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: Consolidation of Certain Reporting and Recordkeeping Under Section 8 of the Toxic Substances Control Act (TSCA)

EPA ICR No.: 2703.01

OMB Control No.: 2070-[NEW]

Docket ID No.: EPA-HQ-OPPT-2021-0728

Abstract

This is a new ICR that consolidates the information collection activities currently covered by several ICRs previously approved by OMB under the separate OMB control numbers identified below.

Previously Approved ICRs Being Consolidated					
OMB Control No.	**EPA ICR No.**	**ICR Title [ICR Status]**	**Total Responses**	**Total Burden (Hours)**	**Total Costs (Dollars)**
2070-0004	0575.16	Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies [Approved through November 30, 2022.]	34	313	$ 23,501
2070-0017	1031.12	Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment [Renewal is pending at OMB, so existing approval is extended each month until OMB takes an action on the renewal.]	26,336	25,527	$ 0
2070-0054	0586.14	TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) and Subpart B of 40 CFR part 766 [Approved through January 31, 2023]*	1	33	$ 0
2070-0067	1198.10	Chemical-Specific Rules, TSCA Section 8(a) [Expired June 30, 2018, pending reinstatement.]	4	275	$ 0

* Covers EPA Form Numbers 7710-35 (Manufacturer's Report Preliminary Assessment Information) and 7710-51 (Dioxin/Furans Report).

These ICRs all involve reporting and recordkeeping activities established under TSCA section 8 for chemical substances and Subpart B of 40 CFR part 766 which was previously consolidated within the OMB-approved ICR for the TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR). Although imposed for a specific chemical substance, the activities are already established and only vary based on the

specific authority under TSCA section 8 and 40 CFR 766 and the need for the information for that chemical. EPA is consolidating these ICRs to streamline the presentation of the paperwork burden estimates for these various activities, which will in turn facilitate and reduce the administrative burden for both the public reviewers and the Agency in terms of reviewing and updating the ICR every three (3) years as required by the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., as well as allow for a better assessment of the paperwork burden and costs associated with reporting and recordkeeping activities established under TSCA section 8 for specific chemical substances.

This information collection request (ICR) covers reporting and recordkeeping requirements imposed under the authorities in section 8 of TSCA, 15 U.S.C. 2607, for persons who manufacture (the term “manufacture” includes import under TSCA) (Attachment 1) or process chemical substances, mixtures, or categories, or distribute them in commerce. The purpose of the information collection activities is to collect data that will help the Agency evaluate the potential for human health and environmental risks that may be caused by the manufacture, processing, and distribution in commerce of chemical substances, mixtures, or categories.

This ICR addresses the following four (4) types of information collections (ICs) required by TSCA section 8 and identifies the persons required to keep records and report such information. The ICs are numbered to facilitate the presentation in the ICR and link to supporting information; and the numbering is not otherwise intended to convey any sequencing or prioritization.

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

Under section 8(a), persons who manufacture or import chemical substances listed at 40 CFR 712.30 are subject to the section 8(a) Preliminary Assessment Information Rule (PAIR) requirements. PAIR requires these manufacturers and importers to submit information about production, use, and/or exposure-related data. Certain specific chemical testing and reporting requirements under Subpart B of 40 CFR part 766 (Attachment 3) that are very similar to the PAIR requirements are also covered within this information collection activity.

Chemical-Specific Rules, TSCA Section 8(a)

Also, under section 8(a), persons who manufacture, import, or process certain chemical substances or mixtures, or propose to manufacture, import, or process certain chemical substances or mixtures, are subject to chemical-specific rules promulgated under section 8(a) of TSCA. A chemical-specific 8(a) rule requires more detailed and more types of information than is required by a PAIR rule. For example, a chemical-specific 8(a) rule might require information that includes, but is not limited to, chemical names,

categories of use, production volume, byproducts of chemical production, existing data on health and environmental effects, exposure data, and disposal information. Any chemical covered by TSCA for which OPPT, other EPA offices or another federal agency has a reasonable need for information, and which cannot be satisfied via readily available sources or by use of other rulemakings, is a proper potential subject for a chemical specific TSCA section 8(a) rulemaking.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

Under section 8(c), persons who manufacture, import, process, or distribute in commerce any chemical substance or mixture must keep records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. TSCA section 8(c) requires that allegations of adverse reactions to the health of employees be kept for thirty years, and all other allegations be kept for five years. The rule also prescribes the conditions under which a firm must submit or make the records available to a duly designated representative of the Administrator.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

Under section 8(d), certain persons, who manufacture, import, process, or distribute in commerce (or propose to manufacture, import, process, or distribute in commerce) chemical substances and mixtures, are required to submit to EPA lists and copies of health and safety studies in their possession which relate health and/or environmental effects of the chemical substances and mixtures.

Summary Total Burden and Costs

Section 8 Consolidated ICR Summary Responses, Respondents, and Total Burden and Costs

Activity	Number of Responses	Number of Respondents	Total Annual Burden (hours)	Annual Cost
TSCA section 8(a) Preliminary Assessment Information Rule (PAIR)	1	1	33	$2,824
Chemical Specific Rules TSCA section 8(a)	47	47	192	$14,790
Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment TSCA section 8(c)	26,336	13,160	25,526	$5,050,295

Activity	Number of Responses	Number of Respondents	Total Annual Burden (hours)	Annual Cost
Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies TSCA section 8(d)	41	41	475	$41,607
Industry total	26,425	13,249	26,226	$5,109,515
Agency total	0	0	5,066	$425,835

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) Preliminary Assessment Information Rule (PAIR)

EPA has in the past used the TSCA Preliminary Assessment Information Rule (PAIR) to collect information to help identify, assess, and manage human health and environmental risks from chemical substances, mixtures and categories listed at 40 CFR 712.30. PAIR required these chemical manufacturers and importers to complete and submit standardized information about production, use, or exposure-related data to help evaluate the potential for human health and environmental risks caused by the manufacture or importation of identified chemical substances, mixtures or categories, or exposure-related data. PAIR is also available to the EPA for the purpose of informing the prioritization and risk evaluation activities required under the 2016 amendments to TSCA enacted when the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) was signed into law on June 22, 2016. However, other rulemakings such as the Chemical Data Reporting (CDR) rule have been more recently and regularly used by the EPA to collect similar information under TSCA section 8(a) to inform LCSA activities.

EPA promulgated the generic section 8(a) Preliminary Assessment Information Rule (PAIR) (40 CFR part 712) under the TSCA (Attachment 2). EPA uses PAIR to collect information to help identify, assess, and manage human health and environmental risks from chemical substances, mixtures and categories listed at 40 CFR 712.30. PAIR requires chemical manufacturers and importers of these chemicals to complete and submit standardized information about production, use, or exposure-related data to help evaluate the potential for human health and environmental risks caused by the manufacture or importation of identified chemical substances, mixtures or categories.

EPA or other federal agencies (e.g., the agencies that are part of the Interagency Testing Committee (ITC) as authorized under TSCA section 4(e)) can identify chemicals for a TSCA section 8(a) PAIR expediated rulemaking that have a justifiable need for production, use, or exposure-related data.

This information collection activity also covers certain specific chemical testing and reporting requirements under Subpart B of 40 CFR part 766 (Attachment 3) that are very similar to the PAIR requirements. The Agency rarely receives submissions of the information required by 40 CFR 766. EPA received less than five submissions over the course of the last OMB approval for this aspect of the information collection. However, collection of this information is covered under the PAIR ICR because the requirements are similar and because the PRA requires that recordkeeping and reporting activities contained in any regulation be approved by OMB even if they involve less than ten respondents or would otherwise not require approval (see 5 CFR 1320.3(c)(4)(i)).

The dibenzo-para-dioxin/dibenzofuran regulations at 40 CFR part 766 require that any person who manufactures, imports, or processes a chemical substance listed at 40 CFR 766.25 test that chemical substance and submit appropriate information to EPA according to the schedules described at 40 CFR 766.35. Persons who commence manufacture, import, or processing of a chemical substance listed at 40 CFR 766.25 must submit a letter of intent to test or an exemption application within 60-days of starting any of those activities. Each person who is manufacturing or processing a chemical listed in 40 CFR 766.25, must submit a protocol for testing according to the schedule at 40 CFR 766.35(a)(2). Persons who manufacture or import a chemical substance listed under 40 CFR 766.25 must report positive test results, using the Dioxin/Furan Report Form (EPA Form 7710-51; see Attachment 4), of all existing test data that show that chemical substance has been tested for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), as well as any health and safety studies for the chemical substance, as defined in the regulation, no later than 90 days after the date of submission of the positive test result. Additionally, any manufacturer or importer of a chemical substance listed in 40 CFR 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA, in accordance with various provisions of 40 CFR 716, no later than 90 days after the person first manufactures or imports the chemical substance.

Chemical-Specific Rules, TSCA Section 8(a)

EPA may need chemical-specific information under TSCA section 8(a) to evaluate the potential for exposure and/or adverse human health and environmental effects caused by the manufacture, processing, use or disposal of identified chemical substances and

mixtures. EPA may use TSCA section 8(a) to require such information to assess the need or set priorities for testing and/or further regulatory action.

The information required in TSCA section 8(a) chemical-specific rules can be custom-tailored to aid in achieving EPA's goals of protecting human health and the environment. Information collected may vary depending on the substance, its current and potential uses and EPA's concerns about potential human or environmental risks caused by exposures to the substance. As noted above, TSCA section 8(a) rules may require persons manufacturing, or processing the chemical substance, or intending to manufacture or process, to report to EPA on specific information on a chemical listed at 40 CFR 704, subpart B such as: a chemical's composition, byproducts, quantity produced, employee exposure and environmental release.

The legal authority for this information collection is TSCA section 8(a), 15 U.S.C. 2607(a) (Attachment 1) and TSCA section 26(p), 15 U.S.C. 2625 (Attachment 5). TSCA section 8(a) chemical-specific rules have been codified at 40 CFR 704, subpart B; see Attachment 6.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

The TSCA section 8(c) reporting and recordkeeping requirements are of central importance in the administration of TSCA section 8 as a whole. Without the ability to administer these paperwork requirements, EPA would not be able to meet its obligation under TSCA.

Since the statute does not contain an automatic reporting provision, EPA must either inspect company files or require reporting of records that relate to specific substances of concern in order to obtain and use information about allegations of significant adverse reactions. EPA's authority to inspect and require such reporting is codified in 40 CFR 717.17 (Attachment 7). EPA will review relevant TSCA section 8(c) records in connection with its TSCA chemical assessment activities.

All studies submitted to EPA will be verified and the contents of the submissions recorded and inspected for the inclusion of confidential business information. Copies of the documents will then be prepared for inclusion in EPA's public docket and distributed, as appropriate and based on the associated chemical identity, to program offices at EPA and/or to other federal agencies for scientific analysis. A coding form will be completed to capture certain descriptive information such as identity, document control number, confidentiality indicator, document title, document date, receipt date and chemical identity.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

TSCA section 8(d), 15 U.S.C. 2607(d), authorizes EPA to promulgate rules requiring certain persons who manufacture, process or distribute in commerce, or propose to manufacture, process or distribute in commerce chemical substances and mixtures, to submit to EPA lists and copies of health and safety studies in their possession with respect to such chemical substances and mixtures. EPA regulations implementing the statute are codified at 40 CFR Part 716 (Attachment 8). TSCA as amended by the Lautenberg Chemical Safety for the 21st Century Act requires EPA to develop a pipeline of chemicals for prioritization and risk evaluation. Information from section 8(d) health and safety studies could help to inform the Agency's prioritization and risk evaluation work, as well as determine whether additional information on hazard, health or environmental effects, or exposure of the listed chemicals exist is necessary to assess risks; and for considering control actions. Collection of unpublished health and safety studies can reduce the need for testing. Additionally, other federal agencies use the studies when they are assessing a listed chemical substance for health or environmental effects.

Responses to the collection of information are mandatory (see 40 CFR part 716). Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

EPA also amends the list of subject chemicals in 40 CFR part 716 periodically to add chemical substances and mixtures. The listed chemical substances and mixtures include chemicals recommended for testing under TSCA section 4 by the Interagency Testing Committee (ITC) and other chemical substances that EPA (particularly the Office of Pollution Prevention and Toxics (OPPT)), or other federal agencies, choose to assess for health or environmental effects.

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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

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

EPA uses PAIR and subpart B of 40 CFR 766 data to (1) monitor domestic manufacture and/or importation of chemical substances, mixtures and categories, (2) identify possible routes of human or environmental exposure, (3) support regulations designed to prevent possible adverse health effects and (4) support EPA programs. The information provided by PAIR and subpart B of 40 CFR 766 is needed to complete assessments of chemicals of interest and to assist in the development of regulations to

control hazardous chemicals. In particular, PAIR can be used to support the activities under TSCA section 6 for risk-based prioritization and risk evaluation of TSCA chemicals.

All EPA program offices are potential users of the PAIR and subpart B of 40 CFR 766. The information helps EPA prioritize and evaluate the potential for adverse human health or environmental effects caused by the manufacture and importation of the identified chemical substance, mixture or category.

Other federal agencies, which require data on the human health and environmental effects of a chemical, use PAIR information. States also have access to public portions of PAIR and subpart B of 40 CFR 766 information. Public interest groups use information reported under the public portions of PAIR and subpart B of 40 CFR 766.

Chemical-Specific Rules, TSCA Section 8(a)

EPA will also use the information obtained through the TSCA section 8(a) reporting rules to satisfy chemical-specific data needs. The information collected will be relevant to prioritization, all stages of risk evaluation, and/or risk management. Receipt of TSCA section 8(a) information may also give the Agency an opportunity to work with the respondent, if necessary, to minimize exposure risks associated with specific uses. Generally, a specific information collection request would be made by the EPA. However, other regulatory agencies and departments, such as Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), and other members of the ITC may also present a need for and subsequently use TSCA section 8(a) data to, for example, assess worker or consumer exposures.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

By using the TSCA section 8(c) reporting authority, EPA can examine such records whenever a chemical is discovered to present possible risks to human health or the environment. Information contained in the TSCA section 8(c) allegation records will have several uses. The information collected will be used on a case-specific basis to evaluate suspected adverse health or environmental effects of a chemical substance or mixture already under assessment by EPA's Office of Pollution Prevention and Toxics (OPPT). Most of these substances will be “existing” chemicals, e.g., chemicals for test rule consideration, substances that are the subjects of TSCA section 8(e) notices of substantial risk, or substances or mixtures brought to the attention of OPPT by other EPA programs, other government agencies, industry, or the public. However, TSCA section 8(c) reports also may be required on “new” chemicals as one means of monitoring for any suspected or potential hazards identified during the premanufacture notification (PMN) review period.

On a case-specific basis, requiring reporting of TSCA section 8(c) records will also serve as a discovery function. It will help identify trends of adverse effects across the industry that may not be apparent to any one company. It will also serve as a long-term trend identification function because of the 5-year and 30-year recordkeeping feature of the statute.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

Studies submitted pursuant to TSCA section 8(d) rules will be evaluated in conjunction with other available data as EPA assesses risks of existing chemicals. EPA and other federal agencies will use the data to construct a complete picture of the known effects of the chemical substance. From this picture, OPPT will be able to determine what kinds of information gaps, if any, exist and whether testing may be needed. The TSCA section 8(d) studies will ensure that OPPT bases its testing decisions on the most complete information available and does not require unnecessary or duplicative testing, which is consistent with the requirements of TSCA section 4(h).

In addition, EPA may require that copies of unpublished health and safety studies be submitted on chemicals that are being considered for prioritization under section 6 of TSCA or in the early stages of risk assessment or when action to control exposure is being considered by EPA or another federal agency. These chemicals may be ones for which persons have submitted a substantial risk notification under TSCA section 8(e), or other chemicals for which data are needed to support a control measure under sections 5 and 6 of TSCA or under other EPA-administered statutes. If this information collection did not exist, EPA would not be able to obtain the available information on a chemical and evaluate the need for testing or data development under section 4 of TSCA or controlling chemical substances under TSCA sections 5 and 6.

In the past, EPA's Office of Air and Radiation (OAR) has used the submitted studies for developing Tier II analyses and the EPA's Office of Research and Development (ORD) has used the information for developing extended risk assessments. In addition, other organizations have utilized the submitted studies: the Consumer Product Safety Commission (CPSC) for assessing the hazards of known consumer exposure; the American Council for Government Industrial Hygienists (ACGIH); and the National Institute for Occupational Safety and Health (NIOSH) for developing recommended occupational exposure levels.

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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.

TSCA section 8 collections can be submitted electronically via the Agency's Central Data Exchange (CDX). All information sent by the submitter via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission is claimed as CBI, a non-CBI copy of the submission must be provided by the submitter. The CDX User Guides (Attachments 9 and 10) instruct users on how to submit and substantiate CBI information using the Chemical Information Submission System (CIS).

EPA developed the CDX reporting tool for use in submitting data electronically to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. The CIS is a tool that provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments.

The Agency ensures secure transmission of the data, reports, and other documents sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 and subsequent versions updated as needed are widely used approaches for securing Internet transactions by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet.

In addition, CDX enables the submitter to electronically sign, encrypt, and transmit submissions, which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. The CDX reporting tool encrypts using a module based on the 256-bit Advanced Encryption Standard (AES) adopted by NIST. Details about AES can be found in FIPS 197 pdf on the NIST website at http://csrc.nist.gov/publications/PubsFIPS.html and EPA may incorporate other encryption modules into future versions of the tool. Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards.

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.

Section 8(a)(5) of TSCA states, "the Administrator shall, to the extent feasible… not require reporting which is unnecessary or duplicative." The reporting requirements of TSCA section 8(a) rules only require information that EPA believes will assist in a reasoned evaluation of the human health and environmental effects of chemical

substances and mixtures. This information is unlikely to be duplicative since, (1) EPA estimates that each chemical-specific rule will generate only a few submissions, (2) the information required by the TSCA section 8(a) rule is unique to the manufacturer or processor (e.g., the proposed date of production or importation, the amount produced or imported, the chemical composition, and uses of the chemical substance or mixture), (3) the information on employee health effects required by the TSCA section 8(c) rule will be unique for the various affected employees of manufacturers and processors, (4) the studies required by the TSCA section 8(d) rule that are unpublished and in the possession of a company are most likely proprietary and unique for each manufacturer/processor, and (5) EPA thoroughly checks other public and unpublished sources to see if the required data may already be available prior to issuing such rules. If EPA were to become aware of a source of substantially similar information, for example via comments on a proposed rule, EPA would not continue with the information collection.

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

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

In accordance with TSCA section 8(a)(1)(B), PAIR contains a small business exemption. A manufacturer or importer is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than $30 million for the reporting period and (2) its total production and/or importation of the chemical substances, mixture or category, for the reporting period, does not exceed 100,000 pounds (45,400 kilograms) at an individual site owned and controlled by the firm. In accordance with amended TSCA the EPA consulted with the Administrator of the Small Business Administration to review the adequacy of the standards for determining which entities are considered small for the purposes of TSCA section 8(a). The agency determined that a revision of the standard is warranted (82 FR 56824, November 30, 2017) and initiated rulemaking to update the standard.

The small manufacturer/importer exemptions apply to PAIR, regardless of which office or agency nominates a chemical. In some instances, the EPA Administrator can remove these exemptions on a chemical-specific basis, provided notice and comment rulemaking is utilized. EPA expects that those offices that have a critical need for reporting from small businesses usually exempt from PAIR reporting will use other mechanisms to gather the data. EPA does not expect to issue a PAIR rule during the next 3 years that would impact small businesses.

Chemical-Specific Rules, TSCA Section 8(a)

Section 8(a) of TSCA generally exempts small manufacturers and processors. However, under TSCA section 8(a)(3), EPA may require small manufacturers and processors to report or keep records if the substance or mixture is subject to a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6 or with respect to which relief has been granted pursuant to a civil action brought under sections 5 or 7 of TSCA. All respondents to TSCA section 8(a) chemical-specific rules, including small businesses, are granted flexibility in their reporting format.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

Unlike TSCA section 8(a) of TSCA, Congress did not include a specific exemption of small businesses in TSCA section 8(c). This rule does not exempt small manufacturers (including importers) or processors of chemicals from its provisions. This is due to EPA's belief that workers, plant neighbors and consumers may be adversely affected by products, emissions, etc., produced or created by firms of all sizes.

However, the TSCA section 8(c) rule was written to concentrate the recordkeeping and reporting burdens on those firms generally associated with the mainstream chemical industry. EPA specifically eliminated most distributors and effectively limits the number of processors subject to the rule. By doing so, EPA has eliminated a large number of small businesses from the purview of the rule without compromising its objectives.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

The TSCA section 8(d) rule applies to all manufacturers and, when specified, processors of chemicals and others in possession of studies, regardless of size. However, EPA does not anticipate that many small businesses possess health and safety studies because they are unlikely to have the financial resources to perform the studies on chemicals subject to the rule. Therefore, the burden on such companies is expected to be minimal.

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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.

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

Under PAIR or subpart B of 40 CFR 766, persons are required to report only once for a chemical listed in the PAIR or subpart B of 40 CFR 766. However, for PAIR, if information received from the initial report indicates human health and environmental risks, then the Agency may require that additional information be submitted at some future date to monitor any changes pertaining to that chemical. As such, the reporting

frequency for PAIR and subpart B of 40 CFR 766 cannot be reduced without effectively suspending the information collection requirement.

Chemical-Specific Rules, TSCA Section 8(a)

Generally, companies are required to report only once under a TSCA section 8(a) chemical-specific reporting rule, although EPA may consider requiring reporting on an annual, semiannual, monthly or other basis if the Administrator deems this necessary to protect human health and the environment. EPA tailors each rule to meet chemical-specific information requirements, thus reducing the potential for too frequent data collections.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

Currently, EPA uses its authority to collect information pursuant to the TSCA section 8(c) rule sparingly. Currently, EPA anticipates issuing infrequent requests (less than 2 per year) for TSCA section 8(c) reporting. However, reporting requests may occur more frequently because individual notices or letters containing such TSCA section 8(c) requests may be clustered in the same year. The information will be collected on a case-specific basis to evaluate suspected adverse health or environmental effects of a chemical substance or mixture already under assessment by OPPT or when a chemical not under assessment by OPPT is discovered to present possible risks to human health or the environment. For example, chemical disasters are obviously unpredictable and OPPT must reserve the capability to require records submission on an as-needed basis in order to gather relevant information related to such matters. TSCA section 8(c) allegation records are part of such related information.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

In most instances, respondents will be required to make only initial submissions under the TSCA section 8(d) rule. However, after the initial submission of lists and studies, respondents are required to notify EPA when certain health and safety studies are initiated by submitting a list of newly initiated studies. Because the reporting frequency for the TSCA section 8(d) rule is generally only once, the reporting frequency cannot be reduced. If the information requirement were less frequent, EPA would not be able to obtain the necessary information for evaluating the need for additional information under section 4 of TSCA or evaluating and controlling chemical substances under sections 5 and 6 of TSCA.

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7. Explain any special circumstances that require the collection to be conducted in a manner:

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 record retention provisions of TSCA section 8(c) and 40 CFR part 717 exceed the Paperwork Reduction Guidelines (5 CFR 1320.6) in that they require respondents to maintain records other than health, medical, or tax records, for more than three years. TSCA section 8(c) authorizes EPA to require persons (i.e., manufacturers (including importers), processors, or distributors) to maintain records of adverse reactions to the health of employees for a period of 30 years from the date such reactions were first reported or known to the person maintaining the record. Any other record of such adverse reactions (e.g., to the environment, non-employees) is required to be retained for a period of 5 years. 40 CFR part 717 incorporates these record retention provisions authorized by TSCA.

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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 reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to several interested parties via email Attachment 13. The individual entities contacted were:

- American Chemistry Council
- Earthjustice
- Bergeson & Campbell, P.C.
- Environmental Defense Fund
- Society of Chemical Manufacturers & Affiliates
- Natural Resources Defense Council, Ince.

A copy of EPA's consultation to the above potential respondents and the response received are in Attachment 13 and are available in the docket. EPA did not receive any comments following consultation.

EPA did not receive any comments in response to the previously provided 60-day public review opportunity (87 FR 12954) (FRL-9155-01-OCSPP).

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

Not applicable.

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.

Submitters may designate information as confidential, trade secret, or proprietary. EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with TSCA section 14 and 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.

Under section 8, EPA does not seek submission of information 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'.

The North American Industrial Classifications System (NAICS) codes of respondents affected by this collection activity are mainly 325 (Chemicals and Allied Products Manufacturers) and 32411 (Petroleum Refining) for TSCA section 8 collection activities.

Wage and fringe benefit data for each labor category (e.g., managerial, professional/technical, clerical, and attorney labor) are taken from the U.S. Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation (ECEC) Supplementary Tables (BLS 2021) or the BLS Occupational Employment Statistics (OES) Estimates (BLS 2020). In the BLS reports, wages are represented by the "wages and salaries" cost component and fringe benefits are represented by "total benefits." Overhead costs are assumed to equal 20% of the sum of wages plus fringe benefits. This loading factor, as described in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (EPA 2020), is reflective of multiplier values used in prior EPA RIAs and ICRs that are based on industry- and occupation-specific overhead rates affected by EPA regulations and is

consistently applied with Office of Pollution Prevention and Toxics economics practices. This overhead loading factor is multiplied by the total compensation (i.e., wages plus fringe benefits). For example, the fully loaded wage for professional/technical labor is ($44.63 + $22.45) * 1.2 = $80.50. Fully loaded costs for additional labor categories are calculated in a similar manner. The calculated overhead costs are shown in Table 1 with the total hourly loaded wages.

Table 1. Manufacturing and Legal Services Industry Wage Rates (2020$)

Labor Category	Data Series [a]	Date	Wage	Fringe Benefit	Total Compensation	Overhead % of Total Compensation [b]	Overhead	Hourly Loaded Wages [c]
			(a)	*(b)*	*(c) = (a)+(b)*	*(d)*	*(e)=(c)*(d)*	*(f)=(c)+(e)*
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-20	$54.32	$24.46	$78.78	20%	$15.76	$94.54
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-20	$44.63	$22.45	$67.08	20%	$13.42	$80.50
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-20	$20.86	$9.62	$30.48	20%	$6.10	$36.58
Attorney	BLS OES "Legal Services - Lawyers," BLS ECEC, "Professional and Business Services [d]	May-20	$60.89	$17.96	$78.85	20%	$15.77	$94.62

Footnotes

[a] Source: Employer Costs for Employee Compensation (ECEC) Supplementary Tables: December 2006 – December 2020 (U.S. Bureau of Labor Statistics, 2021).

[b] 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 2020)

[c] Wage data are rounded to the closest cent in this analysis.

[d] BLS Occupational Employment Statistics (OES) May 2020 National Industry-Specific Occupational Employment and Wage Estimates (BLS, 2020)

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

PAIR requires manufacturers (includes importers) of the listed chemical substances, mixtures or categories to report to EPA information such as the substances' chemical

identification, quantity produced or imported, chemical processes, employee exposure, environmental releases, uses and products. Respondents are only required to report *information that is known or reasonably ascertainable by them;* extensive file searches are not required. The PAIR reporting requirements are included in the PAIR form (EPA Form 7710-35) and instructions (see Attachment 11).

In addition, each person who is manufacturing or processing a chemical listed in 40 CFR 766.25, must submit a protocol for testing according to the schedule at 40 CFR 766.35(a)(2). Persons who manufacture or import a chemical substance listed under 40 CFR 766.25 must report positive test results, using the Dioxin/Furan Report Form (EPA Form 7710-51; see Attachment 5), of all existing test data that show that chemical substance has been tested for the presence of halogenated dibenzodioxins/halogenated dibenzofurans (HDDs/HDFs), as well as any health and safety studies for the chemical substance, as defined in the regulation. Additionally, any manufacturer or importer of a chemical substance listed in 40 CFR 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA.

A representative respondent would engage in the following activities:

- Conduct an initial review of the rule to determine if their company must report;
- Familiarize themselves with the PAIR and subpart B of 40 CFR 766 requirements;
- Complete the PAIR and subpart B of 40 CFR 766 reporting via the Agency's Central Data Exchange (CDX);
- Provide trade name notification;
- Indicate CBI status if so desired; and
- Keep a copy for recordkeeping requirements.

The PAIR (40 CFR part 712) and subpart B of 40 CFR 766 generally requires one-time reporting and establishes the reporting period for the listed chemical substances, mixtures or categories. Therefore, a reporting schedule is not required.

This section presents the Agency's estimates of the burden associated with the reporting and recordkeeping requirements under the TSCA section 8(a) PAIR and subpart B of 40 CFR 766. The total annual industry burden for both reporting and recordkeeping is estimated to be 33.0 hours. These estimates are based on the level of PAIR and subpart B of 40 CFR 766 reporting activity expected during the ICR period of FY 2019 through 2021. In conducting any study that will be submitted to EPA under TSCA, the respondent must comply with the Good Laboratory Practice Standards (GLPS)at 40 CFR part 792 (see Attachment 12). Since the GLPS represent basic

standard practices used by laboratories, any burden and costs related to the GLPS are fully captured in the cost and burden estimates provided below.

The methodology used to develop these cost estimates follows principles that have been used in previous ICRs. The methodology and calculations used in this analysis assume the employee responsible for filling out the form has a reasonable level of familiarity with the company and knowledge of the operation at the site. The analysis deals with the marginal costs of complying with this specific request and not the total costs to the company of initial employee training and costs associated with collecting and storing records or of file maintenance that enable a company to comply with a range of other federal and state environmental, health and safety regulations or accounting requirements that rely on this type of information. Based on conversations with respondents, gathering information for an 8(a) PAIR request is similar to other efforts they perform which require familiarity with EPA, state and other federal agency requests for chemical information and does not involve additional familiarization or training to comply with information requested under this ICR.

Number of Sites and Reports per Site

The burden hour estimates in this analysis are based on an estimate of the level of PAIR and subpart B of 40 CFR 766 reporting activity during the next three-year ICR approval period (FY 2022 to FY 2025). This, in turn, is related to the number of expected PAIR and subpart B of 40 CFR 766 chemical reports and reporting sites. During fiscal years 2012 to 2022, EPA received 0 PAIR submissions. Some PAIR reports submitted during a given fiscal year may be for chemicals added to the PAIR during previous years. EPA received less than five submissions over the course of the last OMB approval for subpart B of 40 CFR 766. For the purposes of this analysis, EPA assumes an annual average of 1 site (respondent) submitting 1 report (form), for an average of 1 report per respondent. This is a realistic estimate as EPA, at this time, does not plan to issue a PAIR rule in this renewal cycle because EPA will most likely use other rulemakings such as the Chemical Data Reporting (CDR) rule to collect similar data however, the following describes respondents' burden if such an event were to occur.

To estimate the burden and costs to industry respondents, several reporting activities (or burden factors) are analyzed. These burden items include: form familiarization; report preparation; trade name notification; CBI substantiation; recordkeeping; CDX registration; and report submission. Each of these activities requires the skills of various labor categories. The section below details each separate activity and presents the estimated labor hours required by each task, by labor category (i.e., clerical, technical and managerial).

All burden estimates are taken from the *Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule, Final Report* (EPA, 1981), previous TSCA Section 8(a) PAIR ICRs updates, and the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012), unless otherwise noted. The 2012 EA estimates the burden associated with electronic PAIR and subpart B of 40 CFR 766 submissions, including the burden associated with CDX registration, the reduction in recordkeeping burden, and the reduction of the clerical burden associated with report submission. This ICR follows the practice of the last ICR update where EPA removed the clerical burden associated with all other PAIR and subpart B of 40 CFR 766 submission activities. This change was made to be consistent with the burden estimates provided for the electronic reporting of TSCA Section 5 Notices in *The Economic Analysis of the Premanufacture Notification Electronic Reporting Rule* (EPA, 2009) and the electronic submission of TSCA 8(b) Chemical Data Reporting (CDR) submissions in the *Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule* (EPA, 2011).

Form Familiarization

In the 1981 PAIR economic analysis[1], it was estimated that form familiarization would require 3 hours of effort from managerial personnel and 4 hours from technical personnel for a total of 7 hours per site. The estimate includes efforts for rule familiarization and to determine if reporting is required. Because EPA only expects one report from one site in the next ICR cycle, both the per-report and per-site burden is estimated to be 7 hours. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

Report Preparation

The 1981 PAIR economic analysis estimated that direct reporting activities would require a total of 16 hours of effort per report. This consists of the burden related to the completion of the PAIR (EPA Form No. 7710-35) or subpart B of 40 CFR 766 form (EPA Form No. 7710-51). As indicated previously, the respondents are not expected to conduct an exhaustive search of their files. Respondents are only required to report what is known or reasonably ascertainable to them (see 40 CFR 712.7). The relative distribution of reporting burden between managerial, technical and clerical personnel was developed for the 1992 PAIR ICR update. For this ICR update, EPA assumes that per-report burden for report preparation is the same as in the prior ICR update. EPA only expects one report from one site in the next ICR cycle, and both the per-report and per-site total burden estimate is 14.75 hours. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

[1] Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule, Final Report, prepared for the EPA by ICF, Inc., Washington, D.C., 1981.

Trade Name Notification

Some companies may report their customers' uses as "unknown" for more than twenty percent of their volume. These companies must list under Item 10 of the PAIR reporting form the market (trade) name(s) under which they distribute the chemical. This reporting is referred to as trade name notification.[2]

All commercial manufacturing, importing and processing sites that distribute any of the chemicals subjected to a PAIR reporting rule under a trade name must take steps to ensure that information about the downstream processors is submitted to EPA. Firms may choose among several options to meet trade name notification requirements, including:

- Submit trade name data to EPA for listing in the Federal Register;
- Notify all customers of the need to report; or
- Complete the reporting requirements for each customer.

This ICR assumes that companies will adopt the least-costly reporting alternative of providing a trade name list to EPA for inclusion in the Federal Register. However, trade name notification is not relevant if processor reporting is not required.

Furthermore, this ICR also assumes that all manufacturers and importers will incur trade name notification costs, but does not address processors due to the lack of data on processor reporting. In the 1994 EPA PAIR ICR,[3] the unit burden of trade name notification was given as 3.2 hours (i.e., 2.2 hours managerial and 1.0 hours clerical), for this analysis the 1.0 hours of clerical burden is removed to adjust for electronic submissions, for a total burden of 2.2 hours per report. Because EPA only expects one report from one site in the next ICR cycle, both the per-report and per-site burden is 2.2 hours. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

CBI Substantiation

A company may make claims of confidentiality for any data element contained in its submission. For each CBI (confidential business information) claim, generic information must be supplied for a non-CBI copy of the submission (i.e., a sanitized version must also be submitted). It is assumed that most of the time required for CBI substantiation involves managerial staff discussion of whether or not to make a CBI claim. Furthermore, it is assumed that all firms will review their submissions for CBI content.

[2] 40 CFR 712.28 (July 1, 1993).

[3] Burden Hour and Cost Estimates for PAIR Section 8(a) Reporting (1994 Update), internal U.S. EPA memorandum from Carol Rawie, Economics, Exposure, and Technology Division to Karen Boswell, Chemical Testing and Information Branch, May 16, 1994.

The Lautenberg Act, passed in 2016 reformed TSCA and increased requirements for TSCA CBI substantiation claims. These changes significantly change the CBI substantiation burden from prior ICR updates. The previous ICR assumed that all CBI substantiation burden was a managerial decision. The Lautenberg Act changed TSCA to require a statement that the submitter has (1) taken reasonable measures to protect the confidentiality of the information, (2) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law, (3) has a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and (4) has a reasonable basis to believe that the information is not readily discoverable through reverse engineering.[4] These additional questions make CBI substantiation more a technical than a managerial decision. This update uses the previous ICR update estimates 1.27 hours of managerial time and 4.08 hours of technical time per report for a total of 35 hours per report.

Based on an analysis of CBI claims for reporting to the TSCA Inventory (discussed in the 1986 CAIR economic analysis), only 75 percent of reports are expected to make CBI claims. The burden distributed across all reports is 5.35 hours x 0.75, or 4.01 hours. Because EPA only expects one report from one site in the next ICR cycle, both the per-report and per-site burden is 4.01 hours. See 22Error: Reference source not found for the summary of estimated annual burden hours.

Recordkeeping

Pursuant to TSCA section 8(a), the manufacturer/importer or processors of the chemical substances identified under PAIR must also maintain records of the information submitted to EPA. In addition, since manufacturer/importer or processors that submit data to EPA must comply with the GLPS in 40 CFR 792, this ICR also generally covers the burden associated with maintaining records as required under the GLPS. These records are used for compliance monitoring and enforcement purposes.

EPA estimates that the recordkeeping burden associated with this ICR involves about half an hour of time for both the clerical and the technical labor category, based on the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012). This burden estimate represents the time necessary for the individuals to identify the information, determine the appropriate location for the record to be kept, and placing the record in such a location. The per-report recordkeeping burden is therefore estimated to be 1.00 hour. Because EPA only expects one report from one site in the next ICR cycle, both the per-report and per-site burden is 1.00 hour. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

[4] TSCA, Sec. 14(c)(1)(B), (C)

CDX Registration, Electronic Signature, and Rule Familiarization

As part of EPA's electronic reporting requirements, submitters of PAIR and subpart B of 40 CFR 766 reports are required to register and submit information electronically with EPA's CDX system. EPA estimates that companies registering with CDX for the first time would incur a one-time burden to complete CDX registration activities, obtain a CDX electronic signature, and familiarize themselves with electronic reporting requirements. The total burden associated with CDX registration is available at www.cdx.epa.gov, which is informed by the CROMERR cost benefit analysis (EPA 2021) and is estimated to be 3.48 hours per company. This includes 0.91 hours for CDX Registration assuming 1 managerial staff and 4 technical staff, 1.75 hours for completing electronic signature agreements, and 0.82 hours for rule familiarization.

For the purposes of this analysis EPA assumes that the one site submitting PAIR or subpart B of 40 CFR 766 data will register with CDX, for a total per-site burden of 3.48 hours. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

Report Submission

Report submission consists of the preparation, review and electronic submission of a report in accordance with 40 CFR Part 712, Subpart B, as amended by 78 FR 72818 (December 4, 2013), which required electronic submission.

EPA estimates that the per-report submission will require 0.05 hours of clerical time and 0.5 hours of managerial time for a total of 0.55 hours. The clerical burden is taken from the *Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule* (EPA, 2012) and includes time to prepare and submit a report electronically. The managerial time assumes an involvement in the preparation of the transmittal letter and review of the report package before it is submitted to EPA. Because EPA only expects one report from one site in the next ICR cycle, both the per-report and per-site burden of 0.55 hours. See Table 2Error: Reference source not found for the summary of estimated annual burden hours.

Total Industry Burden Estimates

Table 2Error: Reference source not found presents the summary of the annual burden hour estimates for respondents.

Table 2. Estimated Annual Burden Hours (assuming 1 report per site and a total of 1 report per year) for Section 8(a) PAIR

Burden Item	Managerial	Technical	Clerical	Hours Per Report	Total Number of Reports per Site	Hours Per Site	Total Number of Sites	Total Annual Hours
Form Familiarization	3.00	4.00	0.00	7.00	1	7.00	1	7.00
Report Preparation	5.50	9.25	0.00	14.75	1	14.75	1	14.75
Trade Name Notification [1]	2.20	0.00	0.00	2.20	1	2.20	1	2.20
CBI Substantiation [2]	0.95	3.06	0.00	4.01	1	4.01	1	4.01
Recordkeeping	0.00	0.50	0.50	1.00	1	1.00	1	1.00
CDX Registration [3]	0.18	0.73	0.00	N/A	N/A	0.91	1	0.91
CDX Electronic Signature [3]	0.75	1.00	0.00	N/A	N/A	1.75	1	1.75
Rule Familiarization [3]	0.55	0.27	0.00	N/A	N/A	0.82	1	0.82
Report Submission	0.50	0.00	0.05	0.55	1	0.55	1	0.55
Totals	**13.63**	**18.81**	**0.55**	**29.51**	**N/A**	**32.99**	**N/A**	**32.99**

[1] Clerical burden is removed to adjust for electronic submission.
[2] Burden hours per report for each labor category are scaled by 75% to account for number of CBI claims based on past data.
[3] CDX activities include CDX Registration, CDX Electronic Signature and Rule Familiarization are assumed to occur at the site level only.

In summary, an average of one respondent per year would be required to spend an estimated total of 32.99 hours each year to respond to PAIR and subpart B of 40 CFR 766 rules during the period of FY 2021 through FY 2023, resulting in an average burden of 32.99 hours per response.

Estimating Respondent Costs

This section presents estimates of the cost expected to be incurred due to reporting under the TSCA section 8(a) PAIR and subpart B of 40 CFR 766. The total annual industry cost for both reporting and recordkeeping is estimated to be $2,824. This estimate is based on the cost of the burden estimate provided above, and includes other costs associated with this ICR.

Labor costs in 1) are multiplied by the estimated burden hours per activity and added to any non-labor costs to develop total unit costs per report in Table 33Error: Reference source not found.Error: Reference source not found. It is estimated that only the CDX registration task will require expenditures other than labor.

Total non-burden costs per report are estimated to be $2.90 associated with mailing CDX electronic signature forms to EPA. With an annual estimate of 1 report expected, the total annual non-burden cost for this ICR is $2.90. Finally, unit costs per report are multiplied by the number of reports per site per year to arrive at unit costs per site (i.e., respondent costs), and are summarized in Table 3Error: Reference source not found.

Table3. Reporting Costs by Labor Category and Reporting Activity TSCA Section 8(a) PAIR (assuming 1 report per site and a total of 1 report per year)

Cost Element	Managerial $94.54	Technical $80.50	Clerical $36.58	Total Annual Burden Hours	Total Labor Costs	Other Direct Costs	Total Cost Per Report	Total Number of Reports	Total Cost Per Site	Total Number of Sites	Total Annual Industry Cost
Form Familiarization	3.00	4.00	0.00	7.00	$606		$606	1	$606	1	$606
Reporting	5.50	9.25	0.00	14.75	$1,265		$1,265	1	$1,265	1	$1,265
Trade Name Notification	2.20	0.00	0.00	2.20	$208		$208	1	$208	1	$208
CBI Substantiation	0.95	3.06	0.00	4.01	$336		$336	1	$336	1	$336
Recordkeeping	0.00	0.50	0.50	1.00	$59		$59	1	$59	1	$59
CDX Registration	0.18	0.73	0.00	0.91	$76		$76	1	$76	1	$76
CDX Electronic Signature [a]	0.75	1.00	0.00	1.75	$151	$2.90	$154	1	$154	1	$154
Rule Familiarization	0.55	0.27	0.00	0.82	$74		$74	1	$74	1	$74
Report Submission	0.50	0.00	0.05	0.55	$49		$49	1	$49	1	$49
TOTAL	**13.63**	**18.81**	**0.55**	**32.99**	**$2,824**	**$2.90**	**$2,824**	**1**	**$2,827**	**1**	**$2,824**

[a] Other direct costs related are excluded from total annual industry cost

The average respondent is assumed to spend $2,824 per report, or $2,824 in total per respondent per year. As noted earlier, the Agency is estimating an average of 1 reporting sites and 1 report per year. As a result, total industry cost for complying with PAIR and subpart B of 40 CFR 766 rules is estimated to be $2,824 per year during the period of FY 2022 through FY 2025.

Chemical-Specific Rules, TSCA Section 8(a)

Items requested of manufacturers or processors of certain chemicals vary with each collection request, but will not repeat information previously requested through other information gathering tools. Some data items requested under TSCA section 8(a) chemical-specific rules in the past include: notification and description of changes in the end use of identified substances and mixtures, information on planned manufacturing and on-site processing, and notification of changes to the method of manufacturing the substance (see 40 CFR 704 subpart B).

An example of a TSCA section 8(a) chemical-specific rule is one issued on certain nanoscale materials. It requires persons that manufacture (includes import), or processes certain nanoscale materials to report to EPA information on chemical identity; production volume; methods of manufacture and processing; exposure and release information; and environmental and health effects.

Activities a respondent may be required to perform as a result of a TSCA section 8(a) chemical-specific rule are as follows. However, as discussed at the end of this section, not all respondents are likely to be required to perform all tasks under each labor category. Therefore, the ranges of labor hours presented for each labor category (e.g., 9.50 to 29.50 hours for managers) are the maximums and are based on the assumption that all tasks are performed for each notice.

0.75 Hours of Attorney Labor

- Gather and prepare information to substantiate a claim of confidentiality.

9.50 to 29.50 Hours of Managerial Labor

- Identify listed chemicals;
- Assign principal technical contact person;
- Identify by-product; impurities; physical properties;
- Review marketing data;
- Research the date of the initiation of manufacture of the chemical;
- Research occupational exposure, environmental release, health and environmental information, disposal methods; risk management practices; and

- Process, compile, and review information for accuracy, substantiate a claim of confidential business information.

17.5 to 110 Hours of Technical Labor

- Identify chemical and trade name and chemical composition;
- Identify by-product; impurities; physical properties;
- Describe use of chemical;
- Report quantity manufactured or imported;
- Research occupational exposures, environmental releases, health and environmental information, and disposal methods; risk management practices; and
- Provide occupational description.

7 to 21 Hours of Clerical Labor (0.5 - 1.5 Hours for Electronic Reporting)

- Format research on occupational exposures, environmental releases, health and environmental information; risk management practices;
- Format attachments;
- Prepare notice;
- E-Reporting;
- CBI substantiation and
- Recordkeeping.

Recordkeeping

TSCA section 8(a) chemical-specific rules may contain recordkeeping requirements. The recordkeeping estimate is reasonably related to the maximum reporting burden. EPA estimates that recordkeeping will account for approximately four percent of the reporting burden for paper-based submission and less than one percent for electronic submission.

Loaded hourly wage rates are shown in Table and are utilized with the burden estimates contained in Table to derive annual burden and costs.

This ICR maintains the assumption of the previous ICR that, on average, four notices per year are submitted in response to one section 8(a) chemical-specific rule per year. Current labor rates and burden hours used to calculate the cost to respondents are listed below.

The cost to a respondent for filing a TSCA section 8(a) notice depends upon the various tasks performed. These tasks could include gathering the required data, preparing and submitting the TSCA section 8(a) notice, and possibly keeping records. Based on promulgated TSCA section 8(a) rules, EPA estimates that each respondent will submit

one notice per TSCA section 8(a) chemical-specific rule. EPA anticipates an average of one TSCA section 8(a) rule per year and expects to receive an average of four notices per year.

The cost to a respondent for submitting a TSCA section 8(a) notice is a function of the number of hours and the hourly labor costs for the individuals developing and preparing the notice.

Total annual burden hours range from 70 – 314 hours and total annual costs range from $5,311 - $24,268 (Table 4) and each range represents expected maximums. The midpoint for total annual burden hours is 192 hours and for total annual burden costs is $14,791.

Table 4. Total Annual Respondent Burden and Costs Associated with Preparing and Filing a TSCA Section 8(a) Notice

Activity	Managerial		Technical		Clerical		Attorney		Notices per Year	Annual Burden Hours		Annual Costs	
	$94.54 per hour		$80.50 per hour		$36.58 per hour		$94.62 per hour						
	Total burden hours		Total burden hours		Total burden hours		Total burden hours						
	Lower Max	Upper Max	Lower Max	Upper Max	Lower Max	Upper Max	Lower Max	Upper Max		Lower Max	Upper Max	Lower Max	Upper Max
Manufacturer ID and Principal Technical Contact	1	4	0	0	0	0	0	0	4	4	16	$378	$1,513
Chemical and Trade Name	0	0	1	5	0	0	0	0	3	3	15	$241	$1,207
Chemical Composition	0	0	0.5	6	0	0	0	0	4	2	24	$161	$1,932
Byproduct ID	1	1	1	5	0	0	0	0	2	4	12	$350	$994
Use Description	0	0	1	5	0	0	0	0	4	4	20	$322	$1,610
Quantity Manufactured or Imported	0	0	1	5	0	0	0	0	4	4	20	$322	$1,610
Marketing Data	1	2	0	0	0	0	0	0	2	2	4	$189	$378

Date of Initiation of Manufacture or Importation	0.5	0.5	0	0	0	0	0	0	4	2	2	$189	$189
Occupational Exposure	1	4	2	17	1	3	0	0	2	8	48	$584	$3,713
Environmental Release	1	4	1	9	1	3	0	0	2	6	32	$423	$2,425
Occupational Description	0	0	1	11	0	0	0	0	1	1	11	$80	$885
Health and Environmental Data	2	8	8	41	1	3	0	0	1	11	52	$870	$4,166
Disposal Methods	1	2	1	7	0	0	0	0	1	2	9	$175	$753
Attachments	0	0	0	0	2	6	0	0	1	2	6	$73	$219
Preparation of Notice	0	0	0	0	1	3	0	0	4	4	12	$146	$439
Managerial/Legal Review of Submission	1	4	0	0	0	0	0.75	0.75	4	7	19	$662	$1,796
Recordkeeping	0	0	0	0	1	3	0	0	4	4	12	$146	$439
TOTAL	**9.50**	**29.50**	**17.50**	**111.00**	**7.00**	**21.00**	**0.75**	**0.75**	**47**	**70**	**314**	**$5,313**	**$24,268**

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

Required data elements for allegations of adverse effects include records that are responsive to TSCA 8(c) are maintained pursuant to 40 CFR Part 717 and must consist of the following:

- The original health effects allegation as received.
- An abstract of the allegation and other pertinent information as follows:
    - The name and address of the plant site that received the allegation.
    - The date the allegation was received at that site.
    - The implicated substance, mixture, article, company process or operation, or site discharge
    - A description of the alleger (e.g., employee, neighbor), including age and sex, if ascertainable.
    - A description of the health effects, including explanation of how the effects became known and the route of exposure, if explained in the allegation.
- The results of any self-initiated investigation with respect to an allegation. (EPA does not require such investigation under the TSCA section 8(c) rule. Copies of any further required records relating to the allegation (e.g., records required under OSHA).
- Each person who is required to keep records under this part must submit copies of those records to EPA as required by the Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements by notice in the Federal Register.

Respondents must do two things: (1) maintain records of allegations of significant adverse reactions, and (2) submit copies of these allegation records when required by EPA. Entities subject to the rule must record significant reactions alleged to have been caused by substances or mixtures that they manufacture, import, or process. These firms must establish a recordkeeping system for such allegations and monitor incoming complaints to determine if they meet the criteria for filing. Allegations that are filed must be retained for 30 years if they are employee-related and for 5 years for all other types/sources of allegations.

Firms subject to the rule must keep their TSCA section 8(c) records at company headquarters or at a site central to their chemical operations. A multi-site company will usually require the responsible official at the individual plant site to forward potentially recordable TSCA section 8(c) allegations to a designated TSCA coordinator at their operations headquarters. Depending on the size of the company, such allegations will

be reviewed by a committee to determine if the allegations relate to the company's product, operations, or discharges. If so, the effects cited in the allegation are compared against the rule's definition and examples of "significant adverse reaction." If the allegation meets this test, it is recorded. The actual allegation record is to be comprised of an abstract of the allegation along with a record of any company-initiated investigation and other pertinent documents. The rule does not require further investigation. EPA requires that allegations be filed so that they may be readily retrievable by the alleged "cause" of the reaction. EPA does not, however, require a specific form under this rule.

Firms subject to this rule must maintain an awareness of their reporting requirements. A reporting requirement will take the form of a letter directed to selected respondents or it will be a notice in the Federal Register. Respondents are responsible for monitoring the Federal Register for such notices. Whenever feasible, EPA will also notify those companies that can be identified with the production, importation or processing of a substance or mixture in question. Respondents then must determine if they manufacture or process the chemical substance or mixture. If so, they must conduct a search of their TSCA section 8(c) files to determine if there are any relevant records of significant adverse reactions alleged to have been caused by the substance or mixture. If such records are present, they must submit those records to EPA. The company should note that they have submitted such records to EPA so that future duplicative reporting will not occur.

Based on the original TSCA section 8(c) analysis, EPA estimates that a firm's TSCA section 8(c) coordinator will spend 2 to 3 hours to determine the status of an allegation.[5] For the purposes of this analysis, it is assumed that 3 hours are needed. This level of effort will occur for all allegations received. If the allegation is found to be recordable, the coordinator completes a form, has it typed, and checks it for accuracy. This requires 0.5 hours of clerical time and an additional 0.5 hours of managerial time. Assuming that all allegations are recordable, a total of 4 hours are expended per allegation (3.5 hours managerial plus 0.5 hours clerical). Storage costs for the allegations are believed to be negligible. The unit cost per allegation is $349.16.

Based on the original TSCA section 8(c) analysis, EPA estimates that a management level company official will spend one hour reviewing the Federal Register notice or letter from EPA to determine whether the company manufactures (including imports) or processes substances subject to the reporting requirement.

Technical personnel would then spend an estimated two hours conducting a search of the company's TSCA section 8(c) files for any relevant allegation records. Once the file

[5] U.S.EPA. "Economic Analysis of TSCA Section 8(c) Significant Adverse Reaction Recordkeeping Rule, OTS/ETD/RIB." January 1983.

search is complete, EPA estimates that a managerial employee would spend two hours preparing a transmittal letter and other explanatory material to accompany the allegation records. An upper-level management official would spend an additional two hours reviewing these materials. One hour of clerical labor would be required to prepare and mail the response. A total of eight hours is expended per report (five managerial hours, two technical hours and one clerical hour). The unit cost for reporting, per report, is $670.25.

Based on the original TSCA section 8(c) analysis, EPA estimates that 0.25 hour of managerial labor would be required to review each Federal Register notice Table 5. The unit cost for Federal Register notice review is $23.63.

Table 5 summaries the unit burden hours and costs for the activities described.

Table 5. Summary Unit Respondent Burden and Cost Estimates for TSCA Section 8(c) (2021$)

Activity	Managerial $94.54 per hour		Technical $80.50 per hour		Clerical $36.58 per hour		Total	
	Hours	Cost	Hours	Cost	Hours	Cost	Hours	Cost
Recordkeeping, per allegation	3.5	$330.88	0	$0.00	0.5	$18.29	**4**	**$349.17**
Reporting, per report	5	$472.68	2	$160.99	1	$36.58	**8**	**$670.25**
Federal Register notice review, per notice	0.25	$23.63	0	$0.00	0	$0.00	**0.25**	**$23.63**
Unit totals	8.75	$827.19	2	$160.99	1.5	$54.87	**12.25**	**$1,043.05**

The unit burden for recordkeeping is multiplied by the total number of allegations. Total annual recordkeeping burden is 22,108 hours. The unit cost for recordkeeping of $349 is multiplied by the average annual number of allegations per year (5,527) and the total annual recordkeeping cost is $1,929,863 shown in Table 6.

Table 6. Summary of Total Annual Respondent Burden and Cost for TSCA Section 8(c) (2021$)

Activity	Unit Burden Hours	Unit Cost	Applicable # and Unit		# Firms	Burden Hours	Cost
Recordkeeping, per allegation	4	$349	5,527	Allegations per year	N/A	22,108	$1,929,863
Reporting, per report	8	$670	16	Reports per year	N/A	128	$10,724
Federal Register Notice review, per Notice	0.25	$24	10	Notices per year per firm	13,160	3,290	$3,109,708
Total Burden/Cost						**25,526**	**$5,050,295**

Despite the infrequency with which the Agency actually publishes TSCA section 8(c) notices, EPA conservatively assumes that 16 TSCA section 8(c) reports will be submitted annually, in response to the publication of a single, assumed TSCA section 8(c) notice per year.

Historically, the Agency has published an average of only 0.08 notices each year since 1983, as EPA has published only two notices to date. In light of that history, EPA conservatively assumes that it will publish a single, TSCA section 8(c) notice each year.

The total paperwork burden on the regulated community imposed by TSCA section 8(c) is the sum of the three components identified above (recordkeeping, reporting, and Federal Register notice review) and estimated at 25,526 hours annually with an associated annual cost of $5,050,295. These totals, shown in Table 7, is the estimated annual burden and burden costs for each of the three years covered by this ICR. There are no separate or additional costs associated with maintenance and operations (i.e., non-burden costs).

Table 7. Overall Total Industry Burden and Cost for TSCA Section 8(c) (2021$)

Collection Activity	Number of Responses	Total Annual Burden Hours	Total Annual Burden Cost
Recordkeeping	13,160	22,108	$1,929,863
Reporting	16	128	$10,724
Federal Register	13,160	3,290	$3,109,708

Review [1]			
Total/Overall	**26,336**	**25,526**	**$5,050,295**
[1] Compliance Determination			

Table 8 presents the average annual cost and burden per respondent. On average each firm will spend a total of 1.94 hours and $165.16 annually to complete TSCA 8(c) information collection activities.

Table8. Average Annual Cost and Burden per Respondent TSCA Section 8(c)

Activity	Hours/ Respondent	Hours/ Response	Cost/Respondent	Cost/Response
Recordkeeping [a]	1.68	1.68	$146.64	$146.64
Reporting [b]	8.00	8.00	$670.25	$670.25
Federal Register review [c]	0.25	0.25	$23.63	$23.63
Average	1.94	0.97	$165.16	$82,53

Notes:

[a] Calculated as the average cost (or hourly burden) per allegation times the average number of allegations per year.

[b] Calculated as the total industry reporting costs (or total burden) divided by the total number of firms.

[c] Calculated as the total industry review costs (or total burden) divided by the total number of firms.

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

Persons who manufacture (which includes import) chemical substances and mixtures, or propose to do so, and processors of such substances and mixtures (if specifically identified in a particular rule) must submit copies of the unpublished health and safety studies in their possession for the listed substances or mixtures. They must also submit lists of reportable studies that they initiate or, about which they know, for each of the listed substances or listed mixtures.

All submitted studies must be accompanied by a cover letter that contains the following data (40 CFR 716.30):

- Name,
- Job title,
- Address, and
- Telephone numbers of the submitting official.
- Name and address of the manufacturing or processing establishment on whose behalf the submission was made.
- Identify any impurity or additive known to have been present in the substance or listed mixtures as studied, unless so noted in the study.
- Identify that the study is being submitted under Part 716.

Respondents may voluntarily choose to develop and submit robust summaries of the full toxicological study reports in conjunction with the submitted full study reports. The robust summaries should contain technical information to adequately describe the study and results and should be written such that the information provided is sufficient to allow a technically qualified person to evaluate study results. Typically, a robust summary would include a description of the test substance, methods, results, conclusions, data quality description, and references associated with the full study.

List of studies shall include (40 CFR 716.35): (A) ongoing health and safety studies conducted by or initiated by respondents; (B) studies respondents know about but do not have copies of; and (C) studies that have been sent to another federal agency with no claims of confidentiality.

For ongoing health and safety studies conducted by or initiated for the respondent, the list should include the following data:

- Beginning date of the study
- Purpose of the study
- Types of data to be collected
- Anticipated date of completion
- Name and address of the laboratory conducting the study.

For studies known to the respondent but for which they do not possess copies, the list

should include the following data:

- Name and address of a person known to them that possesses a copy of the study.

For studies previously sent to a federal agency with no claims of confidentiality, the list should include the following data:

- Title of the study
- Name and address of the person to whom the study was sent
- Month and year in which the study was submitted.

A representative respondent would engage in the following activities in order to produce the lists of studies and required data:

- Determine whether the firm may be required to report. If so, review the rule in more detail;
- Conduct a corporate review to identify which firm sites must be searched to locate the appropriate health and safety studies;
- Search the files at appropriate sites to locate relevant studies;
- Compile and transcribe lists of studies being submitted, ongoing studies, newly initiated studies, studies known to exist but not known to be in the respondent's possession, and studies previously submitted to other federal agencies without confidentiality claims;
- Photocopy or prepare electronic versions of the studies;
- Voluntarily prepare robust summaries of the studies;
- Review the responses for possible confidential business information and prepare information to substantiate a claim of confidentiality; and
- Submit the studies to EPA electronically, and, after initial study submissions, notify EPA when other studies are initiated; submit studies completed after the reporting period.

The methodology used for estimating the burden and costs to industry resulting from the addition of chemicals to the TSCA section 8(d) rule over the next three years is derived from the previous ICR. EPA has added chemicals to the TSCA section 8(d) list on an episodic basis. As shown in Table 9, chemicals have been added to the list five times since 1996 yielding a historical average of 13 chemicals per year for the years between 1996 and the present. As such, EPA uses a basis of 13 chemical additions per year for the 2022-2025 ICR period.

Table 9. Number of Chemicals Added to the TSCA Section 8(d) Reporting List

Year	1996	1997-2003	2004	2005	2006*	2007	2008**	2009-2017	2018-2021	Average/Year
Number of Chemicals	47	0	15	0	208	0	12	0	50	13

* EPA issued a TSCA section 8(d) rule (71 FR 47130) on August 16, 2006 for 243 HPV chemicals that were not sponsored in the voluntary portion of the HPV Challenge Program. EPA later withdrew 33 of these chemicals in a final rule issued on September 29, 2006 (71 FR 57439). In a subsequent direct final rule issued on April 30, 2007, EPA removed two additional chemicals (72 FR 21119), resulting in a total of 208 chemicals subject to Section 8(d) reporting. (**) The TSCA Interagency Testing Committee added Lead and Lead Compounds to the Priority List as part of its 60th ITC Report. Based on this addition, EPA issued a final rule on January 20, 2008 (73 FR 5190) which added 12 Lead and Lead compounds to 40 CFR 716.120.

Moreover, to characterize the reporting implications per chemical addition associated with Section 8(d) reporting, this analysis uses TSCA Inventory Update Rule data from the 1998, 2002, and 2006 reporting cycles, and Chemical Data Reporting Rule data from the 2012 reporting cycle.[6] Table 10 summarizes the models and bases, as applied to the 2022-2025 ICR renewal.

Table 10. Reporting Implications per Chemical Added TSCA Section 8(d)

Metric	ICR Model Year	Number of firms	Number of chemicals	Number of reports or studies	Reporting basis	Reporting basis unit
Number of firms potentially impacted per chemical	2015-2018 [a]	344	208	N/A	1.7	Firms/ chemicals
	2018-2021 [b]	348	220		1.6	
	2022-2025 [c]	129	50		2.6	
Sites per firm	2015-2018 [a]	N/A	N/A	N/A	1.5	Sites/firms
	2018-2021 [b]				1.5	
	2022-2025 [c]				1.5	

[6] According to 40 CFR 716.5, persons are required to report under a TSCA section 8(d) rule if, during the 10 years preceding the effective date of the rule, they manufactured (including imported) or planned to manufacture (including import) a listed chemical. The CDR data for this analysis is not limited to reporting from chemical manufacturers and petroleum refiners. This scope does not affect the accuracy of the results, given that only firms regulated under TSCA 8(d) submit reports.

Metric	ICR Model Year	Number of firms	Number of chemicals	Number of reports or studies	Reporting basis	Reporting basis unit
Fraction of firms potentially affected who submit reports of studies	2015-2018 [a]	344	208	59	0.17	Firms submitting reports/firms
	2018-2021 [b]	348	220	63	0.18	
	2022-2025 [c]	129	50	63	0.49	
Number of studies per submitting firm	2015-2018 [a]	59	208	527	9	Studies/ firm
	2018-2021 [b]	63	220	542	9	
	2022-2025 [c]	63	50	542	9	
Average length of study, pages	2015-2018 [a]	N/A	N/A	N/A	20	Pages
	2018-2021 [b]					
	2022-2025 [c]					
Percent studies with robust summaries; number of firms affected	2015-2018 [a]	N/A	N/A	10% of total studies; 10% of reports	1	Robust summary/firm
	2018-2021 [b]					
	2022-2025 [c]					
Percent of affected firms submitting second responses	2015-2018 [a]	N/A	N/A	5% affected	5	Percent
	2018-2021 [b]					
	2022-2025 [c]					

Sources:
[a] TSCA IUR data, all manufacturers 1998, 2002, 2006

[b] TSCA IUR/CDR data, all manufacturers 1998, 2002, 2006, 2012

[c] TSCA Section 8(d): Economic Impact Analysis for Adding 50 Chemicals from the 74th ITC Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule

Estimating Respondent Burden

Firms will undertake a number of actions in response to a TSCA section 8(d) listing and the unit burden associated with each of these tasks is discussed in detail below.

Review the Rule: Firms in the relevant industries that may have unpublished health and safety studies will have to determine whether they manufacture (including import) a listed chemical and may thus be required to report. If so, they will have to review the rule in detail to understand its requirements, such as the types of health and safety studies EPA is asking for, the grade or purity of the test material, and the timeframe of the reporting period.

Note that, unless EPA specifies otherwise, the coverage of section 8(d) rules is limited to chemical manufacturers and petroleum refineries. Most firms in these industries will not manufacture a listed chemical, and many will spend a de minimis amount of time making that determination. Those firms that manufacture a listed chemical must review the rule to understand its specific requirements. This is estimated to take an average of 2 hours of managerial time for each firm manufacturing a listed chemical.

Conduct Corporate Review for Site Identification: Firms that manufacture a listed chemical will need to conduct a corporate review to identify which of the firm's sites must be searched for appropriate health and safety studies. This corporate review is estimated to require an average of 3 managerial hours per firm.

Conduct Site File Search: Firms that manufacture a listed chemical must search the files at appropriate sites to look for studies that are responsive to the TSCA section 8(d) rule. It is estimated that the search will take an average of 3 hours of technical time per site. EPA estimates that each firm will have an average of 1.5 sites manufacturing a listed chemical. This yields an average burden of 4.5 technical hours per firm for site file searching (3 hours per site * 1.5 sites per firm).

Provide Study Title Lists: Respondents are required to submit lists containing the titles of any studies being submitted, titles of studies that are initiated or ongoing during the reporting period but that have not yet been completed, titles of any unpublished studies that the respondent knows to exist but does not have in its possession, and titles of studies previously submitted to other federal agencies without confidentiality claims. EPA expects that the major burden of compiling this list was incurred during the file search and would already be available in electronic format; therefore, there is no additional burden associated with this activity.

Prepare Robust Summaries: Respondents may choose to develop and submit robust summaries of the full toxicological study reports. The robust summaries should contain technical information to adequately describe the study and results and should be written in such a way that the information provided is sufficient to allow a technically qualified person to evaluate study results. Typically, a robust summary would include a

description of the test substance, methods, results, conclusions, data quality description, and references associated with the full study. It is estimated that 8 to 16 hours of technical time are needed to develop and review a robust summary, depending on the type of study conducted. This ICR assumes an average of 12 hours of technical time to prepare a robust summary. Because submission of robust summaries is voluntary, EPA does not expect that many companies will undertake this activity. EPA estimates that each firm will submit an average of 9 studies, with 10% of those studies including a robust summary; therefore, EPA expects to receive an average of 0.9 robust summaries per firm submitting studies, which we round up to 1 robust summary per firm submitting studies. The estimated average burden per robust summary is 12 hours of technical time.

Review Responses for CBI: Firms will need to review responses for possible CBI and delete any material that is considered by the firm to be CBI from one copy of the study. A separate copy of the study must be submitted without deletions of CBI. CBI review is estimated to take an average of 1 hour of managerial time for each study. Since each of the 34 firms is submitting an average of 9 studies, CBI review results in an estimated average of 9 hours of managerial time per firm.

CBI Legal Review and Confidential Business Substantiation: Firms will need to gather and prepare information to substantiate a claim for confidentiality. This will also involve approximately 1.5 hours of managerial and attorney time, split evenly between staff.

Post-Reporting Period Submission (Submit Ongoing or Newly Initiated Studies): Firms that have an ongoing or newly initiated study during the reporting period are required to provide EPA with a copy of the study once it is completed. CBI review and submission of ongoing or newly initiated studies are estimated to require an average of 1 hour of managerial time.

Table 11. Unit Burden for TSCA Section 8(d) Reporting

Collection Activity	Affected Respondents (Weight)*	Average Burden per Firm (Hours)	Labor Category
Review of Rule	1	2	Managerial
Site Identification	1	3	Managerial
Site File Search**	1	4.5	Technical
Robust Summaries	0.008	12	Technical
CBI Review	0.168	9	Managerial
CBI Legal Review and CBI	0.168	0.75	Managerial

Substantiation	0.168	0.75	Attorney
Post-Reporting Period Submission	0.008	1	Managerial
*Not all respondents perform all activities. This weight reflects that for every firm that has to check for reports: 18% will submit reports, of which 1 firm (about 10%) will provide robust summaries and 5% (about 1 firm) will provide a second response.			
** Basis of 1.5 sites per firm			

These unit burden estimates are average values. Large multi-divisional, multi-departmental firms may require more than the average time to comply. However, there are smaller firms that are less complicated, and these firms may have a simpler process that requires less time.

Estimating the Respondent Universe

EPA has added a total of 332 chemicals to the list since 1996 (47 in 1996, 15 in 2004, 208 in 2006, 12 in 2008, and 50 between 2018 and 2021), which is an overall program historical average of approximately 13 chemicals per year. For estimates in this ICR, EPA assumes that the historical average of 13 chemicals per fiscal year will be added to the section 8(d) list. Assuming that each chemical that is added to the list impacts 2.6 firms, then EPA expects 34 chemical manufacturing firms to be affected per year by this ICR.

Based on the reporting bases stated on Table , EPA assumes that 18% percent of the potentially affected manufacturers will submit studies each year, yielding 6 firms submitting studies (0.18 * 34 manufacturers) and they will also conduct CBI review. Each submitting firm is expected to submit a total of 9 studies, yielding an estimated total of 54 studies annually (6 firms * 9 studies per firm). A total of 10% of the studies are expected to contain robust summaries, yielding a total of 1 robust summary per firm (9 studies * 0.10, and rounding up to 1); and approximately 1 firm (5% of 4 firms) is estimated to submit a second response (for a newly initiated or ongoing study) after the reporting period ends.

The number of firms estimated to engage in the various reporting activities is summarized in12. Note that not all respondents incur every aspect of reporting burden.

Table 12. Number of Firms Affected per Year, by Activity (13 Chemicals Added Per Year) TSCA Section 8(d)

Collection Activity	No. of Firms
Review of Rule	34
Site Identification	34
Site File Search	34
Robust Summaries	6
CBI Review	6
Post-Reporting Period Submission	1

The number of firms or studies described above is combined with the estimated average unit burden hours and wages Table and Table 1, respectively, to estimate the total burden hours and cost per year based on three types of response activities: searching files, submitting studies during the reporting period, and submitting studies after the reporting period.

Table 13. Annual Respondent Burden Hour and Cost Estimates TSCA Section 8(d) (2021$)

Information Collections	Response Activities	Burden per Response (Hours)	Labor Category	Cost per Response	Number of Responses	Total Burden (Hours)	Total Cost
Compliance determination and data search	Rule review	2	Managerial $94.54	$835	34	323	$28,390
	Site Identification	3	Managerial $94.54				
	Site File Search	4.5	Technical $80.50				
Submission of health and safety studies during the reporting period and CBI Substantiation	Robust summaries	12	Technical $80.50	$1,959	6	135	$11,754
	CBI Review	9	Managerial $94.54				
	CBI Legal Review and CBI Substantiation	0.75	Managerial $94.54				
		0.75	Attorney $94.62				

Information Collections	Response Activities	Burden per Response (Hours)	Labor Category	Cost per Response	Number of Responses	Total Burden (Hours)	Total Cost
Notification and submission of health and safety studies initiated and/or completed after the reporting period	Post-reporting period submission	1	Managerial $94.54	$95	1	1	$95
Subtotal					**41**	**459**	**$40,239**
CDX Registration & E-signature		0.93	Managerial $94.54	$228	6	16	$1,368
		1.73	Technical $80.50				
Electronic signature agreements		N/A	N/A	$3.05			$18.30
Subtotal					**6**	**16**	**$1,386**
Total					**41**	**478**	**$41,607**

A typical firm submitting a response is conservatively estimated to engage in review of the rule, site identification, site file search, preparing study title lists, CBI review, CBI substantiation, and possibly submit a robust summary and/or a post-reporting period submission. Assuming 13 chemicals per year are added to the TSCA section 8(d), including the added CBI substantiation, the average annual burden and cost per response is 11 hours and $981, respectively (using the subtotal values in Table 13).

CDX Registration Activities to Enable Electronic Reporting

EPA estimates that respondents will incur a small amount of cost in carrying out the additional paperwork activities that were imposed by the *Electronic Reporting under the Substances Control Act (TSCA) Final Rule*. This includes the burden associated with activities that facilitate submission of an electronic report: CDX registration and CDX electronic signature. These activities occur only once for each submitter. Some submitters may already have registered to use the e-TSCA web reporting tool in CDX (and obtained an accompanying electronic signature) in order 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 in order to file their health and safety studies. While there may be some overlap in the specific individuals that have already completed CDX activities, EPA is using a conservative assumption that all submitters who will file electronically will need to register with CDX and, thus, incur associated burdens. This assumption may overestimate the burdens and costs actually experienced by respondents.

The *one-time* CDX burden includes the following:

- *CDX Registration* – Based on www.cdx.epa.gov, which is based on the CROMERR Cost Benefit Analysis, EPA assumed that companies would spend 11 minutes per employee to register with CDX. Furthermore, EPA assumed that an average of four technical staff members and one manager would need to register for each company, resulting in 55 minutes of burden per firm.
- *CDX electronic signature (labor burden)* – Based on www.cdx.epa.gov, which is based the CROMERR Cost Benefit Analysis, EPA assumed that firms would spend 15 minutes preparing, submitting, and filing an electronic signature agreement (i.e., authentication of Identity) form to EPA per employee. One manager and four technical staff members per firm would incur this burden, totaling 75 minutes of burden per company. In addition, EPA estimates that a manager would spend an additional 30 minutes accessing, preparing, and submitting verification forms (Verification of Authorization) for all authorized submitters to EPA. The total burden incurred by firms submitting and then verifying electronic signature agreements would be 105 minutes. It should be noted that the burden associated with CDX Electronic Signatures does not include costs associated with contacting EPA's CDX help desk to notify a change of submitter status, should one occur.
- Non-labor costs include a $0.58- stamp (2021$) and a $0.03 standard business envelope for each of five required electronic signature agreements. The total non-labor cost for electronic signature agreements equals $3.05. This amounts to $18.30 in non-labor costs per year. Note, this non-labor cost is excluded from both the subtotal and total cost estimate in Table 13.
- Conservatively assuming all 6 firms submitting studies will need to register with CDX, the average burden and cost per CDX registration is 2.67 hours and $231, respectively using the values related to CDX registration activities contained in Table .

Total estimated burden hours are 475 hours and total estimated costs are $41,607.

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

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 or maintenance costs associated with this collection.

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.

Table 14 provides annual agency wage rates for multiple GS and step levels for agency federal staff in the Washington-Baltimore-Northern Virginia-West Virginia locality pay region.

Table 14. Agency Wage Rates (2021$)

Labor Category	Data Source for Wage Information (Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area)	Wage ($/hour)	Fringes as % wage[b]	Fringe Benefit	Total Compensation	Overhead as % total compensation[c]	Overhead	Loaded Wage ($/hr)
		(a)	(b)	(c) = (a)*(b)	(d) = (a)+(c)	(e)	(f) = (d)*(e)	(g) = (d)+(f)
EPA staff	**GS-12 Step 1** pay rates [a]	$41.78	63.90%	$26.70	$68.48	20%	$13.70	$82.18
	GS-13 Step 1 pay rates [a]	$49.68	63.90%	$31.75	$81.43	20%	$16.29	$97.72
	GS-13 Step 5 pay rates [a]	$56.31	63.90%	$35.98	$92.29	20%	$18.46	$110.75
	GS-15 Step 1 pay rates [a]	$69.06	63.90%	$44.13	$113.19	20%	$22.64	$135.83

Footnotes:

a Source: U.S. Office of Personnel Management. (2021). Salary Table 2021-DCB. Retrieved February 1, 2022 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB_h.aspx.

b Source: Falk, J. 2012. "Comparing Benefits and Total Compensation in the Federal Government and the Private Sector." Congressional Budget Office Working Paper Series. https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/workingpaper/2012-04fedbenefitswp0.pdf

[c] 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 2020).

TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)

Although, it will be unlikely that the EPA will issue a PAIR rule in this renewal cycle because EPA will most likely use other rulemakings such as the Chemical Data Reporting (CDR) rule to collect similar data, the following describes the EPA's burden if such an event were to occur. The activities routinely conducted by EPA related to the rule development, processing, analysis and storage of the information collected under a PAIR rule (40 CFR part 712) and subpart B of 40 CFR 766 are as follows:

- Chemical nomination, review and selection;
- Rule development;
- Evaluation of the rule (including impact assessments);
- Industry/public assistance;
- Compliance monitoring; and

- Processing of data received for listed chemicals (includes receipt, dissemination, evaluation, etc.).

This analysis assumes that an annual average of 1 report will be submitted over the three-year period of the ICR. Personnel burden and costs associated with industry/public assistance and data processing activities have been adjusted based on that estimate. From the 1989 PAIR ICR update it has been derived that industry/public assistance required approximately 1.5 hours per report or 0.0007 FTE. Similarly, the 1989 PAIR ICR update estimated that about 3.75 hours, or 0.002 FTE, of data processing/system support personnel time would be required per report.

Data processing costs have been updated from 2017 to average 2021 dollars using the GDP implicit price deflator from the Bureau of Economic Analysis (BEA). The BEA GDP price index series with a base of 2012 = 100 has the 2017 index at 107.742 and the 2021 index at 118.477 so the adjustment factor from 2017 to 2021 is 1.0996 (118.477/107.742 = 1.0996). Data processing costs for the 2017 PAIR ICR update were estimated to be approximately $295.01 per report. Adjusting this number to 2021 with the GDP implicit price deflator yields an adjusted data processing cost of $324.39 per report (i.e., $295.01 x 1.0996 = $324.39).).

Table 15 summarizes the government's activities in developing and administrating the PAIR and subpart B of 40 CFR 766. The required FTEs per activity are retained from the 1996 PAIR ICR update and from the previous 8(a) PAIR ICR renewal analyses, for all activities except for the recalculation of the burden associated with industry/public assistance and data processing/system support personnel time. Costs are calculated assuming agency staff at GS 12 Step 1 would perform these activities and the loaded wage rate is in .

Table 15. Agency Burden Summary for TSCA Section 8(a) PAIR (2021$)

Activity	Annual Burden	Annual Cost
Chemical nomination, review, and selection	0.25	$222,669
Rule development	0.90	
Evaluation of rule	0.05	
Industry/public assistance	0.0007	
Compliance monitoring	0.10	

Data processing and system support personnel	0.002	
Government data processing cost	N/A	$324
Total	**1.3**	**$222,994**

Table 16 presents a summary of the costs to the federal government for TSCA Section 8(a) PAIR information collection. The full-time work year is considered 2,080 hours, and there are 2,710 annual burden hours associated with a 1.3 FTE.

Table 16. Government Estimated Annual Burden and Cost Summary for TSCA Section 8(a) PAIR (2021$)

Total FTEs	1.3
Annual burden hours	2,710
Loaded cost per FTE	$170,929
Government labor cost	$222,669
Government data processing cost	$324
Total annual government cost	**$222,993**

Chemical Specific Rule; TSCA Section 8(a)

For any TSCA section 8(a) chemical-specific rule the Agency would have to perform a number of tasks. They are:

- Industry/Public Assistance (answering questions regarding rule);
- Data Processing and System Support Personnel;
- Review the information submitted;
- Analyze submissions for confidentiality and provide appropriate protection for confidential data;
- Storage and Distribution; and
- Compliance Monitoring.

The Agency has developed the following burden hour estimates for activities related to promulgating a section 8(a) Chemical Specific rule.

Table17. Agency Summary of Burden Hours and Cost Estimates for TSCA Section 8(a) Chemical Specific

Activity	Burden (FTE)	Burden Hours	Annual Cost

Industry/Public Assistance *(answering questions regarding the rule)*	0.1	208	$17,093
Data processing and systems support personnel	0.2	416	$34,186
Storage and distribution	0.1	208	$17,093
Compliance monitoring	0.1	208	$17,093
Total	**0.5**	**1,040**	**$85,465**

The OPPT bases its burden hour and labor cost estimates on prior experience in gathering and processing information associated with other information collections. Because these activities involve a team approach, the Agency has used a composite burden hour estimate containing workers at various GS levels and calculated hourly costs based upon the wage rate for a GS-12 Step 1 employee (Table 17). The full-time work year is considered 2,080 hours, so there are 1,040 burden hours associated with 0.5 FTE at a cost of $85,465.

Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment

The information collected by employers under 8(c) on employee health effects will involve the following activities:

- Monitoring recordkeeping by employer.
- Initiating requests that employer report employee health effects.
- Reviewing responses of employer to EPA's requests.
- Logging in submissions and reviewing them for confidentiality considerations.
- Making copies of submissions available to offices within OPPT that are assessing the substances of concern.
- Placing non-confidential versions of the submissions in a public docket and making them available for review by other government agencies and the public.

The total annual cost to EPA for TSCA section 8(c) for each of the three years covered by this ICR is estimated to be $90,208. This figure is based on activities identified in the 1986 and 1989 ICRs. Costs are estimated based on wages for GS-15 Step 1, GS-13 Step 1, and GS-12 Step 1 employees shown in .

Annual costs to EPA associated with the recordkeeping portion of the rule include general administration of the rule, education and outreach activities, and compliance monitoring. Costs associated with reporting involve preparation of reporting notices, Federal Register printing costs, document control, and document review. Annual costs to EPA are derived based on an analysis of the cost of performing these various activities. The various factors that contribute to EPA costs include:

- Each year, general administration of the rule involves approximately one-tenth of a staff specialist's time plus approximately one week's time each for two management personnel at the branch, division and OPPT Office Director's level.
- Education and outreach activities will include ongoing rule support.
- Compliance monitoring costs primarily involve the costs of the TSCA section 8(c) portion of inspection carried out by regional personnel and other administrative costs for headquarters personnel to target and review results of such inspections.
- To date, a total of only 31 reports have been received. Based on historical data, over the life of the rule an average of only 0.08 notices have been issued per year and an average of only 1.3 reports received. EPA expects that reporting activity under TSCA section 8(c) will remain at low levels during the period covered by this ICR renewal. EPA costs associated with reporting have been adjusted to reflect this large decrease in the level of expected activity. Labor involved in developing the reporting notices will require decision meetings and either the development of letters, separate Federal Register notices, or the insertion of boilerplate segments in other rule preambles.
- Time will be required to process submissions based upon reporting requirements and to review them for confidentiality considerations.
- The Federal Register notices will be reviewed by the office directly requesting the information as well as by OPPT.

Table 18 presents a summary of Agency annual burden and costs with burden totaling as 1,258 hours with an annual cost of $110,903.

Table 18. Agency Annual Burden and Cost Estimates for TSCA Section 8(c)

Activity	GS-Level	Burden Hours	Annual Cost
Administrative maintenance	GS-13 Step 1	208	$20,325
	GS-15 Step 1	80	$10,866

Subtotal		288	$31,191
Education/Outreach	GS-12 Step 1	240	$19,723
Compliance monitoring	GS-12 Step 1	400	$32,871
Develop reporting notices	GS-12 Step 1	160	$13,148
Document control functions	GS-12 Step 1	10	$822
Notice review, referral, and data entry	GS-12 Step 1	160	$13,148
Total		**1,258**	**$110,903**

Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

The activities routinely conducted by EPA related to the rule development, processing, analysis and storage of the information collected under this rule include the following:

- Review and select chemicals;
- Develop and issue an amendment to the TSCA section 8(d) rule to add the substances or mixtures;
- Answer respondents' questions;
- Process and analyze rule submissions;
- Maintain and distribute the data; and
- Analyze submissions for confidentiality and analyze the information provided to substantiate the confidentiality claim.

The activities routinely conducted by EPA related to processing and storage of the information collected under this rule include processing and analyzing the materials submitted under the rule, including requests for confidentiality; and maintaining and distributing data.

The activities associated with Agency responses to TSCA Section 8(d) listings are assumed to be accomplished by a GS 13 Step 5 federal employee, and the 2021 loaded hourly wage rate for this GS and step level is shown in .

The estimated annual cost to the federal government for TSCA section 8(d) data collection totals $6,473 for 58.45 hours, as presented in Table 19.

Table19. Agency Annual Burden and Cost Estimates for TSCA section 8(d)

Collection Activity	FTEs	Hours	Annual Cost
Data processing and system support	0.025	41.75	$4,624
Storage and distribution	0.010	16.70	$1,850
Total	**0.035**	**58.45**	**$6,474**

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

This information collection combines the burdens from four previously approved ICRs. The total burden hours requested for this ICR is 26,226 and the total estimated cost is $5,109,515. There was an increase in the estimated number of responses for Section 8(d) Health and Safety Studies and Chemical Specific Section 8(a) because of the reinstatement of this ICR, and increased number of potential Section 8(d) submissions. The increase for these two information collections is 50 responses, 7 for Section 8(d) Health and Safety Studies and 43 Chemical Specific Section 8(a) respectively, from the two previously approved ICRs. The total combined cost burden from the Section 8(d) Health and Safety Studies and the Chemical Specific Section 8(a) currently approved ICRs is $23,501 ($23,501 + $0), respectively, and the total cost burden requested for these information collections is ICR is $56,397 ($41,607 + $14,790).

Once this ICR is approved, it will replace the existing ICRs, resulting in an increase in the estimated total cost burden of $297,119 [$5,109,515 – $4,812,396]. The difference between the current cost burden request and the previously approved requests are due to the consolidation and reinstatement of the individual ICRs when calculating the burden, as well as adjustments in EPA's estimates of the number of respondents and of the burden. In addition to the adjustments listed above, the wage rates and material costs were revised to reflect 2021 dollars for this information collection request.

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.

Not applicable.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

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

SUPPLEMENTAL INFORMATION

PRA Burden Statement for Collection Instruments

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-NEW; EPA ICR No. 2701.01). Responses to this collection of information are mandatory for certain persons, as specified at 15 U.S.C. 2607. 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 **50 hours per** initial Section 8(a) PAIR submission; **68 hours** for Chemical Specific Section 8(a) Rules, **11 hours** for Health and Safety Section 8(d); and .**97 hours** for Section 8(c). 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.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPPT-2021-0728, which is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via http://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

All comments received by EPA will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

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-2021-0768.

Ref.	Title
1.	15 U.S.C. 2607
2	8(a) Preliminary Assessment Information Rule (PAIR) 40 CFR 712
3	8(a) PAIR and Dibenzo-para-dioxins/dibenzofurans, 40 CFR 766
4	Dioxin/Furan Report Form EPA Form 7710-51 and instructions
5	15 U.S.C. 2625
6	Chemical Specific Rules, 40 CFR 704
7	Allegations of Adverse Effects, 40 CFR 717
8	Health and Safety Data Reporting, 40 CFR 716
9	CDX User Guide 8(d) Health and Safety Data
10	CDX Section 8(a) PAIR User Guide
11	Manufacturer's Report Preliminary Assessment Information Form (EPA Form 7710-35) and instructions
12	Good Laboratory Practice Standards – 40 CFR 792
13.	Consultation
14.	Wage Rates

LIST OF REFERENCES

Economic Impact and Small Business Definition Analysis for the Final TSCA Section 8(a) Preliminary Assessment Information Rule, Final Report (EPA, 1981), previous TSCA Section 8(a) PAIR ICRs updates

Economic Analysis for the Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule (EPA, 2012)

The Economic Analysis of the Premanufacture Notification Electronic Reporting Rule (EPA, 2009) and the electronic submission of TSCA 8(b) Chemical Data Reporting (CDR) submissions in the

Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule (EPA, 2011).

U.S. Bureau of Labor Statistics. 2021. Employer Costs for Employee Compensation (ECEC) Supplementary Tables: December 2006 – December 2020.

U.S. Bureau of Labor Statistics. 2020. Occupational Employment Statistics (OES) May 2020 National Industry-Specific Occupational Employment and Wage Estimates.

US EPA. 2020. Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other EPA Actions. Accessed on January 25, 2022. https://www.epa.gov/sites/default/files/2020-12/documents/epa_handbook_on_valuing_changes_in_time_use_121520_final_508.pdf

US EPA. 2021. Supporting Statement for EPA Information Collection Request Number 2002.08 “Cross-media Electronic Reporting Rule”.