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:** Trichloroethylene; Regulation under Toxic Substances Control Act (TSCA) Section 6(a) (Final Rule; RIN 2070-AK83)

**EPA ICR No.:** 2775.02

**OMB Control No.:** 2070-0232

**Docket ID No.:** EPA-HQ-OPPT-2020-0642

## Abstract

The Environmental Protection Agency (EPA) is finalizing a rule under section 6 of the Toxic Substances Control Act (TSCA) to address the unreasonable risk to human health presented by trichloroethylene (TCE) under its conditions of use. EPA is issuing a final rule under TSCA section 6(a) to:

* Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all uses (including all consumer uses), with longer compliance timeframes for manufacture, processing, and distribution in commerce related to certain industrial and commercial uses;
* Prohibit most industrial and commercial uses of TCE, with longer compliance timeframes for certain uses;
* Prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon 134a (HFC-134a), following an 8.5-year phaseout;
* Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in solid rocket booster nozzle production by Federal agencies or their contractors, following a 10-year phaseout;
* Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for asphalt testing and recovery, following a 10-year TSCA section 6(g) phaseout;
* Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in batch vapor degreasing for essential aerospace parts and components and narrow tubing used in medical devices, following a 7-year TSCA section 6(g) exemption;
* Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for rocket engine cleaning by federal agencies and their contractors, following a 7-year TSCA section 6(g) exemption;
* For vessels of the Armed Forces and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems, prohibit the industrial and commercial use of TCE as: potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra- high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning agents to satisfy cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordnance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes, following a 10-year TSCA section 6(g) exemption;
* Prohibit the emergency industrial and commercial use of TCE in furtherance of National Aeronautics and Space Administration’s mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, following a 10-year TSCA section 6(g) exemption;
* Prohibit the manufacture (including import), processing, distribution in commerce, disposal, and use of TCE as a processing aid for manufacturing battery separators for lead acid batteries, following a 20-year TSCA section 6(g) exemption;
* Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for manufacturing specialty polymeric microporous sheet materials following a 15-year TSCA section 6(g) exemption;
* Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities, following a 50-year TSCA section 6(g) exemption;
* Require strict workplace controls to limit exposure to TCE, including compliance with a TCE workplace chemical protection program (WCPP), which would include requirements for an interim existing chemical exposure limit, as well as dermal protection, for conditions of use with long term phaseouts or time-limited exemptions under TSCA section 6(g);
* Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, through a phaseout allowing for longer timeframes for disposal necessary for certain industrial and commercial uses, along with a 50-year TSCA section 6(g) exemption for disposal for cleanup projects before prohibition and interim requirements for wastewater worker protection; and
* Establish recordkeeping and downstream notification requirements.

The information collection activities contained in the final rule are:

* Downstream notification requirements though Safety Data Sheets (SDS),
* Information generation related to the WCPP or other workplace controls, including recordkeeping and notification requirements, such as:
	+ Development of exposure control plans;
	+ Exposure level monitoring and related recordkeeping;
	+ Development of documentation for a Personal Protective Equipment (PPE) program and related recordkeeping;
	+ Development of documentation for a respiratory protection program and related recordkeeping;
	+ Development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation; and
	+ Recordkeeping related to exemptions proposed under TSCA section 6(g) demonstrating compliance with the specific conditions of the exemptions (including compliance with the WCPP).
* Recordkeeping requirements related to a proposed phaseout, demonstrating compliance with the conditions of the phaseout for processing TCE as an intermediate in the manufacture of HFC-134a.
* Recordkeeping requirements related to commercial use of TCE in energized electrical cleaner (for which each owner and operator must retain records regarding compliance with either the prescriptive controls required or the WCPP, and each distributor must maintain sales records)

## Summary of Annual Burden and Costs

|  |
| --- |
| Summary of Three-Year Average Incremental Burden Hours and Costs  |
| **Activity** | **Number of Respondents** | **Average Annual Responses Per Respondent** | **Total Respondents**  | **Average Annual Total Labor Burden (Hours)** | **Average Annual Total Labor Costs (2022$)** | **Average Annual Total Non-Labor Costs (2022$)** | **Average Annual Total Costs (2022$)** |
| Agency Burden | - | - | - |  -  | - | - | - |
| Rule Familiarization (WCPP firms. Prescriptive controls, and prohibition ) | 23,070 | 0.33 | 8,737 | 8,808 | $837,384 |   | $837,384  |
| Downstream Notification (SDS) | 11 | 1 |  11  |  7.3  | $695  |   | $695  |
| Develop Exposure Control Program |  1,677  | 1 |  1,677  |  2,800  | $199,720  |   | $199,720  |
| Respiratory Monitoring, Recordkeeping, and Notifications |  1,009  |  1.12  | 1,130 | 27,010  | $1,563,819 | $5,351,750  | $6,915,569 |
| **All Activities** | **23,070** |  | **11,555** |  **38,625**  | **$2,601,617**  | **$5,351,750**  | **$7,953,367** |

*Legal authority:* The Toxic Substances Control Act (TSCA), 15 U.S.C. § 2605(a).

*Respondents/affected entities*: Persons that manufacture (including import), process, use, distribute in commerce, or dispose of TCE or products containing TCE.

*Respondent’s obligation to respond*: Mandatory. 15 U.S.C. 2605(a) and 40 CFR part 751.

*Confidentiality of responses:* Not applicable.

## Total Burden and Costs

*Estimated total number of potential respondents*: 23,070.

*Frequency of response*: On occasion.

*Estimated total annual burden:* 38,625 hours. Burden is defined at 5 CFR 1320.3(b).

*Estimated total annual costs*: $7,953,367 includes $5,351,750 annualized capital or operation and maintenance costs, including ongoing monitoring costs incurred by respondents associated with monitoring equipment, laboratory analysis, and shipping costs, as presented under Q13.

*Changes in the estimates*: Not applicable. This is a request for a new OMB Control Number.

# 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.

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must, by rule, apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Section 6(a) authorizes EPA to:

* 1. Prohibit or restrict manufacture, processing, or distribution in commerce,
	2. Prohibit or restrict the manufacture, processing, or distribution in commerce of the chemical substance above a specified concentration,
	3. Require minimum warnings or instructions with respect to use, distribution, or disposal,
	4. Require manufacturers or processors to make and retain records,
	5. Prohibit or regulate any manner of commercial use,
	6. Prohibit or regulate any manner of disposal, and/or
	7. Require manufacturers or processors to give notice of the unreasonable risk of injury, and to recall products if required.

Pursuant to TSCA section 6(b), EPA determined that TCE presents an unreasonable risk of injury to health. Accordingly, to address the unreasonable risk, EPA is issuing this final rule under TSCA section 6(a) to:

1. Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all conditions of use (including all consumer uses), with longer compliance timeframes for manufacture, processing, and distribution in commerce related to certain industrial and commercial uses;
2. Prohibit the industrial and commercial use of TCE, with longer compliance timeframes for certain uses;
3. Prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon 134a (HFC-134a), following an 8.5-year phaseout;
4. Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in solid rocket booster nozzle production by Federal agencies and their contractors, following a 10-year phaseout;
5. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for asphalt testing and recovery, following a 10-year phaseout;
6. Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in batch vapor degreasing for essential aerospace parts and components and narrow tubing used in medical devices, following a 7-year TSCA section 6(g) exemption;
7. Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for rocket engine cleaning by federal agencies and their contractors, following a 7-year TSCA section 6(g) exemption;
8. For vessels of the Armed Forces and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems, prohibit the industrial and commercial use of TCE as: potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra-high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordnance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes, following a 10-year TSCA section 6(g) exemption;
9. Prohibit the emergency industrial and commercial use of TCE in furtherance of National Aeronautics and Space Administration’s mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, following a 10-year TSCA section 6(g) exemption;
10. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for manufacturing battery separators for lead acid batteries, following a 20-year TSCA section 6(g) exemption;
11. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for manufacturing specialty polymeric microporous sheet materials following a 15-year TSCA section 6(g) exemption;
12. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities, following a 50-year TSCA section 6(g) exemption;
13. Require strict workplace controls to limit exposure to TCE, including compliance with a TCE workplace chemical protection program (WCPP), which would include requirements for an interim existing chemical exposure limit, as well as dermal protection, for conditions of use with long term phaseouts or time-limited exemptions under TSCA section 6(g);
14. Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, through a phaseout allowing for longer timeframes for disposal necessary for certain industrial and commercial uses, along with a 50-year TSCA section 6(g) exemption for disposal for cleanup projects before prohibition and interim requirements for wastewater worker protection;
15. Establish recordkeeping and downstream notification requirements.

## 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.

The information collection activities covered by this ICR are necessary to mitigate the unreasonable risk from TCE under the conditions of use.

Downstream Notification. Without the downstream notification requirement, there is a greater likelihood that non-prohibited uses of TCE could be diverted to prohibited uses, or that users would buy or use materials that they do not realize are subject to the restrictions in the final rule. This would result in continuation of the risk that EPA has determined to be unreasonable. Downstream notification is required to be carried out by updates to the relevant SDS and is necessary for effective implementation and enforcement of the rule as it provides a record of notification on use restrictions throughout the supply chain. Downstream notification is required for manufacturers, processors, and distributors in commerce of TCE, who would provide notice to companies downstream upon shipment of TCE about the prohibitions. The information submitted to downstream companies through the SDS provides knowledge and awareness of the restrictions to these companies.

Information generation, recordkeeping, and notification requirements related to the WCPP or workplace controls. EPA has authority under section 6 of TSCA to require recordkeeping related to the regulatory requirements imposed by EPA. This is especially important where, as here, such records are needed for effective implementation and enforcement of the TSCA section 6 rule to eliminate unreasonable risk. Information collection activities for such records required by the TCE WCPP provide potentially exposed persons in a workplace with clear and necessary information and provide EPA with a necessary evidential mechanism for effective enforcement. The regulated entities must develop, compile, and retain records that are necessary for implementing the exposure controls of the WCPP, provide workplace notification to potentially exposed persons, and serve as a reference for EPA or authorized entities. These records include WCPP records, general business records such as invoices or bills-of-lading, exposure monitoring records, and exposure control plan records. These records demonstrate that regulated entities are in compliance with the requirements in this rule. Compliance with the WCPP or workplace controls and conditions of any exemption are required to reduce the unreasonable risk to human health identified by EPA for TCE. These recordkeeping requirements are also necessary to permit the EPA to conduct its enforcement activities and to ensure compliance within the regulated community.

Information generation related to a proposed phaseout, including recordkeeping. Similar to the recordkeeping requirements for the interim WCPP, information collection activities for such records needed to demonstrate compliance with a phaseout are needed for effective implementation and enforcement of the TSCA section 6 rule. These records provide documentation of appropriate reduction or attempts at reduction of TCE processed by manufacturers of HFC-134a and provide EPA with a necessary evidential mechanism for effective enforcement of the phase-out. These records include production volume records establishing a baseline annual volume of TCE processed as an intermediate and subsequent production volume records on documenting production volume decreases in accordance with the schedule in the proposed rule.

EPA. This information collection activity will ensure the availability of information to EPA upon inspection. The final rule does not establish requirements that result in the submission of information to EPA.

## 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.

The final rule does not establish reporting requirements, so no information will be submitted to EPA. Therefore, there is no need for any technology facilitation under the final rule related to the information collection activities. The recordkeeping requirement does not specify a particular technology or method of retaining the required information; therefore, regulated entities may retain records in any manner that is convenient or cost-effective.

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

The EPA’s collection pursuant to the TSCA section 6(a) regulations for this rulemaking do not duplicate any other information collection activity. TSCA requires that when EPA determines that a chemical substance presents unreasonable risk that EPA address by rule the unreasonable risk of injury to health or the environment and apply requirements to the extent necessary so the chemical no longer presents unreasonable risk. EPA is requiring information to ensure the elimination of unreasonable risk. Because there are no existing statutes that have established precedence in the regulation of TCE with criteria similar to the authorities granted under TSCA, the information collection activity is not a duplication. Lastly, while this collection activity required by EPA is similar to those of other Federal agencies such as OSHA, EPA is setting a lower exposure threshold than the OSHA PEL; in this way, some entities who were not previously required to maintain certain records under the OSHA standard may be subject to recordkeeping requirements in order to demonstrate compliance with the rulemaking under TSCA, which aims to address the unreasonable risk identified by EPA. The requirements of this rulemaking also include regulated entities where OSHA requirements are not applicable (e.g., public sector workers not covered by an OSHA State plan, and self-employed workers). Thus, these are unprecedented and EPA-specific collection activity guidelines for the regulation of TCE under TSCA and therefore has no duplicative requirements.

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

At the recommendation of the Small Business Review Panel, EPA: requested comment on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already required under OSHA’s regulations for TCE. In addition, EPA requested comment on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing TCE; implementation of new engineering or administrative controls; changes to labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management challenges. EPA also requested comment on the feasibility of entities complying with and monitoring for a potential ECEL of either 0.004 ppm or 0.0011 ppm, including on information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations. Furthermore, EPA requested comment on a training and certification program for commercial users, and on a *de minimis* level in the case of an impurity in products. EPA also requested comment on whether to allow the use of TCE by entities that could, based on demonstrated ability through monitoring data, meet the ECEL under a workplace chemical protection program; and on whether the use of TCE in a closed-loop vapor degreasing system, when combined with requirements of a potential workplace chemical protection program, could meet the ECELs for TCE. EPA also requested comment on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

Commenters on EPA’s proposed rule provided information in response to these requests. Specifically, in response to comments received, EPA has provided a regulatory threshold for TCE (referred to in the proposal as a de minimis level). EPA also has determined that additional time is needed to comply with the prohibition due to recertification standards for use of TCE in energized electrical cleaner and in adhesives and sealants for aerospace applications. Therefore, EPA’s final rule is delaying compliance with the prohibition to 3 years for the industrial and commercial use of TCE in energized electrical cleaner, and to 5 years for the industrial and commercial use of TCE in adhesives and sealants for aerospace applications. While requirements to reduce exposures and maintain records will take effect before the prohibitions, EPA expects this information to be part of normal business records.

## 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.

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements, (see #1 above) to the extent necessary so that the chemical substance or mixture no longer presents such risk. EPA has authority under section 6 of TSCA to require recordkeeping related to the regulatory requirements imposed by EPA. This is important where, as here, such records and reports are necessary for effective implementation and enforcement of the section 6 rule.

Due to the nature of the triggering events that initiate information collection activities under the final rule (i.e., the exposure of potentially exposed persons, consumers, and bystanders to unreasonable risk) a shorter timeframe for record retention is not feasible. The information collection activities covered by this ICR are necessary in order to ensure the effective mitigation of unreasonable risk from TCE. Due to EPA’s determination that TCE presents an unreasonable risk to health, the risk management rule involves information collection activities that are intended to ensure that TCE does not present an unreasonable risk, thus any associated burdens to the regulated entities are necessary for the implementation of a TSCA section 6(a) rulemaking. Should the records in this information collection activity not be maintained nor be made accessible in accordance with the rulemaking, effective implementation of the WCPP would be compromised and EPA would not be able to determine if unreasonable risk is mitigated, leading to the possibility of injury or death and will hinder investigative efforts by the regulated entity and by EPA.

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

1. **requiring respondents to report information to the agency more often than quarterly;**
2. **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
3. **requiring respondents to submit more than an original and two copies of any document;**
4. **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
5. **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;**
6. **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
7. **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**
8. **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.**

This rulemaking and information collection activity requires that regulated entities retain records for a duration of five years from the date of its inception such as downstream notification. EPA has tailored this timeframe to coincide with the statute of limitations for civil penalty enforcement (28 U.S.C. 2842). Though EPA does not require that regulated entities retain their records for 30 years as OSHA does (29 CFR 1910.1020), EPA expects that five-year retention of records for a WCPP is necessary for effective implementation and enforcement of this rulemaking.

## 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.**

There was a public comment period for this proposed rule on October 31, 2023, (88 FR 74712)(FRL 8317-01-OCSPP))EPA has addressed the comments received during the comment period in the final rule. Copies of the proposed rule, ICR, comments received, and EPA’s Response to Comments (in the final rule’s preamble) are available in the docket.

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

This collection does not provide any payment or gift to respondents.

## 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 system of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

EPA will not be collecting any information. Therefore, confidential information will not be submitted to EPA.

## 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.

The information collection activities do not include questions of a sensitive nature.

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

1. **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.**
2. **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
3. **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’.**

EPA’s *Economic Analysis of the Final Regulation of Trichloroethylene (TCE) Under TSCA* (U.S. EPA, 2024) provides the detailed methodology for estimating the number of respondents.

The paperwork burden and associated costs include the activity types listed below. Note that not all entities will incur burden or costs from these activities because they may already be meeting the requirements under as part of their usual business practices.

* Rule familiarization
	+ The 1,009 facilities complying with WCPP requirements and the 668 firms complying with prescriptive control requirements are assumed to incur an initial cost of $284 for a 3-hour burden associated with rule familiarization. This results in an annual average burden and cost of 1,677 hours and $158,864.
	+ The 21,393 facilities complying with prohibition requirements are assumed to incur an initial cost of $95 for a 1-hour burden associated with rule familiarization. This results in an annual average burden and cost of 7,131 hours and $678,520.
* Downstream notification
	+ Each person who processes or distributes in commerce TCE or TCE-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom TCE is shipped, in writing, of the restrictions on its use. It is assumed that the two manufacturers accomplish this by modifying the SDS to note the restrictions and the burden associated with the downstream notification requirements, including the related recordkeeping, is 2 hours, with an associated labor cost of $189. This results in an annual average burden and cost of 7.3 hours and $695. Shipment records are assumed to be kept as part of ordinary business practices, and therefore no incremental burden is estimated for this requirement.
* WCPP or prescriptive controls
	+ Dermal Protection
		- Under the final rule, facilities required to comply with dermal controls include those facilities complying with the rule through a WCPP or prescriptive controls. These facilities would be required to develop a dermal protection control program (estimated 5 initial hours per facility).
		- EPA estimates that 1,677 respondents will incur a total average annual cost of $199,720 for dermal protection over the first three years of the rule from an average annual total time burden of 2,800 hours.
	+ Respiratory Protection
		- Under the final rule, the 1,009 facilities complying with the rule through a WCPP are required to develop exposure control plans, monitor exposure levels, maintain records of this monitoring, provide employees with information about how they can access to the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation, and obtain an acknowledgment from the employee that they have received the information. The estimated costs and burdens are as follows:
			* The estimated burden and costs for the respiratory exposure monitoring plan and conducting exposure monitoring (generating the exposure monitoring results) depend on the TCE levels determined by the monitoring and are described in Chapter 7of the economic analysis of the final rule.
			* The estimated burden and costs for recordkeeping related to respiratory exposure monitoring depend on the TCE levels determined by the monitoring and are presented in Chapter 7 of the economic analysis of the final rule.
			* The estimated burden and costs for notifications related to exposure monitoring (notifying potentially exposed workers; providing them with access to exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation) depend on the TCE levels determined by the monitoring and are described in Chapter 7 of the economic analysis of the final rule.
		- Under the final rule, 1,009 facilities complying with the rule through a WCPP would be doing so as part of a phaseout or time-limited exemption. For those firms continuing to use TCE under a proposed exemption under TSCA section 6(g), documentation related to exemptions would be required to maintain their compliance with the terms of the exemption and would include usual business records demonstrating that their manufacturing (including import), processing, or use of TCE is for lead-acid and lithium battery separator manufacturing or laboratory use.
* Information related to proposed phaseouts
	+ Under the final rule, 2 facilities complying with the rule through a phase-out for processing TCE as an intermediate to manufacture HFC-134a would be required to maintain records that document appropriate reduction or attempts at reduction of use of TCE. Documentation related to production volumes would be considered usual business records.
	+ The burden and cost of recordkeeping related to demonstrating that the end use is in rocket booster nozzle production for Federal agencies or their contractors, and records that demonstrate that a final pre-launch test of rocket booster nozzles without using TCE was completed using an alternative to TCE in the production of rocket booster nozzles for Federal agencies and their contractors are described in the economic analysis of the final rule.

The table below presents the labor rates used to estimate the costs of the labor burdens under the ICR.

## Industry Wage Rates (2022$/hour)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Labor Category** | **Data Series** | **Date** | **Wage** | **Fringe Benefits**  | **Overhead1** | **Hourly Loaded Wages** |
| **(a)** | **(b)** | **(c)** | **(d)= (a)+(b)+(c)** |
| Manufacturing/Managerial  | BLS ECEC, Private Manufacturing industries, “Mgt, Business, and Financial”2  | Dec-22  | $54.29   | $24.66  | $15.79   | $94.74   |
| Manufacturing/ Production Worker  | BLS ECEC, Private Manufacturing Industries, “Production occupations”2  | Dec-22  | $21.79   | $11.63  | $6.68   | $40.10   |
| Transportation and Public Utilities/Managerial  | BLS *ECEC*, Trade, Transportation, and Utilities Industries*,* “Mgt, Business, and Financial” 2  | Dec-22  | $54.12   | $21.82  | $15.19   | $91.13   |
| Transportation and Public Utilities/Maintenance and Repair Worker  | BLS *ECEC*, Trade, Transportation, and Utilities Industries*,* “Installation, maintenance, and repair"2  | Dec-22  | $31.08   | $15.29  | $9.27   | $55.64   |
| Services/Managerial  | BLS ECEC, Service-providing Industries, Management, professional, and related occupations, “Mgt, Business, and Financial”  | Dec-22  | $54.77   | $24.99  | $15.95   | $95.71   |
| Services/Maintenance and Repair Worker  | BLS ECEC, Service-providing Industries, Natural resources, construction, and maintenance occupations, “Installation, maintenance, and repair"  | Dec-22  | $28.39   | $13.15  | $8.31   | $49.85   |
| Certified Industrial Hygienist  | Wage*: BLS OEWS Occupational Health & Safety Specialists (19-5011)* Fringes as percent of wage: BLS ECEC, Private Manufacturing industries, “Professional and related occupations” 3,4  | May-22  | $39.47   | $19.96   | $11.89   | $71.32   |
| Technical Specialist  | Wage*: BLS OEWS Occupational Health & Safety Technicians (19-5012)* Fringes as percent of wage: BLS ECEC, Private Manufacturing industries, “Professional and related occupations” 3,4  | May-22  | $30.40   | $15.38  | $9.16   | $54.93   |
| Vapor Degreasing Technician  | Wage*: BLS OEWS Plant and Systems Operators (51-8000)* Fringes as percent of wage: BLS ECEC, Manufacturing industry 3,4  | May-22  | $33.85   | $17.12  | $10.19   | $61.16   |
| Senior Engineer and Technical Advisor (vapor degreasing)   | Wage*: BLS OEWS Architectural and Engineering Managers (11-9041)* Fringes as percent of wage: BLS ECEC, Manufacturing industry 3,4  | May-22  | $78.52   | $39.71  | $23.65   | $141.88   |
| 1 An overhead rate of 20% of total compensation ((a)+(b)) is used based on assumptions in *Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions* (EPA 2020f).2 Source: Employer Costs for Employee Compensation Historical Supplementary Tables, National Compensation Survey: December 2022 (BLS 2023b).3 Source: Occupational Employment Statistics (Occupational Employment and Wage Statistics) for May 2022 (BLS 2023c).4 Fringe benefits are not reported in the BLS Occupational Employment and Wage Statistics (OEWS; BLS 2023c). It is therefore assumed that fringes as a percentage of wages are 50.576 percent, based on the percentage for Private Manufacturing Industries, “Professional and related” in the BLS ECEC (BLS 2023b).  |

The table below presents the summary of the average annual burden hours and costs per facility associated with the final rule. See Chapter 7 of the economic analysis (U.S. EPA, 2024) for a more detailed description of how the time burden and wage rates were estimated. The burden and cost estimates provided reflect the figures provided in the accompanying Information Collection Request (ICR) for the rule.

## Summary of 3-Year Average Incremental Burden Hours and Costs for Primary Option

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Activity** | **Number of Respondents** | **Average Annual Responses Per Respondent** | **Average Annual Burden Per Respondent** | **Average Annual Total Labor Burden** | **Average Annual Total Labor Costs (2022$)** | **Average Annual Total Non-Labor Costs (2022$)** | **Average Annual Total Costs (2022$)** |
| Agency Burden | - | - | - |  -  | - | - | - |
| Rule Familiarization (WCPP or prescriptive control firms) | 1,677 | 0.33 |  1.00  |  1,677  | $158,864  |   | $158,864  |
| Rule Familiarization (prohibition firms) | 21,393 | 0.33 |  0.33  |  7,131  | $678,520  |   | $678,520  |
| Downstream Notification (SDS) | 11 | 1 |  0.67  |  7.3  | $695  |   | $695  |
| Develop Exposure Control Program |  1,677  | 1 |  1.67  |  2,800  | $199,720  |   | $199,720  |
| Respiratory Monitoring |  1,009  |  1.12  |  19.01  |  19,175  | $1,099,072  | $5,351,750  | $6,450,822  |
| Respiratory Recordkeeping | 1,009 |  1.12  |  7.01  |  7,070  | $421,359  |   | $421,359  |
| Respiratory Notifications | 1,009 |  1.12  |  0.76  |  765  | $43,388  |   | $43,388  |
| **All Activities** | **23,070** |  |  **1.67**  |  **38,625**  | **$2,601,617**  | **$5,351,750**  | **$7,953,367** |

## 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).

1. **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.**
2. **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.**
3. **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 ongoing monitoring costs incurred by respondents associated with monitoring equipment,[1](#_bookmark0) laboratory analysis, and shipping costs. These costs are expected to vary depending on the extent to which monitoring results are below or above the existing chemical exposure limit (ECEL). EPA’s *Economic Analysis of the Final Regulation of Trichloroethylene (TCE) Under TSCA* (U.S. EPA, 2024) describes these cost estimates in detail. These ongoing non-labor costs are summarized in the table below.

## Paperwork Non-Labor Cost Associated with Respiratory Monitoring

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Threshold** | **Number of Respondents** | **Number of Workers** | **Annual Per Respondent Non-Labor Costs (excludes costs estimated on a per-worker basis)** | **Annual Per-Worker Non-Labor Cost** | **Average Annual Per-Respondent Cost** | **Average Annual Total Cost** |
| **Respondents with three years of WCPP** |
| <Action Level(1 event in first year) |  764.54  |  8,588.4  |   | $362  | $4,066  | $3,109,001  |
| Between Action Level and ECEL (2 events per year) |  50.68  |  255.5  |   | $724  | $3,650  | $184,968  |
| 1 to <10 times the ECEL(4 events per year) |  135.39  |  851.9  |   | $1,448  | $9,111  | $1,233,479  |
| 10 to <25 times the ECEL(4 events per year) |  19.32  |  150.5  |   | $1,448  | $11,278  | $217,895  |
| 25 to <50 times the ECEL(4 events per year) |  14.92  |  134.6  |   | $1,448  | $13,061  | $194,872  |
| 50 to <1,000 times the ECEL(4 events per year) |  21.89  |  234.2  |   | $1,448  | $15,493  | $339,136  |
| 1,000 to <10,000 times the ECEL (4 events per year) |  -  |  -  |   | $1,448  | - | - |
| **Respondents with one year of WCPP** |
| <Action Level(1 event in first year) |  -  |  -  |   | $362  |  -  | - |
| Between Action Level and ECEL (2 events per year) |  -  |  -  |   | $724  |  -  | - |
| 1 to <10 times the ECEL(4 events per year) |  0.08  |  9.52  |   | $1,448  | $172,312  | $13,785  |
| 10 to <25 times the ECEL(4 events per year) |  0.62  |  18.06  |   | $1,448  | $42,179  | $26,151  |
| 25 to <50 times the ECEL(4 events per year) |  0.78  |  13.58  |   | $1,448  | $25,210  | $19,664  |
| 50 to <1,000 times the ECEL(4 events per year) |  0.52  |  8.84  |   | $1,448  | $24,616  | $12,800  |
| 1,000 to <10,000 times the ECEL (4 events per year) |  -  |  -  |   | $1,448  | - | - |
| **All Respondents** |  **1,009**  |  **10,265**  |  | **-** |  **$320,976**  | **$5,351,750** |

1 Monitoring equipment is assumed to be rented, so it is an ongoing cost rather than a capital cost.

## 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.

There will be no agency collection activities under the final rule. There will only be third-party notification and recordkeeping requirements.

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

This is a new, rule-related information collection. Therefore, the reported burden reflects a program change.

## 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

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0232). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR Part 700. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be between .33 – 18.78 hours per response. Send comments on the Agency’s need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Information Engagement 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.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via https://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.

# LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR. The docket for this ICR is accessible electronically through [http://www.regulations.gov](http://www.regulations.gov/) using Docket ID Number: EPA-HQ-2020-0642.

|  |  |
| --- | --- |
| **Attachment** | **Title (hyperlink)** |
| 1. | TSCA section 6 (15 U.S.C. 2605) |
| 2. | Final Rule |
| 3. | Economic Analysis |
| 4. | Stakeholder Meeting Index (Updated)  |