For both manufacturers and article importers, EPA uses employment and revenue distribution data from the Census' Statistics of U.S. Businesses (SUSB) to estimate the percentage of firms that are small. The percentage of businesses that are small for NAICS with employment-based small business definitions are calculated using the 2019 SUSB by detailed employment size (U.S. Census Bureau 2022). It is assumed that firms are uniformly distributed within an employment bracket. Thus, small firms include those in brackets below the small business threshold as well as a proportional portion of those in brackets that span a threshold. For example, if a small business threshold is the midpoint of an employment bracket, then it is assumed that half of firms in that bracket are small. The percentage of businesses that are small for NAICS with revenue-based small business definitions are calculated using the 2017 SUSB by revenue, with revenues inflated to 2021\$. Similar to the approach for employment-based definitions, small firms include those in brackets below the small business threshold as well as a proportional portion of those in brackets that span a threshold.

EPA estimates that 93% of manufacturers and 97.3% of article importers affected by the rule are small businesses, for a total of 127,794 affected small firms. See section 7 Small Business Impact Analysis for more detail on the affected small entities.

5. Description of the Proposed Reporting, Recordkeeping, and Other Compliance Requirements

Projected Compliance Requirements

EPA is proposing a one-time, retroactive reporting and recordkeeping requirements for PFAS manufacturers, including article importers, under TSCA section 8(a)(7). As explained above, EPA is proposing to define PFAS using a structural definition. Based on this definition, EPA has identified 1,364 chemical substances using its listed chemicals on the TSCA Inventory (those known to be in the U.S. commerce after June 2006) and new chemicals submitted as LVEs.

TSCA section 8(a)(7) further specifies that PFAS manufacturers would report on “information described in subparagraphs (A) through (G) of paragraph (2) [of section 8]” for each year since January 1, 2011, in which a PFAS was manufactured. Therefore, this TSCA section 8(a)(7) rule proposed a one-time reporting of the information described in section 8(a)(2)(A)-(G), which includes specific chemical identity, categories of use, production volume, byproducts, environmental and health effects, number of persons exposed and duration of exposure, and disposal.

Specifically, EPA proposed to request the following information:

- Chemical name (multiple if mixture), or the generic name(s) if the chemical name(s) is CBI
- Chemical ID(s) (CASRN, TSCA Accession Number, or LVE case number)
- Trade name or common name
- Representative molecular structure
- Physical form of chemical or mixture
- Industrial processing and use: type of process or use; sector(s); functional use category(ies); percent of production volume for each use

- Consumer and commercial use: indicator for whether this is a consumer and/or commercial product; product category; function category(ies); percent production volume for each use; maximum concentration in any product; indicator for use in products intended for children
- Production volumes: domestically manufactured; imported; directly exported; maximum first 12 months production volume; maximum yearly production volume in any 3 years
- Indicator for imported but never physically at site
- Indicator for site-limited
- Maximum quantity stored on-site at any time
- Total volume recycled (on-site)
- For byproducts produced during the manufacture, processing, use, or disposal of each PFAS:
 - Chemical name(s) or description (if identity is unknown), or the generic name(s) if the byproduct name(s) is CBI
 - Chemical ID(s) (CASRN, TSCA Accession Number, or LVE case number)
 - Indicator for whether the byproduct(s) production resulted from manufacture, process, use, or disposal
 - Indicator for whether the byproduct(s) is released to the environment; if so, volume of byproduct(s) released and to which environmental media
- Worker exposure: Description of worker activity(ies) at each manufacturing site
- Worker exposure at the manufacturing site: number of workers reasonably likely to be exposed at the manufacturing site, for each worker activity; maximum duration of exposure for any worker, for each worker activity (both hours per day and days per year)
- Worker exposure for each industrial process and use: number of workers reasonably likely to be exposed for each industrial process and use; maximum duration of exposure for any worker for each industrial process and use (both hours per day and days per year)
- Worker exposure for each commercial use: number of workers reasonably likely to be exposed for each commercial use; maximum duration of exposure for any worker for each commercial use (both hours per day and days per year)
- Description of disposal process(es), and description of any changes to the disposal process or methods since 2011
- Total volume released: land disposal; water; air
- Total volume incinerated (on-site) and incineration temperature
- All existing information related to health or environmental effects, using the Organisation for Economic Co-operation and Development (OECD) harmonized template relevant to the existing study, as well as full study reports and any other supporting information
- Other data relevant to health and environmental effects (e.g., range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, adverse effects reports).

Certain information that is requested in the CDR that falls under TSCA section 8(a)(2)(A)-(G) would be required by this rule, such as information on specific chemical identity, categories of use, production volume, byproducts, and number of persons exposed and duration of exposure. In instances where PFAS manufacturers under this proposed rule have already reported the requested information to EPA under certain reporting programs, EPA proposed that they would not be required to re-report. EPA is proposing the reporters simply indicate they have already submitted such information to EPA.

Pursuant to TSCA section 8(f), this proposed rule includes entities who have manufactured for commercial purposes. The rule proposed to define “manufacture for commercial purposes” similarly to other TSCA rules:

“*Manufacture for commercial purposes* means: (1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such “manufacture” of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

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

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

Thus, the proposed rule would include anyone who has manufactured (including imported) a PFAS for commercial purposes at any time since January 1, 2011. As noted above, this proposed rule would be inclusive of entities such as domestic producers, chemical bulk importers, small manufacturers, article importers, and other PFAS material importers (e.g., importers of PFAS in wastes or scrap). The proposed rule did not include processors or other users of PFAS, unless they are also manufacturers.

Additionally, any person required to report under this proposed rule would supply the information identified in the form to the extent it is known to or reasonably ascertainable by them, or a reasonable estimate when actual data are not available (i.e., known or reasonably ascertainable). The reporting standard of “known or reasonably ascertainable” is consistent with the standard provided in TSCA section 8(a)(2) and has been applied to other TSCA section 8 reporting rules.

This reporting standard includes “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” – does not confine inquiry to what is known to managerial and supervisory employees (though not necessarily an exhaustive survey of all employees in the organization) and it may include inquiries outside of the company (e.g., to suppliers), if appropriate. This includes but is not limited to: information possessed by the manufacturer’s employees (e.g., R&D, manufacturing), existing customer surveys, sales reports, SDS or supplier notifications, information learned through technical publications or symposia. This is a case-specific determination; the level of information “known to or reasonably ascertainable” will vary for companies. While this reporting standard assumes a level of due diligence on the part of the manufacturer, it does not include a testing requirement.

As noted in the Panel Report, SERs expressed many concerns based on the proposed requirement to report all known or reasonably ascertainable information on PFAS chemicals. Several SERs went on to say that many small entities may not know or be able to reasonably ascertain whether they have imported PFAS in their articles or products, especially if the PFAS is present as a confidential chemical whose generic name does not include “fluor” or as an impurity or in de minimis amounts. Such entities would have to rely on the cooperation of their suppliers, which may include suppliers with which the PFAS manufacturer no longer has a business relationship. Other SERs described the complexities of different industries’ supply chains in determining whether a specific chemical substance may be present in an imported product or article or waste (e.g., recyclers). SERs also discussed opacity in downstream supply chains and the inability to provide required downstream use and disposal information. Some SERs representing entities that may import PFAS-containing articles discussed the difficulty or improbability of those entities having knowledge that they have imported a covered PFAS, or with

identifying the specific PFAS. These SERs relayed that their industries include original equipment manufacturers (OEMs) with more complex and/or variable supply chains, and many small businesses import thousands of products or components. For instance, one of these SERs described the complexity of their industry's supply chain with respect to small businesses by describing that their industry's supply chain may have upwards of 14 layers, with the small businesses largely beyond the second tier. The SER shared that a single OEM for a very complex product could be a three-story tall mining truck and it might have 100,000 parts in it. This could lead to tens of thousands of different suppliers in a supply chain that is 14 layers deep. Beyond the second layer is when you start getting into the small manufacturers. With very large supply chains, having different suppliers importing such articles and components from abroad would increase the difficulty of obtaining information from the suppliers, especially for a chemical integrated into a solid article.

SERs also described challenges of obtaining all requested information for the whole lookback period in the proposed rule (i.e., since January 1, 2011). Comments cited personnel departures as well as a lack of recordkeeping requirements for all years of the reporting period and the limitations and challenges of accessing older legacy recordkeeping systems or files, including those that are no longer maintained. Some entities shared that they may only have records for the previous five to seven years. None of the SERs volunteered that they would have records spanning the whole reporting period.

Professional Skills Needed to Comply

For the proposed rule, complying with some of the reporting requirements may involve special skills or expertise. For example, understanding the structural definition of PFAS included in the rule and other reporting requirements may involve special expertise of PFAS. EPA identified and quantified attorney/professional costs only for assistance in understanding the structural definition of PFAS in the rule, but seeks comment on whether professional skills would be needed for other aspects of the regulation, including compliance determination, form completion, CBI claim substantiation, and recordkeeping.

EPA assumes that manufacturing and importing firms and large article importers will have staff with the technical knowledge to understand a structural definition more easily. However, small article importers may not have such expertise on staff and will require more time for this activity. Some SERs expressed concern over their ability to determine whether they have manufactured a covered PFAS. They described concerns with having a structural definition instead of a finite list of covered substances, which can add complexity in determining whether they have a covered substance, especially for entities without chemistry knowledge on staff. Some SERs suggested that deep expertise in chemistry would be need for compliance purposes, and that they would have to contract for this expertise. One SER said it is unclear how some importers may discern whether there is a covered PFAS in their imports if their suppliers do not reveal the chemical identity or provide a generic name that suggests the presence of PFAS. Another SER commented that time and resources spent confirming whether the information requested by this rule is known to or reasonably ascertainable would still impose a large burden on small businesses, and that even without having information meeting the known to or reasonably ascertainable, small entities will still engage in the effort to demonstrate compliance and expend related costs. Often mentioned was the cost of contractors to perform testing or calculations to confirm or produce the needed information, and the burden of inquiring through each of many complex product lines and supply chains involving multiple companies.

Based on best professional judgement and input from public comments and SERs, EPA also assumes 10 percent of these small article importer firms will rely on consultant attorneys for help understanding structural definitions, although compliance with this rule (i.e., what a “reasonable person, similarly situated, might be expected to possess, control, or know”) does not necessarily require potentially affected entities to hire such consultants or additional staff.

However, SERs did express concerns related to the limited experience of small entities in reporting chemical information, especially for article importers. They also pointed that fewer organization resources and regulatory familiarity as potential reasons that small companies may face greater compliance costs, as some companies may decide to hire more expensive consultants. One SER estimated that a TSCA non-attorney consultant may charge \$300-\$400 per hour and \$400-\$1000 for TSCA attorney. Another SER estimated the costs of a consultant inquiring a complex supply chain to be \$3,000 - \$10,000 per component. One SER mentioned the limited personnel of small businesses in their organization may force the businesses to rely on more expensive counsel for reporting compliance.

While some SERs did mention they would consult chemists or accountants, EPA assumes some small article importers will only rely on attorneys. According to U.S. Bureau of Labor Statistics’ (BLS) Employer Costs for Employee Compensation (ECEC) data for December 2021, attorneys have a higher hourly annual wage rate compared to chemists and accountants, thus using attorney labor rates results in a more conservative estimate. The remaining 90 percent of firms are assumed to rely on in-house technical staff and may also reach out to a trade association for support and guidance. Additionally, environmental and health effects data may require some technical knowledge to report. But EPA assumes that the entities that have this data also have staff with the technical knowledge to report this information.

While EPA assumes that some small article importers may contract an attorney to understand the structural definition, EPA acknowledges that firms may contract attorneys for other compliance activities as well. EPA is soliciting comment regarding contracting outside attorneys (i.e., for which compliance activity, how much counsel time, would the contracting of an attorney displace or be additional to estimated managerial and technical time associated with the activities). The compliance schedule proposed by EPA includes a six-month deferral of the data submission period following the effective date of the final rule, and then another six-month information submission period. Thus, the reporting deadline would be one year from the effective date of the final rule. All information would be reported electronically through EPA’s Central Data Exchange platform. EPA proposed that each person who is subject to the reporting requirements must retain records that document any information reported to EPA. Consistent with the CDR rule, EPA proposed a five-year recordkeeping period, beginning on the last date of the submission period; this may require retention of records beyond when they would ordinarily be maintained, given the lookback to 2011. Some SERs described some entities as not having much, if any, experience with chemical reporting regulations, as these small entities may have been exempt from previous TSCA reporting requirements. Some SERs stated that delays associated with obtaining information from suppliers would not allow for compliance with the 6-month submission period because that does not allow for enough time to determine whether components such as O-rings, seals, and valve diaphragms contain PFAS and to report the required data; some SERs sharing the same concern suggested that 18 months might be sufficient. A few SERs also described the challenges of the proposed compliance timeline (i.e., reporting is due twelve months following the reporting period) especially if an entity has no experience with prior TSCA reporting or using EPA’s CDX platform, or has many products or articles to assess. These SERs suggested that they or their members would need additional time to provide sufficient data, especially on top of existing responsibilities. Relatedly, a few

SERs implored EPA to fully validate the new CDX reporting tool which will need to be established for this rule's reporting.

6. Identification of Relevant Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Regulations

Several regulatory activities related to PFAS precede, coincide with, or post-date the proposed rule.

Toxic Substances Control Act

Under TSCA, EPA is directed to prioritize, evaluate, and regulate chemicals manufactured (including imported) or processed in the United States.

- Under the new chemicals program, since 2006, EPA has reviewed at least 294 new PFAS before they have commenced commercial production and has regulated at least 191 PFAS through Significant New Use Rules (SNURs) and other Orders under section 5(e).⁹
- In March and December 2002, EPA published a SNUR to require notification to EPA before any future manufacture (including import) of 13 PFAS specifically included in the voluntary phase out PFOS by 3M that took place between 2000 and 2002. The SNUR exempted ongoing uses that were limited to a few specifically limited, highly technical uses of these chemicals for which no alternatives were available, and which were characterized by very low volume, low exposure, and low releases.
- In October 2007, EPA finalized a SNUR on 183 PFAS believed to no longer be manufactured (including imported) or used in the United States.
- In October 2013, EPA issued a rule requiring companies to report all new uses of certain PFOA-related chemicals as part of carpets, a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance. Companies must now report to EPA their intent to manufacture (including import) these chemical substances intended for use as part of carpets or to treat carpets, as well as import carpets already containing these chemical substances.
- In July 2020, EPA finalized a SNUR to require manufacturers (including importers) and processors of certain long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances to notify EPA before commencing use of LCPFACs that have been phased out. In addition, articles containing LCPFACs as a surface coating and carpets containing perfluoroalkyl sulfonate chemical substances cannot be imported without notice and EPA review.
- EPA may collect some information from PFAS manufacturers, including on production volume and use in commerce, under the Chemical Data Reporting (CDR) rule. This information is collected every four years and, in general, applies to chemicals with production volumes of 25,000 lbs. or more at a single site in a single year. The next CDR reporting cycle is in 2024, covering the calendar years 2020 through 2023 (2023 being the principal reporting year). Under 40 CFR 711, the reporting period would be open June 1 through September 30, 2024. The timing of PFAS reports submitted under this proposed 8(a)(7) rule may impact the submissions to CDR in 2024. 40 CFR 711.22(a) states: “Any person subject to the requirements of this part who previously has complied with reporting requirements of a rule under TSCA section 8(a) by submitting the information described in § 711.15 for a chemical substance described in § 711.5 to EPA, and has done so within 1 year of the start of a submission period described in § 711.20,

⁹ See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas>

is not required to report again on the manufacture of that chemical substance at that site during that submission period.”

- Pursuant to EPA’s TSCA authority to compel health and environmental effects testing, in October 2021, EPA announced a National PFAS Testing Strategy which will provide the agency with toxicity data and information on categories of PFAS to inform future regulatory efforts.¹⁰ The first test order pursuant to this testing strategy was issued on June 6, 2022.
- In December 2021, EPA granted a petition that requested EPA to compel certain companies to conduct testing of PFAS and submit the toxicity data to EPA. Specifically, EPA indicated it would initiate a rulemaking proceeding or issue an order under TSCA section 4(a)(1)(A)(i) compelling health and environmental effects testing regarding PFAS.¹¹
- Under TSCA section 8(d), EPA may require the submission of health and safety studies for specific chemical substances.
- Section 8(e) of TSCA requires that EPA be immediately notified when a manufacturer, processor, or distributor of chemical substances or mixtures obtains information which reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment.

Emergency Planning and Community Right-to-Know Act

- Section 7321 of the National Defense Authorization Act for Fiscal Year 2022 (NDAA) (15 U.S.C. 8921) added over 170 PFAS to the Toxics Release Inventory (TRI) toxic chemical list, under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and provided a statutory framework for additional PFAS to be added to the TRI chemical list. Beginning with Reporting Year 2020, facilities subject to TRI reporting requirements are required to report their releases and other waste management information on listed PFAS; the first set of preliminary TRI data on PFAS was published in July 2021. TRI information provides the public, government agencies, non-governmental organizations, and companies with information about chemical releases and pollution prevention activities reported by industrial and federal facilities to support informed decision making. As of Reporting Year 2022, there are 180 individual PFAS on the TRI chemical list.
- As of this writing, EPA is developing a proposal to add the PFAS subject to TRI reporting to the list of Lower Thresholds for Chemicals of Special Concern (Chemicals of Special Concern).¹² The addition of the PFAS to the Chemicals of Special Concern list will eliminate the use of the de minimis exemption, eliminate the option to use the shorter Form A, and will limit the use of range reporting. In addition, EPA’s proposed rule would eliminate the use of the de minimis exemption under the Supplier Notification Requirements for facilities that manufacture or process all chemicals included on the Chemicals of Special Concern list.

Safe Drinking Water Act

Under the Safe Drinking Water Act (SDWA), EPA sets public health goals and enforceable standards for drinking water quality. In March 2021, EPA published Regulatory Determinations for Contaminants on the Fourth Contaminant Candidate List which included a final determination to

¹⁰ See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy>

¹¹ See <https://www.epa.gov/system/files/documents/2021-12/pfaspetitionresponse.pdf>.

¹² See <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2070-AK97>.

regulate Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in drinking water.¹³ The Agency is now developing a proposed National Primary Drinking Water Regulation (NPDWR) for these chemicals. NPDWRs include legally enforceable maximum contaminant levels (MCLs) and/or treatment techniques that apply to public water systems and limit the levels of contaminants in drinking water to the extent feasible. EPA has conducted a separate Small Business Advocacy Review Panel for this proposed rulemaking.

Additionally, in October 2022, EPA published the Fifth Contaminant Candidate List (CCL5). The CCL is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, but are known or anticipated to occur in public water systems. The CCL5 included, among other chemicals, any PFAS other than PFOA and PFOS (which were included in the CCL4). For the purpose of the CCL5, “PFAS” was defined as: per- and polyfluorinated substances (except for PFOA and PFOS) that contain at least one of these three structures:

1. R-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons, and none of the R groups can be hydrogen
2. R-CF₂OCF₂-R', where both the CF₂ moieties are saturated carbons, and none of the R groups can be hydrogen
3. CF₃C(CF₃)RR', where all the carbons are saturated, and none of the R groups can be hydrogen.¹⁴

In October 2021, EPA’s Office of Water also published the final human health toxicity assessment for hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt, collectively known as “GenX chemicals.” The assessment provides hazard identification, dose-response information, and derives toxicity values called oral reference doses (RfDs) for chronic and subchronic exposures to GenX chemicals. The assessment will help inform a national drinking water health advisory for GenX chemicals.

Under SDWA, EPA is authorized to issue health advisories for drinking water contaminants not subject to a national primary drinking water regulation. In June 2022, EPA published interim updated drinking water health advisories for PFOA and PFOS, replacing those that had been issued in 2016, reflecting updated data and considering lifetime exposures. These interim health advisories were based on draft health assessments that had not completed Science Advisory Board review. EPA also issued two new final health advisories, for perfluorobutane sulfonic acid (PFBS) and the GenX chemicals.¹⁵ The health advisory for GenX chemicals reflects the final human health toxicity assessment published in October 2021¹⁶, and the health advisory for PFBS reflects the final human health toxicity assessment published in April 2021.¹⁷

Additionally, the third Unregulated Contaminant Monitoring Rule (UCMR3) required monitoring for 30 contaminants between 2013 and 2015, including six PFAS. The rule allows EPA to collect data on chemicals that are suspected drinking water contaminants but for which EPA has not set health-based standards under the SDWA. In December 2021, EPA published the fifth UCMR to require samples of 30 chemical constituents, 29 of which are PFAS, between 2023 and 2025.¹⁸

¹³ See <https://www.epa.gov/ccl/regulatory-determination-4>

¹⁴ See <https://www.epa.gov/ccl/contaminant-candidate-list-5-ccl-5>

¹⁵ See <https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos>

¹⁶ See https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf

¹⁷ See https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=542393

¹⁸ See <https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule>

Finally, SDWA requires EPA to use scientifically robust and validated analytical methods to assess contaminants of emergency concern. Under EPA's PFAS Strategic Roadmap, EPA is working to update and validate analytical methods to monitor additional PFAS in drinking water. This effort includes EPA's review of reports of PFAS of concern and evaluation of certified reference standards, an evaluation of previously published analytical methods for PFAS in drinking water, and finally multi-laboratory validation studies and peer review prior to publishing any updated EPA PFAS analytical methods for drinking water. This is expected in Fall 2024.¹⁹

Comprehensive Environmental Response, Compensation, and Liability Act

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund, EPA is authorized to address certain or threatened environmental releases of hazardous substances. In August 2022, EPA proposed designating PFOA and PFOS as hazardous substances under CERCLA.²⁰

In May 2022, EPA added five PFAS to the Regional Screening Levels and Regional Remedial Management Levels. These risk-based values help EPA determine if response or remediation activities are required under CERCLA.²¹

Clean Water Act

In March 2021, EPA published an advance notice of proposed rulemaking (ANPRM) to solicit data regarding manufacturers of PFAS and the presence and treatment of PFAS in discharges from Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) point source category (86 FR 14560). EPA also requested information regarding PFAS formulators, which are facilities that produce a variety of PFAS products and materials from PFAS feedstocks. EPA will use any data and information obtained via public comment on the ANPRM to inform its decision about whether a proposed rulemaking may be necessary under the Clean Water Act. EPA's PFAS Strategic Roadmap also includes the initiation of a rulemaking to revise effluent limitations for Metal Finishing facilities to address PFAS in wastewater discharges from chromium plating operations.²²

In April 2022, EPA issued a memo outlining a new approach under the National Pollutant Discharge Elimination System (NPDES) programs it oversees to restrict PFAS discharges to water bodies. Under this approach, EPA will require monitoring for PFAS, implementing best management practices, and establishing practices to address PFAS-containing firefighting foam in stormwater.

Additionally, in May 2022, EPA published the Draft Recommended Aquatic Life Ambient Water Quality Criteria for both PFOA and PFOS. Both drafts were open for public comment through July 2022 and reflect the latest scientific knowledge regarding the impacts of PFOA and PFOS on freshwater organisms. When the draft CWA criteria are finalized, these can inform tribes' and states' efforts to adopt water quality standards related to PFOA and PFOS. Under EPA's PFAS Strategic Roadmap, the

¹⁹ See https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

²⁰ See <https://www.epa.gov/superfund/proposed-designation-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos>

²¹ See <https://www.epa.gov/risk/regional-screening-levels-rsls-whats-new>

²² See https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

aquatic life criteria are expected in Winter 2022, and the human health criteria are expected in Fall 2024.²³

EPA is also working to collect and share more data on PFAS found in fish tissue in U.S. lakes. This multi-year data collection will help EPA better understand the impact of PFAS on subsistence fishers. EPA also plans to publish a list of PFAS for tribal and state fish advisory programs as guidance for their own monitoring and advisory work. This publication is expected in Spring 2023.²⁴

Resource Conservation and Recovery Act

In October 2021, EPA announced the initiation of two rulemakings under the Resource Conservation and Recovery Act (RCRA), in response to a petition from the Governor of New Mexico. One future rulemaking will propose listing certain PFAS as RCRA Hazardous Constituents; that rule is slated for proposal in Summer 2023.²⁵ The other future rulemaking will propose clarification to RCRA Corrective Action Program regulations. According to the Spring 2022 Unified Agenda, EPA plans to publish this proposed rule in January 2023.²⁶

Other Federal Activities

Several other federal agencies are conducting actions to further research PFAS or to address health concerns related to PFAS. In May 2021, the Agency for Toxic Substances and Disease Registry published a final toxicological profile on perfluoroalkyls.²⁷ The Department of Defense (DOD) is currently conducting cleanup assessments at DOD sites where PFAS was used or may have been released, in addition to extensive research into PFAS detection and treatment methodologies.²⁸ Other federal agencies currently conducting research into or monitoring of the presence of PFAS in food, products, and environmental media: the Department of Agriculture, the Department of Health and Human Services (Food and Drug Administration, Centers for Disease Prevention and Control, National Institute of Health), the Department of Homeland Security, the Department of Transportation (Federal Aviation Administration), and the General Services Administration.²⁹

Minimizing Duplicative Reporting in the Proposed Rule

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. EPA reviewed the data elements submitted under the CDR rule and determined that there may be some overlap with the information requested under the proposed rule. EPA proposed to allow reporting entities to indicate in the reporting tool that they have previously provided such information to EPA through CDR for certain data elements.

²³ See https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

²⁴ See https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

²⁵ See <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2050-AH26>

²⁶ See <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2050-AH27>

²⁷ See <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>.

²⁸ See <https://denix.osd.mil/dod-pfas/>.

²⁹ Information available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/>.

The Agency has identified the following data elements which the reporter may be able to indicate has already been submitted to EPA:

- Physical state of the chemical or mixture;
- 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.

If an entity covered under this proposed rule has previously submitted required information to EPA for some years since 2011, but not for all years, EPA proposed that the entity may indicate in the reporting tool the year(s) for which the entity has already submitted that data to EPA as part of CDR. For instance, CDR reporters are required to submit the total annual domestically manufactured production volume and the total annual imported volume separately, but only for the principal reporting year (e.g., 2019 for the 2020 reporting cycle). However, CDR reporters only needed to report the combined total annual production volume for the non-principal reporting years during the reporting cycle, so the disaggregated totals of the domestically manufactured production volume and the total imported production volume were not already reported for those non-principal reporting years. In this case, a reporter under this proposed rule would be able to indicate that the two different production volumes have been previously submitted to EPA for the CDR principal reporting year, but would still need to report for the non-principal reporting year(s) those data elements were not previously submitted under CDR. Additionally, there are some data elements for which CDR reporters may have previously reported information to EPA, although these data elements were only added to the CDR reporting requirements in 2020. Therefore, some entities under this proposed rule may have submitted the following information to CDR for some years covered by this proposed rule, but not all, and would still be required to report this information for the missing year(s):

- Domestically manufactured production volume;
- Imported production volume;
- Volume directly exported; and
- Indicator for imported but never physically at site.

The next CDR reporting cycle is in 2024, covering the calendar years 2020 through 2023 (2023 being the principal reporting year). Under 40 CFR 711, the reporting period would begin June 1 and last through September 30, 2024. The timing of PFAS reports due for this proposed 8(a)(7) rule may impact whether they would also be reported to CDR. 40 CFR 711.22(a) states: “Any person subject to the requirements of this part [i.e., a CDR reporter] who previously has complied with reporting requirements of a rule under TSCA section 8(a) by submitting the information described in § 711.15 for a chemical substance described in § 711.5 to EPA, and has done so within 1 year of the start of a submission period described in § 711.20, is not required to report again on the manufacture of that chemical substance at that site during that submission period.”

7. Small Business Impact Analysis

The Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires regulators to assess the effects of regulations on small entities,

including businesses, nonprofit organizations, and governments. The RFA relies on the definition of “small business” found in the Small Business Act, which authorizes the Small Business Administration (SBA) to develop definitions for “small businesses” for industries in each North American Industry Classification System code. These definitions can be based either on a company’s number of employees or its sales, depending on SBA’s criteria for that industry.

For manufacturing firms, this analysis applies the SBA small business definitions to the 14 6-digit NAICS for PFAS manufacturers. These NAICS were determined by identifying the NAICS listed for the global parent company in the Dun & Bradstreet database for each site in the 2016 CDR that manufactures a PFAS subject to the rule (Dun & Bradstreet Hoovers 2020). The ultimate parent NAICS codes and corresponding small business size standards are shown in Table 14.

Table 14: Ultimate Parent NAICS Codes and Small Business Thresholds

Ultimate Parent NAICS Code	NAICS Description	Small Business Threshold
325130	Synthetic Dye and Pigment Manufacturing	1,000 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325211	Plastics Material and Resin Manufacturing	1,250 employees
325320	Pesticide and Other Agricultural Chemical Manufacturing	1,000 employees
327910	Abrasive Product Manufacturing	750 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
336111	Automobile Manufacturing	1,500 employees
423690	Other Electronic Parts and Equipment Merchant Wholesalers	250 employees
424690	Other Chemical and Allied Products Merchant Wholesalers	150 employees
447190	Other Gasoline Stations	\$16.5 million
515210	Cable and Other Subscription Programming	\$41.5 million
551112	Offices of Other Holding Companies	\$22.0 million
561499	All Other Business Support Services	\$16.5 million

In addition, article importers across several industries are expected to be affected by the rule, including the following NAICS:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities could also be affected. For a detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, please, see Appendix C. For article importers, EPA applies the SBA small business definitions to the 6-digit NAICS under each of these industry categories.

Estimate the Percentage of Firms That are Small

For both manufacturers and article importers, EPA uses employment and revenue distribution data from the Census' Statistics of U.S. Businesses (SUSB) to estimate the percentage of firms that are small. The percentage of businesses that are small for NAICS with employment-based small business definitions are calculated using the 2019 SUSB by detailed employment size (U.S. Census Bureau 2022). It is assumed that firms are uniformly distributed within an employment bracket. Thus, small firms include those in brackets below the small business threshold as well as a proportional portion of those in brackets that span a threshold. For example, if a small business threshold is the midpoint of an employment bracket, then it is assumed that half of firms in that bracket are small. The percentage of businesses that are small for NAICS with revenue-based small business definitions are calculated using the 2017 SUSB by revenue, with revenues inflated to 2021\$. Similar to the approach for employment-based definitions, small firms include those in brackets below the small business threshold as well as a proportional portion of those in brackets that span a threshold. EPA estimates that 93% of manufacturers and 97.3% of article importers affected by the rule are small businesses, for a total of 127,794 affected small firms.

Estimate the Distribution of Annual Revenues and Costs for Small Parent Entities

EPA assumes that the costs incurred by a given firm will be dependent on the number of PFAS for which it will submit reports. EPA could not identify any information that would allow for an estimation of the distribution of expected report submissions per firm. In the absence of these data, EPA assumes that the number of PFAS manufactured or imported per firm is proportional to firm revenue. EPA seeks comment on this simplifying assumption. EPA recognizes that the per-firm costs can vary significantly among entities and that there will be outliers to this assumption, however the cost estimates in this analysis reflect an industry average. This analysis estimates a distribution of revenues for the affected NAICS using data on annual receipts per firm from the 2017 U.S. Census Statistics of U.S. Businesses (SUSB) (U.S. Census Bureau 2021). The SUSB data divides firms into 17 revenue brackets according to the firm's annual receipts, which are defined as "all revenue in whatever form received or accrued from whatever source, including from the sales of products or services" from all affiliates in a given year (13 CFR 121.104).

Note that the lowest revenue bracket in the SUSB data has a minimum revenue of zero. However, no affected firms are expected to have zero revenue, as a firm would have to manufacture or import a PFAS in order to be affected by the rule, and presumably they receive some sales revenue for their products. Therefore, EPA estimates a minimum revenue to use as the revenue floor for the first revenue bracket. The minimum revenue is estimated as the cost of employing one part-time technical worker (0.5 FTE). The loaded wage rate for technical workers is approximately \$81.40 per hour (see Appendix A for wage rate calculations), which equates to an annual salary of \$84,651.84 for an employee working 20 hours a week for 52 weeks a year.

Using the revenue brackets and firm counts from the SUSB data, an annual revenue distribution is estimated by assuming that revenues are uniformly distributed within the revenue brackets. For NAICS with employment-based small business definitions, it is assumed that the large firms are those in the top revenue brackets and EPA therefore excludes the large firms from the top of the revenue distribution. For NAICS with revenue-based small business definitions, all firms in brackets above the small business threshold are excluded from the revenue distribution. Estimated revenue distributions at the 1st, 5th, 25th, 50th, 75th, 95th, and 99th percentile for small entities across all potentially affected NAICS are presented in Table 15.

Table 15: Estimated Revenue Distribution

Firm Type	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile
Manufacturers	\$85,989	\$91,336	\$180,390	\$433,529	\$1,060,817	\$5,955,288	\$13,815,814
Article Importers	\$86,098	\$91,881	\$224,033	\$600,488	\$2,258,544	\$13,520,826	\$56,270,558

Manufacturers with lower sales are expected to manufacture proportionally fewer chemicals and incur lower costs, and similarly for article importers. Note that because firm revenues are positively skewed (see Table 15), this assumption results in the expectation that most firms will only submit reports for 1 or 2 PFAS, with the highest earners accounting for the majority of submissions, as shown in Table 16. Additionally, Table 17 shows the estimated distribution of total PFAS reported, by revenue percentile.

Table 16: Estimated Distribution of PFAS per Firm

Firm Type	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile	Average
Manufacturers	1.01	1.01	1.04	1.16	1.65	39.05	82.19	5.85
Article Importers	1.02	1.02	1.06	1.17	1.60	5.78	57.13	5.00

Table 17: Estimated Distribution of Total PFAS, by Revenue Percentile

Firm Type	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile
Manufacturers	0.3%	1%	4%	9%	15%	40%	84%
Article Importers	0.4%	1%	5%	11%	17%	28%	46%

Reinforcing EPA’s estimates of PFAS per firm, comments submitted by one small-entity representative for the Small Business Advocacy Review Panel indicated that many firms expect to only identify one or two reportable chemicals. However, EPA received another SER comment that stated their company would need to report on approximately 198 PFAS. EPA recognizes that the per-firm costs can vary significantly among entities and that there will be outliers to the assumption that the number of PFAS manufactured or imported per firm is proportional to firm revenue. EPA is soliciting public comment on the number of PFAS entities may submit reports for under this rule, particularly regarding small entities. EPA is also soliciting public comment on the number of reportable PFAS that are above the industry average (i.e., outliers) and on the estimated distribution of PFAS per firm.

Additionally, not all firms will incur costs for all reporting elements. Tables 18 and 19 present the percentage of manufacturing and article importer firms expected to incur that cost, respectively. For more detail on the costs per firm and the percentage of firms incurring cost listed in Tables 18 and 19, see the Updates to the Economic Analysis section. Note, the percentage of firms incurring cost for CBI substantiation has decreased from 25% to 16%. After reviewing the estimates, EPA updated the methodology for how the CBI substantiation costs were calculated. According to CDR data (EPA 2020a), 10% of the reports claim the company, site, technical contact, or authorized official as CBI, and

6% of reports claim other data as CBI that requires upfront substantiation. Thus, EPA estimates that 16% of submissions include a CBI claim that requires substantiation.

Table 18: Percentage of Firms Incurring Costs, by Reporting Element (Manufacturers)

Element	Reporting Element	Updated Cost per Firm (\$2021)	Updated Percentage of Firms Incurring Cost	Percentage of Firms Incurring Cost from Draft EA
RF	Rule Familiarization	\$2,362	100%	100%
CBI	CBI Substantiation	\$336	16%	25%
RC	Recordkeeping	\$347	100%	100%
CDX	CDX Registration and Electronic Signature	\$231	100%	100%
FC/EH	Form Completion - Environmental and health effects data	\$23,037	18%	18%
FC/OT	Form Completion - All other form elements	\$18,115	100%	100%

Table 19: Percentage of Firms Incurring Costs, by Reporting Element (Article Importers)

Element	Reporting Element	Cost per Firm (\$2021)	Percentage of Firms Incurring Cost
RF/NR	Rule Familiarization – Non-Reporting firms	\$786	90%
RF/R	Rule Familiarization - Reporting firms	\$2,036	10%
RF/IH	Rule Familiarization – In house structural definition familiarization	\$326 - \$570	90%
RF/CT	Rule Familiarization – Consultant structural definition familiarization	\$849	10%
CD	Article Importer Compliance Determination	\$3,916	100%
CBI	CBI Substantiation	\$287	1.6%
RC	Recordkeeping	\$296	10%
CDX	CDX Registration and Electronic Signature	\$231	10%
FC/EH	Form Completion - Environmental and health effects data	\$2	0.1%
FC/PV	Form Completion - Production volume	\$225	0.5%
FC/OT	Form Completion - All other form elements	\$10,776	9.4%

Table 20 presents each combination of reporting elements for manufacturers from Table 18 and for each estimates the distribution of total cost per firm and the distribution of cost-revenue ratios using the revenue distribution from Table 15. Table 21 similarly presents the distribution of revenues, total cost, and cost-revenue ratios for article importers. The affected firms may experience a wide range in per-firm

costs. There will be affected article importers that incur costs for rule familiarization and compliance determination, but find they are not required to report. The reporting firms will have varying amounts of information to report, as some firms may report on all data elements, others may not. Additionally, some reporting firms may have CBI claims, while others do not. All these factors result in a range of per-firm costs among firms that also have a wide range in revenues. Tables 20 and 21 show the range of costs and cost-revenue ratios firms may experience depending on company revenue, the number of PFAS they report on, and the amount of information they have. For example, for a firm in the second row of Table 20, incurring costs for all reporting elements, its cost -revenue ratio would be more than 13 percent if the firm has revenues in the 25th percentile.

Table 20: Distribution of Per-Firm Revenue, Cost, and Cost-Revenue Ratio (Manufacturers)

Reporting Elements Incurred	Parameter	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile
All	Per-Firm Revenue	\$85,989	\$91,336	\$180,390	\$433,529	\$1,060,817	\$5,955,288	\$13,815,814
RF, CBI, RC, CDX, FC/EH, FC/OT	Per-Firm Cost	\$24,620	\$24,630	\$24,758	\$25,233	\$26,329	\$35,017	\$47,380
	Cost-Revenue Ratio	28.63%	26.97%	13.72%	5.82%	2.48%	0.59%	0.34%
RF, AI, RC, CDX, FC/PV, FC/OT	Per-Firm Cost	\$24,258	\$24,269	\$24,395	\$24,862	\$25,940	\$34,485	\$46,645
	Cost-Revenue Ratio	28.21%	26.57%	13.52%	5.73%	2.45%	0.58%	0.34%
RF, AI, CBI, RC, CDX, FC/OT	Per-Firm Cost	\$6,913	\$6,915	\$6,941	\$7,034	\$7,249	\$8,952	\$11,375
	Cost-Revenue Ratio	8.04%	7.57%	3.85%	1.62%	0.68%	0.15%	0.08%
RF, RC, CDX, FC/OT	Per-Firm Cost	\$6,552	\$6,554	\$6,577	\$6,662	\$6,859	\$8,420	\$10,641
	Cost-Revenue Ratio	7.62%	7.18%	3.65%	1.54%	0.65%	0.14%	0.08%

Table 21: Distribution of Per-Firm Revenue, Cost, and Cost-Revenue Ratio (Article Importers)

Reporting Elements Incurred	Parameter	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile
All	Per-Firm Revenue	\$86,098	\$91,881	\$224,033	\$600,488	\$2,258,544	\$13,520,826	\$56,270,558
RF/CT, CD, CBI, RC, CDX, FC/PV, FC/EH, FC/OT	Per-Firm Cost	\$9,435	\$9,441	\$9,561	\$9,924	\$11,471	\$21,445	\$43,580
	Cost-Revenue Ratio	10.96%	10.28%	4.27%	1.65%	0.51%	0.16%	0.08%
	Per-Firm Cost	\$9,116	\$9,122	\$9,242	\$9,605	\$11,152	\$21,126	\$43,261

RF/IH, CD, CBI, RC, CDX, FC/PV, FC/EH, FC/OT	Cost-Revenue Ratio	10.59%	9.93%	4.13%	1.60%	0.49%	0.16%	0.08%
RF/CT, CD, CBI, RC, CDX, FC/PV, FC/OT	Per-Firm Cost	\$9,394	\$9,400	\$9,518	\$9,877	\$11,408	\$21,277	\$43,177
	Cost-Revenue Ratio	10.91%	10.23%	4.25%	1.64%	0.51%	0.16%	0.08%
RF/IH, CD, CBI, RC, CDX, FC/PV, FC/OT	Per-Firm Cost	\$9,074	\$9,081	\$9,199	\$9,558	\$11,089	\$20,957	\$42,858
	Cost-Revenue Ratio	10.54%	9.88%	4.11%	1.59%	0.49%	0.16%	0.08%
RF/CT, CD, RC, CDX, FC/PV, FC/EH, FC/OT	Per-Firm Cost	\$9,069	\$9,075	\$9,183	\$9,512	\$10,915	\$19,958	\$40,028
	Cost-Revenue Ratio	10.53%	9.88%	4.10%	1.58%	0.48%	0.15%	0.07%
RF/IH, CD, RC, CDX, FC/PV, FC/EH, FC/OT	Per-Firm Cost	\$8,750	\$8,756	\$8,864	\$9,193	\$10,596	\$19,639	\$39,709
	Cost-Revenue Ratio	10.16%	9.53%	3.96%	1.53%	0.47%	0.15%	0.07%
RF/CT, CD, RC, CDX, FC/PV, FC/OT	Per-Firm Cost	\$9,027	\$9,033	\$9,140	\$9,466	\$10,852	\$19,790	\$39,625
	Cost-Revenue Ratio	10.49%	9.83%	4.08%	1.58%	0.48%	0.15%	0.07%
RF/IH, CD, RC, CDX, FC/PV, FC/OT	Per-Firm Cost	\$8,708	\$8,714	\$8,821	\$9,146	\$10,533	\$19,470	\$39,305
	Cost-Revenue Ratio	10.11%	9.48%	3.94%	1.52%	0.47%	0.14%	0.07%
RF/CT, CD, CBI, RC, CDX, FC/EH, FC/OT	Per-Firm Cost	\$8,516	\$8,520	\$8,612	\$8,890	\$10,075	\$17,711	\$34,659
	Cost-Revenue Ratio	9.89%	9.27%	3.84%	1.48%	0.45%	0.13%	0.06%
RF/IH, CD, CBI, RC, CDX, FC/EH, FC/OT	Per-Firm Cost	\$8,196	\$8,201	\$8,293	\$8,571	\$9,756	\$17,392	\$34,340
	Cost-Revenue Ratio	9.52%	8.93%	3.70%	1.43%	0.43%	0.13%	0.06%
RF/CT, CD, CBI, RC, CDX, FC/OT	Per-Firm Cost	\$8,474	\$8,479	\$8,569	\$8,843	\$10,012	\$17,542	\$34,256
	Cost-Revenue Ratio	9.84%	9.23%	3.82%	1.47%	0.44%	0.13%	0.06%
RF/IH, CD, CBI, RC, CDX, FC/OT	Per-Firm Cost	\$8,155	\$8,160	\$8,250	\$8,524	\$9,693	\$17,223	\$33,937
	Cost-Revenue Ratio	9.47%	8.88%	3.68%	1.42%	0.43%	0.13%	0.06%

RF/CT, CD, RC, CDX, FC/EH, FC/OT	Per-Firm Cost	\$8,149	\$8,154	\$8,234	\$8,478	\$9,519	\$16,224	\$31,106
	Cost-Revenue Ratio	9.47%	8.87%	3.68%	1.41%	0.42%	0.12%	0.06%
RF/IH, CD, RC, CDX, FC/EH, FC/OT	Per-Firm Cost	\$7,830	\$7,835	\$7,915	\$8,159	\$9,199	\$15,905	\$30,787
	Cost-Revenue Ratio	9.09%	8.53%	3.53%	1.36%	0.41%	0.12%	0.05%
RF/CT, CD, RC, CDX, FC/OT	Per-Firm Cost	\$8,108	\$8,112	\$8,191	\$8,431	\$9,455	\$16,055	\$30,703
	Cost-Revenue Ratio	9.42%	8.83%	3.66%	1.40%	0.42%	0.12%	0.05%
RF/IH, CD, RC, CDX, FC/OT	Per-Firm Cost	\$7,789	\$7,793	\$7,872	\$8,112	\$9,136	\$15,736	\$30,384
	Cost-Revenue Ratio	9.05%	8.48%	3.51%	1.35%	0.40%	0.12%	0.05%
RF/CT, CD	Per-Firm Cost	\$4,365	\$4,365	\$4,375	\$4,406	\$4,539	\$5,392	\$7,287
	Cost-Revenue Ratio	5.07%	4.75%	1.95%	0.73%	0.20%	0.04%	0.01%
RF/IH, CD	Per-Firm Cost	\$4,045	\$4,046	\$4,056	\$4,087	\$4,220	\$5,073	\$6,967
	Cost-Revenue Ratio	4.70%	4.40%	1.81%	0.68%	0.19%	0.04%	0.01%

Summary of Impacts for Small Entities

Table 22 presents the summary of the small business impacts of the proposed rule. For the small firms subject to the rule, 61% are expected to have cost impacts of less than 1% of annual revenues, 18% are expected to have impacts between 1-3%, and 21% are expected to have impacts of more than 3% of annual revenues. The distribution of per-firm costs for manufacturers are estimated to range from \$6,553 to \$1,800,068. Per-firm costs for article importers are estimated to range from \$4,046 to \$224,734. The affected small businesses subject to the rule are expected to incur \$863,483,965 in costs for this one-time reporting.

Note that many of these small entities would have been outside the scope of previous TSCA section 8(a) and CDR reporting because they are considered small manufacturers by the 8(a) definition (either revenues less than \$120 million and less than 100,000 lbs. in production volume, or revenues less than \$12 million regardless of production volume). EPA estimates approximately 98% of all affected firms would be defined as small under the 8(a) definition. Because 8(a) small manufacturers would not be exempt from reporting and recordkeeping requirements under the rule, these firms will still incur costs associated with these activities.

Table 22: Summary of Small Business Impacts

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	234	93%	218	70 (32%)	66 (30%)	82 (38%)
Article Importer	131,157	97%	127,576	77,794 (61%)	23,072 (18%)	26,709 (21%)
Total Industry	131,391	97%	127,794	77,864 (61%)	23,138 (18%)	26,791 (21%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

8. Significant Regulatory Alternatives

A. SMALL BUSINESS ADVOCACY REVIEW PANEL

As required by section 609(b) of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA conducted outreach to small entities and convened a Small Business Advocacy Review Panel on April 20, 2022, to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The Panel solicited input on all aspects of these proposed regulations. Thirteen potentially impacted small entities served as small-entity representatives (SERs) to the Panel, representing a broad range of small entities from diverse geographic locations. The Panel concluded its deliberations on August 2, 2022.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to elements of the Initial Regulatory Flexibility Analysis (IRFA). It is important to note that the Panel's findings and discussion were based on the information available at the time the final report was prepared. EPA has continued to conduct analyses relevant to the rule.

The Panel recommended the following:

- The Panel recommends that EPA carefully consider in the final rule each of the regulatory flexibility alternatives suggested by SERs and provide flexibilities where compliance with the rule as proposed would be infeasible or overly burdensome; to promote consistency in scope and exemptions and avoid duplicative reporting under other EPA reporting programs such as CDR and TRI; and to maximize the data quality, practical utility, necessity and benefit of information collected.
- The Panel recommends that EPA issue and take comment on the Initial Regulatory Flexibility Analysis (IRFA), including on all the small business issues discussed and referenced in the recommendations below, prior to finalizing the proposed rule. The Panel recommends that EPA include in its IRFA a discussion of trade-offs of the different regulatory flexibilities that have been raised by SERs, including an assessment of whether or not those flexibilities would still accomplish the agency's objectives under TSCA section 8(a)(7). The IRFA should include any updated burden, cost, and benefit discussions based on any updates to the economic analysis estimates. The IRFA should use available and reliable data and incorporate cost input from the SERs as applicable to this rule's requirements. This analysis should include the costs of determining whether an entity is subject to the rule including identifying covered substances and the cost of obtaining scientific or technical experts, professional consultants, or legal counsel for compliance purposes, if appropriate.
- The Panel recommends that the IRFA consider the compliance obstacles and costs associated with supply chain communication for importers of articles such as tracking down information for articles dating back to 2011 (for example, if suppliers have gone out of business) and the likely number of suppliers the regulated entities will need to trace to obtain the information required by EPA. The Panel recommends that the IRFA should also explain EPA's assumptions in estimating average industry compliance costs, including for article importers within more complex supply chains. In addition to estimated average industry cost, EPA should include a discussion in the IRFA on potential outliers of those average costs and should request public comment on estimates related to those outliers (for example, companies manufacturing a larger number of chemicals, or entities with many imported articles or product components).
- The Panel recommends that EPA include in its IRFA an exemption for all small entities including small chemical manufacturers and small importers of articles as a significant alternative to the proposed rule.
- The Panel recommends that, in addition to a broad small entity exemption, EPA considers flexibilities including: only reporting for a finite list of chemicals; reporting exemptions for imported articles, R&D substances, byproducts, impurities, recyclers, and intermediates; and implementing a reporting threshold.
- The Panel recommends that EPA clarify whether certain entities are in scope of the final rule, such as different recyclers, article importers, and processors.
- The Panel recommends that EPA clarify the scope of activities required to determine whether an entity has a covered chemical for reporting purposes. For instance, if the agency intends to use a structural definition for PFAS rather than a finite list of chemicals, such clarification or guidance should include examples of activities that entities may conduct to make this determination. Specifically, the Panel recommends that EPA clarify that obtaining a CAS Number and that testing products or chemicals is beyond the scope of the rule.
- The Panel recommends that EPA clarify its due diligence standard to discuss the application of that standard to entities who may be covered under this reporting rule (i.e., who knows or can reasonably ascertain that they have manufactured a PFAS at any point since 2011). The Panel further recommends that EPA provide guidance, training, and webinars for compliance,

including a detailed account of what qualifies as due diligence. The guidance should include EPA's expectations of what is considered "known to or reasonably ascertainable" information to the manufacturers, including importers of articles, including the extent of inquiry within and beyond the organization. Such guidance should also reflect the varying capabilities of the potentially regulated entities to access the required information, including how lack of or varying access to information pursuant to the due diligence standard relates to reporting requirements.

- The Panel recommends that EPA reconsider the proposed timeframe and/or consider providing additional compliance time to small entities, taking into account potential trade-offs such as whether this would extend the reporting timeframe and any potential for duplicative reporting. The Panel recommends that the agency consider means to minimize duplicative reporting under the CDR rule if the compliance timeframes overlap. The Panel further recommends that EPA consider a tiered approach with different deadlines for article importers than for domestic producers and bulk importers. The Panel further recommends that as part of the consideration of a tiered approach, the agency consider first requiring reporting from chemical manufacturers, then extending the requirement to importers of articles.
- The Panel recommends that EPA further update its economic analysis to refine the estimate of the number of small entities impacted by the proposed rule, consider the specific compliance costs raised by SERs, and examine the reduced compliance costs and other potential trade-offs associated with specific regulatory flexibility alternatives in the Initial Regulatory Flexibility Analysis (IRFA).
- The Panel recommends that EPA take all steps available to ensure the CDX tool is available prior to the reporting period and has been adequately vetted to remove bugs or other user interface issues.

Separate from the Panel recommendations, SBA's Office of Advocacy recommended that the agency consider adopting a different due diligence standard that is limited to only known information for this rulemaking. SBA's Office of Advocacy's recommendation states that a different standard is permissible under section 8(a)(7) because the provision does not incorporate the "known or reasonably ascertainable" standard under section 8(a)(2), which only references section 8(a)(1) requirements.

- B. Alternatives Considered

EPA is considering several regulatory flexibility alternatives, discussed below, for this proposed rule, including small business exemptions, removing the structural definition of PFAS, including reporting threshold exemptions, and providing simplified reporting forms for certain entities. When analyzing the regulatory flexibility alternatives, EPA will also consider the factors under section 8(a)(5), which requires EPA, to the extent feasible, to: (A) not require reporting which is unnecessary or duplicative; (B) minimize the cost of compliance on small manufacturers; and (C) apply any reporting obligations on those persons likely to have information relevant to the effective implementation of TSCA.

Small Business Exemptions

- Exemption for businesses with less than \$12 million in sales.

SERs recommended implementing a broad small entity exemption in the final rule. Thus, EPA considered exempting small businesses whose total sales, combined with those of the parent company,

domestic or foreign (if any), are less than \$12 million. This threshold was chosen because firms who meet this standard would be considered “small manufacturers” under the existing section 8(a)(1) definition, and these firms are generally exempt from CDR and other section 8(a)(1) reporting rules (except for substances subject to certain TSCA actions).

Under this regulatory flexibility alternative, 79% of the affected manufacturers would be exempt from the rule and the number of affected manufacturers would decrease from 234 to 49. Of the 49 manufacturing firms, 36 are small businesses. Additionally, 92% of the affected article importers would be exempt from the rule. The number of affected article importers would decrease from 131,157 to 10,493 and the number of article importers that are estimated to report under this rule would decrease from 13,116 to 1,049. Of the 10,493 affected article importers, 7,988 firms are small. As shown in Table 24, under this alternative, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 50,289 PFAS reported; a 25 percent decrease in reports. The total industry cost would decrease from \$875,994,972 to \$71,424,941. The affected small businesses under this alternative would be expected to incur \$50,713,807 in costs for this one-time reporting. This alternative would limit reporting from small manufacturers and thus minimize costs on small manufacturers. However, a chemical manufacturer SER indicated they would have relevant PFAS information under the proposed rule.

Given that the number of reporting firms and PFAS reports decreases under this alternative, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers.

Table 23: Reporting Universe with <\$12M Sales Exemption

Firm Type	All Firms ¹	Percentage Exempted Firms ²	Number of Exempted Firms ³	Number of Affected Firms ⁴	Number of Reporting Firms ⁵
Manufacturers	234	79%	184.86	49	49
Article Importers	131,157	92%	120,664	10,493	1,049
Total Industry	131,391	92%	120,849	10,542	1,098

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS

² Based on 2017 SUSB data.

³ Number of firms with parent revenues less than \$12 million

⁴ Number of firms with parent revenues greater than \$12 million manufacturing PFAS or potentially importing articles containing PFAS. Article importers assumed to incur costs for rule familiarization and for determining if imported products contain PFAS.

⁵ Number of firms with parent revenues greater than \$12 million assumed to submit reports under the rule

Table 24: Number of Reports with <\$12M Sales Exemption

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
Manufacturers	1,369	1,150	84%
Article Importers	65,578	49,139	75%
Total Industry	66,947	50,289	75%

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS

² PFAS reported by firms with parent revenues greater than or equal to \$12 million

EPA estimates that 8,024 small firms would be affected by the rule under this alternative. Of those small firms, 100% are expected to have cost impacts of less than 1% of annual revenue for this one-time reporting.

Table 25: Small Entity Impacts with <\$12M Sales Exemption

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	49	73%	36	36 (100%)	0 (0%)	0 (0%)
Article Importer	10,493	76%	7,988	7,988 (100%)	0 (0%)	0 (0%)
Total Industry	10,542	76%	8,024	8,024 (100%)	0 (0%)	0 (0%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

- Exemption for businesses with less than \$6 million in sales.

SERs recommended implementing a broad small entity exemption in the final rule. In estimating the impact of a potential small entity exemption, EPA developed a sensitivity analysis based on the existing definition for “small manufacturer” at 40 CFR 704.3. As part of this, EPA also considered implementing a small entity threshold 50% below the existing section 8(a)(1) definition. Therefore, EPA considered exempting small businesses whose total sales, combined with those of the parent company, domestic or foreign (if any), are less than \$6 million.

Under this regulatory flexibility alternative, 71% of the affected manufacturers would be exempt from the rule and the number of affected manufacturers would decrease from 234 to 68. Of the 68 manufacturing firms, 61 firms are small. Additionally, 87% of the affected article importers would be exempt from the rule. The number of affected article importers would decrease from 131,157 to 17,050 and the number of article importers that are estimated to report under this rule would decrease from 13,116 to 1,705. Of the 17,050 affected article importers, 15,252 firms are small. As shown in Table 27, under this alternative, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 52,279 PFAS reported; a 22 percent decrease in reports. The total industry cost would decrease from \$875,994,972 to \$115,548,005. The affected small businesses under this alternative would be expected to incur \$96,751,102 in costs for this one-time reporting. This alternative would limit reporting from small manufacturers and thus minimize costs on small manufacturers. However, a chemical manufacturer SER indicated they would have reportable PFAS information. Given that the number of reporting firms and PFAS reports decreases under this alternative, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers.

Table 26: Reporting Universe with <\$6M Sales Exemption

Firm Type	All Firms ¹	Percentage Exempted Firms ²	Number of Exempted Firms ³	Number of Affected Firms ⁴	Number of Reporting Firms ⁵
Manufacturers	234	71%	166.14	68	68
Article Importers	131,157	87%	114,106	17,050	1,705
Total Industry	131,391	87%	114,272	17,118	1,773

- ¹ All firms manufacturing PFAS or potentially importing articles containing PFAS
- ² Based on 2017 SUSB data.
- ³ Number of firms with parent revenues less than \$6 million
- ⁴ Number of firms with parent revenues greater than \$6 million manufacturing PFAS or potentially importing articles containing PFAS. Article importers assumed to incur costs for rule familiarization and for determining if imported products contain PFAS.
- ⁵ Number of firms with parent revenues greater than \$6 million assumed to submit reports under the rule

Table 27: Number of Reports with <\$6M Sales Exemption

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
Manufacturers	1,369	1,181	86%
Article Importers	65,578	51,097	78%
Total Industry	66,947	52,279	78%

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS
² PFAS reported by firms with parent revenues greater than or equal to \$6 million

EPA estimates that 15,313 small firms would be affected by the rule under this alternative. Of those small firms, 100% are expected to have cost impacts of less than 1% of annual revenue for this one-time reporting.

Table 28: Small Entity Impacts with <\$6M Sales Exemption

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	68	90%	61	61 (100%)	0 (0%)	0 (0%)
Article Importer	17,050	89%	15,252	15,252 (100%)	0 (0%)	0 (0%)
Total Industry	17,118	89%	15,313	15,313 (100%)	0 (0%)	0 (0%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

- Exemption for article importers with less than \$6 million in sales.

EPA also considered exempting small article importers, rather than all small firms, from this one-time reporting rule as part of the sensitivity analysis based on the existing section 8(a)(1) definition for “small manufacturer.” Therefore, EPA considered implementing a small entity threshold for article importers 50% below the existing definition at 40 CFR 704.3, as multiple SERs recommended including reporting exemptions for imported articles. This alternative would exempt small article importers whose total sales, combined with those of the parent company, domestic or foreign (if any), are less than \$6 million. Under this regulatory flexibility alternative, 87% of the affected article importers would be exempt from the rule. The number of affected article importers would decrease from 131,157 to 17,050 and the number of article importers that are estimated to report under this rule would decrease from

13,116 to 1,705. Of the 17,050 affected article importers, 15,252 firms are small and of the 234 manufacturing firms, 218 are small. As shown in Table 30, under this alternative, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 52,466 PFAS reported; a 22 percent decrease in reports. The total industry cost would decrease from \$875,994,972 to \$122,922,972. The affected small businesses under this alternative would be expected to incur \$98,430,490 in costs for this one-time reporting. This alternative would limit reporting from certain small manufacturers and thus minimize costs on small manufacturers. Given that the number of reporting article importer firms and PFAS reports decreases under this alternative, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers.

Table 29: Reporting Universe with <\$6M Sales Exemption for Article Importers

Firm Type	All Firms ¹	Percentage Exempted Firms ²	Number of Exempted Firms ³	Number of Affected Firms ⁴	Number of Reporting Firms ⁵
Manufacturers	234	0%	0	234	234
Article Importers	131,157	87%	114,106	17,050	1,705
Total Industry	131,391	87%	114,106	17,284	1,939

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS
² Based on 2017 SUBS data.
³ Number of firms manufacturing or importing PFAS, or firms with parent revenues less than \$6M (for article importers)
⁴ Number of firms manufacturing or importing PFAS, or firms with parent revenues greater than \$6M potentially importing articles containing PFAS. Article importers assumed to incur costs for rule familiarization and for determining if imported products contain PFAS.
⁵ Number of firms manufacturing or importing PFAS, or article importers with parent revenues greater than \$6M assumed to submit reports under the rule

Table 30: Number of Reports with <\$6M Sales Exemption for Article Importers

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
Manufacturers	1,369	1,369	100%
Article Importers	65,578	51,097	78%
Total Industry	66,947	52,466	78%

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS
² PFAS reported by manufacturers or article importers with parent revenues greater than or equal to \$6 million

EPA estimates that 15,557 small firms would be affected by the rule under this alternative. Of those small firms, 99% are expected to have cost impacts of less than 1% of annual revenue for this one-time reporting.

Table 31: Small Entity Impacts with <\$6M Sales Exemption for Article Importers

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%

Manufacturer	234	93%	218	70 (32%)	66 (30%)	82 (38%)
Article Importer	17,050	89%	15,252	15,252 (100%)	0 (0%)	0 (0%)
Total Industry	17,284	90%	15,470	15,322 (99%)	66 (0%)	82 (1%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

- Exemption for article importers with less than \$2 million in revenue.

As part of the sensitivity analysis based on the existing section 8(a)(1) definition for “small manufacturer,” EPA also considered implementing a small entity threshold for article importers approximately 84% below the existing definition at 40 CFR 704.3. Therefore, EPA considered exempting small article importers whose total sales, combined with those of the parent company, domestic or foreign (if any), are less than \$2 million, as multiple SERs recommended including reporting exemptions for imported articles. Under this regulatory flexibility alternative, 70% of the affected article importers would be exempt from the rule. The number of affected article importers would decrease from 131,157 to 39,347 and the number of article importers that are estimated to report under this rule would decrease from 13,116 to 3,935. Of the 39,347 affected article importers, 36,081 firms are small and of the 234 manufacturing firms, 218 are small. As shown in Table 33, under this alternative, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 56,508 PFAS reported; a 16 percent decrease in reports. The total industry cost would decrease from \$875,994,972 to \$270,083,083. The affected small businesses under this alternative would be expected to incur \$229,662,145 in costs for this one-time reporting. This alternative would limit reporting from certain small manufacturers and thus minimize costs on small manufacturers. Given that the number of reporting article importer firms and PFAS reports decreases under this alternative, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers.

Table 32: Reporting Universe with <\$2M Sales Exemption for Article Importers

Firm Type	All Firms ¹	Percentage Exempted Firms ²	Number of Exempted Firms ³	Number of Affected Firms ⁴	Number of Reporting Firms ⁵
Manufacturers	234	0%	0	234	234
Article Importers	131,157	70%	91,810	39,347	3,935
Total Industry	131,391	70%	91,810	39,581	4,169

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS

² Based on 2017 SUSB data.

³ Number of firms manufacturing or importing PFAS, or firms with parent revenues less than \$2M (for article importers)

⁴ Number of firms manufacturing or importing PFAS, or firms with parent revenues greater than \$2M potentially importing articles containing PFAS. Article importers assumed to incur costs for rule familiarization and for determining if imported products contain PFAS.

⁵ Number of firms manufacturing or importing PFAS, or article importers with parent revenues greater than \$2M assumed to submit reports under the rule

Table 33: Number of Reports with <\$2M Sales Exemption for Article Importers

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
Manufacturers	1,369	1,369	100%
Article Importers	65,578	55,139	84%
Total Industry	66,947	56,508	84%

¹ All firms manufacturing PFAS or potentially importing articles containing PFAS
² PFAS reported by manufacturers or article importers with parent revenues greater than or equal to \$2 million

EPA estimates that 36,299 small firms would be affected by the rule under this alternative. Of those small firms, 99% are expected to have cost impacts of less than 1% of annual revenue for this one-time reporting.

Table 34: Small Entity Impacts with <\$2M Sales Exemption for Article Importers

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	234	93%	218	70 (32%)	66 (30%)	82 (38%)
Article Importer	39,347	92%	36,081	36,081 (100%)	0 (0%)	0 (0%)
Total Industry	39,581	92%	36,299	36,151 (99%)	66 (0%)	82 (1%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

Removing the Structural Definition

- Limit the scope to a finite list of PFAS subject to the rule.

EPA considered limiting the PFAS subject to the rule to a finite list rather than providing a structural definition for PFAS, as this alternative was recommended by multiple SERs. This alternative simplifies rule familiarization for affected entities and removes the cost and burden of understanding the structural definition of PFAS. 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. For example, under the proposed structural definition, over 200 PFAS have the term “fluorine” masked in their generic names. EPA is unable to include the generic names of these substances on a list of PFAS (which, by definition, contain fluorine) as it would reveal masked structural information on these substances. If EPA limited the scope to a discrete list of PFAS on the TSCA Inventory and LVEs that could be specifically named under the proposed definition, 578 PFAS would be subject to the rule.³⁰ With 786 fewer identified PFAS within the scope of the rule, the estimated number of reporting firms decreases to 6,657. This alternative would reduce the number of reporting firms, including small businesses, and thus minimize costs on small entities. Under this regulatory flexibility alternative, the number of affected manufacturers would decrease from 234 to 99 and the number of article importers that are estimated to report under this rule would decrease from 13,116 to 6,558. Under this alternative,

³⁰ In the proposed rule, EPA identified 1,364 PFAS that would fall under the structural definition. But if the scope was limited to a finite list of PFAS, EPA would only be able to list 578 PFAS due to CBI claims.

92 small manufacturing firms and 127,576 small article importers would be affected. The proposed rule would affect 218 small manufacturers, but under this alternative 126 small manufacturing firms would be exempt. As shown in Table 35, if EPA were to limit the scope of the rule to a finite list of PFAS, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 33,368 PFAS reported; a 50 percent decrease in reports. Given that both the number of chemicals subject to the rule and the number of reporting firms decrease under this alternative, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers.

EPA estimates that 127,668 small firms would be affected by the rule under this alternative. Of those small firms, 62% are expected to have cost impacts of less than 1% of annual revenue, 18% are expected to have impacts between 1-3%, and 20% are expected to have impacts of more than 3% of annual revenues for this one-time reporting. The total industry cost would decrease from \$875,994,972 to \$706,856,766 due to the decrease in the number of reportable substances and the subsequent decrease in reporting firms. The affected small businesses under this alternative would be expected to incur \$644,584,194 in costs for this one-time reporting.

Table 35: Number of Reports with Finite List of PFAS

Firm Type	Estimated PFAS Reported with Structural Definition	Estimated PFAS Reported with Finite List	Estimated Percentage PFAS Reported
Manufacturers	1,369	578	42%
Article Importers	65,578	32,790	50%
Total Industry	66,947	33,368	50%

Note: Totals may not sum due to rounding.

Table 36: Small Entity Impacts – Finite list of PFAS

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	99	93%	92	30 (33%)	27 (30%)	34 (37%)
Article Importer	131,157	97%	127,576	78,956 (62%)	22,508 (18%)	26,112 (20%)
Total Industry	131,256	97%	127,668	78,986 (62%)	22,535 (18%)	26,147 (20%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

Reporting Threshold Exemptions

- Reporting Threshold of either 2,500 lbs. per year or 25,000 lbs. per year.

EPA considered providing a reporting threshold exemption, as this alternative was recommended by multiple SERs. For this alternative, EPA considered providing an annual reporting threshold exemption of 2,500 lbs. per year and an annual reporting threshold exemption of 25,000 lbs. per year. These thresholds were chosen because manufacturers are required to report to CDR if they meet certain annual production volume thresholds, generally 25,000 lbs. or more of a chemical substance at a single site. However, a reduced reporting threshold of 2,500 lbs. applies to chemical substances subject to certain TSCA actions. Additionally, many SERs recommended that EPA implement a CDR-based reporting threshold in the final rule. Reporting would be triggered if the annual reporting threshold at a manufacturing (including importing) site is met during any of the calendar years since January 1, 2011. The majority of costs for this rule come from rule familiarization and article compliance determination activities, which would likely not be affected by implementing a reporting threshold. Based on public comments EPA received on the proposed rule, not all article importers will readily know or reasonably ascertain if the imported articles contain PFAS or the total import volumes of the PFAS; and consequently, these firms may still need to conduct compliance determination activities even with a reporting threshold in place. Therefore, this alternative is not expected to lower per-firm costs. A reporting threshold would likely decrease the number of reporting entities but given the lack of data it is difficult to accurately estimate the effect, particularly since article importers may not know enough about the concentration or volumes of the PFAS in their imported articles to know if they are below the reporting threshold. EPA is soliciting public comment on the number of entities that would be affected by a reporting threshold of either 2,500 lbs. per year or 25,000 lbs. per year. EPA is soliciting public comment on the number of entities that would be affected by a reporting threshold of either 2,500 lbs. per year or 25,000 lbs. per year.

While this alternative is not expected to reduce per-firm costs, it is expected to reduce total industry costs as some firms, including small entities, will be exempt from reporting if they are under the reporting threshold. However, some SERs indicated they would have reportable PFAS information and be under these reporting thresholds. To give an idea of the effect a reporting threshold could potentially have, EPA provides low- and high-end estimates for this alternative. Given the lack of data on low production volumes and article importers' lack of knowledge regarding the concentration or volumes of the PFAS in their imported articles, EPA was unable to provide estimates for the specific 25,000 lbs. and 2,500 lbs. reporting threshold exemptions. Instead, EPA alters the number of article importers reporting under this alternative, regardless of the specific reporting threshold chosen, to show the potential decrease in reporting firms. In the primary analysis, EPA estimates that 131,157 firms import articles potentially containing PFAS, but only 10% of those firms import articles containing PFAS and are subject to the rule's reporting requirements. For the low-end estimate, EPA assumes that 5% of the affected article importer firms import articles containing PFAS above a given threshold and are subject to the rule's reporting requirements. Thus, the low-end estimate assumes that the number of article importers reporting under the rule would decrease from 13,116 to 6,558 firms, 6,379 of which are small. Under this alternative for the low-end estimate, EPA estimates that total number of PFAS reports submitted would decrease by 49 percent. Of those small firms, 62% are expected to have cost impacts of less than 1% of annual revenue, 18% are expected to have impacts between 1-3%, and 20% are expected to have impacts of more than 3% of annual revenues for this one-time reporting. And the total industry cost would decrease from \$875,994,972 to \$790,303,775. The affected small businesses under this alternative would be expected to incur \$780,132,292 in costs for this one-time reporting.

Table 37: Number of Reports with Reporting Threshold (Low)

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
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Manufacturers	1,369	1,369	100%
Article Importers	65,578	32,790	50%
Total Industry	66,947	34,159	51%
¹ All firms manufacturing PFAS or potentially importing articles containing PFAS regardless of volume ² PFAS reported by manufacturers or article importers with volumes greater than the reporting threshold			

Table 38: Small Entity Impacts – Reporting Threshold (Low Estimate)

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	234	93%	218	70 (32%)	66 (30%)	82 (38%)
Article Importer	131,157	97%	127,576	78,9564 (62%)	22,508 (18%)	26,112 (21%)
Total Industry	131,391	97%	127,794	79,026 (62%)	22,508 (18%)	26,194 (20%)
Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.						

As shown in Table 18, EPA assumes that 0.5% of all affected article importers will know enough information to report on the production volume. Therefore, even if EPA were to include a reporting threshold exemption, many article importers may not know enough to determine if they are below the threshold. Given this, for the high-end estimate, EPA assumes that 9.5% of the affected article importer firms import articles containing PFAS above a given threshold and are subject to the rule’s reporting requirements. EPA assumes that the number of article importers reporting under the rule would decrease from 13,116 to 12,460 firms, 12,120 of which are small. As shown in Table 39, under this alternative for the high-end estimate, EPA estimates that total number of PFAS reports submitted would decrease from 66,947 PFAS to 63,669 PFAS reported; a 5 percent decrease in reports. Of those small firms, 62% are expected to have cost impacts of less than 1% of annual revenue, 18% are expected to have impacts between 1-3%, and 21% are expected to have impacts of more than 3% of annual revenues for this one-time reporting. And the total industry cost would decrease from \$875,994,972 to \$867,425,852. The affected small businesses under this alternative would be expected to incur \$855,148,798 in costs for this one-time reporting.

Table 39: Number of Reports with Reporting Threshold (High)

Firm Type	Expected PFAS for All Firms ¹	Estimated PFAS Reported by Non-Exempt Firms ²	Estimated Percentage PFAS Reported
Manufacturers	1,369	1,369	100%
Article Importers	65,578	62,300	95%
Total Industry	66,947	63,669	95%
¹ All firms manufacturing PFAS or potentially importing articles containing PFAS regardless of volume ² PFAS reported by manufacturers or article importers with volumes greater than the reporting threshold			

Table 40: Small Entity Impacts – Reporting Threshold (High Estimate)

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	234	93%	218	70 (32%)	66 (30%)	82 (38%)
Article Importer	131,157	97%	127,576	77,711 (61%)	23,016 (18%)	26,650 (21%)
Total Industry	131,391	97%	127,794	77,980 (61%)	23,082 (18%)	26,732 (21%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

Reporting Timeline

- Longer Reporting Timeline for Small Businesses

The compliance schedule proposed by EPA includes a six-month deferral of the data submission period following the effective date of the final rule, and then another six-month information submission period. Thus, the reporting deadline would be one year from the effective date of the final rule. EPA considered providing a longer reporting timeline for small businesses whose total sales, combined with those of the parent company, domestic or foreign (if any), are less than \$12 million. Additionally, many SERs recommended that EPA implement longer reporting timeline in the final rule. SERs suggested extending the reporting timeline or implementing a phased-in (or tiered) reporting approach for different substances or entities. SERs also suggested modifying the reporting period (or, the lookback period), including considering the limited availability of historical records. Many SERs suggested that the proposed timeline is extended by at least six months, with some SERs suggesting up to two years, to allow more time for small entities to familiarize themselves with the rule and its requirements, including the CDX reporting platform. SERs provided that the additional time would be important for entities who do not have experience with TSCA regulations, the section 8(a) reporting standard, or using CDX. A longer timeframe could potentially decrease opportunity costs if firms are diverting resources from other business activities to report information under the rule.

Under this regulatory alternative, six more months would be added 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 would then be followed by a six-month reporting submission period. Thus, information would be due 18 months following the effective date of this rule. The submission period under this alternative would end June 1, 2024 (if the rule was finalized January 1, 2023). This alternative may reduce the opportunity costs on affected firms, particularly small entities.

As discussed previously, the next CDR submission period is June 1 to September 30, 2024. Manufacturers will determine their need to report to CDR based on production volumes from the years 2020 to 2023. Some of the data elements under this proposed rule may overlap with the data required under the 2024 CDR reporting cycle, though the scope of such overlap is not significant. There are several differences between the CDR rule and this rule that limit the scope of any potential overlaps between the datasets. First, CDR includes several reporting exemptions and a reporting threshold based on production volume that are not included in this rule: imported articles, certain byproducts, non-isolated intermediates, small quantities of R&D chemicals, 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 reporting threshold will not have reported such information to CDR before and reporting from these entities 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. Additionally, the scope of PFAS that have been reportable under CDR are a subset of the scope of PFAS for this rule. The scope of CDR chemical substances is limited to those on the TSCA 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.

Simplified Reporting Forms

Other alternatives considered by EPA for this rule involved providing simplified reporting forms for certain entities. EPA considered a simplified reporting form for R&D substances manufactured in volumes of less than 10 kg per year and a simplified reporting form for article importers. EPA considered these alternatives following input from SERs regarding the information likely known to or reasonably ascertainable by both article importers and manufacturers of R&D substances in very low quantities (i.e., for laboratory analytical purposes only). EPA anticipates that both alternatives would still allow EPA to collect most of the relevant historical PFAS data from manufacturers and article importers while lessening the burden on industry.

- Simplified reporting form for R&D substances manufactured in volumes of less than 10 kg per year.

EPA considered providing a streamlined reporting form for R&D substances manufactured in volumes of less than 10 kg per year. The data elements required on the simplified form would include, for each year: (1) company and plant site information, (2) specific or generic chemical name/ID, and (3) production volume of PFAS. Based on EPA’s knowledge of manufacturers of R&D substances in low quantities and input from SERs, such manufacturers may have less information to report under this rule than other manufacturers. EPA understands from stakeholder input that low volumes of R&D substances are used for laboratory analytical purposes only, and therefore such manufacturers would not likely know or reasonably ascertain any of the reportable information other than chemical identity and production volume. Therefore, this option could still enable EPA to collect all the known or reasonably ascertainable historical PFAS data and reduce industry burden. Due to the lack of data on R&D substances (including reporting exemptions for small quantities of R&D substances under both CDR and PMN reporting), EPA was unable to determine the number of affected entities and substances for this alternative, and hence was unable to estimate total potential cost savings. The table below shows the per-firm burden and costs associated with simplified form completion for an R&D manufacturing firm. This alternative would reduce the reporting burden on research and development substance manufacturers, some of which are small entities. Under the proposed rule, EPA estimates each manufacturing firm will incur an average of approximately 507 burden hours and \$41,151.54 in costs per firm. For this alternative, EPA estimates an R&D manufacturing firm will incur an average of approximately 105 burden hours and \$8,340 in costs per firm.

Table 41: Per-Firm Industry Burden and Cost: Simplified Reporting Form for R&D Substances (2021\$)

Reporting Element	Burden per Firm (hours)				Cost per Firm (2021\$)			
	Clerical	Technical	Managerial	Total	Clerical (\$37.18/hr)	Technical (\$81.40/hr)	Managerial (\$93.18/hr)	Total

Company and plant site information	0	0.024	0.009	0.033	\$0.00	\$1.95	\$0.84	\$2.79
Common or trade name, chemical identity, and molecular structure	10.24	26.33	5.85	42.41	\$380.59	\$2,142.75	\$545.10	\$3,068.44
Total production volume	0	50.19	12.69	62.89	\$0.00	\$4,085.51	\$1,182.87	\$5,268.38
Total	10.24	76.544	18.549	105.33	\$380.59	\$6,230.21	\$1,728.81	\$8,339.61

Note: Estimates may not sum due to rounding

Sources: EPA 1994; EPA 2018a; BLS 2022a

- Simplified reporting form for article importers.

EPA also considered providing a simplified reporting for article importers. The data elements required on the simplified form would include, for each year: (1) a checkbox/indicator for importing PFAS-containing articles, (2) volume/quantity of imported articles, (3) industrial processing/use and consumer/commercial use information (i.e., processing/use codes), (4) specific or generic chemical name/ID, or description of the PFAS-containing article/component (e.g., coating name), and (5) company information. Additionally, article importers would have the option to provide more information and documentation if such information were known or reasonably ascertainable. With this alternative, article importers would not be required to report existing environmental and health effects data, environmental release and disposal data, or occupational exposure data.

Based on EPA’s knowledge of article importers and input from SERs, article importers may have less information to report under this rule than other manufacturers. Therefore, this option could still enable EPA to collect all the known or reasonably ascertainable historical PFAS data and reduce industry burden. Compared to the proposed rule, this option would reduce the average per-firm burden on all article importers, including those who would not submit reports, from 90 hours to 73 hours, with a reduction in average per-firm cost from \$6,603 to \$5,201.

This alternative would reduce the reporting burden on article importers, 97.3 percent of which are small entities. For small article importers who would report, this option would reduce per-firm burden from 247 hours to 142 hours, with a reduction in per-firm cost from \$19,154 to \$10,628. The total industry cost would decrease from \$875,994,972 to \$692,112,495. The affected small businesses subject to the rule are expected to incur \$613,463,399 in costs for this one-time reporting. Of those small firms, 63% are expected to have cost impacts of less than 1% of annual revenue, 19% are expected to have impacts between 1-3%, and 18% are expected to have impacts of more than 3% of annual revenues for this one-time reporting.

Table 42: Small Entity Impacts – Simplified Reporting Form for Article Importers

Firm Type	Affected Firms			Number and Percent of Small Firms by Cost-Impact Ratio		
	All Firms	Percent Small	Small Firms	<1%	1-3%	>3%
Manufacturer	234	93%	218	139 (64%)	39 (18%)	39 (18%)
Article Importer	131,157	97.3%	127,576	80,984 (63%)	24,008 (19%)	22,584 (18%)
Total Industry	131,391	97.3%	127,794	81,123 (63%)	24,047 (19%)	22,624 (18%)

Note: Estimates for the number of firms are rounded to the nearest firm, so totals may not sum due to rounding.

Other Exemptions Considered

EPA also considered providing reporting exemptions for research and development substances, byproducts, impurities, recyclers, and intermediates. Additionally, many SERs suggested that EPA implement such exemptions, and the SBAR Panel recommended that EPA consider such exemptions. Given the lack of data on all these types of substances, EPA is unable to estimate the total industry cost of exempting them from the rule.

Though if exempted, EPA may not be able to collect all known or reasonably ascertainable historical PFAS data from manufacturers and importers, particularly since EPA would typically not otherwise receive this type of information on R&D substances, byproducts, impurities, recyclers, and

intermediates. Providing wholesale exemptions for substances such as these would likely not enable EPA to achieve its goal of better understanding the entire scope of existing information on these substances.

Table 43: Summary Table

Alternative	Total Deduction in Cost	Total Deduction in Small Business Cost	Total Small Business Cost	Total Cost
Notice of Proposed Rulemaking Regulatory Proposal	\$0	\$0	\$863,483,965	\$875,994,972
Exemption for businesses with less than \$12 million in revenue.	\$804,570,031	\$812,770,158	\$50,713,807	\$71,424,941
Exemption for businesses with less than \$6 million in revenue.	\$760,446,967	\$766,732,863	\$96,751,102 (\$115,548,005
Exemption for article importers with less than \$6 million in revenue.	\$753,072,000	\$765,053,475	\$98,430,490	\$122,922,972
Exemption for article importers with less than \$2 million in revenue.	\$605,911,899	\$633,821,820	\$229,662,145	\$270,083,083
Limit the scope to a finite list of PFAS subject to the rule.	\$169,138,206	\$218,899,771	\$644,584,194	\$706,856,766
Reporting Threshold of either 2,500 lbs. per year or 25,000 lbs. per year	\$85,491,197 - \$85,691,197	\$83,351,673 - \$8,335,167	\$780,132,292 - \$855,148,798	\$790,303,775 - \$867,427,511
Longer Reporting Timeline for Small Businesses	Not quantified, potential decrease in opportunity costs	N/A	N/A	N/A
Simplified reporting form for R&D substances manufactured in volumes of less than 10 kg per year	Not quantified in aggregate costs	N/A	N/A	N/A
Simplified reporting form for article importers	\$183,882,477	\$250,020,566	\$613,463,399	\$692,112,495
Exemptions for research and development substances, byproducts, impurities, recyclers, and intermediates	Not quantified	N/A	N/A	N/A

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Appendix A: Wage Rate Calculations

This appendix describes the derivation of the fully loaded wage rates used in calculating costs of labor, materials, and other inputs. All cost estimates are presented in 2021 dollars.

Wage rates for managerial, professional/technical, and clerical labor are from the U.S. Bureau of Labor Statistics' (BLS) Employer Costs for Employee Compensation (ECEC) historical data for December 2021 (BLS 2022a). For attorney, the wage rate was taken from the BLS Occupational Employment Statistics (OES) May 2021 National Industry-Specific Occupational Employment and Wage Estimates for Sectors 31, 32, and 33 – Manufacturing and SOC Code 23-1011 – Lawyers (BLS 2020; BLS 2022b).

The costs of fringe benefits such as paid leave and insurance, specific to each labor category, are taken from the same BLS report (BLS 2022a). Overhead costs are assumed to equal 20% of the sum of wages plus fringe benefits. This loading factor is described in *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions* (EPA 2020c) and is reflective of multiplier values used in prior EPA economic analyses and ICRs that are based on industry- and occupation-specific overhead rates affected by EPA regulations. This overhead loading factor is multiplied by the total compensation (wages plus fringe benefits). For example, the fully loaded wage rate for professional/technical labor is $(\$44.99 + \$22.84) * 1.2 = \$81.40$. Fully loaded costs for managerial, clerical, and attorney labor are calculated in a similar manner. The calculated overhead costs (20% of the total compensation) are shown in Table A-1 as well as the total hourly loaded wages.

Table A-1: Loaded Industry Wage Rates (2021\$)

Labor Category	Data Source for Wage Information	Wage ¹	Fringe Benefit ²	Total Compensation	Overhead % of Total Compensation ³	Overhead	Hourly Loaded Wages ⁴
		A	B	C = A + B	D	E = C x D	F = C + E
Clerical	BLS ECEC, Private Manufacturing industries, "Office and administrative support occupations"	\$21.48	\$9.50	\$30.98	20%	\$6.20	\$37.18
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related occupations"	\$44.99	\$22.84	\$67.83	20%	\$13.57	\$81.40
Managerial	BLS ECEC, Private Manufacturing industries, "Management, business, and financial occupations"	\$53.49	\$24.16	\$77.65	20%	\$15.53	\$93.18
Attorney	BLS OES, Occupational Employment and Wages, 23-1011 Lawyers	\$71.17	\$29.90	\$101.07	20%	\$20.21	\$121.28

¹ Source: Employer Costs for Employee Compensation Tables: December 2021 (BLS 2022a); National Industry-Specific Occupational Employment and Wage Estimates, May 2021 (BLS 2022b).

² Source: Employer Costs for Employee Compensation Tables: December 2021 (BLS 2022a)

³ An overhead rate of 20% is used based on assumptions in *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and other U.S. EPA Actions* (EPA 2020c).

⁴ Values may not sum due to rounding. Wage rates are rounded to the nearest cent.

Unit wage rates for EPA staff are calculated based on annual federal salaries for the Washington-Baltimore area published by the Office of Personnel Management (OPM) and effective January 2021 (OPM 2021). The average salary for one full-time equivalent (FTE) technical/professional staff member is estimated as the salary for a GS-13 Step 5 employee, and the average salary for on FTE attorney staff member is estimated as the salary for a GS-14, Step 5 employee. EPA’s *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other EPA Actions* (EPA 2020c) recommends a study by the Congressional Budget Office (Falk 2012) for estimating benefit values for federal government workers. The study reports that total benefits account for 63.9 percent of average wages in the federal government sector. Therefore, 63.9 percent of the wage is used to calculate the fringe in the derivation of Agency wage rates. An additional factor of 20 percent is applied to wages to account for overhead, consistent with the approach described in Section A.1 for industry wage rates.

The loaded hourly salary of EPA staff was calculated to be \$110.75. Fully loaded costs for Agency labor are shown in Table A-2.

Table A-2: Derivation of Loaded Agency Wage Rates (2021\$)

Labor Category	Data Source for Wage Information	Wage (\$/hour)	Fringes as % of Wage ²	Fringe Benefit	Total Compensation	Overhead as % of Total Compensation ³	Overhead	Loaded Wage (\$/hr)
		A	B	$C = A * B$	$D = A + C$	E	$F = D * E$	$G = D + F$
Technical	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates ¹	\$56.31	63.9%	\$35.98	\$92.29	20.0%	\$18.46	\$110.75

¹ Source: U.S. Office of Personnel Management 2021

² Source: Falk 2012

³ An overhead rate of 20% is used based on assumptions in *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions* (EPA 2020c)

Appendix B: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
3701 Photo Plates & Film, Flat, Sensitized, Unexposed	Photographic industry	Photographic materials, such as films and papers
3703 Photo Paper, Paperboard & Textiles, Sens, Unexpos	Photographic industry	Paper and plates
3704 Photo Plates, Flm, Paper, Etc, Exposed, Nt Develop	Photographic industry	Paper and plates
3705 Photo Plates & Still Film, Exposed & Developed	Photographic industry	Paper and plates
39 Plastics And Articles Thereof	Automotive	Interior
	Coatings, paints and varnishes	Coatings
		Paints
	Household applications	Threads and joints
	Laboratory supplies, equipment and instrumentation	Consumable materials (vials, caps, tape)
	Oil and gas industry	Oil and gas transport
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Plastic and rubber	Plastic
		Polycarbonate resins
		Resin
Production of plastic and rubber	Fluoroelastomer formulation	
Sealants and adhesives	Adhesives	
40 Rubber And Articles Thereof	Coatings, paints and varnishes	Paints
	Laboratory supplies, equipment and instrumentation	Personal protective equipment (gloves)
	Pharmaceutical industry	Reaction vessels, stirrers, and other components
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Plastic and rubber	Bonding of rubber to steel
		Rubber and plastic
		Thermoplastic
Production of plastic and rubber	Fluoroelastomer formulation	
Sealants and adhesives	Silicone rubber seals	
4104 Bovine Or Equine Leather, No Hair Nesoi	Leather	Repellent treatment (genuine leather)

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
4105 Sheep Or Lamb Skin Leather, No Wool Nesoi		
4106 Other Animal N Leather, No Hair Nesoi		
4107 Leather Furt Prep Aft Tan/crust, No Hair On,nes		
4108 Chamois (including Combination Chamois) Leather		
4109 Patent & Patent Laminated Leather; Metallzd Leathr		
411000 Leather Waste; Leather Dust, Powder And Flour		
4111 Composition Lea, Lea Fiber In Slabs, Sheets, Strip		
4112 Sheep/lamb Ltr,ft Prp Tan/crus, W/o Wool,nt Hd4114		
4113 Lthr Fthr Perp After Tanning,of Oth Aml, W/o Wl/hr		
4114 Chamois/patent/patent Laminated/metallized Leather		
4115 Comps. Lthr,fbr Slb/sht/srp;lthr Wst/dust/pwd/flou		
42 Leather Art; Saddlery Etc; Handbags Etc; Gut Art		
4410 Particle Board & Similar Board Of Wood Etc.	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate Wood particleboard
4411 Fiberboard Of Wood Or Other Ligneous Materials	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate Wood particleboard
4412 Plywood, Veneered Panels & Similar Laminated Wood	Wood industry	Coating for wood substrate
		Wood particleboard
4414 Wooden Frames Paintings, Photographs, Mirrors, Etc	Wood industry	Coating for wood substrate
		Wood particleboard
4415 Packings Etc, Wood; Pallets, Collars Etc, Of Wood	Wood industry	Coating for wood substrate
		Wood particleboard
4416 Casks, Barrels, Vats, Etc. And Parts, Of Wood	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate Wood particleboard

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
4417 Tools/tool & Broom Bodies Etc Shoe Last/trees Wood	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate
		Wood particleboard
4418 Builders' Joinery And Carpentry Of Wood	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate
		Wood particleboard
4419 Tableware And Kitchenware, Of Wood	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate
		Wood particleboard
4420 Wood Marquetry Etc; Jewel Case Etc & Wd Furn Nesoi	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate
		Wood particleboard
4421 Articles Of Wood, Nesoi	Sealants and adhesives	Adhesives
	Wood industry	Coating for wood substrate
		Wood particleboard
4805 Paper & Paperboard, Uncoat, Nesoi, Rolls Or Sheets	Paper and packaging	Paper and cardboard
4807 Composite Paper & Paperboard, No Surf Coat, Rl Etc	Paper and packaging	Paper and cardboard
	Pharmaceutical industry	Packaging
4808 Paper And Paperboard, Corrugated Etc, Rolls Etc	Paper and packaging	Paper and cardboard
	Pharmaceutical industry	Packaging
4810 Paper & Paperboard, Coated With Kaolin Etc, Rl Etc	Paper and packaging	Paper and cardboard
	Pharmaceutical industry	Packaging
4811 Paper, Paperboard, Wad Etc, Coat Etc Nesoi, Rl Etc	Paper and packaging	Paper and cardboard
	Pharmaceutical industry	Packaging
4814 Wallpaper Etc.; Window Transparencies Of Paper	Paper and packaging	Paper and cardboard
4819 Cartons Etc Paper; Office Box Files Etc, Paper Etc	Pharmaceutical industry	Packaging
	Paper and packaging	Paper and cardboard
4823 Paper, Paperboard, Cellul Wad To Size & Arts Nesoi	Pharmaceutical industry	Packaging
	Paper and packaging	Paper and cardboard
51 Wool & Animal Hair, Including Yarn & Woven Fabric	Textile and upholstery	Weaving yarn
52 Cotton, Including Yarn And Woven Fabric Thereof		
53 Veg Text Fib Nesoi; Veg Fib & Paper Yns & Wov Fab		
54 Manmade Filaments, Including Yarns & Woven Fabrics		
	Automotive	Interior

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
57 Carpets And Other Textile Floor Coverings	Floor covering including carpets and floor polish	Soil release finishes for carpets
58 Spec Wov Fabrics; Tufted Fab; Lace; Tapestries Etc	Textile and upholstery	Surface treatment
59 Impregnated Etc Text Fabrics; Tex Art For Industry	Floor covering including carpets and floor polish	Resilient linoleum
	Textile and upholstery	Surface treatment
6201 Men's Or Boys' Overcoats, Cloaks Etc, Not Knit Etc	Apparel	Long-lasting durable water repellent finish
6202 Women's Or Girls' Overcoats Etc, Not Knit Or Croch		
6210 Garments, Of Felt Etc, Or Fabric Impregnated Etc		
6211 Track Suits, Ski-suits & Swimwear, Not Knit Etc		
6216 Gloves, Mittens And Mitts, Not Knit Or Crocheted		
63 Textile Art Nesoi; Needlecraft Sets; Worn Text Art	Textile and upholstery	Surface treatment
6401 Waterproof Footwear, Rubber Or Plastics, Bond Sole	Apparel	Long-lasting durable water repellent finish
6402 Footwear, Outer Sole & Upper Rubber Or Plast Nesoi		
6403 Footwear, Outer Sole Rub, Plast Or Lea & Upper Lea		
6406 Parts Of Footwear; Insoles Etc; Gaitors Etc, Parts		
6601 Umbrellas & Sun Umbrellas & Other Umbrellas	Textile and upholstery	Surface treatment
68 Art Of Stone, Plaster, Cement, Asbestos, Mica Etc.	Automotive	Brake pad additives
	Coatings, paints and varnishes	Coatings
	Stone, concrete and tile	Stone, concrete and tile
	Building and construction	Architectural membranges (e.g. in roofs)
69 Ceramic Products	Building and construction	Architectural membranges (e.g. in roofs)
	Coatings, paints and varnishes	Coatings
		Paints
70 Glass And Glassware	Coatings, paints and varnishes	Coatings
		Paints
	Glass	Surface treatment

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
	Laboratory supplies, equipment and instrumentation	Consumable materials (vials, caps, tape)
	Pharmaceutical industry	Reaction vessels, stirrers, and other components
73 Articles Of Iron Or Steel	Aerospace	Thermal control and radiator surfaces
	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Oil and gas industry	Drilling - insulating material for cable and wire
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
74 Copper And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
75 Nickel And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire
76 Aluminum And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
78 Lead And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire
79 Zinc And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire
80 Tin And Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire
81 Base Metals Nesoi; Cermet; Articles Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
	Oil and gas industry	Drilling - insulating material for cable and wire
82 Tools, Cutlery Etc. Of Base Metal & Parts Thereof	Building and construction	Cable and wire insulation, gaskets & hoses
	Electronic devices	Razors
	Manufacture of metal products	Treatment of coating of metal surfaces

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
	Oil and gas industry	Drilling - insulating material for cable and wire
	Pipes, pumps, fittings and liners	Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners
	Wire and cable	Wire and cable
83 Miscellaneous Articles Of Base Metal	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
	Oil and gas industry	Drilling - insulating material for cable and wire
Wire and cable	Wire and cable	
84 Nuclear Reactors, Boilers, Machinery Etc.; Parts	Automotive	Cylinder head coatings and hoses
		Electronics
		Engine and steering system
	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Energy	Wind mill blades
	Machinery and equipment	Machinery and equipment
	Oil and gas industry	Drilling - insulating material for cable and wire
	Printing (inks)	Ink-jet recording heads
		Lithographic printing plates
	Semiconductor industry	Antireflective coating
		Multilayer circuit board
		Photoresist
Technical equipment in contact with process chemical or reactive plasma		
Wafer thinning		
Wire and cable	Wire and cable	
85 Electric Machinery Etc; Sound Equip; Tv Equip; Pts	Aerospace	Wire and cable
	Building and construction	Cable and wire insulation, gaskets & hoses
	Coatings, paints and varnishes	Coatings
		Paints
	Electronic devices	Acoustical equipment
		Capacitors
		Electroluminescent lamps
		Light management films in flat panel display
		Liquid crystal displays (LCDs)
	Printed circuit boards	
Energy	Alkaline manganese batteries	

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
		Ion exchange membrane in vanadium redox batteries
		Lithium batteries
		Photovoltaic cells
		Polymer electrolyte fuel cells
		Solar collectors and photovoltaic cells
		Zinc batteries
	Flame retardants	Polycarbonate resin
	Laboratory supplies, equipment and instrumentation	Liquid chromatography columns
		Liquid chromatography instruments
	Oil and gas industry	Drilling - insulating material for cable and wire
	Semiconductor industry	Antireflective coating
		Multilayer circuit board
Photoresist		
Technical equipment in contact with process chemical or reactive plasma		
Wafer thinning		
Wire and cable	Wire and cable	
86 Railway Or Tramway Stock Etc; Traffic Signal Equip	Coatings, paints and varnishes	Coatings
		Paints
	Manufacture of metal products	Treatment of coating of metal surfaces
87 Vehicles, Except Railway Or Tramway, And Parts Etc	Aerospace	Wire and cable
		Automotive waxes
		Brake pad additives
		Car body
		Cylinder head coatings and hoses
		Electronics
		Engine and steering system
		Fuel lines, steel hydraulic brake tubes
	Interior	
	Coatings, paints and varnishes	Coatings
		Paints
88 Aircraft, Spacecraft, And Parts Thereof	Aerospace	Wire and cable
	Coatings, paints and varnishes	Coatings
		Paints
89 Ships, Boats And Floating Structures	Coatings, paints and varnishes	Coatings
		Paints
	Sport article	Sailing boat equipment
9101 Watches, Wrist, Pocket Etc, Prec Metal Or Cld Case	Watchmaking industry	Lubricants

Table B-1: Crosswalk of Harmonised Tariff System Codes and PFAS Uses in Articles

HTS Code	Industry	Use
9102 Watches, Wrist, Pocket Etc, Case Not Prec Nor Clad		
9104 Inst Panel Clk & Clk Simlr,for Vehicle,aircft,etc	Automotive	Automotive
9108 Watch Movements, Complete & Assembled	Watchmaking industry	Lubricants
9110 Comp Watch Or Clock Mvt; Incom Watch Or Clock Mvt		
9201 Pianos, Harpsichords & Other Keyboard String Instr	Music instruments	Piano
9202902000 Guitars Not Over \$100, Excl'd The Value Of The Case (no)	Music instruments	Guitar strings
9202904000 Guitars, Nesoi (no)		
930610 Cartridges For Riveting Or Similar Tools & Parts	Ammunition	Ammunition
930629 Air Gun Pellets And Parts Of Shotgun Cartridges	Ammunition	Ammunition
930690 Bomb Mines Ot Ammnition Projections Etc And Parts	Ammunition	Ammunition
9401 Seats (except Barber, Dental, Etc), And Parts	Automotive	Interior
9403 Furniture Nesoi And Parts Thereof	Textile and upholstery	Surface treatment
9404 Mattress Supports; Articles Of Bedding Etc.		
9406 Prefabricated Buildings	Building and construction	Greenhouse
		Architectural membranes (e.g. in roofs)
95 Toys, Games & Sport Equipment; Parts & Accessories	Sport article	Bicycle
		Climbing ropes
		Fishing lines
		Golf gloves
		Ski wax
		Tennis rackets

Note: This table presents a crosswalk of HTS codes and identified PFAS uses from Glüge et al. 2020. However, not all industries and uses listed are within the scope of the rule (e.g. pharmaceutical uses).

Appendix C: Industry Sectors Potentially Affected by EPA's Proposed Action

Table C-1: Industry Sectors Potentially Affected by EPA's Proposed Action

Name of Industry/Sector	NAICS Code	SBA Size Standard for Small Business
New Single-family Housing Construction (Except For-Sale Builders)	236115	\$39.5 million
New Multifamily Housing Construction (except For-Sale Builders)	236116	\$39.5 million
New Housing For-Sale Builders	236117	\$39.5 million
Residential Remodelers	236118	\$39.5 million
Industrial Building Construction	236210	\$39.5 million
Commercial and Institutional Building Construction	236220	\$39.5 million
Water and Sewer Line and Related Structures Construction	237110	\$39.5 million
Oil and Gas Pipeline and Related Structures Construction	237120	\$39.5 million
Power and Communication Line and Related Structures Construction	237130	\$39.5 million
Land Subdivision	237210	\$30 million
Highway, Street, and Bridge Construction	237310	\$39.5 million
Other Heavy and Civil Engineering Construction	237990	\$39.5 million
Poured Concrete Foundation and Structure Contractors	238110	\$16.5 million
Structural Steel and Precast Concrete Contractors	238120	\$16.5 million
Framing Contractors	238130	\$16.5 million
Masonry Contractors	238140	\$16.5 million
Glass and Glazing Contractors	238150	\$16.5 million
Roofing Contractors	238160	\$16.5 million
Siding Contractors	238170	\$16.5 million
Other Foundation, Structure, and Building Exterior Contractors	238190	\$16.5 million
Electrical Contractors and Other Wiring Installation Contractors	238210	\$16.5 million
Plumbing, Heating, and Air Conditioning Contractors	238220	\$16.5 million
Other Building Equipment Contractors	238290	\$16.5 million
Drywall and Insulation Contractors	238310	\$16.5 million
Painting and Wall Covering Contractors	238320	\$16.5 million
Flooring Contractors	238330	\$16.5 million
Tile and Terrazzo Contractors	238340	\$16.5 million
Finish Carpentry Contractors	238350	\$16.5 million
Other Building Finishing Contractors	238390	\$16.5 million
Site Preparation Contractors	238910	\$16.5 million
All Other Specialty Trade Contractors	238990	\$16.5 million
Fiber, Yarn, and Thread Mills	313110	1250 employees
Broadwoven Fabric Mills	313210	1000 employees
Narrow Fabric Mills and Schiffli Machine Embroidery	313220	500 employees
Nonwoven Fabric Mills	313230	750 employees
Knit Fabric Mills	313240	500 employees
Textile and Fabric Finishing Mills	313310	1000 employees

Fabric Coating Mills	313320	1000 employees
Carpet and Rug Mills	314110	1500 employees
Curtain and Linen Mills	314120	750 employees
Textile Bag and Canvas Mills	314910	500 employees
Rope, Cordage, Twine, Tire Cord, and Tire Fabric Mills	314994	1000 employees
All Other Miscellaneous Textile Product Mills	314999	500 employees
Hosiery and Sock Mills	315110	750 employees
Other Apparel Knitting Mills	315190	750 employees
Cut and Sew Apparel Contractors	315210	750 employees
Men's and Boys' Cut and Sew Apparel Manufacturing	315220	750 employees
Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	315240	750 employees
Other Cut and Sew Apparel Manufacturing	315280	750 employees
Apparel Accessories and Other Apparel Manufacturing	315990	500 employees
Leather and Hide Tanning and Finishing	316110	500 employees
Footwear Manufacturing	316210	1000 employees
Women's Handbag and Purse Manufacturing	316992	750 employees
All Other Leather Good and Allied Product Manufacturing	316998	500 employees
Sawmills	321113	500 employees
Wood Preservation	321114	500 employees
Hardwood Veneer and Plywood Manufacturing	321211	500 employees
Softwood Veneer and Plywood Manufacturing	321212	1250 employees
Engineered Wood Member (except Truss) Manufacturing	321213	750 employees
Truss Manufacturing	321214	500 employees
Reconstituted Wood Product Manufacturing	321219	750 employees
Wood Window and Door Manufacturing	321911	1000 employees
Cut Stock, Resawing Lumber, and Planing	321912	500 employees
Other Millwork (including Flooring)	321918	500 employees
Wood Container and Pallet Manufacturing	321920	500 employees
Manufactured Home (Mobile Home) Manufacturing	321991	1250 employees
Prefabricated Wood Building Manufacturing	321992	500 employees
All Other Miscellaneous Wood Product Manufacturing	321999	500 employees
Pulp Mills	322110	750 employees
Paper (except Newsprint) Mills	322121	1250 employees
Newsprint Mills	322122	750 employees
Paperboard Mills	322130	1250 employees
Corrugated and Solid Fiber Box Manufacturing	322211	1250 employees
Folding Paperboard Box Manufacturing	322212	750 employees
Other Paperboard Container Manufacturing	322219	1000 employees
Paper Bag and Coated and Treated Paper Manufacturing	322220	750 employees
Stationery Product Manufacturing	322230	750 employees
Sanitary Paper Product Manufacturing	322291	1500 employees
All Other Converted Paper Product Manufacturing	322299	500 employees
Commercial Printing (except Screen and Books)	323111	500 employees

Commercial Screen Printing	323113	500 employees
Books Printing	323117	1250 employees
Support Activities for Printing	323120	500 employees
Petroleum Refineries	324110	1500 employees
Asphalt Paving Mixture and Block Manufacturing	324121	500 employees
Asphalt Shingle and Coating Materials Manufacturing	324122	750 employees
Petroleum Lubricating Oil and Grease Manufacturing	324191	750 employees
All Other Petroleum and Coal Products Manufacturing	324199	500 employees
Petrochemical Manufacturing	325110	1000 employees
Industrial Gas Manufacturing	325120	1000 employees
Synthetic Dye and Pigment Manufacturing	325130	1000 employees
Other Basic Inorganic Chemical Manufacturing*	325180	1000 employees
Ethyl Alcohol Manufacturing	325193	1000 employees
Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	325194	1250 employees
All Other Basic Organic Chemical Manufacturing *	325199	1250 employees
Plastics Material and Resin Manufacturing*	325211	1250 employees
Synthetic Rubber Manufacturing	325212	1000 employees
Artificial and Synthetic Fibers and Filaments Manufacturing	325220	1000 employees
Paint and Coating Manufacturing	325510	1000 employees
Adhesive Manufacturing	325520	500 employees
Soap and Other Detergent Manufacturing	325611	1000 employees
Polish and Other Sanitation Good Manufacturing	325612	750 employees
Surface Active Agent Manufacturing	325613	750 employees
Printing Ink Manufacturing	325910	500 employees
Explosives Manufacturing	325920	750 employees
Custom Compounding of Purchased Resins	325991	500 employees
Photographic Film, Paper, Plate and Chemical Manufacturing	325992	1500 employees
All Other Miscellaneous Chemical Product and Preparation Manufacturing*	325998	500 employees
Plastic Bag and Pouch Manufacturing	326111	750 employees
Plastics Packaging Film and Sheet (including Laminated) Manufacturing	326112	1000 employees
Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing*	326113	750 employees
Unlaminated Plastics Profile Shape Manufacturing	326121	500 employees
Plastics Pipe and Pipe Fitting Manufacturing	326122	750 employees
Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	326130	500 employees
Polystyrene Foam Product Manufacturing	326140	1000 employees
Urethane and Other Foam Product (except Polystyrene) Manufacturing	326150	750 employees
Plastics Bottle Manufacturing	326160	1250 employees
Plastics Plumbing Fixture Manufacturing	326191	750 employees
All Other Plastics Product Manufacturing	326199	750 employees

Tire Manufacturing (except Retreading)5	326211	1500 employees
Tire Retreading	326212	500 employees
Rubber and Plastics Hoses and Belting Manufacturing	326220	750 employees
Rubber Product Manufacturing for Mechanical Use	326291	750 employees
All Other Rubber Product Manufacturing	326299	500 employees
Pottery, Ceramics, and Plumbing Fixture Manufacturing	327110	1000 employees
Clay Building Material and Refractories Manufacturing	327120	750 employees
Flat Glass Manufacturing	327211	1000 employees
Other Pressed and Blown Glass and Glassware Manufacturing	327212	1250 employees
Glass Container Manufacturing	327213	1250 employees
Glass Product Manufacturing Made of Purchased Glass	327215	1000 employees
Cement Manufacturing	327310	1000 employees
Ready-Mix Concrete Manufacturing	327320	500 employees
Concrete Block and Brick Manufacturing	327331	500 employees
Concrete Pipe Manufacturing	327332	750 employees
Other Concrete Product Manufacturing	327390	500 employees
Lime Manufacturing	327410	750 employees
Gypsum Product Manufacturing	327420	1500 employees
Abrasive Product Manufacturing*	327910	750 employees
Cut Stone and Stone Product Manufacturing	327991	500 employees
Ground or Treated Mineral and Earth Manufacturing	327992	500 employees
Mineral Wool Manufacturing	327993	1500 employees
All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	327999	500 employees
Iron and Steel Mills and Ferroalloy Manufacturing	331110	1500 employees
Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	331210	1000 employees
Rolled Steel Shape Manufacturing	331221	1000 employees
Steel Wire Drawing	331222	1000 employees
Alumina Refining and Primary Aluminum Production	331313	1000 employees
Secondary Smelting and Alloying of Aluminum	331314	750 employees
Aluminum Sheet, Plate and Foil Manufacturing	331315	1250 employees
Other Aluminum Rolling, Drawing, and Extruding	331318	750 employees
Nonferrous Metal (except Aluminum) Smelting and Refining	331410	1000 employees
Copper Rolling, Drawing, Extruding, and Alloying	331420	1000 employees
Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing and Extruding	331491	750 employees
Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	331492	750 employees
Iron Foundries	331511	1000 employees
Steel Investment Foundries	331512	1000 employees
Steel Foundries (except Investment)	331513	500 employees
Nonferrous Metal Die-Casting Foundries	331523	500 employees
Aluminum Foundries (except Die-Casting)	331524	500 employees
Other Nonferrous Metal Foundries (except Die-Casting)	331529	500 employees
Iron and Steel Forging	332111	750 employees

Nonferrous Forging	332112	750 employees
Custom Roll Forming	332114	500 employees
Powder Metallurgy Part Manufacturing	332117	500 employees
Metal Crown, Closure, and Other Metal Stamping (except Automotive)	332119	500 employees
Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	332215	750 employees
Saw Blade and Handtool Manufacturing	332216	750 employees
Prefabricated Metal Building and Component Manufacturing	332311	750 employees
Fabricated Structural Metal Manufacturing	332312	500 employees
Plate Work Manufacturing	332313	750 employees
Metal Window and Door Manufacturing	332321	750 employees
Sheet Metal Work Manufacturing	332322	500 employees
Ornamental and Architectural Metal Work Manufacturing	332323	500 employees
Power Boiler and Heat Exchanger Manufacturing	332410	750 employees
Metal Tank (Heavy Gauge) Manufacturing	332420	750 employees
Metal Can Manufacturing	332431	1500 employees
Other Metal Container Manufacturing	332439	500 employees
Hardware Manufacturing	332510	750 employees
Spring Manufacturing	332613	500 employees
Other Fabricated Wire Product Manufacturing	332618	500 employees
Machine Shops	332710	500 employees
Precision Turned Product Manufacturing	332721	500 employees
Bolt, Nut, Screw, Rivet and Washer Manufacturing	332722	500 employees
Metal Heat Treating	332811	750 employees
Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	332812	500 employees
Electroplating, Plating, Polishing, Anodizing and Coloring	332813	500 employees
Industrial Valve Manufacturing	332911	750 employees
Fluid Power Valve and Hose Fitting Manufacturing	332912	1000 employees
Plumbing Fixture Fitting and Trim Manufacturing	332913	1000 employees
Other Metal Valve and Pipe Fitting Manufacturing	332919	750 employees
Ball and Roller Bearing Manufacturing	332991	1250 employees
Fabricated Pipe and Pipe Fitting Manufacturing	332996	500 employees
All Other Miscellaneous Fabricated Metal Product Manufacturing	332999	750 employees
Farm Machinery and Equipment Manufacturing	333111	1250 employees
Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	333112	1500 employees
Construction Machinery Manufacturing	333120	1250 employees
Mining Machinery and Equipment Manufacturing	333131	500 employees
Oil and Gas Field Machinery and Equipment Manufacturing	333132	1250 employees
Food Product Machinery Manufacturing	333241	500 employees
Semiconductor Machinery Manufacturing	333242	1500 employees
Sawmill, Woodworking, and Paper Machinery Manufacturing	333243	500 employees
Printing Machinery and Equipment Manufacturing	333244	750 employees

Other Industrial Machinery Manufacturing	333249	500 employees
Optical Instrument and Lens Manufacturing	333314	500 employees
Photographic and Photocopying Equipment Manufacturing	333316	1000 employees
Other Commercial and Service Industry Machinery Manufacturing	333318	1000 employees
Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	333413	500 employees
Heating Equipment (except Warm Air Furnaces) Manufacturing	333414	500 employees
Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	333415	1250 employees
Industrial Mold Manufacturing	333511	500 employees
Special Die and Tool, Die Set, Jig and Fixture Manufacturing	333514	500 employees
Cutting Tool and Machine Tool Accessory Manufacturing	333515	500 employees
Machine Tool Manufacturing	333517	500 employees
Rolling Mill and Other Metalworking Machinery Manufacturing	333519	500 employees
Turbine and Turbine Generator Set Unit Manufacturing	333611	1500 employees
Speed Changer, Industrial High-Speed Drive and Gear Manufacturing	333612	750 employees
Mechanical Power Transmission Equipment Manufacturing	333613	750 employees
Other Engine Equipment Manufacturing	333618	1500 employees
Air and Gas Compressor Manufacturing	333912	1000 employees
Measuring, Dispensing, and Other Pumping Equipment Manufacturing	333914	750 employees
Elevator and Moving Stairway Manufacturing	333921	1000 employees
Conveyor and Conveying Equipment Manufacturing	333922	500 employees
Overhead Traveling Crane, Hoist and Monorail System Manufacturing	333923	1250 employees
Industrial Truck, Tractor, Trailer and Stacker Machinery Manufacturing	333924	750 employees
Power-Driven Hand Tool Manufacturing	333991	500 employees
Welding and Soldering Equipment Manufacturing	333992	1250 employees
Packaging Machinery Manufacturing	333993	500 employees
Industrial Process Furnace and Oven Manufacturing	333994	500 employees
Fluid Power Cylinder and Actuator Manufacturing	333995	750 employees
Fluid Power Pump and Motor Manufacturing	333996	1250 employees
Scale and Balance Manufacturing	333997	500 employees
All Other Miscellaneous General Purpose Machinery Manufacturing*	333999	500 employees
Electronic Computer Manufacturing	334111	1250 employees
Computer Storage Device Manufacturing	334112	1250 employees
Computer Terminal and Other Computer Peripheral Equipment Manufacturing	334118	1000 employees
Telephone Apparatus Manufacturing	334210	1250 employees
Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	334220	1250 employees
Other Communications Equipment Manufacturing	334290	750 employees
Audio and Video Equipment Manufacturing	334310	750 employees
Bare Printed Circuit Board Manufacturing	334412	750 employees
Semiconductor and Related Device Manufacturing	334413	1250 employees

Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	334416	500 employees
Electronic Connector Manufacturing	334417	1000 employees
Printed Circuit Assembly (Electronic Assembly) Manufacturing	334418	750 employees
Other Electronic Component Manufacturing	334419	750 employees
Electromedical and Electrotherapeutic Apparatus Manufacturing	334510	1250 employees
Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing*	334511	1250 employees
Automatic Environmental Control Manufacturing for Residential, Commercial and Appliance Use	334512	500 employees
Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	334513	750 employees
Totalizing Fluid Meter and Counting Device Manufacturing	334514	750 employees
Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	334515	750 employees
Analytical Laboratory Instrument Manufacturing	334516	1000 employees
Irradiation Apparatus Manufacturing	334517	1000 employees
Other Measuring and Controlling Device Manufacturing	334519	500 employees
Blank Magnetic and Optical Recording Media Manufacturing	334613	1000 employees
Software and Other Prerecorded Compact Disc, Tape, and Record Reproducing	334614	1250 employees
Electric Lamp Bulb and Part Manufacturing	335110	1250 employees
Residential Electric Lighting Fixture Manufacturing	335121	750 employees
Commercial, Industrial and Institutional Electric Lighting Fixture Manufacturing	335122	500 employees
Other Lighting Equipment Manufacturing	335129	500 employees
Small Electrical Appliance Manufacturing	335210	1500 employees
Major Household Appliance Manufacturing	335220	1500 employees
Power, Distribution and Specialty Transformer Manufacturing	335311	750 employees
Motor and Generator Manufacturing	335312	1250 employees
Switchgear and Switchboard Apparatus Manufacturing	335313	1250 employees
Relay and Industrial Control Manufacturing	335314	750 employees
Storage Battery Manufacturing	335911	1250 employees
Primary Battery Manufacturing	335912	1000 employees
Fiber Optic Cable Manufacturing	335921	1000 employees
Other Communication and Energy Wire Manufacturing	335929	1000 employees
Current Carrying Wiring Device Manufacturing	335931	500 employees
Noncurrent Carrying Wiring Device Manufacturing	335932	1000 employees
Carbon and Graphite Product Manufacturing	335991	750 employees
All Other Miscellaneous Electrical Equipment and Component Manufacturing	335999	500 employees
Automobile Manufacturing*	336111	1500 employees
Light Truck and Utility Vehicle Manufacturing	336112	1500 employees
Heavy Duty Truck Manufacturing	336120	1500 employees
Motor Vehicle Body Manufacturing	336211	1000 employees

Truck Trailer Manufacturing	336212	1000 employees
Motor Home Manufacturing	336213	1250 employees
Travel Trailer and Camper Manufacturing	336214	1000 employees
Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	336310	1000 employees
Motor Vehicle Electrical and Electronic Equipment Manufacturing	336320	1000 employees
Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	336330	1000 employees
Motor Vehicle Brake System Manufacturing	336340	1250 employees
Motor Vehicle Transmission and Power Train Parts Manufacturing	336350	1500 employees
Motor Vehicle Seating and Interior Trim Manufacturing	336360	1500 employees
Motor Vehicle Metal Stamping	336370	1000 employees
Other Motor Vehicle Parts Manufacturing	336390	1000 employees
Aircraft Manufacturing	336411	1500 employees
Aircraft Engine and Engine Parts Manufacturing	336412	1500 employees
Other Aircraft Part and Auxiliary Equipment Manufacturing ⁷	336413	1250 employees
Guided Missile and Space Vehicle Manufacturing	336414	1250 employees
Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	336415	1250 employees
Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	336419	1000 employees
Railroad Rolling Stock Manufacturing	336510	1500 employees
Ship Building and Repairing	336611	1250 employees
Boat Building	336612	1000 employees
Motorcycle, Bicycle and Parts Manufacturing	336991	1000 employees
Military Armored Vehicle, Tank and Tank Component Manufacturing	336992	1500 employees
All Other Transportation Equipment Manufacturing	336999	1000 employees
Wood Kitchen Cabinet and Counter Top Manufacturing	337110	750 employees
Upholstered Household Furniture Manufacturing	337121	1000 employees
Non-upholstered Wood Household Furniture Manufacturing	337122	750 employees
Metal Household Furniture Manufacturing	337124	750 employees
Household Furniture (except Wood and Metal) Manufacturing	337125	750 employees
Institutional Furniture Manufacturing	337127	500 employees
Wood Office Furniture Manufacturing	337211	1000 employees
Custom Architectural Woodwork and Millwork Manufacturing	337212	500 employees
Office Furniture (Except Wood) Manufacturing	337214	1000 employees
Showcase, Partition, Shelving, and Locker Manufacturing	337215	500 employees
Mattress Manufacturing	337910	1000 employees
Blind and Shade Manufacturing	337920	1000 employees
Jewelry and Silverware Manufacturing	339910	500 employees
Sporting and Athletic Goods Manufacturing	339920	750 employees
Doll, Toy, and Game Manufacturing	339930	500 employees
Office Supplies (except Paper) Manufacturing	339940	750 employees
Sign Manufacturing	339950	500 employees
Gasket, Packing, and Sealing Device Manufacturing	339991	500 employees

Musical Instrument Manufacturing	339992	1000 employees
Fastener, Button, Needle and Pin Manufacturing	339993	750 employees
Broom, Brush and Mop Manufacturing	339994	500 employees
Burial Casket Manufacturing	339995	1000 employees
All Other Miscellaneous Manufacturing	339999	500 employees
Automobile and Other Motor Vehicle Merchant Wholesalers	423110	250 employees
Motor Vehicle Supplies and New Parts Merchant Wholesalers	423120	200 employees
Tire and Tube Merchant Wholesalers	423130	200 employees
Motor Vehicle Parts (Used) Merchant Wholesalers	423140	100 employees
Furniture Merchant Wholesalers	423210	100 employees
Home Furnishing Merchant Wholesalers	423220	100 employees
Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers	423310	150 employees
Brick, Stone, and Related Construction Material Merchant Wholesalers	423320	150 employees
Roofing, Siding, and Insulation Material Merchant Wholesalers	423330	200 employees
Other Construction Material Merchant Wholesalers	423390	100 employees
Photographic Equipment and Supplies Merchant Wholesalers	423410	200 employees
Office Equipment Merchant Wholesalers	423420	200 employees
Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	423430	250 employees
Other Commercial Equipment Merchant Wholesalers	423440	100 employees
Ophthalmic Goods Merchant Wholesalers	423460	150 employees
Other Professional Equipment and Supplies Merchant Wholesalers	423490	150 employees
Metal Service Centers and Other Metal Merchant Wholesalers*	423510	200 employees
Coal and Other Mineral and Ore Merchant Wholesalers	423520	100 employees
Electrical Apparatus and Equipment, Wiring Supplies, and Related Equipment Merchant Wholesalers	423610	200 employees
Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	423620	200 employees
Other Electronic Parts and Equipment Merchant Wholesalers	423690	250 employees
Hardware Merchant Wholesalers	423710	150 employees
Plumbing and Heating Equipment and Supplies (Hydronics) Merchant Wholesalers	423720	200 employees
Warm Air Heating and Air Conditioning Equipment and Supplies Merchant Wholesalers	423730	150 employees
Refrigeration Equipment and Supplies Merchant Wholesalers	423740	100 employees
Construction and Mining (except Oil Well) Machinery and Equipment Merchant Wholesalers	423810	250 employees
Farm and Garden Machinery and Equipment Merchant Wholesalers	423820	100 employees
Industrial Machinery and Equipment Merchant Wholesalers	423830	100 employees
Industrial Supplies Merchant Wholesalers	423840	100 employees
Service Establishment Equipment and Supplies Merchant Wholesalers	423850	100 employees
Transportation Equipment and Supplies (except Motor Vehicle) Merchant Wholesalers	423860	150 employees
Sporting and Recreational Goods and Supplies Merchant Wholesalers	423910	100 employees
Toy and Hobby Goods and Supplies Merchant Wholesalers	423920	150 employees

Recyclable Material Merchant Wholesalers	423930	100 employees
Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	423940	100 employees
Other Miscellaneous Durable Goods Merchant Wholesalers	423990	100 employees
Printing and Writing Paper Merchant Wholesalers	424110	200 employees
Stationery and Office Supplies Merchant Wholesalers	424120	150 employees
Industrial and Personal Service Paper Merchant Wholesalers	424130	150 employees
Piece Goods, Notions, and Other Dry Goods Merchant Wholesalers	424310	100 employees
Men's and Boys' Clothing and Furnishings Merchant Wholesalers	424320	150 employees
Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers	424330	100 employees
Footwear Merchant Wholesalers	424340	200 employees
General Line Grocery Merchant Wholesalers	424410	250 employees
Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	424610	150 employees
Other Chemical and Allied Products Merchant Wholesalers*	424690	150 employees
Petroleum Bulk Stations and Terminals	424710	200 employees
Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	424720	200 employees
Farm Supplies Merchant Wholesalers	424910	200 employees
Book, Periodical, and Newspaper Merchant Wholesalers	424920	200 employees
Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers	424930	100 employees
Paint, Varnish, and Supplies Merchant Wholesalers	424950	150 employees
Other Miscellaneous Nondurable Goods Merchant Wholesalers	424990	100 employees
Business to Business Electronic Markets	425110	100 employees
Wholesale Trade Agents and Brokers	425120	100 employees
New Car Dealers	441110	200 employees
Used Car Dealers	441120	\$27 million
Recreational Vehicle Dealers	441210	\$35 million
Boat Dealers	441222	\$35 million
Motorcycle, ATV, and All Other Motor Vehicle Dealers	441228	\$35 million
Automotive Parts and Accessories Stores	441310	\$16.5 million
Tire Dealers	441320	\$16.5 million
Furniture Stores	442110	\$22 million
Floor Covering Stores	442210	\$8 million
Window Treatment Stores	442291	\$8 million
All Other Home Furnishings Stores	442299	\$22 million
Household Appliance Stores	443141	\$12 million
Electronics Stores	443142	\$35 million
Home Centers	444110	\$41.5 million
Paint and Wallpaper Stores	444120	\$30 million
Hardware Stores	444130	\$8 million
Other Building Material Dealers	444190	\$22 million
Outdoor Power Equipment Stores	444210	\$8 million
Nursery and Garden Centers	444220	\$12 million

Gasoline Stations with Convenience Stores	447110	\$32 million
Other Gasoline Stations*	447190	\$16.5 million
Men's Clothing Stores	448110	\$12 million
Women's Clothing Stores	448120	\$30 million
Children's and Infants' Clothing Stores	448130	\$35 million
Family Clothing Stores	448140	\$41.5 million
Clothing Accessories Stores	448150	\$16.5 million
Other Clothing Stores	448190	\$22 million
Shoe Stores	448210	\$30 million
Jewelry Stores	448310	\$16.5 million
Luggage and Leather Goods Stores	448320	\$30 million
Sporting Goods Stores	451110	\$16.5 million
Hobby, Toy and Game Stores	451120	\$30 million
Sewing, Needlework and Piece Goods Stores	451130	\$30 million
Musical Instrument and Supplies Stores	451140	\$12 million
Book Stores	451211	\$30 million
News Dealers and Newsstands	451212	\$8 million
Department Stores	452210	\$35 million
Warehouse Clubs and Supercenters	452311	\$32 million
All Other General Merchandise Stores	452319	\$35 million
Florists	453110	\$8 million
Office Supplies and Stationery Stores	453210	\$35 million
Gift, Novelty and Souvenir Stores	453220	\$8 million
Used Merchandise Stores	453310	\$8 million
Pet and Pet Supplies Stores	453910	\$22 million
Art Dealers	453920	\$8 million
Manufactured (Mobile) Home Dealers	453930	\$16.5 million
All Other Miscellaneous Store Retailers (except Tobacco Stores)	453998	\$8 million
Electronic Shopping and Mail-Order Houses	454110	\$41.5 million
Vending Machine Operators	454210	\$12 million
Fuel Dealers	454310	100 employees
Other Direct Selling Establishments	454390	\$8 million
Materials Recovery Facilities	562920	\$22 million

*NAICS industries for affected manufacturers that were included in the draft economic analysis for the proposed rule. (All other codes were not included in the draft EA, based on information available to EPA at that time and are newly added here.)

Source: U.S. Small Business Administration Table of Small Business Size Standards Available at:

<https://www.sba.gov/document/support--table-size-standards>

Note: The list of affected NAICS has been updated since publishing the draft economic analysis. This list now includes NAICS industries for affected manufacturers and article importers.

Appendix D: Sensitivity Analyses

This Appendix presents sensitivity analyses related to the number of PFAS that would be reported on under the proposed rule and the varying assumptions for the number of article importers affected by the rule.

Number of PFAS Reported

EPA has identified at least 1,364 chemical substances and mixtures that are PFAS and would be subject to reporting under the proposed rule. In the primary analysis, EPA estimates that all 1,364 identified PFAS will be reported on. This sensitivity analysis evaluates the alternative assumptions of 1,000 PFAS and 2,000 PFAS being reported on as low and high estimates. As shown in Table D-1, this results in an estimated 171 manufacturing firms reporting as the low-estimate and 342 manufacturing firms reporting as the high estimate. EPA did not identify any data sources with information on the percentage of imported articles that contain PFAS, and thus based the primary estimate of 10 percent of affected firms importing PFAS in articles on professional judgement. For this sensitivity analysis, the low-end estimate uses the same assumption as in the primary analysis (10 percent of affected firms importing PFAS in articles). For the high-end estimate EPA assumes 15 percent of affected firms import PFAS in articles.

Table D-1 Estimated Number of PFAS, Primary and Alternative Estimates

Parameter	Primary Analysis	Low Estimate	High Estimate
Number of Chemicals	1,364	1,000	2,000
Number of affected manufacturing firms	234	171	342
Number of affected manufacturing sites	351	257	513

Tables D-2 and D-3 presents the total industry burden and costs under the low- and high-end alternative estimates. The low-end estimate results in a total burden of approximately 11.9 million hours and a total cost of approximately \$873 million. The high-end estimate results in a total burden of approximately 13 million hours and a total cost of approximately \$966 million. For comparison, the primary analysis results in a total industry burden of 11.9 million hours and a total industry cost of approximately \$875.9 million.

Table D-2 Total Industry Burden and Costs (2021\$), Low-End Estimates for the Number of PFAS

Activity	Number of Affected Firms	Average Burden per Firm (hours)	Total Burden (hours)	Average Cost per Firm (2021\$)	Total Cost (2021\$)
Manufacturers					
Rule Familiarization	171	28	4,788	\$2,362	\$403,829
Form Completion	171	507	86,681	\$41,152	\$7,036,913
CBI Claim Substantiation	171	4	701	\$336	\$57,400
Recordkeeping	171	6	1,002	\$347	\$59,408
CDX Registration and Electronic Signature	171	3	456	\$231	\$39,553
<i>Manufacturer Total</i>	<i>171</i>	<i>548</i>	<i>93,628</i>	<i>\$44,428</i>	<i>\$7,597,104</i>
Article Importers					
Rule Familiarization: Compliance Determination	118,041	9	1,091,878	\$786	\$92,833,513
Structural Definition Familiarization for Large Article Importers	3,581	4	14,323	\$326	\$1,165,854
Structural Definition Familiarization for Small Article Importers	127,576	7	893,030	\$598	\$76,251,208
Rule Familiarization: Reporting Firms	13,116	24	314,776	\$2,036	\$26,703,370
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	13,116	138	1,807,462	\$11,003	\$144,309,397
CBI Claim Substantiation	13,116	4	45,957	\$287	\$3,762,880
Recordkeeping	13,116	5	65,578	\$296	\$3,887,874
CDX Registration and Electronic Signature	13,116	3	34,975	\$231	\$3,033,709
<i>Article Importer Total</i>	<i>131,157</i>	<i>90</i>	<i>11,789,809</i>	<i>\$6,600</i>	<i>\$865,598,935</i>
Industry Total	131,328	-	11,883,437	-	\$873,196,039

Table D-3 Total Industry Burden and Costs (2021\$), High-End Estimates for the Number of PFAS

Activity	Number of Affected Firms	Average Burden per Firm (Hours)	Total Burden (hours)	Average Cost per Firm (2021\$)	Total Cost (2021\$)
Manufacturers					
Rule Familiarization	342	28	9,576	\$2,362	\$807,659
Form Completion	342	507	173,362	\$41,152	\$14,073,826
CBI Claim Substantiation	342	4	1,402	\$336	\$114,800
Recordkeeping	342	6	2,004	\$347	\$118,816
CDX Registration and Electronic Signature	342	3	912	\$231	\$79,106
<i>Manufacturer Total</i>	<i>342</i>	<i>548</i>	<i>187,256</i>	<i>\$44,428</i>	<i>\$15,194,207</i>
Article Importers					
Rule Familiarization: Compliance Determination	111,483	9	1,031,218	\$786	\$87,676,095
Structural Definition Familiarization for Large Article Importers	3,581	4	14,323	\$326	\$1,165,854
Structural Definition Familiarization for Small Article Importers	127,576	7	893,030	\$598	\$76,251,208
Rule Familiarization: Reporting Firms	19,673	24	472,164	\$2,036	\$40,055,055
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	19,673	138	2,711,193	\$11,003	\$216,464,095
CBI Claim Substantiation	19,673	4	68,936	\$287	\$5,644,319
Recordkeeping	19,673	5	98,367	\$296	\$5,831,811
CDX Registration and Electronic Signature	19,673	3	52,463	\$231	\$4,550,563
<i>Article Importer Total</i>	<i>131,157</i>	<i>98</i>	<i>12,863,523</i>	<i>\$7,253</i>	<i>\$951,290,133</i>
Industry Total	131,499	-	13,050,779	-	\$966,484,340

Number of Reporting Importers of Articles

EPA did not identify any data sources with information on the percentage of imported articles that contain PFAS, and thus based the primary estimate of 10 percent of firms importing PFAS in articles on professional judgement. This sensitivity analysis evaluates alternative assumptions of 1 percent and 20 percent of firms importing PFAS in articles as low and high estimates, respectively. As shown in Table D-4, this results in an estimated 1,312 article importers reporting under the rule under the low-end estimate and 26,231 reporting article importers under the high-end estimate, as compared to 13,116 article importers assumed for the primary analysis.

Table D-4 Estimated Number of Importers of Articles Containing PFAS, Primary and Alternative Estimates

Parameter	Primary Analysis	Low Estimate	High Estimate
Estimated importers of articles potentially containing PFAS	131,157	131,157	131,157
Percentage of firms importing PFAS in articles	10%	1%	20%
Estimated number of reporting firms	13,116	1,312	26,231

Table D-5 presents the total industry burden and costs under the primary and alternative estimates. The low-end estimate results in a total burden of approximately 10 million hours and a total cost of approximately \$723 million. The high-end estimate results in a total burden of approximately 14 million hours and a total cost of approximately \$1 billion. This represents an approximately 16 percent decrease and an 18 percent increase in total costs under the low-end and high-end assumptions, respectively.

Table D-5 Total Industry Burden and Costs (2021\$), Primary and Alternative Estimates for Number of Importers of Articles Containing PFAS

Activity	Number of Affected Firms	Average Burden per Firm (Hours)	Total Burden (hours)	Average Cost per Firm (2021\$)	Total Cost (2021\$)
Primary Estimate					
Rule Familiarization	131,391	18	2,306,236	\$1,494	\$196,340,700
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	13,350	144	1,926,078	\$11,531	\$153,938,856
CBI Claim Substantiation	13,350	4	46,917	\$288	\$3,841,427
Recordkeeping	13,350	5	66,950	\$297	\$3,969,169
CDX Registration and Electronic Signature	13,350	3	35,599	\$231	\$3,087,834
Total, Primary Estimate	131,391	91	11,917,931	\$6,667	\$875,994,972
Low Estimate					
Rule Familiarization	131,391	16	2,157,192	\$1,398	\$183,731,245
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	1,546	194	299,362	\$15,567	\$24,060,399
CBI Claim Substantiation	1,546	4	5,555	\$294	\$454,835
Recordkeeping	1,546	5	7,929	\$304	\$470,083
CDX Registration and Electronic Signature	1,546	3	4,122	\$231	\$357,496
Total, Low Estimate	131,391	77	9,995,988	\$5,501	\$722,725,190
High Estimate					
Rule Familiarization	131,391	19	2,524,758	\$1,635	\$214,869,463
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	26,465	141	3,733,540	\$11,269	\$298,248,253
CBI Claim Substantiation	26,465	4	92,874	\$287	\$7,604,307
Recordkeeping	26,465	5	132,528	\$297	\$7,857,043
CDX Registration and Electronic Signature	26,465	3	70,574	\$231	\$6,121,543
Total, High Estimate	131,391	108	14,076,102	\$7,979	\$1,048,351,739

Number of Importers of Articles Potentially Containing PFAS

The approach for estimating the number of importers of articles potentially containing PFAS is described in the Small Business Importers of Articles section. As previously described, the analysis assumes that the number of firms importing articles that may contain PFAS is proportional to the total customs value of commodities that may contain PFAS (58 percent; see Table 2). However, this assumption is subject to uncertainty regarding the market for imported articles that may contain PFAS. The analysis may underestimate the number of firms if more firms import smaller volumes of articles. It may also overestimate the number of firms if fewer firms import larger volumes of articles.

This sensitivity analysis evaluates alternative assumptions of 50 percent and 70 percent of firms importing articles potentially containing PFAS. Table D-6 presents the estimated number of importers potentially containing PFAS and the estimated number of reporting firms under the primary and alternative assumptions.

Table D-6: Estimated Number of Importers of Articles Containing PFAS, Primary and Alternative Estimates for Importers of Articles Potentially Containing PFAS

Parameter	Primary Analysis (58 percent of total article importers)	Low Estimate (50 percent of total article importers)	High Estimate (70 percent of total article importers)
Estimated importers of articles potentially containing PFAS	131,157	112,350	157,289
Percentage of firms importing PFAS in articles	10%	10%	10%
Estimated number of reporting firms	13,116	11,235	15,729

Table D-7 presents the total industry burden and costs under the primary and alternative estimates. The low-end estimate results in a total burden of approximately 11.3 million hours and a total cost of approximately \$826 million. The high-end estimate results in a total burden of approximately 12.5 million hours and a total cost of approximately \$920 million. This represents an approximately 5 percent decrease and a 5 percent increase in total costs under the low-end and high-end assumptions, respectively.

Table D-7 Total Industry Burden and Costs (2021\$), Primary and Alternative Estimates for Importers of Articles Potentially Containing PFAS

Activity	Number of Affected Firms	Average Burden per Firm (Hours)	Total Burden (hours)	Average Cost per Firm (2021\$)	Total Cost (2021\$)
Primary Estimate					
Rule Familiarization	131,391	18	2,306,236	\$1,494	\$196,340,700
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	13,350	144	1,926,078	\$11,531	\$153,938,856
CBI Claim Substantiation	13,350	4	46,917	\$288	\$3,841,427
Recordkeeping	13,350	5	66,950	\$297	\$3,969,169
CDX Registration and Electronic Signature	13,350	3	35,599	\$231	\$3,087,834
Total, Primary Estimate	131,391	91	11,917,931	\$6,667	\$875,994,972
Low Estimate					
Rule Familiarization	131,391	15	1,997,956	\$1,295	\$170,099,957
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	11,469	145	1,666,906	\$11,618	\$133,246,311
CBI Claim Substantiation	11,469	4	40,327	\$288	\$3,301,867
Recordkeeping	11,469	5	57,546	\$297	\$3,411,686
CDX Registration and Electronic Signature	11,469	3	30,584	\$231	\$2,652,830
Total, Low Estimate	131,391	87	11,315,147	\$6,289	\$826,363,782
High Estimate					
Rule Familiarization	131,391	19	2,479,927	\$1,606	\$211,057,634
Compliance Determination	131,157	57	7,521,829	\$3,916	\$513,651,131
Form Completion	15,963	143	2,286,208	\$11,445	\$182,691,951
CBI Claim Substantiation	15,963	4	56,073	\$288	\$4,591,166
Recordkeeping	15,963	5	80,016	\$297	\$4,743,813
CDX Registration and Electronic Signature	15,963	3	42,568	\$231	\$3,692,289
Total, High Estimate	131,391	96	12,466,620	\$7,005	\$920,427,984