

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. (84 FR 16826) as it applies to the TSCA Inventory Notification (Active-Inactive) Requirements Rule (“Active-Inactive Rule”). 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: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications

EPA ICR No.: 2565.04. OMB Control No.: 2070-0201

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

Reference ICR: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (EPA ICR No.: 2594.02 OMB Control No.: 2070-0210)

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 B requirements for the Active-Inactive Rule. A second ICR addendum is being prepared to account for the burden associated with the new Form A requirements as applied to the SNPRM.

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 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 under the Active-Inactive Rule.

This ICR addendum accounts for the burden for these additional burdens caused by the new Form B requirements for the Active-Inactive Rule.

A second ICR addendum is being prepared to account for the burden associated with the new Form A requirements as applied to the SNPRM.

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. The information provided in a NOA Form B about the new questions covered in this ICR Addendum need to be answered.

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.

The 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 two chemical-specific NOA Form B submissions from one company on an annual basis. EPA estimates reporting based on a total of 30 chemical-specific submissions from 20 different companies, five percent of which would include CBI chemID claims (EPA, 2017). For a more detailed description of estimated reporting, 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. For one company with two chemical-specific submissions in a NOA Form B requiring CBI chemID substantiation in a given year, the incremental respondent burden is 0.380 hours on an annual basis.

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). For one company with two chemical-specific submissions in a NOA Form B requiring CBI chemID substantiation in a given year, the incremental respondent cost is \$29 on an annual basis.

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 Active-Inactive 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 are 0.4 hours and \$29 on an annual basis, as described in Sections 6(a) and 6(b), respectively.

Table 1. Annual Incremental Burden for the SNPRM to the Active-Inactive Rule

Burden Category	Burden Hours
	Average Annual ICR Period
Form B – Future Submissions with Full CBI Substantiation	0.4
Industry Burden, Total	0.4

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 1. The total burden to industry for this ICR period is 0.4 hours occurring on an annual basis after the rule is enacted.

6(f) Burden Statement

The industry burden for this collection of information annually is estimated to average 0.400 hours per response. An Agency may not conduct or sponsor such a request and a person or 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 oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

7. REFERENCES

- EPA. (2017). Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements. Docket Number EPA-HQ-OPPT-2016-0426 (August 11, 2017).
- 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).