

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

3 **EXECUTIVE SUMMARY**

4 **Identification of the Information Collection – Title and Numbers**

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

7 **EPA ICR No.:** 2775.02

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

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

10 **Abstract**

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

- 14 • Prohibit the manufacture (including import), processing, and distribution in commerce of TCE  
15 for all uses (including all consumer uses), with longer compliance timeframes for manufacture,  
16 processing, and distribution in commerce related to certain industrial and commercial uses;
- 17 • Prohibit most industrial and commercial uses of TCE, with longer compliance timeframes for  
18 certain uses;
- 19 • Prohibit the manufacture (including import) and processing of TCE as an intermediate for the  
20 manufacturing of hydrofluorocarbon 134a (HFC-134a), following an 8.5-year phaseout;
- 21 • Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor  
22 degreasing for rayon fabric scouring for end use in solid rocket booster nozzle production by  
23 Federal agencies or their contractors, following a 10-year phaseout;
- 24 • Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
25 TCE as a laboratory chemical for asphalt testing and recovery, following a 10-year TSCA  
26 section 6(g) phaseout;
- 27 • Prohibit the manufacture (including import), processing, distribution in commerce, and industrial  
28 and commercial use of TCE as a solvent in batch vapor degreasing for essential aerospace parts  
29 and components and narrow tubing used in medical devices, following a 7-year TSCA section  
30 6(g) exemption;

- 31 • Prohibit the manufacture (including import), processing, distribution in commerce, and industrial  
32 and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for rocket  
33 engine cleaning by federal agencies and their contractors, following a 7-year TSCA section 6(g)  
34 exemption;
- 35 • For vessels of the Armed Forces and their systems, and in the maintenance, fabrication, and  
36 sustainment for and of such vessels and systems, prohibit the industrial and commercial use of  
37 TCE as: potting compounds for naval electronic systems and equipment; sealing compounds for  
38 high and ultra- high vacuum systems; bonding compounds for materials testing and maintenance  
39 of underwater systems and bonding of nonmetallic materials; and cleaning agents to satisfy  
40 cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor  
41 degreasing) for: materials and components required for military ordnance testing; temporary  
42 resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion  
43 for electronic systems and equipment repair and installation of elastomeric materials; various  
44 naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to  
45 remove coolant and other residue from machine parts; machined part fabrications for naval  
46 systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required  
47 for substrate surface preparation prior to electroplating processes, following a 10-year TSCA  
48 section 6(g) exemption;
- 49 • Prohibit the emergency industrial and commercial use of TCE in furtherance of National  
50 Aeronautics and Space Administration’s mission for specific conditions which are critical or  
51 essential and for which no technically and economically feasible safer alternative is available,  
52 following a 10-year TSCA section 6(g) exemption;
- 53 • Prohibit the manufacture (including import), processing, distribution in commerce, disposal, and  
54 use of TCE as a processing aid for manufacturing battery separators for lead acid batteries,  
55 following a 20-year TSCA section 6(g) exemption;
- 56 • Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
57 TCE as a processing aid for manufacturing specialty polymeric microporous sheet materials  
58 following a 15-year TSCA section 6(g) exemption;
- 59 • Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
60 TCE as a laboratory chemical for essential laboratory activities and some research and  
61 development activities, following a 50-year TSCA section 6(g) exemption;
- 62 • Require strict workplace controls to limit exposure to TCE, including compliance with a TCE  
63 workplace chemical protection program (WCPP), which would include requirements for an  
64 interim existing chemical exposure limit, as well as dermal protection, for conditions of use with  
65 long term phaseouts or time-limited exemptions under TSCA section 6(g);
- 66 • Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned  
67 treatment works, through a phaseout allowing for longer timeframes for disposal necessary for  
68 certain industrial and commercial uses, along with a 50-year TSCA section 6(g) exemption for  
69 disposal for cleanup projects before prohibition and interim requirements for wastewater worker  
70 protection; and
- 71 • Establish recordkeeping and downstream notification requirements.

72 The information collection activities contained in the final rule are:

- 73 • Downstream notification requirements through Safety Data Sheets (SDS),
- 74 • Information generation related to the WCPP or other workplace controls, including  
75 recordkeeping and notification requirements, such as:
  - 76 ○ Development of exposure control plans;
  - 77 ○ Exposure level monitoring and related recordkeeping;
  - 78 ○ Development of documentation for a Personal Protective Equipment (PPE) program and  
79 related recordkeeping;
  - 80 ○ Development of documentation for a respiratory protection program and related  
81 recordkeeping;
  - 82 ○ Development and notification to potentially exposed persons (employees and others in the  
83 workplace) about how they can access the exposure control plans, exposure monitoring  
84 records, PPE program implementation documentation, and respirator program  
85 documentation; and
  - 86 ○ Recordkeeping related to exemptions proposed under TSCA section 6(g) demonstrating  
87 compliance with the specific conditions of the exemptions (including compliance with the  
88 WCPP).
- 89 • Recordkeeping requirements related to a proposed phaseout, demonstrating compliance with the  
90 conditions of the phaseout for processing TCE as an intermediate in the manufacture of HFC-  
91 134a.
- 92 • Recordkeeping requirements related to commercial use of TCE in energized electrical cleaner  
93 (for which each owner and operator must retain records regarding compliance with either the  
94 prescriptive controls required or the WCPP, and each distributor must maintain sales records)

95

96 **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
<b>All Activities</b>	<b>23,070</b>		<b>11,555</b>	<b>38,625</b>	<b>\$2,601,617</b>	<b>\$5,351,750</b>	<b>\$7,953,367</b>

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

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

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

101 *Confidentiality of responses:* Not applicable.

102 **Total Burden and Costs**

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

104 *Frequency of response:* On occasion.

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

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

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

110

111 **SUPPORTING STATEMENT**

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

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

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

131 Pursuant to TSCA section 6(b), EPA determined that TCE presents an unreasonable risk of injury to  
132 health. Accordingly, to address the unreasonable risk, EPA is issuing this final rule under TSCA section  
133 6(a) to:

- 134 1) Prohibit the manufacture (including import), processing, and distribution in commerce of  
135 TCE for all conditions of use (including all consumer uses), with longer compliance  
136 timeframes for manufacture, processing, and distribution in commerce related to certain  
137 industrial and commercial uses;
- 138 2) Prohibit the industrial and commercial use of TCE, with longer compliance timeframes for  
139 certain uses;
- 140 3) Prohibit the manufacture (including import) and processing of TCE as an intermediate for the  
141 manufacturing of hydrofluorocarbon 134a (HFC-134a), following an 8.5-year phaseout;
- 142 4) Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor  
143 degreasing for rayon fabric scouring for end use in solid rocket booster nozzle production by  
144 Federal agencies and their contractors, following a 10-year phaseout;

- 145 5) Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
146 TCE as a laboratory chemical for asphalt testing and recovery, following a 10-year phaseout;
- 147 6) Prohibit the manufacture (including import), processing, distribution in commerce, and  
148 industrial and commercial use of TCE as a solvent in batch vapor degreasing for essential  
149 aerospace parts and components and narrow tubing used in medical devices, following a 7-  
150 year TSCA section 6(g) exemption;
- 151 7) Prohibit the manufacture (including import), processing, distribution in commerce, and  
152 industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary  
153 for rocket engine cleaning by federal agencies and their contractors, following a 7-year  
154 TSCA section 6(g) exemption;
- 155 8) For vessels of the Armed Forces and their systems, and in the maintenance, fabrication, and  
156 sustainment for and of such vessels and systems, prohibit the industrial and commercial use  
157 of TCE as: potting compounds for naval electronic systems and equipment; sealing  
158 compounds for high and ultra-high vacuum systems; bonding compounds for materials  
159 testing and maintenance of underwater systems and bonding of nonmetallic materials; and  
160 cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor  
161 degreasing) for: materials and components required for military ordnance testing; temporary  
162 resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane  
163 adhesion for electronic systems and equipment repair and installation of elastomeric  
164 materials; various naval combat systems, radars, sensors, equipment; fabrication and  
165 prototyping processes to remove coolant and other residue from machine parts; machined  
166 part fabrications for naval systems; installation of topside rubber tile material aboard vessels;  
167 and vapor degreasing required for substrate surface preparation prior to electroplating  
168 processes, following a 10-year TSCA section 6(g) exemption;
- 169 9) Prohibit the emergency industrial and commercial use of TCE in furtherance of National  
170 Aeronautics and Space Administration's mission for specific conditions which are critical or  
171 essential and for which no technically and economically feasible safer alternative is  
172 available, following a 10-year TSCA section 6(g) exemption;
- 173 10) Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
174 TCE as a processing aid for manufacturing battery separators for lead acid batteries,  
175 following a 20-year TSCA section 6(g) exemption;
- 176 11) Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
177 TCE as a processing aid for manufacturing specialty polymeric microporous sheet materials  
178 following a 15-year TSCA section 6(g) exemption;
- 179 12) Prohibit the manufacture (including import), processing, distribution in commerce, and use of  
180 TCE as a laboratory chemical for essential laboratory activities and some research and  
181 development activities, following a 50-year TSCA section 6(g) exemption;
- 182 13) Require strict workplace controls to limit exposure to TCE, including compliance with a  
183 TCE workplace chemical protection program (WCPP), which would include requirements  
184 for an interim existing chemical exposure limit, as well as dermal protection, for conditions  
185 of use with long term phaseouts or time-limited exemptions under TSCA section 6(g);

186 14) Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly  
187 owned treatment works, through a phaseout allowing for longer timeframes for disposal  
188 necessary for certain industrial and commercial uses, along with a 50-year TSCA section 6(g)  
189 exemption for disposal for cleanup projects before prohibition and interim requirements for  
190 wastewater worker protection;

191 15) Establish recordkeeping and downstream notification requirements.

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

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

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

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

223 Information generation related to a proposed phaseout, including recordkeeping. Similar to the  
224 recordkeeping requirements for the interim WCPP, information collection activities for such records  
225 needed to demonstrate compliance with a phaseout are needed for effective implementation and  
226 enforcement of the TSCA section 6 rule. These records provide documentation of appropriate reduction  
227 or attempts at reduction of TCE processed by manufacturers of HFC-134a and provide EPA with a  
228 necessary evidential mechanism for effective enforcement of the phase-out. These records include

229 production volume records establishing a baseline annual volume of TCE processed as an intermediate  
230 and subsequent production volume records on documenting production volume decreases in accordance  
231 with the schedule in the proposed rule.

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

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

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

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

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

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

265 At the recommendation of the Small Business Review Panel, EPA: requested comment on the extent to  
266 which a regulation under TSCA section 6(a) could minimize requirements, such as testing and  
267 monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already  
268 required under OSHA's regulations for TCE. In addition, EPA requested comment on reasonable  
269 compliance timeframes for small businesses, including timeframes for reformulation of products or  
270 processes containing TCE; implementation of new engineering or administrative controls; changes to



271 labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices;  
272 and supply chain management challenges. EPA also requested comment on the feasibility of entities  
273 complying with and monitoring for a potential ECEL of either 0.004 ppm or 0.0011 ppm, including on  
274 information on potential costs that could be incurred using strategies to meet the requirements of such a  
275 standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for  
276 entities to implement these strategies in their operations. Furthermore, EPA requested comment on a  
277 training and certification program for commercial users, and on a *de minimis* level in the case of an  
278 impurity in products. EPA also requested comment on whether to allow the use of TCE by entities that  
279 could, based on demonstrated ability through monitoring data, meet the ECEL under a workplace  
280 chemical protection program; and on whether the use of TCE in a closed-loop vapor degreasing system,  
281 when combined with requirements of a potential workplace chemical protection program, could meet the  
282 ECELS for TCE. EPA also requested comment on establishing differing compliance or reporting  
283 requirements or timetables that take into account the limited resources available to small entities.

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

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

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

305 Due to the nature of the triggering events that initiate information collection activities under the final  
306 rule (i.e., the exposure of potentially exposed persons, consumers, and bystanders to unreasonable risk) a  
307 shorter timeframe for record retention is not feasible. The information collection activities covered by  
308 this ICR are necessary in order to ensure the effective mitigation of unreasonable risk from TCE. Due to  
309 EPA's determination that TCE presents an unreasonable risk to health, the risk management rule  
310 involves information collection activities that are intended to ensure that TCE does not present an  
311 unreasonable risk, thus any associated burdens to the regulated entities are necessary for the  
312 implementation of a TSCA section 6(a) rulemaking. Should the records in this information collection  
313 activity not be maintained nor be made accessible in accordance with the rulemaking, effective  
314 implementation of the WCPP would be compromised and EPA would not be able to determine if

315 unreasonable risk is mitigated, leading to the possibility of injury or death and will hinder investigative  
316 efforts by the regulated entity and by EPA.

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

- 319 a) **requiring respondents to report information to the agency more often than quarterly;**
- 320 b) **requiring respondents to prepare a written response to a collection of information in**  
321 **fewer than 30 days after receipt of it;**
- 322 c) **requiring respondents to submit more than an original and two copies of any document;**
- 323 d) **requiring respondents to retain records, other than health, medical, government**  
324 **contract, grant-in-aid, or tax records, for more than three years;**
- 325 e) **in connection with a statistical survey, that is not designed to produce valid and reliable**  
326 **results that can be generalized to the universe of study;**
- 327 f) **requiring the use of a statistical data classification that has not been reviewed and**  
328 **approved by OMB;**
- 329 g) **that includes a pledge of confidentiality that is not supported by authority established in**  
330 **statute or regulation, that is not supported by disclosure and data security policies that**  
331 **are consistent with the pledge, or which unnecessarily impedes sharing of data with**  
332 **other agencies for compatible confidential use; or**
- 333 h) **requiring respondents to submit proprietary trade secrets, or other confidential**  
334 **information unless the agency can demonstrate that it has instituted procedures to**  
335 **protect the information's confidentiality to the extent permitted by law.**

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

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

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

350 **Consultation with representatives of those from whom information is to be obtained or those**  
351 **who must compile records should occur at least once every 3 years - even if the collection of**

352 **information activity is the same as in prior periods. There may be circumstances that may**  
353 **preclude consultation in a specific situation. These circumstances should be explained.**

354 The final rulemaking serves as the public notice for this ICR. Interested parties should submit comments  
355 referencing Docket ID No. EPA-HQ-OPPT-2020-0642 to the address listed at the end of this document.  
356 EPA will address any comments received from OMB or the public concerning the information collection  
357 activities contained in the rule, and the agency's response, when developing the final rule.

358 EPA has engaged in significant consultation and outreach with the regulated community and other  
359 affected entities during development of the proposed and final rulemaking. Key opportunities to obtain  
360 public input on the availability and type of data that should be required, frequency of monitoring, and  
361 methods for carrying out downstream notification include the outreach meetings with small entity  
362 representatives held as part of the Small Business Advocacy Review (SBAR) Panel, where submitted  
363 exposure measurements indicated an ability to achieve a WCPP for certain uses; presentations to small  
364 business stakeholders and the general public in December 2020; and discussions with representatives  
365 from different industries, non-governmental organizations, technical experts and users of TCE. A list of  
366 external meetings held during the development of the proposed and final rule is in the docket. The  
367 purpose of these discussions was to create awareness and educate stakeholders and regulated entities on  
368 the provisions for risk management required under section 6(a) of TSCA; obtain input from  
369 manufacturers, processors, distributors, users, academics, advisory councils, and members of the public  
370 health community about uses of TCE; identify workplace practices, engineering controls, administrative  
371 controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to  
372 TCE under the conditions of use; generate potential risk reduction strategies; and understand the type of  
373 recordkeeping, notifications, and reporting already ongoing.

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

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

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

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

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

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

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

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

407 EPA’s *Economic Analysis of the Final Regulation of Trichloroethylene (TCE) Under TSCA* (U.S. EPA,  
408 2024) provides the detailed methodology for estimating the number of respondents.

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

- 412 • Rule familiarization
- 413 ○ The 1,009 facilities complying with WCPP requirements and the 668 firms complying  
414 with prescriptive control requirements are assumed to incur an initial cost of \$284 for a 3-  
415 hour burden associated with rule familiarization. This results in an annual average burden  
416 and cost of 1,677 hours and \$158,864.
- 417 ○ The 21,393 facilities complying with prohibition requirements are assumed to incur an  
418 initial cost of \$95 for a 1-hour burden associated with rule familiarization. This results in  
419 an annual average burden and cost of 7,131 hours and \$678,520.
- 420 • Downstream notification
- 421 ○ Each person who processes or distributes in commerce TCE or TCE-containing products  
422 for any use must, prior to or concurrent with the shipment, notify companies to whom  
423 TCE is shipped, in writing, of the restrictions on its use. It is assumed that the two  
424 manufacturers accomplish this by modifying the SDS to note the restrictions and the  
425 burden associated with the downstream notification requirements, including the related  
426 recordkeeping, is 2 hours, with an associated labor cost of \$189. This results in an annual  
427 average burden and cost of 7.3 hours and \$695. Shipment records are assumed to be kept

428 as part of ordinary business practices, and therefore no incremental burden is estimated  
429 for this requirement.

430 • WCPP or prescriptive controls

431 ○ Dermal Protection

432 ■ Under the final rule, facilities required to comply with dermal controls include  
433 those facilities complying with the rule through a WCPP or prescriptive controls.  
434 These facilities would be required to develop a dermal protection control program  
435 (estimated 5 initial hours per facility).

436 ■ EPA estimates that 1,677 respondents will incur a total average annual cost of  
437 \$199,720 for dermal protection over the first three years of the rule from an  
438 average annual total time burden of 2,800 hours.

439 ○ Respiratory Protection

440 ■ Under the final rule, the 1,009 facilities complying with the rule through a WCPP  
441 are required to develop exposure control plans, monitor exposure levels, maintain  
442 records of this monitoring, provide employees with information about how they  
443 can access to the exposure control plans, exposure monitoring records, PPE  
444 program implementation documentation, and respirator program documentation,  
445 and obtain an acknowledgment from the employee that they have received the  
446 information. The estimated costs and burdens are as follows:

447 • The estimated burden and costs for the respiratory exposure monitoring plan  
448 and conducting exposure monitoring (generating the exposure monitoring  
449 results) depend on the TCE levels determined by the monitoring and are  
450 described in Chapter 7 of the economic analysis of the final rule.

451 • The estimated burden and costs for recordkeeping related to respiratory  
452 exposure monitoring depend on the TCE levels determined by the monitoring  
453 and are presented in Chapter 7 of the economic analysis of the final rule.

454 • The estimated burden and costs for notifications related to exposure  
455 monitoring (notifying potentially exposed workers; providing them with  
456 access to exposure control plans, exposure monitoring records, PPE program  
457 implementation documentation, and respirator program documentation)  
458 depend on the TCE levels determined by the monitoring and are described in  
459 Chapter 7 of the economic analysis of the final rule.

460 ■ Under the final rule, 1,009 facilities complying with the rule through a WCPP  
461 would be doing so as part of a phaseout or time-limited exemption. For those firms  
462 continuing to use TCE under a proposed exemption under TSCA section 6(g),  
463 documentation related to exemptions would be required to maintain their  
464 compliance with the terms of the exemption and would include usual business  
465 records demonstrating that their manufacturing (including import), processing, or  
466 use of TCE is for lead-acid and lithium battery separator manufacturing or  
467 laboratory use.

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- Information related to proposed phaseouts

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- 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.

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- 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.

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

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482 **Industry Wage Rates (2022\$/hour)**

Labor Category	Data Series	Date	Wage	Fringe Benefits	Overhead <sup>1</sup>	Hourly Loaded Wages
			(a)	(b)	(c)	(d)= (a)+(b)+(c)
Manufacturing/ Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial" <sup>2</sup>	Dec-22	\$54.29	\$24.66	\$15.79	\$94.74
Manufacturing/ Production Worker	BLS ECEC, Private Manufacturing Industries, "Production occupations" <sup>2</sup>	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" <sup>2</sup>	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" <sup>2</sup>	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" <sup>3,4</sup>	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" <sup>3,4</sup>	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 <sup>3,4</sup>	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 <sup>3,4</sup>	May-22	\$78.52	\$39.71	\$23.65	\$141.88

<sup>1</sup> 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).

<sup>2</sup> Source: Employer Costs for Employee Compensation Historical Supplementary Tables, National Compensation Survey: December 2022 (BLS 2023b).

<sup>3</sup> Source: Occupational Employment Statistics (Occupational Employment and Wage Statistics) for May 2022 (BLS 2023c).

<sup>4</sup> 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).

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

488 **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
<b>All Activities</b>	<b>23,070</b>		<b>1.67</b>	<b>38,625</b>	<b>\$2,601,617</b>	<b>\$5,351,750</b>	<b>\$7,953,367</b>

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

- 493 a) **The cost estimate should be split into two components: (a) a total capital and start-up**  
 494 **cost component (annualized over its expected useful life) and (b) a total operation and**  
 495 **maintenance and purchase of services component. The estimates should take into**  
 496 **account costs associated with generating, maintaining, and disclosing or providing the**  
 497 **information. Include descriptions of methods used to estimate major cost factors**  
 498 **including system and technology acquisition, expected useful life of capital equipment,**  
 499 **the discount rate(s), and the time period over which costs will be incurred. Capital**  
 500 **and start-up costs include, among other items, preparations for collecting information**  
 501 **such as purchasing computers and software; monitoring, sampling, drilling and**  
 502 **testing equipment; and record storage facilities.**



- 503           b) **If cost estimates are expected to vary widely, agencies should present ranges of cost**  
504 **burdens and explain the reasons for the variance. The cost of purchasing or**  
505 **contracting out information collections services should be a part of this cost burden**  
506 **estimate. In developing cost burden estimates, agencies may consult with a sample of**  
507 **respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment**  
508 **process and use existing economic or regulatory impact analysis associated with the**  
509 **rulemaking containing the information collection, as appropriate.**
- 510           c) **Generally, estimates should not include purchases of equipment or services, or**  
511 **portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory**  
512 **compliance with requirements not associated with the information collection, (3) for**  
513 **reasons other than to provide information or keep records for the government, or (4)**  
514 **as part of customary and usual business or private practices.**

515 There are ongoing monitoring costs incurred by respondents associated with monitoring equipment,<sup>1</sup>  
516 laboratory analysis, and shipping costs. These costs are expected to vary depending on the extent to  
517 which monitoring results are below or above the existing chemical exposure limit (ECEL). EPA’s  
518 *Economic Analysis of the Final Regulation of Trichloroethylene (TCE) Under TSCA* (U.S. EPA, 2024)  
519 describes these cost estimates in detail. These ongoing non-labor costs are summarized in the table  
520 below.

521 **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
<b>Respondents with three years of WCPP</b>						
<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	-	-
<b>Respondents with one year of WCPP</b>						
<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	-	-
<b>All Respondents</b>	<b>1,009</b>	<b>10,265</b>		-	<b>\$320,976</b>	<b>\$5,351,750</b>

522 <sup>1</sup> Monitoring equipment is assumed to be rented, so it is an ongoing cost rather than a capital cost.

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

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

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

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

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

538 Not applicable.

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

541 Not applicable.

542 **18. Explain each exception to the certification statement identified in “Certification for**  
543 **Paperwork Reduction Act Submissions.”**

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

545 **SUPPLEMENTAL INFORMATION**

546 The annual public burden for this collection of information is estimated to average approximately 18.78  
547 hours annually for respondents complying with a WCPP or other respiratory protection requirements  
548 and 0.33 hours annually for respondents with only a rule familiarization burden. According to the  
549 Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by

550 persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For  
551 this collection it includes the time needed to review and understand instructions; prepare and submit  
552 reports (including searching data sources); complete and review the collection of information; transmit  
553 the information; and keep records.

554 **LIST OF ATTACHMENTS**

555 The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is  
556 provided in the list below. The docket for this ICR is accessible electronically through  
557 <http://www.regulations.gov> using Docket ID Number: EPA-HQ-2020-0642.

<b>Attachment</b>	<b>Title (hyperlink)</b>
1.	TSCA section 6 ( <a href="#">15 U.S.C. 2605</a> )
2.	Final Rule
3.	Economic Analysis
4.	Stakeholder Meeting Index (Updated)

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