

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

EPA ICR No.: 1031.12

OMB Control No.: 2070-0017

Docket ID No.: EPA-HQ-OPPT-2015-0688

Abstract

Section 8(c) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(c), requires that “any person who manufactures (including imports), processes, or distributes 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.

EPA promulgated 40 CFR 717, “Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment; Subpart A -- Recordkeeping and Reporting,” on August 22, 1983 (48 FR 38178). This rule became effective on November 21, 1983. The rule requires manufacturers (including importers) and processors of chemical substances and mixtures to keep records of “significant adverse reactions” alleged to have been caused by such substances or mixtures. 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.

Summary Total Burden and Costs

	ANNUAL BURDEN HOURS	ANNUAL COSTS
RESPONDENTS	25,527	\$4,788,895
AGENCY	1,258	\$90,208

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.

The recordkeeping and reporting activities associated with this collection of information are required by statute (Attachment 1). 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 2). 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.

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

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.

The recordkeeping and reporting activities associated with this collection of information are required by statute. 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.

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

EPA has not identified a more efficient, less expensive or more flexible means of obtaining the required data. At present there is no new technology applicable to the collection of this information that would minimize the collection burden.

Any reporting requirements will have a minimum reporting schedule of forty-five days as outlined in the regulation. Neither the rule nor EPA requires the use of any particular methodology or technology for the retention or transmittal of TSCA section 8(c) records.

To aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA section 8(c) reporting as well as other regulatory information. When Hotline staff members are unable to answer questions regarding TSCA section 8(c), the questions are referred to OPPT/CCD staff for appropriate resolution.

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.

Information recorded and reported on alleged adverse effects on health or the environment is specific for compliance with the TSCA section 8(c) rule. Records required to be maintained under this rule include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source.

Allegation means a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment. TSCA section 8(c) requires that allegations of adverse reactions to the health of employees be kept for 30 years, and all other relevant allegations be kept for 5 years.

No other EPA programs or other agencies/departments that require this specific set of information on alleged adverse effects to be recorded and maintained for this retention period nor does any other government program have direct authority to access such information. If any records or reports relating to the allegation are required by another agency, then copies of those records or reports must be maintained in the TSCA section 8(c) allegation record. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Administration (OSHA) Form 301, or equivalent form, which must be maintained by the firm for only 5 years (see 29 CFR part 1904 for recording and reporting

requirements for occupational injuries and illnesses under the Occupational Safety and Health Act of 1970), then a copy of that OSHA record must be included in the allegation record.

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

Unlike TSCA section 8(a), 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.

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.

4. 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.

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.

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.

On March 29, 2021, the Agency published a Federal Register notice requesting comment on the information collection under TSCA section 8(c) (86 FR16347). Additionally, EPA submitted questions to several interested entities via e-mail (Attachment 3). The entities contacted were:

- American Chemistry Council

- SOCMA
- DuPont USA
- American Petroleum Institute
- Vermont Law School
- Asthma & Allergy Foundation of America
- Lewis & Clark College
- Environmental Working Group
- Natural Resources Defense Council

EPA received one response to its solicitation for consultations and two comments in response to the Federal Register notice on this information collection. One of the comments received in response to the Federal Notice was not related to this information collection request. The other comment—from the Earthjustice, Environmental Defense Fund, Environmental Working Group and Natural Resources Defense Council—was identical to the one response EPA received to its consultation solicitation.

This sole comment requests that EPA make greater use of its Section 8(c) data collection authority, and to issue requests for 8(c) reports covering all chemicals currently undergoing TSCA risk evaluations and all chemicals for which EPA is developing risk management rules. In addition, the comment requests that EPA issue requests for all chemicals that are identified as candidates or proposed for a “high priority” designation in the future and PFAS chemicals.

EPA appreciates the feedback on the TSCA 8(c) statutory authority. EPA is considering increased use of the 8(c) authority as part of its overall effort to make greater use of its data collection authorities under TSCA and has updated the supporting statement for this ICR to reflect such increased use.

A copy of EPA’s consultation with the above potential respondents is available as Attachment 3 and is available in the docket.

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.

Respondents may assert a claim of business confidentiality with respect to all or part of an allegation submission. Such submissions will be handled in accordance with the provisions at 40 CFR Part 2.

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.

Not applicable. The information does not include responses to questions of a sensitive nature.

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

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

Respondents affected by this collection activity are mainly NAICS categories 325 and 32411 (*Chemicals and Allied Products Manufacturers* and *Petroleum Refining*, respectively).

Records maintained pursuant to 40 CFR Part 717 must consist of the following:

- a. The original allegation as received.
- b. An abstract of the allegation and other pertinent information as follows:
 1. The name and address of the plant site that received the allegation.
 2. The date the allegation was received at that site.
 3. The implicated substance, mixture, article, company process or operation, or site discharge.
 4. A description of the allegor (e.g., employee, neighbor), including age and sex, if ascertainable.
 5. A description of the health effects, including explanation of how the effects became known and the route of exposure, if explained in the allegation.

- c. 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.)
- d. 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 make a photocopy of those records and mail it with a cover letter to EPA. The company should note that they have submitted such records to EPA so that future duplicative reporting will not occur.

This section presents the estimates of the industry burden hours and costs associated with TSCA section 8(c) activities. The specific action required to comply with a TSCA section 8(c) reporting are assumed to include review of the **Federal Register** for notices regarding specific chemicals, recording pertinent information on allegations and storing such records, and reporting allegations to EPA when required. Table 1 below, contains a cross-walk between the required activities and the related information collections.

Table 1: Cross-Walk between Industry Activities and Related Information Collections (ICs)

Activity	Description	Related IC(s)
Recordkeeping	Manufacturers, importers and processors of chemical substances or mixtures are required to maintain records of significant adverse reactions to health or the environment that are alleged to be caused by the substance or mixture, or alleged to be associated with its manufacture, processing, or distribution. Allegations that must be recorded include any statement of belief made by any person regarding a link between a particular company's product, process or emission and a significant adverse health or environmental effect.	Prepare and maintain records
Reporting	If EPA has requested TSCA 8(c) records via a Federal Register notice or letter, respondents must find and submit the relevant data. They must also need to prepare and submit a transmittal letter and other explanatory material to accompany the allegation records.	Prepare and submit records, a transmittal letter, and other relevant materials to EPA
Federal Register notice review	Manufacturers, importers and processors of chemical substances or mixtures will need to review each Federal Register notice to see if EPA has requested any TSCA 8(c) record	Review Federal Register

The steps required to estimate burden associated with the activities of (1) maintaining records of significant adverse effects, and (2) submitting copies of allegation records when required by EPA, include estimating the number of affected firms and employees, the number of allegations, and number of reports requested by EPA. Unit estimates of burden for the various activities are also required. These unit estimates are then coupled with the number of allegations, reports, and Federal Register notice reviews to develop total burden estimates for the industry reporting community.

Estimates of costs require estimation of wage rates for personnel who are expected to participate in TSCA section 8(c) activities. These, coupled with the burden hours associated with the various tasks, provide the bases for industry cost estimates.

As in the previous TSCA section 8(c) ICR burden analysis, EPA utilizes Census' *County Business Patterns* database to determine numbers of firms/plants and their employment. The analysis entails computing the average number of employees per firm.¹

The first step is to gather information on the number of firms and employees from the Bureau of the Census's *County Business Patterns* for NAICS code 325 (Chemical and Allied Products) and NAICS code 32411 (Petroleum Refining and Related Industries). EPA chose those NAICS codes to define the firms that manufacture (including import) and process chemical substances. The most recent dataset available is from 2019.

The number of employees per firms is calculated using employment figures from *County Business Patterns* for those firms that fall under NAICS 325 or NAICS 32411. Data from *County Business Patterns* show that compared to the previous ICR renewal, the number of and employees decreased, resulting in about a 3% increase in the number of firms, and a 10% increase in the number of employees, and a 7% increase in average number of employees per firm. Current estimates using 2019 Census data are provided in Table 2.

Table 2. Numbers of Firms and Employees for NAICS 325 and 32411, for 2019

Number of Firms*	Total Number of Employees*	Average Number of Employees per Firm
13,557	881,563	65
* Excludes most government employees, railroad employees, and self-employed persons. Source: US Census Bureau. 2013 <i>County Business Patterns</i> . Release Date: April 2015.		

The total number of allegations is based upon the average number of employees per firm and the number of firms, multiplied by a standard annual allegation rate per firm.

The Agency received numerous public comments following the issuance of the initial TSCA section 8(c) proposal, including many comments about the Agency's estimate of the number of allegations. In response to these comments, EPA contacted a number of firms to develop a consensus estimate. According to the 1983 ICR, the consensus opinion of the firms contacted is that recordable TSCA section 8(c) allegations are likely to be made by 0.5 percent of the employees at an average firm. Additionally, and per the 1983 ICR, EPA assumes that the rate of allegations made by the general public would be about one-third the employee allegation rate. Based on the average number of employees per firm, the estimated annual number of allegations

¹ EPA has used this methodology from 2006 forward because the data source is publically available, making the analysis more transparent. In the program's initial ICR burden analysis, EPA used Dun's Market Identifiers (DMI) from a Dun and Bradstreet database (see U.S. EPA, "Comparison of Data Sources for Characterizing Manufacturers and Processors," Draft Report, Prepared by Centaur Associates, Inc under EPA contract No. 68-02-3980, Washington, DC; November 6, 1986).

per firm is presented below in Table 3. The total number of allegations is calculated by multiplying the total number of firms (13,160) by the average annual number of allegations per firm (.44), for a total of 5,527 allegations per year.

Table 3. Estimated Total Number of Allegations per Year for 2016-2020

Firms	Avg. Number of Employees	Average Annual # of Allegations per Firm			Total Allegations
		Employee	Public	Total	
13,557	65	0.33	0.11	0.44	5,965

EPA’s long-term experience shows that only a very limited amount of reporting has been required under TSCA section 8(c). To date, only two reporting notices have been issued under TSCA section 8(c)² and these two notices covered two chemicals and two chemical categories. A total of 31 reports^{3,4} have been received under TSCA section 8(c), an average of approximately 16 reports per notice. This represents an average of only about 1.1 reports per year since the rule was promulgated in 1983.⁵ However, with the reauthorization of TSCA and the new mandates under section 6 pursuant to the Lautenberg Chemical Safety Act (LCSA), EPA sees potential for collecting 8(c) reports to inform prioritization and possibly risk evaluation activities. EPA expects to issue ten notices per year during the three-year ICR collection period, and therefore, in light of past experience, EPA anticipates that it may receive 160 reports annually.

Loaded wage rates for technical, managerial, and clerical personnel are derived using a standard methodology for the TSCA-regulated community. Wage rate data are obtained from the regularly updated Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation Supplementary Tables*.

Wages and fringe benefits for managerial, professional/technical, and clerical labor are taken from the BLS *Employer Costs for Employee Compensation (ECEC)* data for December 2020, for manufacturing industries.⁶ The cost of fringe benefits (paid leave, insurance and other items) specific to each labor category is taken from the same BLS series.

² U.S.EPA. “Chemical on Reporting Rules Database (CORR),” CCD and CSB, June 1990; and U.S.EPA. “Chemical on Reporting Rules Database (CORR): Update,” CCD and CSB; October 31, 1992.

³ U.S.EPA. [Untitled Computer Printout], IMD; June 3, 1992.

⁴ Sherlock, Scott, Information Management Division. Phone conversation with Wendy Hoffman based upon “TSCA Reports to Congress for EPA Fiscal Years 1992-93;” August 1994.

⁵ In comparison to the estimate of over 5800 allegations, it appears that the allegations rate used to estimate total allegations in Table 2 is overstated. However, given potentials for higher counts of allegations, EPA retains the existing methodology, which provides for a large contingency in additional burden. Moreover, the total burden for this information collection is relatively small despite the use of an overstated estimate for total allegations.

⁶ *Employer Costs for Employee Compensation Supplementary Tables: December 2020*, US Bureau of Labor Statistics, March 18, 2021 (page 2) (<https://www.bls.gov/web/ecec/ecsuptc.pdf>, accessed June 1, 2021)

An additional loading factor of 17 percent is applied to wages to account for overhead. This approach is consistent with OPPT practice, as established in economic analyses for two major rulemakings.⁷ See Table 4 below for calculation details.

Table 4: Industry Wage Rates

Labor Type	Wage	Fringes as % Wage	Over-head % wage ^a	Fringe + Overhead Factor ^b	Loaded Wages ^c
	(a)	(b)	(c)	(d)=(b)+(c)+1	(a)×(d)
Professional / Technical	\$44.63	50%	17%	1.67	\$74.53
Managerial	\$54.32	45%	17%	1.62	\$88.00
Office and administrative support	\$20.86	46%	17%	1.63	\$34.00

Footnotes:

^a An overhead rate of 17% is used based on assumptions in Wage Rates for Economic Analysis of the Toxics Release Inventory Program (Rice, 2002), and the Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (U.S. EPA, 2001).

^b The inflation factor of “1” in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

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

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.**

⁷ For methodology, see: Wage Rates for Economic Analyses of the Toxics Release Inventory Program (U.S.EPA/OEI/EAD/ASB, June 10, 2002) and the Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (U.S. EPA/OPPT/EETD/EPAB. August 2002).

- 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.**

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.⁸ 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 \$308.27.

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 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 \$605.53.

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 (see Table 4). The unit cost for **Federal Register** notice review is \$20.82.

Table 5. Summary Unit Respondent Burden and Cost Estimates

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

Activity	Clerical		Technical		Managerial		Total	
	Hours	Cost (\$2020)	Hours	Cost (\$2020)	Hours	Cost (\$2020)	Hours	Cost (\$2020)
Recordkeeping, per allegation	0.5	\$17.00	0	\$0.00	3.5	\$308.00	4	\$325.00
Reporting, per report	1	\$34.00	2	\$149.06	5	\$440.00	8	\$606.06
Federal Register notice review, per notice	0	\$0.00	0	\$0.00	0.25	\$22.00	0.25	\$22.00
Unit totals	1.5	\$51.00	2	\$149.06	4,25	\$770.00	12.25	\$953.06

Table 6. Summary of Total Annual Respondent Burden and Cost

Activity	Unit Burden Hours	Unit Cost	Applicable # and Unit		# Firms	Burden Hours	Cost
Recordkeeping, per allegation	4	\$325.00	5,527	Allegations per year	N/A	22,109	\$1,796,725
Reporting, per report	8	\$606.06	160	Reports per year	N/A	128	\$96,970
Federal Register Notice review, per Notice	0.25	\$22.00	10	Notices per year per firm	13, 160	3,290	\$2,895,200
Total Burden/Cost						25,527	\$4,788,895

The unit burden for recordkeeping is multiplied by the total number of allegations. Total annual recordkeeping burden is 22,109 hours. The unit cost for recordkeeping of \$325.00 is multiplied by the average annual number of allegations per year (5,527) and the total annual recordkeeping cost is \$1,796,725.

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. The estimated number of 16 annual responses is based on the 31 reports received in response to the two TSCA section 8(c) notices published in the 27-year history of the rule. The estimated annual reporting burden hour is 16 reports x 8 hours per report (from Unit Reporting Burden and Costs), or 128 hours. The cost of submitting these reports is determined by multiplying the annual number of reports by the unit reporting cost (16 x \$606.06). The estimated total annual reporting cost is \$9,697.

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. Given this assumption, an estimated unit burden of 0.25 hours per notice, and an estimated 13,160 firms that will read the **Federal Register** notice to determine compliance obligations, the estimated annual industry burden is 3,290 hours (0.25 x 13,160). The estimated annual cost to industry of reviewing the **Federal Register** notices is estimated using the unit cost for **Federal Register** review at \$22.00 and multiplying by 13,160 firms reading 10 notice per year to obtain \$2,895,200 (\$22 x (13,160 x 10)).

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 25,527 hours annually with an associated annual cost of \$4,701,622. 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

Collection Activity		Number of Responses	Total Annual Burden Hours	Total Annual Burden Cost
Recordkeeping		13,160	22,109	\$1,796,725
Reporting		16	128	\$96,970
Federal Register Review 1		13,160	3,290	\$2,895,200
Total/Overall		26,336	25,527	\$4,788,895

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 \$158.53 annually to complete TSCA 8(c) information collection activities.

Table 8. Average Annual Cost and Burden per Respondent

Activity	Hours/Respondent	Hours/Response	Cost/Respondent	Cost/Response
Recordkeeping ^a	1.68	1.68	\$136.52	\$136.52
Reporting ^b	8.00	8.00	\$606.06	\$606.06
Federal Register review ^c	0.25	0.25	\$22.00	\$22.00
Average	1.94	0.97	\$158.53.02	\$81.87

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.

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

The 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 and salaries in 2020 GS-schedule for the Washington-Baltimore-Northern Virginia Locality Pay Area, for GS-15, Step 1, GS-13, Step 1, and GS-12, Step 1 employees. Wages include an additional 60 percent loading rate to account for overhead and benefits.

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 9. Annual Burden and Cost to the Federal Government

Activity	GS-Level	Loaded Hourly Wage (\$2020)	Burden Hours	Annual Cost
Administrative maintenance	GS-13, Step 1	\$79.49	208	\$16,534

	GS-15, Step 1	\$110.50	80	\$8,840
	<i>Total</i>		288	\$25,374
Education/Outreach	GS-12, Step 1	\$66.85	240	\$16,044
Compliance monitoring	GS-12, Step 1	\$66.85	400	\$26,740
Develop reporting notices	GS-12, Step 1	\$66.85	160	\$10,690
Document control functions	GS-12, Step 1	\$66.85	10	\$670
Notice review, referral and data entry	GS-12, Step 1	\$66.85	160	\$10,690
Totals			1,258	\$90,208

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

The burden hour estimate for this ICR renewal remains the same as that currently approved by OMB. There is, however, an increase in the estimated total burden cost associated with this ICR from \$1,987,487 to \$4,701,622. This change is an adjustment in the burden cost calculation associated with projected compliance determination activities.

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

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0017, is estimated to average 0.97 hours per response. Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a current and valid OMB control number. The OMB control numbers for EPA’s regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

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-2015-0688, 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.

Notice: Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are open to the public *by appointment only*. [Read more about the operating status.](#)

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-2015-0688.

Ref.	Title
1.	Statutory Authority
2.	Implementing Regulation
3.	Consultation