

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: Confidential Business Information Claims under the Toxic Substances Control Act (TSCA)

EPA ICR No.: 2706.03

OMB Control No.: 2070-0223

Docket ID No.: EPA-HQ-OPPT-2025-3955

Abstract

EPA is renewing the information collection 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. Among the changes to TSCA are new provisions on EPA review, submitter maintenance, time limitations for CBI claims, and an option to extend confidentiality claims for up to 10 additional years. 40 CFR 703 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 following submissions under TSCA may include CBI claims and are subject to the procedural requirements in TSCA and its implementing rules¹:

- TSCA Section 4 Test Orders; 40 CFR 79
- 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)

¹ This represents an example of TSCA submissions for standard, rule-required reporting forms. There are also other TSCA submissions, communications for instance, are also subject to 703 requirements.

- 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 CTSCA Section 8(a); 40 CFR 704 and 711
- TSCA Section 8(b); 40 CFR 710
- TSCA Section 8(c) Allegations of Adverse Effects; 40 CFR 717.19
- TSCA Section 8(d) Health and Safety Studies; 40 CFR 716.55(a) and (c)
- TSCA Section 8(e) Notification of Substantial Risk
- TSCA Section 12(b) Notification of Export; 40 CFR 707.75(d)
- TSCA Title VI Formaldehyde Emissions Standards for Composite Wood; 40 CFR 770

Summary Annual Total Burden and Costs

Information Collection	Average Annual Respondents	Responses per Respondent	Average Annual Burden Hours	Average Annual Costs (2025\$)
Withdrawing Confidentiality Claims, Amending Public Copy, and Extending Claims	104	1	73	\$6,201.10
Re-substantiation of CBI Claims	1,100	2	550	\$46,849.00
Respondent Total	1,504		623	\$53,050.10
Agency Total			1,160	\$150,892.80

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

SUPPORTING STATEMENT

1. Need and Authority for the Collection:

Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

Lautenberg included several significant amendments to the provisions on CBI included in Section 14 of the TSCA (Ref. 1). 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, beginning in 2026 for claims made in 2016.

Regulations implementing the statutory mandate in TSCA section 14 are under 40 CFR 703, and incorporated into 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 720, the confidentiality provision for section 5
- 40 CFR 721, the confidentiality provision for section 5
- 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);
- 40 CFR 770 the confidentiality provisions for reporting formaldehyde emissions; and
- 40 CFR 790, the confidentiality provision of rules concerning section 4 test rules, orders, and agreements.

2. Practical Utility/Users of the Data:

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 requirements of TSCA section 14 and implementing rule at 40 CFR 703 apply 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. CBI claims that expire after 10 years, but may be renewed by request, are discussed in TSCA section 14(e), and exclude information

types exempt from substantiation requirements at the time of initial submission, as listed in section 14(c)(2).

3. Use of Technology:

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.

40 CFR 703 requires electronic reporting of CBI claims and substantiation for all TSCA submissions that include CBI claims, with a few narrow exceptions where electronic reporting may not be practicable. The rule requires that requests to extend CBI treatment for expiring CBI claims must be submitted using the appropriate electronic reporting tool available in EPA's Chemical Information Submission System (CISS).

Users prepare and submit their notifications to the Agency electronically using a web-based application. To file electronically, submitters must use the EPA provided application. The application also permits the user to assert CBI claims (often with a simple checkbox) and automatically prompts for required substantiation. All persons asserting CBI claims under TSCA, including those not previously submitted to EPA in electronic form, would be required to use this application. To access the application, users must register with EPA's Central Data Exchange (CDX) (unless the user has already registered). 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 CISS where the submissions can be accessed. (Note: Users who have previously registered with CDX are able to add 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 National Cryptographic Standards (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 1 for information on submissions through CDX.

4. Efforts to Identify Duplication:

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. Minimizing Burden on Small Entities:

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

This rule does not exempt small businesses. The reporting and recordkeeping requirements associated with TSCA section 14 are applicable to all affected entities, regardless of size of business.

6. Effects of Less Frequent Collection:

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.

The collection methodology is event-based, i.e., it is the submitter’s decision to claim information as confidential under section 14 of TSCA, or to request an extension of an expiring CBI claim.

If the collection of information was conducted less frequently, the statutory requirements would not be met.

7. General Guidelines:

Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

There are no special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.5(d)(2).

8. Public Comment Period and Consultations:

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.

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the *Federal Register* on February 25, 2026, (90 FR 9250), announcing the planned renewal of this information collection activity, soliciting public comment on specific aspects of the ICR and providing a 60-day public comment period.

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 report.

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.

The EPA also consulted eight stakeholders, specifically asking them for information on: 1) publicly available data, 2) frequency of collection, 3) clarity of instructions, 4) electronic reporting and recordkeeping, and 5) their assessment of the regulatory burden estimates expressed by the Agency in this ICR (Attachment 14). The stakeholders consulted were:

- 1) American Chemistry Council
- 2) BASF
- 3) Bergeson and Campbell
- 4) Dow
- 5) Integral Corporation
- 6) OxyChem
- 7) Mitsui Chemicals
- 8) Toyota

Of those consulted, EPA received comments from Dow, OxyChem, and the American Chemistry Council (Attachment 15). EPA also received comments from Millipore Sigma and the Vinyl Institute during the comment period (Attachment 16 and 17).

For those consulted, commenters all noted that the information the Agency collects is not publicly available.

Comment Summary 1: Commenters asserted needed clarity regarding the frequency of collection, commenters stated that under the Agency's current approach, each submission would be treated as a distinct CBI claim with its own ten-year substantiation period, and companies would be required to re-substantiate confidentiality for the same chemical identity repeatedly and indefinitely. The commenter noted that this means a "ten-year" confidentiality period would not function as a true ten-year protection, but rather as a rolling and overlapping series of substantiation deadlines. Commenters recommend that EPA consider an approach in which CBI claims are tracked at the chemical substance level, rather than at the individual submission level. The commenter recommended that instead the Agency should adopt a single ten-year substantiation period to apply to all claims of confidentiality for the chemical identity across TSCA submissions during that period. This recommended approach would better align with the intent of TSCA section 14, to reduce unnecessary administrative burden, and improve predictability and manageability for both submitters and the Agency, while still preserving EPA's ability to review and assess confidentiality claims as required. Commenters also suggested that once a CBI claim is substantiated, that CBI claim will continue to be considered substantiated for the entire 10 years by providing the EPA's Unique Identifier.

Response : Per the requirements of section 14(e) of TSCA, all CBI claims (except those exempt under section 14(c)(2)) expire after 10 years unless an extension is requested and approved. Non-chemical identity claims expire ten years after the submission in which they were asserted is made (e.g., non-chemical identity claims made in 2016 in a CDR submission expire in 2026). Expiration of these claims is tracked on the submission level, i.e., all of the claims in a given submission expire at the same time (except chemical identity claims).

The expiration of chemical identity claims is not tracked on the submission level--chemical identity claims are tracked on the individual chemical level. Chemical identity claims expire every ten years also, but the expiration date is ten years after the first claim made on or after June 22, 2016. As EPA explained in (83 FR 30168, June 27, 2018), each confidential chemical identity has one unique identifier and one CBI claim expiration date, both of which are required to be published on a list at least annually (EPA implements this requirement by including the UID and expiration date in the public TSCA Inventory listing, typically updated twice a year). The claim expiration date is not reset each time the same chemical identity is reasserted in a new TSCA submission or else the chemical identity claim would either have multiple expiration dates (corresponding to each submission concerning that substance) or it would never have a fixed expiration date at all, which is inconsistent with the requirements of section 14(e)).

Relatedly, TSCA requires that submitters of CBI claims, including for chemical identity, assert, substantiate, and follow other requirements in section 14 of TSCA each time they submit a CBI claim. Section 14 also requires that EPA review every chemical identity CBI claim asserted for a chemical that is offered for commercial distribution every time it is asserted. EPA cannot waive or ignore these statutory requirements. EPA must deny CBI claims that are asserted without substantiation and will consider CBI claims as waived or withdrawn when information is submitted under TSCA without a claim of CBI. CBI claims only expire after the 10-year period of protection afforded to that particular claim, though such claims may be time-limited by their submitter to less than 10 years, and may be waived, withdrawn, or denied before that 10-year period has elapsed.

Comment Summary 2: For clarity of instructions, commenters asserted that the regulatory requirements are clear however, a commenter suggested needed clarity on the re-substantiation process. Specifically, the commenter noted the Agency should be proactive in reaching out to companies regarding claims because of personnel turnover, and that the CBI claims should be based on chemical substances level and not the initial submission. The commenters also recommended that CBI claims associated with CDR submissions be addressed during the subsequent CDR reporting cycle, rather than triggering independent re-substantiation obligations tied to prior submissions. Commenters noted instructions provided in CDX are clear, although the Agency could provide updates to the reporting templates since they were last updated in 2023. Commenters also asserted that the Agency should provide guidance on re-substantiation submissions that covers 1) submission types in scope for the 10-year expiration and extension process 2) how expiration is claims are calculated 3) duplicative claims for other types of TSCA reporting ie CDR, and sections for “scope and applicability” and a checklist for “what must be substantiated.”

Response: EPA has provided initial guidance and notice of expiring claims on its website <https://www.epa.gov/tsca-cbi/cbi-claim-expiration>; see also (91 FR 371, January 6, 2026) and will be enhancing this initial information as the CBI claim extension request program is implemented. EPA is issuing expiration notices by listing submissions and chemical identities with expiring claims on its website and, where feasible, by individual electronic notice to companies via CDX. This is consistent with the notice requirements in TSCA section 14(e) and 40 CFR 703.5(h).

EPA does not view the assertion of similar CBI claims in subsequent CDR reporting periods as asserting the same claim (except in the case of chemical identity claims). As such, approval of a company's CBI claim for export volume or company identity in 2020 does not depend on whether it made similar claims in 2016. If a company lets its non-chemical identity 2016 CDR claims expire in 2026, the expiration of those claims does not affect the 2020 or 2024 CDR claims the same company may have made for similar information. Even if these periodic claims for similar information were considered the same claim, companies would still have to assert and substantiate the claim each time the information is reported, as is the case with chemical identity claims; TSCA section 14(e) provides that CBI claims automatically expire after 10 years unless extension is requested. Section 14(e) does not provide a 10-year period wherein CBI treatment is guaranteed, however—claims may be reviewed and denied, waived or withdrawn, or expire on a shorter timeframe as specified by the person asserting the claim. Given that CDR reporting is on a four-year cycle, it would be premature for EPA to provide the required section 14(e) 60-day notice of expiration during the next CDR reporting cycle (6 years too early).

TSCA section 14 requires that CBI claims be asserted and supported with substantiation and meet other requirements every time they are submitted (see TSCA section 14(c) and 40 CFR 703; see also (82 FR 6522, January 19, 2017 (FRL-9958-34))). TSCA section 14(g) also requires that these claims be reviewed by EPA and approved or denied each time such claims are submitted (all chemical identity claims and at least 25% of other claims). EPA cannot waive these statutory requirements.

EPA notes that the optional substantiation templates the commenter is likely referring to are no longer in regular use, as substantiation has been incorporated into most reporting applications (the templates may continue to be helpful guides to providing substantiation, so they remain available on EPA's website as a resource). The substantiation templates are not used for requesting extension of CBI claims—as required by 40 CFR 703, virtually all TSCA submissions including CBI claims, including requests for extension, must be made via CDX. The appropriate reporting tool for requesting CBI claim extensions has recently been made available.

With respect to the request for guidance on which types of CBI claims or TSCA submissions are affected by CBI claim expiration, 40 CFR 703.7 describes which TSCA submissions are subject to review under section 14(e) and (g).

Concerning notice, TSCA section 14(e) requires that EPA provide notice of expiration and an opportunity to request an extension of CBI claims prior to being permitted to disclose the information. 40 CFR 703.5(h) explains how EPA will provide notice of expiring claims—by periodically posting a list of claims (listed by submission or chemical identity (usually accession number)) approaching their expiration date, and by electronic notice (to the extent feasible, given company changes and staff turnover).

TSCA section 14(e) defines how expiration dates must be calculated for most claims, and EPA provided additional information on how expiration would be calculated for chemical identity claims in 2018, as related to assigning and applying the unique identifiers required by TSCA section 14(g)(4) and publishing these and chemical identity claim expiration dates (also required by TSCA section 14(g)(4); see (83 FR 30168 June 27, 2018 (FRL-9979-59))).

Comment Summary 3: For electronic reporting, commenters supported the use, however there are challenges with CDX, especially for use as a communication tool with stakeholder, and better help desk support.

Response : EPA appreciates this comment.

Comment Summary 4: After reviewing the burden, the costs estimates provided in the Supporting Statement, commenters believed they were assessed correctly. However, other commenters noted that the wage rate are underestimated and the Agency does not account for industry activities associated with the assertion of CBI claims, and the Agency should also add burden for compliance determination, rule familiarization, and withdrawing confidentiality claims. Another commenter noted that the operational burdens of locating historical claims, updating contacts, legal review, and ownership transfer should be accounted for in the Agency's analysis.

Response: Industry activities associated with asserting or withdrawing CBI claims, rule familiarization and other activities relating to assertion and maintenance of CBI claims up until the time a CBI claims expires are now incorporated into other ICRs supporting the various TSCA reporting rules. Additionally, the TSCA procedural rule implementing TSCA section 14(e) has not been amended since 2023, so there is no new rule to become familiar with as relates to this ICR renewal.

Public Comment Summary 5: Public comments requested the Agency allow companies to submit a single CBI extension to decrease the burden of submitting individual extensions, and

the commenters requested that the Agency allow for extensions to be submitted using a filing number or company name instead of by the authorized agent. Another public commenter requested the Agency account for burden associated with asserting CBI claims for TSCA section 4 test order submissions, as well as the burden of identifying CBI, substantiating the CBI claim, and preparing genericized submissions under TSCA section 6. Commenters also noted that the Agency should increase the burden for submitting information to the Agency through CDX.

Response: The extension request application allows a person to make one request to extend some or all non-chemical identity claims in a given submission (identified by submission number). They can rely on previously provided substantiation or they can provide new substantiation. For chemical identities (identified by accession number or other identifier specific to that chemical), they can request extension for more than one expiring chemical identity at the same time and may, again, rely on previously provided substantiation or provide new substantiation. Any registered CDX user with an AO or secondary AO role may request extension of a claim.

Burdens associated with asserting CBI claims in section 4 and 6 submissions are already included in the ICRs for those sections of TSCA.

The Agency thanks all commenters for their comments and has considered them in developing this ICR.

9. Payments of Gifts to Respondents:

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

No payments or gifts are provided to respondents.

10. Provisions for Protection of Information:

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 CBI when the requirements of TSCA section 14(c) are met. Also, TSCA section 14(b)(2) allows disclosure of health and safety studies pertaining to chemical

substance that have been offered for commercial distribution, 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.

11. Justification for Sensitive Questions:

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 do not include questions of a sensitive nature.

12. Respondent Burden Hours and Labor Costs:

Provide estimates of the hour burden of the collection of information:

- *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.*
 - *If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens. 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*
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information collection activities should not be included here. Instead, this cost should be included as O&M costs under on-labor costs covered under question 13.

12a and b. Respondents/NAICS Codes and Information Requested

Impacted respondents include entities that previously asserted a TSCA CBI claim and have decided to request to extend that CBI claim, or who have been requested to provide substantiation (or waive their CBI claims) in the context of a TSCA section 14(f) CBI review.

12c. Respondent activities and frequency

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 up to 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.

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.

Withdrawing Confidentiality Claims, Amending Public Copy, and Extending CBI Claims.

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 (i.e., the "TSCA Communications" application). The withdrawal correspondence must 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 must 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 is encouraged to 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.

c) Persons whose CBI claims are expiring will need to consider every ten years whether they would like to request extension of the period of protection for these CBI claims for another ten years.

Re-substantiation. Pursuant to TSCA section 14(e), most CBI claims expire ten years after they are asserted. Submitters of expiring claims may request an extension of these claims every ten years, with the first CBI claims expiring in 2026. EPA must provide submitters notification of expiring claims at least 60 days prior to expiration, and submitters who wish to extend the period of CBI protection for their claims must notify EPA at least 30 days before their claims expire. To support a request for CBI claim extension, TSCA 14(e) requires that submitters substantiate the need to extend CBI protections. Submitters may do so by providing new responses to a standard set of substantiation questions, or by referring to previously provided substantiation and certifying that the older substantiation is still accurate and applicable.

Table 2: Activity Level Burdens

Activity	Burden per Firm			
	Managerial Burden	Technical Burden	Clerical Burden	Total Burden (hours)
Compliance Determination	0.000	0.000	0.000	0.000
Withdrawing Confidentiality Claims and Amending Public Copy and Extension of Claims	0.000	0.700	0.000	0.700
Re-substantiation	0.000	0.250	0.000	0.250

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 (2025\$)

Labor Category	Data Series ^a	Date	Wage	Fringe Benefit	Total Compensation	Overhead % of Total Compensation ^b	Overhead	Hourly Loaded Wages ^c
			(a)	(b)	(c) = (a)+(b)	(d)	(e)=(c)*(d)	(f)=(c)+(e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	24-Dec	\$58.01	\$26.57	\$84.58	20%	\$16.92	\$101.50
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	24-Dec	\$47.87	\$23.11	\$70.98	20%	\$14.20	\$85.18
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	24-Dec	\$24.84	\$11.34	\$36.18	20%	\$7.24	\$43.42

Note: Values may not sum due to rounding.

12d. Respondent Burden Hours and Labor Costs

Table 4: Total Burden and Cost to Industry

Activity	Number of Affected Entities	Total Burden (hours)	Total Cost (2025\$)
Withdrawing Confidentiality Claims, Amending Public Copy, and Extension of Claims	104	72.8	\$6,201.10
Re-substantiation	1,100	550	\$46,849.00
Annual		622.8 hours	\$53,050.10

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. Respondent Capital and O&M Costs:

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.

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.

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. Agency Costs:

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.

14a. Agency activities and frequency

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

1) EPA will review all timely requests for extension of claims under Section 14(e) of TSCA within 30 days of receipt.

2) EPA will also review or re-review confidentiality claims under certain other circumstances, as set out in TSCA section 14(f).

In the case that EPA determines that a claim or part of a claim is not entitled to confidential treatment (or continued 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).

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, or, in the case of confidential chemical identities, the TSCA Inventory accession number for that substance. 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 to request extension of CBI protections.

When a confidentiality claim is reviewed pursuant to TSCA section 14(f), EPA will provide, when necessary, notice of such review and an opportunity to substantiate or

re-substantiate 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 substantiating any claims that were previously substantiated.

Table 5: Agency Wage Rate (2026\$)

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	\$66.14	63.90%	\$42.26	\$108.40	20%	\$21.68	\$130.08

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. (2026). Salary Table 2026-DCB. Retrieved January 20th, 2026 from Pay & Leave: Salaries & Wages: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/26Tables/html/DCB_h.aspx

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

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

14b. Agency Burden and Labor Costs

Estimates of Agency labor required to complete substantiation review are discussed in Table 10 of the Economic Analysis for the TSCA Final Rule “Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory” (Ref 14). 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 (2026\$)

Activity	Annual Frequency	Burden per Submission	Total Agency Burden	Total Agency Cost (2026\$)
Review of re-substantiation TSCA section 14(e)	1,100	1 hour	1,100 hours	\$143,088.00
Review of CBI determination under TSCA section 14(f)	5	12 hours	60 hours	\$7,804.80
Total			1,160 hours	\$150,892.80

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

15. Change in Burden:

Explain the reasons for any program changes or adjustments reported on the burden worksheet.

There is a decrease of 709 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's successful implementation of the Lautenberg provisions governing the assertion of CBI claims through the finalization of the Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA) rule published on June 7, 2023 (88 FR 37155 (8223-02-OCSPP)) which amended and reorganized requirements concerning Agency review and treatment of confidentiality claims. This information collection also accounts for provisions that allow submitters the opportunity to request an extension of CBI claims and for EPA to review time limitations for CBI claims and extension of confidentiality claims for up to 10 additional years. This change is an adjustment.

16. Publication of Data:

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.

The Agency does not intend to publish results of this information collection.

17. Display of OMB Control Number and Expiration Date on Instruments:

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

The Agency plans to display the expiration date for OMB approval of the information collection on all instruments.

18. Certification Statement:

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

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

SUPPLEMENTAL INFORMATION

PRA Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0223). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 704, 711, 716, 717, 720, 721, 723, 725, 790. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be between 14 to 525.85 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Data & Enterprise Programs Deputy Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C.

20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

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

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

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR 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-2025-3955.

	Title
1.	CBI Substantiation (EPA Form PFN-7710-57)
2.	Biotech (EPA Form 6300-017)
3.	Premanufacture Notice (EPA No. 7710-25)
4.	Notice of Commencement of Manufacture or Import (NOC) (EPA Form 7710-56)
5.	Form U (9600-010)
6.	TCSA Section 8(e) Notice (EPA Form 9600-030)
7.	TSCA Section 12(b) Export Notification (EPA Form 9600-031)
8.	TSCA Section 8(d) Health and Safety Data Reporting (EPA Form 9600-032)
9.	TSCA Section 4 Submissions (EPA Form 9600-034)
10.	Mercury Electronic Reporting (9600-035)
11.	EPA Risk Evaluation (EPA Form 9600-036)
12.	Formaldehyde Title VI– Annual Laboratory Report, Annual Product Report, Failure to Comply, Third Party Annual Report, Third Party Failure to Comply Quarterly Test, Third Party Quality Control Limit Exceedance, and Third Party Reduced Testing and Exemption Notification (EPA Form 9600-049)
13.	Notice of Activity of Manufacturer, Import or Processing Form A and B (9600-060)
14.	Consultation
15.	Consultation Responses
16.	Public Comment – Milipore Sigma
17.	Public Comment – Vinyl Institute

REFERENCES

1. [15 U.S.C. 2613](#) Toxic Substances Control Act
2. [40 CFR 703](#) - Confidentially Claims
3. [40 CFR 704](#) - Reporting and Recordkeeping
4. [40 CFR 707](#) - Chemical Imports and Exports
5. [40 CFR 716](#) - Health and Safety Data Reporting
6. [40 CFR 717](#) - Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment
7. [40 CFR 720](#) - Premanufacture Notification
8. [40 CFR 721](#) (Subpart A through D) – Significant New Uses of Chemical Substances
9. [40 CFR 721](#) (Subpart A through D) – Significant New Uses of Chemical Substances
10. [40 CFR 770](#) - Formaldehyde Standards for Composite Wood Products
11. [40 CFR 790](#) - Procedures Governing Testing Consent Agreements and Test Rules
12. BLS, 2006. U.S. Bureau of Labor Statistics, *Employment Cost Index News Release Text: Employment Cost Index, March 2006* (April 28, 2006), at <http://www.bls.gov>.
13. BLS, 2018. U.S. Bureau of Labor Statistics. “Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2017” Accessed March 26, 2018. <https://www.bls.gov/web/ecec/ecsuphst.pdf>
14. EPA, 2023 Economic Analysis for the Final Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (April 2, 2023).
15. EPA (2023) Final Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory.