

Supporting Statement for a Request for an Addendum to the Information Collection Request (ICR) under the Paperwork Reduction Act (PRA)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

This document quantifies burden issues associated with the supplemental notice of proposed rulemaking (SNPRM) to the Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Review Plan Rule) proposed rule, April 23, 2019 [RIN: 2070-AK21]. (84 FR 16826). This is an addendum to the ICR and identifies the incremental additional burdens related to the supplement to the proposed rule.

1(a) Title of the Information Collection(s)

TITLE: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

EPA ICR No.: 2594.01 OMB Control No.: 2070-0210

Docket ID No.: EPA-HQ-OPPT-2018-0320

Reference ICR: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications (EPA ICR No. 2565.03; OMB Control No. 2070-0201)

1(b) Short Characterization/Abstract

The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, required EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, EPA finalized a rule, the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive Rule”) requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016. 82 FR 37520 (8/11/17). Included in the Active-Inactive Rule were provisions for the submission of confidential business information (CBI). Submitters were required to substantiate all CBI claims made in that data collection, except for chemical substance identity. If the chemical was reported pursuant a retrospective reporting requirement, submitters had an option to voluntarily substantiate the CBI claim; if the chemical was reported pursuant a prospective reporting requirement, the submitters had to substantiate the CBI claim at the time of filing.

TSCA section 8(b)(4)(C) requirement that “(n)ot later than 1 year after the date on which the Administrator compiles the initial list of active substances, the Administrator shall promulgate a rule that establishes a plan to review all CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the list.” To address this requirement, the Agency published a proposed rule titled Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (RIN 2070-

AK21) (Review Plan Rule) on April 23, 2019 (84 FR 16826). Note that the proposed rule also addresses industry requirements for substantiating CBI claims on Chemical Identity, as asserted in their Form A submissions under the Active-Inactive Rule (see also reference ICR).

EPA is now supplementing and revising certain aspects of that proposal in response to a recent federal court decision remanding the Active-Inactive Rule, which implicates changes to requirements for Form A under the proposed Review Plan Rule and changes to requirements for Form B under the Active-Inactive Rule. EPA is addressing substantiation requirements pertaining to reverse engineering. The SNPRM proposes two additional questions that manufacturers and processors would be required to answer to substantiate CBI claims for specific chemical identifies asserted in an NOA Form A and an NOA Form B and proposes procedures for supplementing previously-submitted substantiations with responses to those questions.

Two ICR addendums are being prepared for incremental changes to both the proposed Review Plan Rule and the Active-Inactive Rule. This ICR addendum accounts for the burden for these additional burdens caused by the new Form A requirements. A second ICR addendum is being prepared to account for the burden associated with the new Form B requirements (as applied to the ICR for the Active-Inactive Rule).

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

For the reasons noted above in order to comply with the statutory requirements of TSCA, EPA is now supplementing and revising certain aspects of the Review Plan Rule proposal in response to a recent federal court decision remanding the Active-Inactive Rule in order for EPA to address substantiation requirements pertaining to reverse engineering. This supplement proposes two additional questions that manufacturers and processors would be required to answer to substantiate CBI claims for specific chemical identifies asserted in a Notice of Activity Form A (retrospective reporting form) or B (prospective reporting form) and proposes procedures for supplementing previously-submitted substantiations. The additional questions in this SNPRM would apply to information proposed to be collected for NOA Form A's under the April 2019 proposed rule. The same two additional questions would apply to information collected in NOA Form B's.

This ICR addendum accounts for the additional burden identified in the Supplemental Notice of Proposed Rulemaking for Form A submissions.

A separate ICR addendum is being developed accounting for the additional burden associated identified in the Supplemental Notice of Proposed Rulemaking for Form B submissions.

2(b) Practical Utility/Users of the Data

No change from reference ICR.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

The collection of the information is mandated by TSCA section 8(b)(4)(C) and (D). The information sought is necessary to address this requirement. While information could have been provided voluntarily pursuant the Active-Inactive Rule, persons who were required to substantiate claims, and did not do so through the voluntary collection, will need to comply with this collection. Additionally, per this SNPRM, requirements for NOA Form A submissions have changed to include two additional questions. These two questions are not part of the Form A reporting requirements for the Active-Inactive Rule. Therefore, these additional questions covered in this ICR Addendum need to be answered. This information provided cannot be obtained elsewhere.

3(b) Public Notice Required Prior to ICR submission to OMB

The proposed rulemaking serves as the public notice for this ICR. Interested parties should submit comments referencing Docket ID No. EPA-HQ-OPPT-2018-0320 to the address listed at the end of this document. Responses will be taken into account in developing the final rulemaking.

3(c) Consultations

There have been no additional consultations to those noted in the reference ICR.

This collection does not exceed any of the Paperwork Reduction Act (PRA) guidelines at 5 CFR 1320.6.

3(d) General Guidelines

No change from reference ICR.

3(e) Confidentiality

No changes from reference ICR.

3(f) Sensitive Questions

No changes from reference ICR.

This collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes No change from reference ICR

4(b) Information Requested

(i) Data elements, including recordkeeping requirements

Persons subject to this are persons subject to the Active-Inactive Rule and who claimed specific chemical identity as confidential in that collection.

This SNPRM proposes two additional questions that these would be required to answer. The additional questions in this SNPRM would apply to information proposed to be collected for NOA Form As under the April 2019 proposed rule and would also apply to information collected for NOA Form Bs under the previous rule, the final TSCA Inventory Notification (Active-Inactive) Requirements Rule (as noted before, the burden is covered by a separate ICR addendum).

The questions are as follows:

1. Does this particular chemical substance leave the site of manufacture or processing in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?
2. If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by the analysis of the product?

Under 40 CFR 710, submitters must keep documentation of information in a TSCA section 8(b) notice for five years from the date of submitting the notice.

(ii) Submitter Activities/Information Collections (ICs)

- Rule familiarization.
- Compliance determination.
- CBI substantiation or identify previous substantiation.
- Date and time stamps.

5. THE INFORMATION COLLECTED—AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

No changes from reference ICR

5(b) **Information Requested**

No changes from referenced ICR except that persons subject to this Rule will be required to address the two additional questions previously identified.

5(c) **Collection Methodology and Management**

No change from referenced ICR.

5(d) **Small Business Flexibility**

No change from reference ICR.

5(e) **Collection Schedule**

No change from reference ICR.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This analysis presents the burden and cost estimates for affected entities, and covers submission of two additional CBI substantiation questions that pertain to a chemical identity's susceptibility to reverse engineering.

Burden and cost calculations are based on EPA's estimates that substantiations will be received for 5,888 chemical-specific amendments to NOA Form As, submitted by 252 companies. EPA estimates reporting according to three groups of reporters: (1) reporters who voluntarily provide upfront substantiation under the Active-Inactive Rule; (2) reporters who cite a previous reference for substantiation claims under the proposed rule; and (3) reporters who provide full substantiation under the proposed rule. For a more detailed description of each group of reporters, see the *Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Docket # EPA-HQ-OPPT-2018-0320)* (Cost Memo) (Nielsen, 2019b)

6(a) Estimating Respondent Burden

This section presents the burden of this information collection activity to respondents in terms of the time required by companies to perform the activities as outlined in Section 3 of this document. The overall unit burden experienced by companies is estimated by combining activity-level unit burdens based on chemical-specific submissions and the estimated total number of chemical-specific submissions to derive the average unit burden per submission, by company. This section details the activity-level unit burden and groups of submission types. For additional details and discussion, see the Cost Memo (Nielsen, 2019b).

The required activities under the SNPRM includes an incremental increase in the number of CBI chemID substantiation questions required, with two questions added to solicit additional information about a specific chemID's susceptibility to reverse engineering. The questions are as follows:

1. Does this particular chemical substance leave the site of manufacture or processing in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?
2. If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by the analysis of the product?

The activity-level unit burden required to complete these two additional questions is 0.190 hours per chemical-specific response.

23 companies in Group (2) with 98 chemical-specific submissions would experience no incremental burden under the SNPRM to the proposed rule since their substantiation fulfillment is not based on the CBI substantiation questions included in the NOA Form A.

For 149 companies in Group (1) with 3,137 chemical-specific submissions, the incremental average burden per respondent is 3.990 hours. For 103 companies in Group (3) with 2,751 chemical-specific submissions, the incremental average burden per respondent is 5.130 hours.

6(b) Estimating Respondent Cost

Estimation of industry unit cost per submission involves combining the activity-level unit burdens identified in Section 6(a) with wage data. Cost estimates are based on the same loaded wage rates used in the economic analysis for the proposed rule (EPA, 2019).

As described in Section 6(a), respondents in Group (2) would experience no incremental burden or cost under the SNPRM to the proposed rule. Industry company-level incremental unit costs are \$309 for the average company in Group (1) and \$398 for the average company in Group (3).

For total industry incremental burden and cost by reporting group, see Table 1 of this document in Section 6(d).

6(c) Estimating Agency Burden and Cost

Regarding the SNPRM, the relevant agency activities involve the management of NOA submissions as part of the CBI data review, as reflected in the proposed rule's burden estimate for Agency review of the CBI chemID claims at 1.5 hours. This estimate is not expected to change appreciably from the current burden estimate in the proposed rule of 1.5 hours per chemical-specific NOA submission (Nielsen, 2018). This basis reflects the view that the current estimate is sufficiently robust to incorporate the additional agency staff review time spent handling the additional two questions in the CBI chemID substantiation (Nielsen, 2019a).

6(d) Bottom Line Burden Hours and Costs

Total industry incremental burden and cost for the SNPRM to the proposed rule are estimated by combining the activity-level unit burden and cost with the total number of responses for each reporting group, as derived in the Cost Memo (Nielsen, 2019b). Total industry burden and cost are presented in Table 1.

Table 1. Estimated Incremental Burden and Cost for the SNPRM to the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

Reporting Group	Respondents	Responses (chemical-specific submissions)	Burden (Hours)	Cost (2017\$)
Form A Group (1) – Submissions with Voluntary Upfront CBI Substantiation	149	3,137	595	\$46,090
Form A Group (2) – Submissions with CBI Substantiation Using Reference	23	98	0	\$0
Form A Group (3) – Submissions with Full CBI Substantiation	103	2,751	528	\$40,964
TOTAL, Form A	275		1,123	\$87,054

General Note: Average burden and cost per respondent as described in Section 6(a) and 6(b), respectively, are based on dividing the total burden or cost for each reporting group by the number of respondents in that reporting group.

The following table displays the annual burden and costs borne by respondents associated with submitting substantiation for claims of confidentiality for chemical substance identity as part of an amended NOA Form A to address two additional substantiation questions as a result of this information collection for the period of this ICR.

Table 2. Annual Incremental Burden for the SNPRM to the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

Burden Category	Burden Hours				
	Year 1	Year 2	Year 3	Total ICR Period	Average Annual ICR Period
Form A Group (1) - Submissions with Voluntary Upfront CBI Substantiation	595	0	0	595	198
Form A Group (2) - Submissions with CBI Substantiation Using Reference	0	0	0	0	0
Form A Group (3) - Submissions with Full CBI Substantiation	528	0	0	528	176
Industry Burden, Total	1,123	0	0	1,123	374

6(e) Reasons for Change in Burden

This is a new data collection activity resulting from the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires additional responsibilities of EPA in maintaining the TSCA Inventory, and imposes reporting requirements on regulated entities wishing to maintain claims of confidentiality for chemical substance identity. Specific to this SNRPM, EPA is addressing substantiation requirements pertaining to reverse engineering in response to a recent court ruling remanding the Active-Inactive Rule by adding two additional substantiation questions. As such, the change being implemented in this ICR period is the addition of new burden and cost for activities associated with the two new questions, as presented in Table 2. The total burden to industry for this ICR period is 1,123 hours, all occurring during a 90-day reporting period after the rule is enacted.

6(f) **Burden Statement**

The industry burden for this collection of information annually is estimated to average 3.990 hours per response where the respondent provided submissions with voluntary upfront CBI substantiation, and 5.130 hours per response where the respondent is providing full CBI substantiation under the proposed rule. An Agency may not conduct or sponsor such a request and a person of facility is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for the rulemaking that includes this ICR under Docket ID No. EPA-HQ-OPPT-2018-0320 which is available for online viewing at <https://www.regulations.gov>, or in-person viewing at the Pollution Prevention and Toxics Docket in EPA Docket Center (EPA/DC). EPA/DC Public Reading Room is located in the William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Ave., N.W., Washington, DC. EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

You may submit comments regarding 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. Submit your comments, referencing Docket ID No. EPA-HQ-OPPT-2018-0320 and OMB Control No. 2070-AK21, to both (1) EPA online using <https://www.regulations.gov> (our preferred method), or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., N.W., Washington, DC 20640, and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

7. REFERENCES

- EPA. (2019). Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory.
- Nielsen, L. (2018). Email from Laura Nielsen to Scott Sherlock and Tracy Williamson. September 27, 2018. TSCA CBI Review Plan Rule - Information for Burden Estimates.
- Nielsen, L. (2019a). Email from Laura Nielsen to Scott Sherlock and Tracy Williamson. June 11, 2019. Cost Memo Bases - SNPRM Procedures for Review of CBI Claims for the Identity of Chemical on the TSCA Inventory.
- Nielsen, L. (2019b, June 27). Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Docket # EPA-HQ-OPPT-2018-0320).