

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: Procedures for submitting information subject to business confidentiality claims under the Toxic Substances Control Act (TSCA)

EPA ICR No.: 2706.01

OMB Control No.: 2070-NEW

Docket ID No.: EPA-HQ-OPPT-2021-0419

Abstract

EPA is proposing new and amended requirements concerning the assertion and maintenance of claims of business confidentiality (also known as Confidential Business Information or “CBI”) under the Toxic Substances Control Act (TSCA), 15 U.S.C. §2601, *et seq.* The Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. 114–182 referred to in this Notice as “Lautenberg”), made significant amendments to TSCA including new provisions governing the assertion of CBI claims and requirements concerning Agency review and treatment of confidentiality claims. This proposed rule specifies procedures for submitting and supporting CBI claims in TSCA submissions, including substantiation requirements applicable at the time of submission, exemptions from the requirement to substantiate, electronic reporting enhancements (which include new electronic reporting requirements, as well as integration of TSCA requirements to provide certain certification statements, substantiation, and generic names when making confidentiality claims), and maintenance or withdrawal of confidentiality claims. The proposed rule also specifies Agency procedures for reviewing and communicating with TSCA submitters about confidentiality claims, including requirements for submitters to maintain contact information, procedures EPA will use to provide notices to submitters concerning their claims, and the manner in which EPA will notify submitters concerning the impending expiration of certain claims.

The proposed rule includes new provisions, as well as amending and reorganizing existing provisions concerning assertion of confidentiality claims in order to conform to new requirements in Lautenberg. Most procedural requirements for asserting and maintaining a confidentiality claim are organized into a new part of the CFR, which would apply to any TSCA submission, except as modified by or elaborated on elsewhere in parts 704, 707, 716, 717, 720, 721, 723, 725, or 790. The following submissions under TSCA will now have new or amended procedures for substantiated claims of confidentiality:

- TSCA Section 8(a); 40 CFR 704
- TSCA Section 12(b) Notification of Export; 40 CFR 707.75(d)
- TSCA Section 8(d) Health and Safety Studies; 40 CFR 716.55(a) and (c)
- TSCA Section 8(c) Allegations of Adverse Effects; 40 CFR 717.19
- TSCA Section 5 Premanufacture Notices (PMNs); 40 CFR 720.85 and 720.90 and 720 Subpart F
- TSCA Section 5 40 CFR 721 Significant New Use Rules (SNURs)
- TSCA Section 5 Polymer Exemption; 40 CFR 723.250(f); and Low Volume Exemptions 40 CFR 723.50
- TSCA Section 5 microorganisms; 40 CFR 725 Subpart C
- TSCA Section 4 Test Orders; 40 CFR 790

Summary Total Burden and Costs

Category	Total Number of Respondents	Number of Responses	Annual Burden Hours	Annual Costs (2020\$)
Respondent	1,100	Varies by activity ^a	2,945 in the first year and 523 in each following year	\$270,783 in the first year and \$44,605 in each following year
Agency			-518 (burden reduction)	-\$73,208 (cost savings)

Note: Burden and cost estimates are rounded to the nearest hour and dollar, respectively. Negative values correspond to burden reductions and cost savings.

^a It is expected that some activities listed under the proposed rule will be undertaken by all respondents and that other activities will only be undertaken in specific cases.

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.**

Lautenberg included several significant amendments to the provisions on CBI included in Section 14 of the Toxic Substances Control Act (TSCA). These included new requirements that persons submitting information under TSCA must substantiate most confidentiality claims at the time of submission, as well as additional certification and generic name requirements. In order to maintain most claims beyond a 10-year period, submitters will also be required to reassert and substantiate those claims. Several new requirements also apply to EPA, including requirements to review and approve or deny all chemical identity claims asserted concerning substances that are offered for commercial distribution, as well a subset of all other confidentiality claims, within 90

days of the claim being asserted. Further requirements that EPA review all confidentiality claims concerning substances listed as active on the TSCA Inventory, a requirement to assign and apply unique identifiers (UIDs) to substances with approved confidentiality claims for chemical identity, as well as new provisions providing expanded access to TSCA Confidential Business Information (CBI), have been discussed in previous Federal Register Documents. 85 FR 13062 (March 06, 2020; review plan rule); 83 FR 30168 (June 27, 2018; UIDs); 83 FR 30171 (June 27, 2018; expanded access to CBI). Additionally, TSCA rules promulgated or amended since the Lautenberg amendments have included confidentiality provisions conforming to the amendments (e.g., 40 CFR 711.30 and 710.37).

Regulations implementing the statutory mandate in TSCA section 14 will be under 40 CFR 703, and include the following provisions:

- 40 CFR 704.7, the confidentiality provision for section 8(a) rules;
- 40 CFR 707.75(d), the confidentiality provision of rules concerning section 12(b) notices of export;
- 40 CFR 716.55, the confidentiality provisions for section 8(d) reporting rules;
- 40 CFR 717.19, the confidentiality provision for section 8(c) recordkeeping and reporting rules;
- 40 CFR 723.50(l) and 723.250 (f), the confidentiality provision for certain exemption requests under section 5 (low volume exemption and low releases and low exposures exemption); and
- 40 CFR 790, the confidentiality provision of rules concerning section 4 test rules, orders, and agreements.

The full text of proposed regulations are provided in Attachment 1.

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 proposed rule applies broadly to any information that is reported to, or otherwise obtained by, the Agency under TSCA. This includes, for example, information that is submitted pursuant to a requirement of TSCA or its implementing regulations (e.g., a section 5 Premanufacture Notification (PMN) or a section 8(e) notice of substantial risk), information that is collected in the course of a TSCA inspection or other TSCA enforcement-related activity, materials that are subpoenaed pursuant to TSCA, and any other information submitted to or obtained by EPA that is used to satisfy a TSCA obligation, or used by EPA to carry out its responsibilities under TSCA.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision

for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

This proposed rule is requiring electronic reporting for substantiation claims for the following provisions:

- TSCA section 4 Test Orders allow the Agency to issue an order requiring the development of information on a chemical if EPA finds that the chemical may present an unreasonable risk of injury to health or the environment and such information is needed to determine whether the chemical presents such an unreasonable risk. EPA may also issue an order under section 4(a)(2) requiring the development of information:
 - o to review a notice submitted under TSCA section 5 or to perform a risk evaluation under TSCA section 6(b);
 - o to implement a requirement imposed in a rule, order, or consent agreement under TSCA section 5(e) or (f), or in a rule promulgated under section 6(a);
 - o at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure;
 - o to determine if a chemical substance or mixture manufactured, processed, or distributed in commerce solely for export presents an unreasonable risk of injury to health or the environment in the U.S., pursuant to TSCA section 12(a)(2); and
 - o to prioritize a chemical substance under TSCA section 6(b) (subject to certain limitations).
- TSCA section 5 – Premanufacture Notices, Notices of Commencement of Manufacturer or Import, Polymer Exemptions, Low Volume Exemptions, and Low Release and Low Exposure, and microorganisms:
 - o TSCA section 5(a) (15 U.S.C. 2604(a)(1)(B)(i)), requires manufacturers (which includes importers) of new chemical substances to submit to the PMN of intent to manufacture a new chemical substance at least 90 days before manufacture begins. TSCA section 5(a)(1) also requires notification from any person who proposes to manufacture or process a chemical substance for a use that EPA has by rule determined to be a significant new use. The notice must include, insofar as known or reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (e.g., chemical identity, use and exposure information), plus test information and descriptions of other information related to the effects on

health and the environment of the manufacture, processing, use, distribution in commerce and disposal of the new chemical substance.

- o After PMN review has been completed, the company that submitted the PMN must provide a Notice of Commencement of Manufacture or Import (NOC) to EPA within 30 calendar days of the date the substance is first manufactured or imported for nonexempt commercial purposes. Once a complete NOC is received by EPA, the reported substance is considered to be on the Inventory and becomes an “existing chemical.”
- o Polymer Exemption applies to polymers that comply with certain chemical characterizations and that therefore will not present an unreasonable risk of injury to health or the environment. See 40 CFR 723.250.
- o Low volume exemptions (LVEs) and low release and low exposures (LoREXs) applies to certain categories of new low-volume chemical substances are exempt from full PMN review, i.e., chemicals manufactured at 10,000 kg/year or less. LVE substances undergo a 30-day review. Pursuant to section 5(h)(4) and section 26 of the Toxic Substances Control Act (TSCA), EPA established an exemption category for certain new chemical substances with low environmental releases and human exposures.
- o Microorganisms applies to EPA’s premanufacture screening program for new microorganisms under section 5 of TSCA. EPA considers intergeneric microorganisms to be those formed from organisms in different genera or those formed with synthetic DNA not from the same genus.
- TSCA section 8(c) rule requires producers, importers, and certain processors of chemical substances and mixtures to keep records concerning significant adverse reaction allegations and report those records to EPA upon notice in the Federal Register or upon notice by letter.
- TSCA section 8(d) Health and Safety Data require industry to provide EPA with documentation regarding chemical production, manufacture, distribution, use, disposal, import, and export.
- TSCA section 8(e) Notices of Substantial Risks requires “any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of

such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.”

- TSCA section 12(b) Export Notification requires any person who exports or intends to export a chemical substance or mixture to notify the EPA of such exportation if actions have been taken under TSCA with respect to that chemical substance or mixture. TSCA section 12(b) requires exporters to submit a notice to EPA for each country to which a chemical subject to TSCA section 12(b) requirements is exported. Specifically, TSCA section 12(b) states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which submission of information is required under TSCA section 4 or 5(b), or for which a rule, action or order has been proposed or promulgated under TSCA section 5, 6, or 7, shall notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of the notice and of EPA’s regulatory action with respect to the substance. This proposed rule will require 12(b) export notifications to be submitted electronically.

The modernization of the TSCA enables electronic reporting for both incoming and outgoing information, which greatly reduces the burden on industry to submit the paper substantiations and on OPPT in the processing of paper submissions.

The modernization of the submitting substantiations claims would allow users to prepare and submit their notifications to the Agency electronically using a web-based application. To file electronically, submitters must use the EPA provided application. To access the application, users must register with EPA’s Central Data Exchange (CDX). CDX is the Agency’s portal for submitting information to EPA in a secure manner. When registering, a user will need to ensure they are registering for the Chemical Safety and Pesticide Programs (CSPP) data flow which will provide them access to the Chemical Information Submission System (CISS) where the submissions can be accessed. (Note: Users who have previously registered with CDX are able to add "Submission for Chemical Safety and Pesticide Program (CSPP)" to their current registration.) This reporting tool is compatible with Windows, Mac, Linux, and UNIX based computers, and uses "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet.

Any information being sent via CDX is transmitted using secure technologies to protect CBI. The software encrypts submissions using a Federal Information Processing Standards (FIPS)-compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is downloaded from CDX, and the corresponding private key is sent to EPA. The encryption remains while the submission is transmitted via CDX. The file can be decrypted only with a private key when it has reached its final destination. The NCS is

the only party that possesses the private key, which converts the encrypted text back into readable text.

The same thing will occur for all correspondence going back to the submitter. Software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the software. This rule also enhances communication through CDX. EPA can more readily assure that a communication is available to a company or particular submitter by using CDX to communicate, rather than certified mail or a courier. In CDX, EPA is able to verify that a particular communication is available to the submitter of a particular submission and is able to track the date the communication was sent. EPA believes that these facts satisfy statutory requirements that certain notifications be sent by means that "allows verification of the fact and date of receipt." See Attachment 2 for information on submissions through CDX.

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.

There is no duplication of this mandate or collection activity, and there are no viable alternate sources for the Agency to obtain the information necessary to satisfy the statutory mandate.

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

There is no impact on small businesses. The reporting and recordkeeping requirements associated with TSCA section 14 are applicable to all affected entities, regardless of size of business.

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.

7. The collection methodology is event-based, i.e., it is the submitter's decision to claim information as confidential under section 14 of TSCA.
8. If the collection of information was conducted less frequently, the statutory requirements would not be met.

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

- a) requiring respondents to report information to the agency more often than quarterly;
- b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

- c) requiring respondents to submit more than an original and two copies of any document;
- d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
- e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Not applicable.

10. 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.

Public comments on this collection are being solicited through the associated Notice of Proposed Rulemaking. EPA will address the comments received during the comment period in the final rule and accompanying Response to Comment document.

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

Not applicable.

12. 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.

The Agency's policies allow public involvement while preserving confidentiality. Amended TSCA section 14(a) prohibits disclosure of trade secret information publicly when the requirements of TSCA section 14(c) are met. Also, TSCA section 14(b) allows disclosure of health and safety studies, including underlying information, unless these studies disclose confidential process or mixture information. Under 40 CFR 720.85 and 720.87 (see also 40 CFR part 2), when the specific chemical identity or use information are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in **Federal Register** notices and the public file. Additionally, the submitter must provide a "sanitized" copy of all health and environmental effects information, with confidential information deleted, for placement in the public docket. Within the Agency, only personnel with the required clearance may handle TSCA CBI.

As amended by the Lautenberg Act, TSCA section 14(c)(3) requires that any CBI claims be substantiated concurrently with the submission of the information, except that CBI claims described in TSCA section 14(c)(2) are not subject to substantiation.

These procedures are detailed in the "TSCA CBI Protection Manual," October 2003. EPA believes these procedures protect confidential business information while providing the public with as much information as possible.

13. 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.

Information requirements under TSCA section 5 do not include questions of a sensitive nature.

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

- a) **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden,**

and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

- b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.
- c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.

Impacted respondents would include entities that reported a confidential chemical substance in the TSCA Inventory Notification (Active-Inactive) Requirements reporting rule collection (82 FR 37520, August 11, 2017, codified at 40 CFR Part 710) through a Notice of Activity (NOA) Form A and sought to maintain an existing CBI claim for the specific chemical identity of the chemical substance. This action may be of particular interest to entities that are regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 324 and 325, among others).

Error: Reference source not found provides a cross-walk of the related information collection category that corresponds to each activity.

Table 1. Crosswalk of Revised Provisions

Collection	Substantiation Activity	OMB Control No.
TSCA Section 4 Test Orders; 40 CFR 790	Moved to provisions in 40 CFR 703	2070-0033
TSCA Section 5 General Provisions 40 CFR 720.80	Moved to 40 CFR 703;	2070-0012
TSCA Section 5 PMNs and NOCs; 40 CFR 720.85 and 720.90 and 720 Subpart F	Moved to provisions in 40 CFR 703; review of generic names for NOCs; deleted 720.85, 720.90, and portions of 40 CFR 790, subpart 7 - NOCs	2070-0012
TSCA Section 5 NOCs 720.102(c)(2) and 40 CFR 720.190	Update and clarify reporting instructions and cross reference 40 CFR 703	2070-0012
TSCA Section 5 Polymer Exemption; 40 CFR 723.250(f)	Require electronic reporting	2070-0012
TSCA Section 5 LVEs and	Moved to provisions in 40 CFR 703	2070-

LoRExs 40 CFR 723.50(l) and 723.250(f)		0012
TSCA Section 5 microorganisms; 40 CFR 725 Subpart C	Moved to provisions in 40 CFR 703	2070-0012
TSCA Section 8(a) 40 CFR 704	Moved to provisions in 40 CFR 703	
TSCA Section 8c Allegations of Adverse Effects; 40 CFR 717.19	Require electronic reporting	2070-0012
TSCA Section 8(d) Health and Safety Studies; 40 CFR 716.55(a) and (c)	Check box for CBI submission and moved provisions to 40 CFR 703	2070-0040
TSCA Section 8(e) Substantial Risk Notifications	Require electronic reporting for substantiation	2070-0046
TSCA Section 12(b) Notification of Export; 40 CFR 707.75	Require electronic reporting and add clarification on chemical identity if CBI	2070-0030

This section presents the burden of this information collection activity to respondents in terms of the time required by respondents to perform the activities. The overall unit burden experienced by respondents is estimated by combining activity-level unit burdens at the appropriate scale (e.g. per company or per chemical) to produce estimates for unit burden per submission, by company.

Burden and cost calculations are based on EPA's estimates that 1,100 firms will undertake some or all of the listed activities. This section details the activity-level unit burdens grouped by type of activity. For additional details see Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims see **Attachment 3**.

Rule Familiarization. The burden associated with rule familiarization involves becoming familiar with the full requirements of the rule, which includes reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which reporting requirements will be met.

Compliance Determination. The burden associated with compliance determination involves determining whether a firm has asserted or will assert claims for confidentiality in a submission to EPA under TSCA. As a firm should already know if it has asserted or will assert any claims for confidentiality, there is no burden or cost associated with this activity.

CDX Registration and Electronic Signature. Firms that include a claim for confidentiality in a submission to EPA under TSCA must register with CDX in order to

comply with electronic reporting requirements. Those firms will incur a small amount of burden and cost to carry out the additional paperwork activities that were imposed by the *Electronic Reporting under the Toxic Substances Control Act (TSCA) Final Rule*. This includes the burden associated with activities that facilitate submission of an electronic report: CDX registration and electronic signature. These activities occur only once for each firm. It is expected that each firm will complete CDX registration and electronic signature for five employees comprised of one manager and four technical staff.

Maintaining Company Contact Information. To facilitate ongoing or future communication concerning TSCA submissions, current contact information for submissions must be maintained in CDX. Technical or other contact information for the individuals associated with a particular TSCA submission may be updated by amending the submission via CDX. For submissions that are not accessible via CDX (e.g., submissions that were originally provided on paper or other physical media), updated company contact must be provided via CDX using the appropriate EPA-provided electronic reporting application. In circumstances where ownership of the company or unit of a company has changed, such that contact information for one or more prior TSCA submissions that include confidentiality claims is affected, a notice of transfer of ownership must be directed to EPA via CDX. Instructions for providing this notice and for requesting access to copies of a prior TSCA submission are available see **Attachment 2**.

Generic Name. In the case that a firm submits a generic name that does not meet EPA's requirements, EPA will provide the firm electronic notice of the deficiency and a short period of time to propose a revised generic name. The burden associated with submitting or negotiating a generic name should already be accounted for in existing ICRs. Therefore, EPA expects that the changes under the proposed rule will have no impact on the current burden estimate associated with submitting or negotiating a generic name.

Withdrawing Confidentiality Claims and Amending Public Copy.

Confidentiality claims in TSCA submissions that were originally made via electronic submission may be withdrawn by reopening the submission in CDX, removing confidentiality markings (e.g., confidential checkmarks or bracketing), revising sanitized attachments or copies as appropriate, and then resubmitting the submission.

For submissions that were originally made on paper, or that are no longer accessible to the submitting company via CDX, confidentiality claims may also be withdrawn via CDX appropriate EPA-provided electronic reporting application (e.g., the "TSCA Communications" application). The withdrawal correspondence should clearly indicate the case or document number (or other applicable document identifier or document identifying details) from which CBI claims are being withdrawn, identify the submitting company, and include a list or description of the information for which CBI claims are

being withdrawn, including page numbers, where relevant. Current contact information for the person withdrawing the claim should also be provided, in the event EPA needs clarification concerning which claim or claims are being withdrawn.

a) Following the expiration or EPA’s denial of a TSCA confidentiality claim, the person who asserted the denied or expired claim may prepare and submit a revised public copy of the submission to EPA, following the procedures for voluntarily withdrawing claims described in paragraph 703.5(i).

b) If the person who asserted the denied or expired claim declines or fails to timely provide a revised public copy of the submission that includes the information for which the confidentiality claim(s) were denied or expired, EPA will prepare an addendum to the original public copy, as needed, in order to provide the newly available information to the public.

Reporting Health and Safety Data using Templates. Firms who submit health and safety study information for which templates exist are required to submit those studies in a templated format using OECD Harmonized Templates (<https://www.oecd.org/ehs/templates/>). As a result of reporting requirements from other countries, it is expected that most firms will have already created a templated version of the health and safety information that they are submitting to EPA and will only need to log in and upload documents.

Table 2: Activity Level Burdens

Activity	Burden per Firm			
	Managerial Burden	Technical Burden	Clerical Burden	Total Burden (hours)
Rule Familiarization	2.000	0.000	0.000	2.000
Compliance Determination	0.000	0.000	0.000	0.000
CDX Registration and Electronic Signature	0.930	1.730	0.000	2.670
Maintaining Company Contact Information ¹	0.010	0.020	0.000	0.030
Generic Name	0.000	0.000	0.000	0.000
Withdrawing Confidentiality Claims and Amending Public Copy	0.000	0.700	0.000	0.700
Reporting Health and Safety Data using Templates	0.000	0.050	0.000	0.050

¹The burden presented accounts for maintain company contact information for five employees.

Estimation of industry unit cost per submission involves combining the activity-level unit burdens identified in wage data from the Bureau of Labor Statistics (BLS), as converted from raw wage rate and benefit data to loaded wage rates. Error: Reference source not

found3 presents the resultant loaded wage rates for managerial, professional/technical, and clerical staff.

Table 3: Industry Wage Rates (2020\$)

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

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

b An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (EPA 2020)

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

Table 4: Total Burden and Cost to Industry

Activity	Number of Affected Entities	Total Burden (hours)	Total Cost (2020\$)
<i>First Year One-Time</i>			
Rule Familiarization	1,100	2,200	\$207,988
CDX Registration and Electronic Signature	165	440	\$38,102
Maintaining Company Contact Information	1,100	33	\$2,811
Withdrawing Confidentiality Claims and Amending Public Copy	208	27	\$2,160
Reporting Health and Safety Data using Templates	350	245	\$19,723
One-time, First Year		2,945 hours	\$270,783
<i>Annual, Ongoing (Years 2 and 3)</i>			
Rule Familiarization	55	110	\$10,399
CDX Registration and Electronic Signature	55	147	\$12,701
Maintaining Company Contact Information	1,100	7	\$562
	55	2	\$141
Withdrawing Confidentiality Claims and Amending Public Copy	104	13	\$1,080
Reporting Health and Safety Data using Templates	350	245	\$19,723
Annual, Ongoing		523 hours	\$44,605

Note: Values may not sum due to rounding. Total industry burden and cost are calculated using unrounded numbers and then rounded to the nearest hour and dollar, respectively. Activities without burden (compliance determination and generic name) are not listed in the table.

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

- a) **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- b) **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates,**

agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

- c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There are no operation and maintenance costs associated with this collection.

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

The following describe the Agency's activities once the submission is received via CDX:

- a) For each submission selected for review as part of the representative subset, EPA reviews every individual confidentiality claim in that submission (except claims that are exempt from substantiation and review under TSCA sections 14(c)(2) and 14(g)), including claims made in attachments and amendments available to EPA at the time of the review.
- b) The Agency selects a representative subset of submissions to assure that a minimum of 25% of TSCA submissions with claims other than for chemical identity are reviewed under TSCA section 14(g).
- c) EPA reviews of confidentiality claims in accordance with the procedures:
 - (1) EPA will review all chemical identity claims asserted in TSCA submissions except those that are exempt from substantiation according to section 14(c)(2)(G) of TSCA, and a representative subset of other confidentiality claims (except those that are exempt from substantiation according to section 14(c)(2) of TSCA), comprising at least 25% of all other such claims.
 - (2) EPA will review all timely requests for extension of claims under Section 14(e) of TSCA within 30 days of receipt.
 - (3) EPA will also review or re-review confidentiality claims under certain other circumstances, as set out in TSCA section 14(f).

(4) The 90-day review period described in TSCA section 14(g) begins on the day that EPA accepts a new TSCA submission that includes confidentiality claims. For claims other than for specific chemical identity, the review will take into account amendments to that submission that are made either up to 60 days from the original submission date, or until the Agency issues a final confidentiality determination for the submission, whichever comes first. If a submission is amended to report an additional or different chemical substance that includes a new specific chemical identity claim, the section 14(g) review period for the added chemical identity begins on the day EPA accepts the amendment including the new claim.

d) In the case that EPA determines that a claim or part of a claim is not entitled to confidential treatment, EPA will provide written notice of the denial to the person who made the claim, and provide reasons for the denial or denial in part. The notice will be provided electronically, as described in 40 CFR 703.5(e); the 30-day notice period described in TSCA section 14(g)(2)(B) begins on the next business day following the date the notice is transmitted to the submitter via CDX. Final confidentiality determinations will be published on EPA's website periodically, in accordance with the requirements of TSCA section 26(j).

If EPA concludes that the proposed generic name is not structurally descriptive or otherwise not consistent with the *Guidance*, EPA will provide the submitter with an electronic notice of the inconsistency or insufficiency (via CDX) and provide 10 working days for the submitter to provide a revised generic name. If EPA concludes that the revised generic name is still not acceptable, EPA will reject the submission as incomplete for a further 10 working days, during which any applicable review period will not commence or will be suspended, and reporting requirements will not be considered to have been met until the submission is amended to provide the missing information; if the missing information is not provided in this period, EPA will proceed with review of the submission and may deny the CBI claim(s).

When it is necessary for EPA to contact a TSCA submitter concerning confidentiality claims (e.g., related to a pending or concluded confidentiality claim review, a deficient or incomplete submission, or in relation to the 10-year expiration of a confidentiality claim (described in TSCA section 14(e))), EPA will provide notices and other correspondence to the submitter via CDX, using the contact information provided in the most recent version of the submission, or using the contact information provided in a more recent notice of transfer of ownership relating to that submission. The fact and date of delivery of such notice is verified automatically by CDX. Alternatively, if this initial CDX notice is not deliverable, EPA will send the notice or other communication via CDX to the company contact provided in the most recent TSCA submission made by that company.

In addition to individual notice provided via CDX communication, EPA will periodically publish on its website a list of TSCA submissions with confidentiality claims that are approaching the end of the ten-year period of protection described in TSCA section 14(e). Such TSCA submissions will be referred to by the TSCA case or document identifier (as described in subparagraph (e)(4)) that was assigned to the submission by EPA when it was originally submitted. This list will be published on the EPA website at least 60 days prior to the end of the ten-year period of protection, along with instructions for reasserting and substantiating expiring claims.

When a confidentiality claim is being reviewed pursuant to TSCA section 14(f), EPA will provide, when necessary, notice of such review and an opportunity to substantiate or resubstantiate the affected confidentiality claim to the submitter via CDX using the contact information for the authorized official and/or technical contact provided in the most recent version of the submission or in a more recent notice of transfer of ownership relating to that submission. The fact and date of delivery of such a notice is verified automatically by CDX. Alternatively, if this initial CDX notice is not deliverable, EPA will send the notice via CDX to the company contact provided in the most recent TSCA submission made by that company. Under circumstances in which the notice is not deliverable via CDX to any of these company contacts, EPA will send the notice via courier or US Mail to the company address provided in the most recent TSCA submission made by that company. The notice will provide instructions for substantiating claims that were exempt or for which the submitter was otherwise not required to provide substantiation at the time of initial submission, and for updating or resubstantiating any claims that were previously substantiated.

Table 5: Agency Wage Rate (2020\$)

Labor Category	Data Source for Wage Information	Wage (\$/hour)	Fringes as % wage ^b	Fringe Benefit	Total Compensation	Overhead as % total compensation ^c	Overhead	Loaded Wage (\$/hr)
		(a)	(b)	(c) = (a)*(b)	(d) = (a) + (c)	(e)	(f) = (d)*(e)	(g) = (d) + (f)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates ^a	\$55.75	63.90%	\$35.62	\$91.37	20%	\$18.27	\$109.65

Note: Values may not sum due to rounding. Costs are rounded to the nearest penny for display purposes.

^a Source: U.S. Office of Personnel Management. (2020). Salary Table 2020-DCB. Retrieved June 17, 2020 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB_h.aspx.

^b Source: Falk, J. 2012. "Comparing Benefits and Total Compensation in the Federal Government and the Private Sector." Congressional Budget Office Working Paper Series.

<https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/workingpaper/2012-04fedbenefitwp0.pdf>

^c An overhead rate of 20% is used based on assumptions in Handbook on Valuing Changes in Time Use Induced by Regulatory Requirements and Other U.S. EPA Actions (EPA 2020b).

Estimates of Agency labor required to complete substantiation review are discussed in Table 10 of the Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory see **Attachment 3**. Agency burden is combined with wage data in Table 5 to estimate Agency cost savings.

Table 6: Total Change in Burden and Cost to the Agency (2020\$)

Activity		Annual Frequency	Reduction in Burden per Submission	Total Reduction in Agency Burden	Reduction in Cost per Submission	Total Agency Cost Savings (2020\$)
Electronic Reporting	Mail/packaging receipt	800	-	-	\$20.50	\$16,400
	Scanning, filing and most data entry burden	800	15 minutes	200 hours	\$27.41	\$21,930
	Generating and mailing paper acknowledgement letters	800	13 minutes	173 hours	\$23.76	\$19,006
	Generating rejection letters and incomplete letters	81	5 minutes	6.75 hours	\$9.14	\$740
	Review of polymer exemptions for CBI	12	30 minutes	6 hours	\$54.83	\$658
Maintaining Company Contact Information		66	2 hours	132 hours	\$219.30	\$14,474
Total Annual Cost Savings				518 hours		\$73,208

Note: Values may not sum due to rounding. Costs are rounded to the nearest penny for display purposes.

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

This is a new data collection activity resulting from the Frank R. Lautenberg Chemical Safety for the 21st Century Act. As such, the change being implemented in this ICR period is the addition of new burden and cost for these activities, as presented in Table 4. The total burden to industry for this ICR period is approximately 3,991 hours. This burden is comprised of a one-time burden of 2,945 hours in the first year after the rule is finalized and an annual, ongoing burden of 523 hours in each following year. The total cost to industry for this ICR period is approximately \$359,993. This cost is comprised of a one-time cost of \$270,783 in the first year after the rule is finalized and an annual, ongoing cost of \$44,605 in each following year.

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

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPPT-2021-0419, which is available at <http://www.regulations.gov>. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above.

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

Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are open to the public *by appointment only*. Read more about the operating status available at <https://www.epa.gov/dockets/epa-docket-center-and-reading-room-open-public-appointment-only>

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 or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through <http://www.regulations.gov> using Docket ID Number: EPA-HQ-OPPT-2021-0419.

Ref.	Title
1.	Proposed Rule.
2.	CDX User Guides – TSCA Section 4, 5, 8(c), 8(e), 8(d) and 12(b)
3.	Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims