

**Supporting Statement for an Information Collection Request (ICR)
Under the Paperwork Reduction Act (PRA)**

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Final Rule

EPA ICR No.: 2682.02

OMB Control No.: 2070-0217

Docket ID No.: EPA-HQ-OPPT-2020-0549

Abstract

EPA is requiring reporting and recordkeeping requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) under the Toxic Substances Control Act (TSCA) as amended by the Fiscal Year 2020 National Defense Authorization Act (NDAA). As mandated by the amendment, EPA will require certain persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to electronically report to EPA certain information. This is a one-time reporting event to provide greater transparency on the uses and risks associated with PFAS and is mandated by the NDAA. The total one-time burden and cost of the action are summarized in Table 1. Table 2 annualizes the burden and cost over a three-year ICR approval period (although the reporting is a one-time activity).

Table 1: Summary Total Burden and Costs

Activity	Number of Firms	Number of Responses	Total 3-Year Burden	Per-Firm Unit Cost	Total 3-Year Cost (2022\$)	Per-Firm Unit Cost	Total 3-Year Cost (2022\$)
				3% Discount Rate		7% Discount Rate	
Rule Familiarization	131,410	67,536	2,642,124	\$1,692	\$222,396,690	\$1,629	\$214,082,795
Compliance Determination	131,410	67,536	7,523,295	\$3,861	\$507,327,191	\$3,654	\$480,190,513
Form Completion	131,410	67,536	1,337,532	\$793	\$104,183,912	\$740	\$97,240,352
CBI Substantiation	131,410	67,536	30,096	\$18	\$2,382,473	\$17	\$2,219,240
Recordkeeping	131,410	67,536	67,536	\$30	\$3,937,169	\$28	\$3,665,229
CDX Registration	131,410	67,536	35,650	\$23	\$2,980,632	\$21	\$2,773,754
Respondent Total	131,410	67,536	11,636,233	\$6,417	\$843,208,067	\$6,089	\$800,171,883
Agency					\$1,612,702		\$1,562,613

Table 2: Summary of Annualized Burden and Costs

Activity	Number of Firms	Number of Responses	Annual Burden	Per-Firm Unit Cost	Annual Cost (2022\$)	Per-Firm Unit Cost	Annual Cost (2022\$)
				3% Discount Rate	7% Discount Rate		
Rule Familiarization	131,410	67,536	880,708	\$564	\$74,132,230	\$543	\$71,360,932
Compliance Determination	131,410	67,536	2,507,765	\$1,287	\$169,109,064	\$1,218	\$160,063,504
Form Completion	131,410	67,536	445,844	\$264	\$34,727,971	\$247	\$32,413,451
CBI Substantiation	131,410	67,536	10,032	\$6	\$794,158	\$6	\$739,747
Recordkeeping	131,410	67,536	22,512	\$10	\$1,312,390	\$9	\$1,221,743
CDX Registration	131,410	67,536	11,883	\$8	\$993,544	\$7	\$924,585
Respondent Total	131,410	67,536	3,878,744	\$2,139	\$281,069,356	\$2,030	\$266,723,961
Agency					\$537,567		\$520,871

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

TSCA section 8(a)(7) (15 USC 2607) requires EPA to collect certain information on PFAS manufactured (including imported) in the United States in any year since January 1, 2011 (Attachment B). In addition, the requirements were put in place following enactment of the FY2020 National Defense Authorization Act, which amended TSCA in December 2019. Claims of confidentiality are covered under TSCA section 14 (See [82 FR 6522](#), January 19, 2017).

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.

Under TSCA, EPA is charged with protecting human health and the environment from potential chemical risks. Through the PFAS Data Call regulation, EPA collects exposure-related manufacturing information and all existing information concerning the environmental and health effects of these chemicals. These data are used by the Agency and others in a wide range of activities.

The information collected under this data call will improve EPA's exposure-related data on manufacturing, processing, and use of chemical substances that are PFAS, as well as require covered manufacturers to provide EPA with all existing information on the environmental or human health effects of such substances.

Additionally, under TSCA section 14, claims of confidentiality (other than for selected data elements such as production volume) must be substantiated at the time information is submitted to EPA, including as part of Chemical Data Reporting (CDR) rule (See [82 FR 6522](#), January 19, 2017). To ensure that EPA can use TSCA section 8(a) data most effectively, TSCA requires substantiation to enable EPA to review the legitimacy of confidentiality claims.

EPA's Office of Pollution Prevention and Toxics (OPPT), other EPA Offices, and/or other public entities (including other federal agencies and tribal, state, and local governments) are generally the primary groups for which information will be collected. However, to the extent that reported information is not considered to be confidential business information (CBI), EPA may provide such data to other non-Federal entities, including the general public.

The reporting methods, including the reporting tool and electronic registration, help to ensure that the information reported to EPA is accurate and in compliance with the statutory requirements. In addition, the data elements have practical utility for users of the data within EPA. Staff in OPPT would be able to use information collected on the production volumes, categories of use, disposal, byproducts, and worker exposure-related information in future screening-level assessments of potential exposure to these PFAS. Additionally, other offices in EPA will benefit from information collected, such as data on the disposal, releases, and other waste management methods of PFAS. Many offices across EPA are fulfilling other statutory obligations and directives under the Agency's PFAS Strategic Roadmap, and this first nationwide dataset on PFAS, production, use, disposal, and exposure-related information will complement these activities and provide necessary screening-level data.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

EPA is requiring electronic reporting for all reporting submissions. Persons submitting information under this section 8(a)(7) rule will be required to use the 8(a)(7) PFAS Reporting Tool, a reporting application accessed through the Agency's CDX platform. The 8(a)(7) PFAS Reporting Tool is currently under development and testing. The tool is based on e-CDRweb, the Agency's online application for completing the CDR reporting form (Form U) in the past CDR reporting cycles. Screenshots of the 8(a)(7) PFAS Reporting Tool are included here (Attachment C).

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The data included in this information collection are not collected comprehensively or systematically at the national level by any other entities. However, EPA identified certain data elements that may be duplicative of other reporting rules: the CDR rule under TSCA section 8; the Greenhouse Gas Reporting Program (GHGRP); the Toxics Release Inventory (TRI). Similarly, past submissions of information concerning environmental and health effects of PFAS may have been provided to EPA as an unpublished health and safety study under TSCA section 8(d), or a notification of substantial risks under TSCA section 8(e). Finally, EPA identified that certain byproducts that were coincidentally manufactured during the manufacture, processing, use, or disposal of a reportable PFAS may also themselves be

reportable PFAS. For example, Byproduct A is produced during the manufacture of PFAS 1. However, Byproduct A's structure meets the definition of PFAS used for this rule. Therefore, Byproduct A is also a reportable PFAS under this rule. Therefore, some information related to the environmental releases of byproducts that are also themselves reportable PFAS may be duplicative under this 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. To address potentially duplicative reporting, EPA is identifying specific types of information that need not be reported again if the reporting entity indicates in the reporting tool that they have previously provided such information to EPA and provides information sufficient to allow the agency to locate that information. In these cases, the manufacturer is required to indicate to which program (and in which year) that information was submitted (e.g., CDR in 2016; section 8(d) health and safety study in 2020).

However, EPA notes that there are many reporting exemptions and other discrepancies between this rule and the CDR, GHGRP, and TRI reporting regulations. Therefore, potential duplication of these data elements to any of the aforementioned rules is limited to the extent that the previous submissions reflect the same activities and quantities that are being requested under this rule. Additionally, this rule requires information to be reported *for each year* in which a PFAS was manufactured since January 1, 2011, while some other rules do not have the same annual reporting requirements. The Agency will avoid collecting data on PFAS that would duplicate information already reported to the Agency, while ensuring it obtains all data required to be collected under TSCA section 8(a)(7) and that such data are submitted in a format that is conducive to the collection and review of a manufactured PFAS dataset.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

Affected small entities are generally small businesses. Because this rule is limited to those who have manufactured PFAS for commercial purposes, there is a very low likelihood of requiring reporting by any small governments or small not-for-profit organizations.

After receiving public comments on the proposed rule, EPA convened a Small Business Advocacy Review Panel under the Regulatory Flexibility Act. EPA considered input from small business representatives and SBA's Office of Advocacy to modify the proposed rule to provide certain flexibilities to minimize burden on small businesses that may be affected by this rule.

While EPA determined that a "small business" or similarly broad exemption would be inconsistent with the obligations under section 8(a)(7), EPA is providing some reporting burden relief for certain types of entities: article importers and manufacturers of small quantities (i.e., below 10 kg/year) of PFAS for R&D purposes. Both types of entities include small businesses, and public input indicated those entities are likely not in a position to know or reasonably ascertain all information requested under this rule. Therefore, EPA is creating streamlined reporting forms for both article importers and certain R&D manufacturers, which include only a

subset of the longer reporting form questions if those submitters are unable to know or reasonably ascertain all other information.

Additionally, EPA is providing more time for reporting than was proposed. In response to public comment from the proposed rule, EPA has decided to finalize a one-year information collection period following the effective date of this rule, which will then be followed by a six-month reporting period. In response to input on behalf of small businesses, EPA is granting an additional six months for reporting to small manufacturers (as defined at 40 CFR 704.3) whose reporting obligations under TSCA section 8(a)(7) are exclusively from article import. "Small manufacturers" as defined at 40 CFR 704.3 include manufacturers who meet one of two standards: (1) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$120 million, and the annual production volume of a chemical substance is less than 100,000 lbs; or (2) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$12 million. Thus, reporting forms will be due 18 months following the effective date of this rule, except for small article importers (as defined at 40 CFR 704.3), whose reporting forms are due 24 months following the effective date of this rule.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

This is a one-time statutorily mandated reporting event.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

- a) requiring respondents to report information to the agency more often than quarterly;**
- b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- c) requiring respondents to submit more than an original and two copies of any document;**
- d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data**

security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The recordkeeping period of this collection is five years. The five-year record retention period is consistent with the statute of limitations and other TSCA reporting rules (e.g., CDR).

Reporters may also assert and substantiate CBI when submitting information under this rule. EPA has long-established procedures for properly handling, storing, processing, and disposing of TSCA confidential information. Transfers of this information to others as allowed under TSCA section 14(d) can be made only if the other entity agrees to adhere to all TSCA confidentiality provisions. EPA will maintain standard confidentiality procedures to protect any confidential, trade secret, or proprietary information from disclosure in accordance with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or report.

EPA developed the proposed rule "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances" and published it in the Federal Register for public comment (86 FR 33926; June 28, 2021). The proposed rulemaking served as the public notice for this ICR amendment, which is available in the public docket. Interested parties were directed to submit comments referencing Docket ID No. EPA-HQ-OPPT-2020-0549. EPA received 109 unique comments on the proposed information collection (including those that requested an extension of the comment period, which EPA granted). Comments were submitted from many types of stakeholders (industry, non-governmental organizations, other federal agencies, state agencies, utilities, and private citizens) and covered many different aspects of the proposed rule, including the cost and hour burden estimates, reporting data elements, frequency of collection, duration of reporting period, and clarity of instructions.

Comments pertaining to the cost and hour burden estimates for the proposed rule from industry and SBA generally stated that EPA had significantly underestimated the burden, including on small businesses, given the inability for EPA to reliably estimate the universe of article importers that would be covered by the proposed rule at the time of the proposed rule's publication. Some comments provided alternative estimates based on their experiences, which

EPA has considered and addressed in the final rule and economic analysis. However, other comments related to estimated burden from other stakeholders addressed the necessity of the data collection for the purpose of public health and environmental protection, as no similar dataset exists. Some commenters also stated that the benefits of this information collection were not sufficiently detailed in the proposed rule and should be better explained in lieu of the estimated costs.

Comments on the proposed rule pertaining to reporting data elements generally recognized that EPA is required to request as many data elements as proposed and for each year that a PFAS was manufactured. A few commenters suggested some modifications (both deletions and additions) to the list of proposed data elements. Similarly, EPA received only a few comments on the frequency of collection. Most commenters supported the one-time data collection, but a few requested that EPA conduct this data collection more frequently in the future.

Comments pertaining to the duration of the reporting period varied by stakeholder type. Generally, industry commenters requested more time to collect and report information than the rule proposed. However, many other stakeholders requested no changes to the proposed reporting period duration, though some supported a reduced reporting period so as to receive the requested data sooner.

Some commenters requested greater clarity of instructions, especially given the reporting standard of TSCA section 8: information must be reported to the extent it is known to or reasonably ascertainable by the submitter. This request was provided in light of article importers and other entities who have generally not been required to report to EPA under most other section 8 rules.

Commenters also urged EPA to convene an SBAR Panel under the RFA to better estimate the universe of small businesses affected by the proposed rule and consider small entities' input on regulatory alternatives to the proposed rule. Accordingly, EPA convened an SBAR Panel in April 2022 and concluded in August 2022. Input from small entity representatives to this SBAR Panel included discussion of the proposed rule's estimated burden and costs (including EPA's since-updated estimates) and methodologies deriving those estimates, the clarity of instructions and guidance in the proposed rule related to the reporting standard, the reporting period duration, and regulatory flexibility alternatives to minimize burden on small entities.

Pursuant to the RFA, EPA published the Initial Regulatory Flexibility Analysis (IRFA) as a Notice of Data Availability for public comment (87 FR 72439; November 25, 2022). EPA specifically requested comments on all aspects of the IRFA, including burden estimates for small entities and regulatory flexibility alternatives for both small and all entities. In this notice, EPA also solicited comments on other aspects of the proposed rule that may have been impacted by other actions since the publication of the notice of proposed rulemaking (e.g., TSCA CBI procedural rule).

In response to the notice of data availability for the IRFA, EPA received 44 unique comments (including requests to extend the comment period, which EPA denied). Commenters included industry trade association and coalitions, individual companies, non-profit organizations,

federal and tribal entities, and private citizens. Comment topics included the consideration of a supplemental proposed rulemaking in lieu of a NODA; the scope of reportable chemicals; support for alternatives presented in the IRFA, opposition to alternatives presented in the IRFA; the burden and cost of the rule and EPA's methodology for estimation; submission of TSCA CBI claims; duplicative reporting and request to extend the public period.

The final rule, Economic Analysis, and ICR were developed with consideration of comments received from the public in response to the notice of proposed rulemaking and notice of data availability, and through the SBAR Panel. EPA has developed a Response to Comments document that summarizes the comments received and EPA's responses that were not included and responded to in the preamble (Attachments D and E).

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This question is not applicable to this ICR

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Confidentiality claims limit access to the PFAS data, especially by the public. EPA recognizes that some information submitted to the Agency is legitimately confidential. Therefore, EPA's review of confidential data is an inherently governmental function that EPA must perform to protect human health and the environment. EPA has identified specific data elements that cannot be claimed as confidential, consistent with TSCA section 14. These data elements are also not allowed to be claimed as confidential in CDR reporting. Also consistent with TSCA CBI submission requirements, EPA will require submitters provide upfront substantiation when asserting eligible data elements as CBI in this rule.

Submitters may claim most information reported to EPA under this rule as confidential if such information would reveal the submitter's trade secrets or proprietary information as defined by TSCA section 14 and existing regulations promulgated by EPA under TSCA.

EPA has long-established procedures for properly handling, storing, processing, and disposing of TSCA confidential information. Transfers of this information to others as allowed under TSCA section 14(d) can be made only if the other entity agrees to adhere to all TSCA confidentiality provisions. EPA will maintain standard confidentiality procedures to protect any confidential, trade secret, or proprietary information from disclosure in accordance with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

EPA asks no questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'**

This section of the ICR describes the respondents, the information collection activities and related estimates of burden and costs associated with those activities. Burden estimates are derived consistent with estimates described in the Economic Analysis for the PFAS Data Call Final Rule (EPA 2023).

Methodology for Estimating Respondent Burden and Costs

The regulated community consists of companies manufacturing (including importing) PFAS chemical substances in any year since January 1, 2011. This final rule will impact manufacturers and article importers across a substantial number of industries, including the following North American Industry Classification System (NAICS) industries:

22 – Utilities

23 – Construction

31-33 – Manufacturing

42 – Wholesale Trade

44-45 – Retail Trade

562 – Waste Management

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.

Data Elements for the PFAS Reporting Form

As mandated under section 8(a)(7), the Agency must collect certain information on PFAS manufactured in any year since 2011. The information requested is authorized under section 8(a)(2), and includes reporting with respect to information including chemical identity, categories of use, production volume (in total and with respect to each category of use), description of byproducts, the number of individuals exposed at their places of work, and the methods of disposal. EPA is also authorized to request all existing information related to environmental and health effects of PFAS.

Specifically, EPA is requesting the following information from any person who has manufactured PFAS in any year since 2011, and the information would be collected for each year in which that PFAS was manufactured:

- 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 Low-Volume Exemption (LVE) case number)
- Trade name or common name
- Representative molecular structure for any PFAS that is not a Class 1 substance on the TSCA Inventory
- Physical form of chemical or mixture
- Industrial processing and use: type of process or use; sector(s); function category(ies); percent of production volume for each use
- Consumer and commercial use: consumer and/or commercial indicator; 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
- Indicator for imported but never physically at site
- Indicator for site-limited
- Total volume recycled (on-site)

- Information on byproducts produced during the manufacture, processing, use or disposal of the PFAS:
- Byproduct chemical name(s) or description (if unknown), or the generic name(s) if the byproduct name(s) is CBI
- Chemical ID(s), if available (CASRN, TSCA Accession Number, or LVE case number)
- Indicator for whether byproduct production stemmed from manufacture, process, use, or disposal
- Indicator for whether the byproduct(s) are released to the environment; if so, volume released and to which environmental media
- Worker activity descriptions at 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 and frequency 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 and frequency 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 and frequency 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 the health or environmental effects, using the OECD harmonized template, as well as study reports and other supporting information
- Other data relevant to health effects (e.g., range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, adverse effects reports)

EPA will allow article importers and firms that manufacture research and develop (R&D) substances in volumes of less than 10 kilograms per year to submit a streamlined reporting form.

EPA is requesting the following information from article importers:

- Company information

- Volume/quantity of imported articles
- 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
- Specific or generic chemical name, or description of the PFAS-containing article/component (e.g., coating name)
- Chemical ID(s) (CASRN, TSCA Accession Number, or LVE case number)
- Trade name or common name
- Representative molecular structure, for any PFAS that is not a Class 1 substance on the TSCA Inventory

Additionally, article importers would have the option to provide more information and documentation if such information were known or reasonably ascertainable.

EPA is requesting the following information from firms that manufacture R&D substances in volumes of less than 10 kilograms per year:

- Company and plant 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, for any PFAS that is not a Class 1 substance on the TSCA Inventory
- Production volumes: domestically manufactured; imported; directly exported

Respondent Activities

Based on 2016 and 2020 CDR data, EPA estimated an average of 5.74 PFAS per firm for manufacturing firms for non-R&D uses. In addition, EPA assumes an average of two PFAS per firm for manufacturing firms for R&D use. Therefore, it is assumed that there is an average of 7.74 responses per manufacturing firm. 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 5.74 and therefore assumes an average of 5 PFAS per reporting article importer.

Incremental activities associated with preparing and submitting a response under the rule include rule familiarization, compliance determination, form completion, CBI claim substantiation, recordkeeping, and CDX registration, including e-signature. General descriptions of changes to activities are as follows (see previous section for detailed data element information):

- **Rule Familiarization:** The final rule requires reporting businesses and their staff to become familiar with the TSCA section 8(a) rule and its various requirements. This activity entails reading the rule, understanding the reporting and administrative requirements, understanding the structural definition of PFAS, and determining what tasks are required in order to meet reporting requirements.
- **Compliance Determination:** For the purpose of this rule, the reporting standard would be information known to or reasonably ascertainable by the firm. This reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard would require that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees) and may also entail inquiries outside the organization to fill gaps in the submitter's knowledge.
- **Form Completion:** The final rule requires one-time reporting of certain information, including chemical identity, categories of use, production volume, byproducts, environmental and health effects, occupational exposure, and disposal.
- **CBI Claim Substantiation:** TSCA requires that anyone seeking protection of CBI must assert a claim and, for certain information, may be required to substantiate that claim. Reporting elements of the final rule for which a submitter might need to substantiate a claim of CBI, if a claim is made, include submitter information; chemical identity; physical properties; production volumes and product concentrations; byproducts; environmental release; worker exposure information; and description of disposal process(es).
- **Recordkeeping:** The final rule requires respondents to retain documentation of information contained in their reports for five years after the date of submission.
- **CDX Registration and Electronic Signature:** Respondents that submit a report will need to register with CDX in order to comply with electronic reporting requirements. This activity occurs only once for each submitter. Some submitters may have already registered to use the e-TSCA web reporting tool in CDX (and obtained an accompanying electronic signature) in order to comply with mandatory electronic reporting requirements of EPA's e-PMN rule and/or CDR rule. Those submitters will not need to repeat the CDX registration and e-signature process in order 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 final rule will need to register with CDX.

Estimating Respondent Burden and Costs

This section presents the relevant unit burdens and costs of the information collection activities to respondents in terms of the time required by reporters to perform the activities as outlined in the introductory section of this document.

PFAS Data Call Reporting

Incremental experienced reporter unit burden for respondent activities associated with the final rule is presented in Table 3. Unit burdens in this table reflect changes in activities that are applied universally to all affected entities. The activity-level unit burden estimates for changes in Table 3 are based on estimates for similar activities (for more detail, see EPA (2020)). The total average burden is estimated to be 88.55 hours per firm.

Table 3: PFAS Data Call Reporting: Activity-Level Reporter Unit Burden

Activity	Clerical Burden (hours)	Technical Burden (hours)	Managerial Burden (hours)	Attorney Burden (hours)	Activity-Level Unit Burden per Average Firm	Proportion of Firms Affected	Average Unit Burden per Firm
Rule Familiarization							
Structural Definition Familiarization for Manufacturing Firms and Large Article Importers	0.00	5.50	0.00	0.00	5.50	0.09	0.50
Structural Definition Familiarization for Small Article Importers	0.00	9.00	0.00	1.00	10.00	0.89	8.85
Reporting Firms	0.00	17.00	7.00	0.00	24.00	0.10	2.44
Non-Reporting Firms	0.00	6.40	2.85	0.00	9.25	0.90	8.31
Compliance Determination							
Manufacturers	0.00	5.80	0.00	0.00	5.80	0.002	0.01
Article Importers	17.00	40.35	0.00	0.00	57.35	0.998	57.24
Form Completion							
Manufacturers	13.55	483.64	35.23	0.00	532.42	0.002	1.03
Article Importers	7.50	64.47	19.74	0.00	91.71	0.10	9.15
CBI Substantiation							
Manufacturers	2.79	19.27	11.84	0.00	33.90	0.0003	0.01
Article Importers	1.80	12.45	7.65	0.00	21.90	0.010	0.22
Recordkeeping							
Manufacturers	3.87	3.87	0.00	0.00	7.74	0.002	0.01
Article Importers	2.50	2.50	0.00	0.00	5.00	0.10	0.50
CDX Registration	0.00	1.73	0.93	0.00	2.67	0.10	0.27
Total average unit burden per firm							88.55
Note: For additional details on development and assumptions associated with items in this table, see the source EA (EPA 2022). Numbers may not sum due to rounding.							

Unit costs are derived by combining relevant wage information with unit burden estimates. See Appendix B for information on the industry wage rates used in this analysis. In addition, EPA

estimates each firm will incur a \$3.15 in material costs for filing the electronic signature agreement when registering with CDX. EPA estimates reporter burden and cost at approximately \$6,089 per firm, shown in Table 4.

Table 4: PFAS Data Call Reporting: Activity-Level Reporter Unit Cost

Activity	Average Unit Burden per Firm	Average Unit Cost per Firm (2022\$)	
		3% Discount Rate	7% Discount Rate
Rule Familiarization			
Structural Definition Familiarization for Manufacturing Firms and Large Article Importers	0.50	\$41	\$39
Structural Definition Familiarization for Small Article Importers	8.85	\$747	\$719
Reporting Firms	2.44	\$205	\$197
Non-Reporting Firms	8.31	\$699	\$673
Compliance Determination			
Manufacturers	0.01	\$1	\$1
Article Importers	57.24	\$3,860	\$3,653
Form Completion			
Manufacturers	1.03	\$82	\$79
Article Importers	9.15	\$710	\$661
CBI Substantiation			
Manufacturers	0.01	\$1	\$1
Article Importers	0.22	\$17	\$16
Recordkeeping			
Manufacturers	0.01	\$1	\$1
Article Importers	0.50	\$29	\$27
CDX Registration	0.27	\$23	\$21
Total	88.55	\$6,417	\$6,089

Note: For additional details on development and assumptions associated with items in this table, see the source EA (EPA 2020). Numbers may not sum due to rounding.

Respondent Universe, Total, and Bottom Line Burden Hours and Costs

PFAS Data Call Reporting

Estimates of the total industry reporting burden and cost are shown in Table 5. Total burden and cost are calculated by multiplying the unit burdens and costs in Table 4 by the respective number of reporting sites. EPA estimates a total burden of 11.6 million hours and a total cost of \$843 million and \$800 million under a 3 percent and 7 percent discount rate, respectively.

Table 5: PFAS Data Call Reporting: Total Estimated Respondent Burden and Costs

Activity	Number of Firms	Number of Responses	Per-Firm Unit Burden	Total 3-Year Burden	Per-Firm Unit Cost	Total 3-Year Cost (2022\$)	Per-Firm Unit Cost	Total 3-Year Cost (2022\$)
					3% Discount Rate		7% Discount Rate	
Rule Familiarization	131,410	67,536	20	2,642,124	\$1,692	\$222,396,690	\$1,629	\$214,082,795
Compliance Determination	131,410	67,536	57	7,523,295	\$3,861	\$507,327,191	\$3,654	\$480,190,513
Form Completion	131,410	67,536	10	1,337,532	\$793	\$104,183,912	\$740	\$97,240,352
CBI Substantiation	131,410	67,536	0.2	30,096	\$18	\$2,382,473	\$17	\$2,219,240
Recordkeeping	131,410	67,536	1	67,536	\$30	\$3,937,169	\$28	\$3,665,229
CDX Registration	131,410	67,536	0.3	35,650	\$23	\$2,980,632	\$21	\$2,773,754
Respondent Total	131,410	67,536	89	11,636,233	\$6,417	\$843,208,067	\$6,089	\$800,171,883
Agency						\$1,612,702		\$1,562,613

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

- a) The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.
- b) If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3)

for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There are no operational and/or maintenance costs.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

The Agency develops and maintains the electronic tool used to collect and verify data and routinely conducts other activities related to the processing, analysis and storage of the information collected under this rule. In this ICR Addendum, only the Agency activities created by the final rule are considered including:

- Data processing and analysis
- Systems support
- Review of CBI claim substantiations

Estimated Agency Costs

The Agency engages in several activities related to TSCA section 8(a) reporting, including: document receipt and tracking; quality control of data, including protection of CBI; backup systems operation; data processing and analysis; systems support; review of CBI claim substantiations; and IT infrastructure and guidance development. For the PFAS Data Call, EPA estimates a total burden of 6,240 hours and a cost of \$1,654,279 to the Agency for the one-time reporting. See Appendix A for a detailed derivation of Agency costs.

Collection Schedule

This is a one-time reporting event. The submission period will begin one year after the final effective date of the rule and will last for six months, and an additional six months will be provided for small manufacturers (as defined at 40 CFR 704.3) whose reporting obligations under this rule are exclusively from article import.

Activity	Timeline
Public outreach efforts: Federal Register publication of proposed rule and 90-day public comment period open; information posted on EPA’s website; presentations to conferences and webinars with potentially affected entities	2021
Public outreach efforts: SBAR Panel convened; Federal Register publication of the IRFA for 30-day public comment period;	2022

Activity	Timeline
information posted on EPA's website; presentations to conferences and webinars with potentially affected entities	
Final rule published; effective date 30 days following rule publication in the Federal Register	Late 2023
Open period for submitting reporting forms and existing data	Beginning 12 months after final effective date; reporting period lasts for 6 months for most manufacturers, and 12 months for small manufacturers (per 40 CFR 704.3) whose reporting obligations under this rule are exclusively from article import

Use of Technology to Facilitate Collection Activities

Submitters are required to submit information associated with this data collection electronically via the Internet using the PFAS Reporting Tool within CDX.

EPA notifies potential submitters of the need to report in three ways: (1) makes available guidance describing reporting requirements through web and listserv announcements, (2) sends email notices to previous TSCA submitters and other potential stakeholders, and (3) publishes press releases. The requirement to report is based on TSCA section 8(a)(7); potential submitters that do not receive a notification as listed above or who do not read published articles are still required to report. Reporting materials, including a non-submission version of the required information and reporting instructions documents will be available on EPA's TSCA website. Submitters can also obtain these materials from the TSCA Hotline. Submitters obtain the PFAS Reporting Tool (which enables the completion of the reporting form for submission) as part of the CDX electronic web-based registration process.

EPA will receive all submissions electronically. The CDX registration process, required for all submitters, provides a user ID, which the submitter uses to access the PFAS Reporting Tool. EPA anticipates that many submitters will already have registered for CDX to fulfill other reporting programs, such as CDR or the Toxics Release Inventory.

Information quality control and validation will begin with the PFAS Reporting Tool, which is programmed to help the submitter provide the information required, in the correct format, as required by the final rule.

To aid persons subject to this information collection, the Agency's TSCA and CDX Hotlines will be available to answer questions regarding the reporting requirements or submission process. When Hotline staff is unable to answer questions, the submitter is referred to OPPT programmatic staff. Other divisions within OPPT or the Office of Mission Support (OMS) may respond as necessary.

15. Explain the reasons for any program changes or adjustments reported in hour or cost burden.

This is a new data collection activity. As such, the change being implemented in this ICR period is the addition of new burden and cost for the one-time collection event. The total burden to industry for this ICR period is approximately 11.6 million hours. The total cost to industry for this ICR period is approximately \$843 million under a 3 percent discount rate and \$800.2 million under a 7 percent discount rate.

16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Not applicable.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

This question not applicable to this ICR

18. Explain each exception to the certification statement identified in Item 19 of OMB Form 83-I.

EPA does not request an exception to the certification of this information collection.

SUPPLEMENTAL INFORMATION

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0217). Responses to this collection of information are mandatory (40 CFR 705). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 89 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address."

REFERENCES

- BLS (U.S. Bureau of Labor Statistics). 2023a. "Employer Costs for Employee Compensation Supplementary Tables - December 2022."
- BLS. 2023b. National Industry-Specific Occupational Employment and Wage Estimates, May 2022.
- EPA. 2002. *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (EPA-HQ-OPPT-2002-0054-0260)*. Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch. August 2002.
- EPA. 2009. *ICR Handbook: EPA's Guide to Writing Information Collection Requests under the Paperwork Reduction Act of 1995*. Retrieved from <https://www.pdfFiller.com/10247637--ICR-Handbook--Environmental-Protection-Agency->.
- EPA. 2017. *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements (RIN 2070-AK24) EPA-HQ-OPPT-2016-0426-0072*.
- EPA. 2021. *Economic Analysis for the Proposed TSCA Section 8(a)(7) reporting Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*.
- EPA. 2022. *TSCA section 8(a)(7) Initial Regulatory Flexibility Analysis (IRFA)*.
- EPA. 2022. *TSCA section 8(a)(7) Small Business Advocacy Review (SBAR) Panel Report*.
- EPA. 2023. *Economic Analysis for the Final TSCA Section 8(a)(7) reporting Requirements for Perfluoroalkyl or and Polyfluoroalkyl Substances*.
- OPM. 2022. "Salary table 2022-DCB."
- Rice. 2002. Wage Rates for Economic Analysis of the Toxics Release Inventory Program. June 10, 2002.

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through <http://www.regulations.gov> using Docket ID Number: EPA-HQ-OPPT-2020-0549.

- A Final Rule
- B [15 U.S.C 2607](#)
- C PFAS Reporting Tool Mockups (EPA Form No. 9600-046)
- D Economic Analysis
- E Response to Comment Document

Appendix

Appendix A. Detailed Derivation of Agency Burden and Cost

EPA Staff Activities

EPA activities affected by the rule involve data processing, systems support, review of CBI claim substantiations, and IT infrastructure. Costs related to EPA activities that involve data use are not included.

EPA labor costs are based on annual federal wage rates, as presented in Error: Reference source not found. EPA assumes that the collection and administrative activities (technical labor) associated with Agency responses to the final rule will be accomplished by a GS-13, Step 5 federal employee in the Washington-Baltimore-Northern Virginia area.

Table: A-1: Agency Wage Rates (2022\$)

Labor Category	Data Source for Wage Information	Wage (\$/hr)	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	\$58.20	63.9%	\$37.19	\$95.39	20.0%	\$19.08	\$114.47

¹ Source: U.S. Office of Personnel Management 2022
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)

Unit burden and cost associated with EPA staff activities are the same as in the economic analysis for the final rule (EPA, 2020) and are presented in Error: Reference source not found.

Table A- 2: Total Agency Burden and Cost (2022\$)

EPA Activity	Burden (hours)	Cost (2022\$)
Data Processing	4,160	\$476,186
Data Analysis	2,080	\$238,093
Contractor Data Processing Support	-	\$10,000
IT Infrastructure	-	\$930,000
Total Agency Burden and Cost	6,240	\$1,654,279

Appendix B. Industry Wage Rates

This section describes the industry wage data used to develop reporting burden estimates. Wage rates for managerial, technical, clerical, and attorney labor are derived and presented in Table B-1.

Loaded wage rates for each labor category are derived by combining data on wages and fringe benefits with estimates of overhead rates. Wage rates and fringe benefits for clerical, professional/technical, managerial, and attorney labor are calculated using the U.S. Bureau of Labor Statistics' (BLS) Employer Costs for Employee Compensation (ECEC) data for December 2022 (BLS, 2023a). The industry wage rate for attorney labor is derived from the National Industry-Specific Occupational Employment and Wage Estimates (BLS, 2023b). 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 2020) and is reflective of multiplier values used in prior EPA economic analyses and Information Collection Requests (ICRs) that are based on industry- and occupation-specific overhead rates affected by EPA regulations.

Error: Reference source not found contains the loaded wage rates for the managerial, technical, clerical, and attorney occupation categories.

Table B-1: Reporter Wage Rates (2022\$)

Labor Category	Wage ¹	Fringe Benefit ²	Total Compensation	Overhead % Wage ³	Overhead	Hourly Loaded Wages ⁴
	A	B	C = A + B	D	E = C x D	F = C + E
Clerical	\$23.11	\$10.33	\$33.44	20%	\$6.69	\$40.13
Professional/ Technical	\$46.01	\$23.27	\$69.28	20%	\$13.86	\$83.14
Managerial	\$54.29	\$24.66	\$78.95	20%	\$15.79	\$94.74
Attorney	\$78.74	\$22.27	\$101.01	20%	\$20.20	\$121.21

¹ Source: Employer Costs for Employee Compensation: December 2022 (BLS 2023a); National Industry-Specific Occupational Employment and Wage Estimates, May 2022 (BLS 2023b).

² Source: Employer Costs for Employee Compensation: December 2022 (BLS 2023a)

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.