

Supporting Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications

OMB Control No.: 2070-0201

EPA ICR No.: 2565.05

EPA Form No.: 9600-06 (Notice of Activity Form B)

Docket ID No.: EPA-HQ-OPPT-2020-0413

1(b) Short Characterization/Abstract

This information collection request (ICR) addresses the reporting and recordkeeping requirements under section 8(b) of the Toxic Substance Control Act (TSCA) that are associated with the TSCA Chemical Substance Inventory (TSCA Inventory), as codified in 40 CFR Part 710. TSCA section 8(b) specifically requires that EPA compile and keep current a list of chemical substances manufactured or processed for commercial purposes in the United States. That mandate was amended in 2016 and TSCA section 8(b)(4) requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. The first TSCA Inventory with all chemical substances designated as “active” or “inactive” published in February 2019.

Starting August 5, 2019, manufacturers and processors are required to notify EPA before reintroducing inactive substances into U.S. commerce. The implementing regulations allow manufacturers and processors to notify EPA that it must change the commercial activity designation of the subject chemical substance from inactive to active on the TSCA Inventory.

In March 2020, EPA amended 40 CFR part 710 to revise the requirements for companies to substantiate their confidential business information (CBI) claims for the specific chemical identities of substances on the TSCA inventory. The burden and activities in that amendment are covered by a rule related addendum to this ICR identified under OMB Control No. 2070-0210 (EPA ICR No. 2594.03).

At this time, the information collection activities covered in the existing ICR related to the time-limited one time reporting (EPA Form No. 9600-05; Notice of Activity Form A), and the retrospective substantiation of CBI imposed by the 2020 amendment that is covered by the ICR addendum identified under OMB Control No. 2070-0210 (EPA ICR No. 2594.03) are now complete and are not included in this ICR.

This ICR addresses the activities and burdens associated with the ongoing reporting (EPA Form No. 9600-06; Notice of Activity Form B), including the substantiation of CBI and related recordkeeping requirements in 40 CFR part 710. (See **Attachment C**).

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

TSCA section 8(b), 15 U.S.C. 2607, requires EPA to compile, keep current and publish a list of each chemical substance that is manufactured or processed, including imports, in the United States for uses under TSCA. As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016, TSCA sections 8(b)(4) and 8(b)(5) define additional EPA responsibilities for maintaining the TSCA Inventory.

Pursuant to TSCA section 8(b)(4) as amended, the first TSCA Inventory with all chemical substances designated as “active” or “inactive” published in February 2019.

TSCA section 8(b)(5)(A) requires EPA to maintain active and inactive designations for chemical substances on the TSCA Inventory. TSCA section 8(b)(5)(B)(i) requires persons that intend to manufacture or process chemical substances for non-exempt commercial purpose that are designated on the Inventory as inactive to notify the Agency prior to the date that these chemicals are reintroduced into U.S. commerce. Upon receiving such notification, TSCA section 8(b)(5)(B)(iii) requires the Agency to change the designation of the chemical substance from inactive to active.

The regulations implementing these mandates are codified in 40 CFR Part 710.

The text of TSCA section 8(b) and of 40 CFR part 710 are available in the public docket established for this ICR at <https://www.regulations.gov> (see also **Attachment A** and **Attachment B**).

The TSCA Inventory plays a central role in the regulation of most industrial chemicals in the United States because, for purposes of regulation under TSCA, if a chemical is on the TSCA Inventory, the substance is considered an "existing" chemical substance in U.S. commerce, and any chemical that is not on the Inventory is considered a “new chemical substance.”

In a 2017 rulemaking, referred to as the TSCA Inventory Notification (Active-Inactive) Requirements Rule¹, EPA established a now completed retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for non-exempt commercial purposes during the ten-year time period ending on June 21, 2016. EPA used the retrospective notifications received to distinguish active substances from inactive substances. EPA included the active and inactive designations for the first time on the February 2019 posting of the public TSCA Inventory. The activities and burden estimates associated with the initial notification activities that are now complete are no longer included in this ICR.

In the 2017 rulemaking, EPA also established procedures for forward-looking electronic notification of chemical substances designated as inactive on the TSCA Inventory for when the manufacturing or processing of such chemical substances for non-exempt commercial purposes is expected to resume. Upon receipt of a forward-looking notifications, EPA must change the designation of the pertinent chemical substances on

¹ Codified in 40 CFR part 710, see also 82 FR 37520, August 11, 2017 (FRL-9964-22) <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0070>.

the TSCA Inventory from inactive to active.

The 2017 Active-Inactive Rule included provisions for the submission of CBI and requests to maintain existing CBI claims for the specific chemical identities of chemical substances. Submitters were required to substantiate all CBI claims made in that collection except for specific chemical identity CBI claims asserted during retrospective reporting—which they had an option to voluntarily substantiate at the time of filing their report. As updated from the original ICR, the ongoing activities are still addressed in this ICR.

The 2017 rulemaking was amended in 2020² to address the mandate in TSCA section 8(b) that requires EPA to establish a rule on CBI claims for specific chemical identities for chemicals reported as “active” in U.S. commerce in response to the 2017 Active-Inactive Rule. In that rule, EPA established the procedures and requirements for companies to substantiate their CBI claims for the specific chemical identities of substances on the TSCA inventory, as well as the plan for how the Agency will review the claims, the timeframes for EPA to complete reviews, and the annual posting of results. Originally addressed in a separate rulemaking ICR addendum, the ongoing reporting and recordkeeping activities are incorporated into this ICR.

2(b) Use/Users of the Data

The information collection activities covered by this ICR are used to satisfy the mandate in TSCA section 8(b). The notification submitted via Form B, which is directly mandated by TSCA section 8(b)(5), will be used by EPA to designate inactive chemical substances as active on the TSCA Inventory when that chemical substance is anticipated to re-enter U.S. commerce.

The recordkeeping requirements are necessary for EPA compliance and enforcement purposes. As part of its compliance program, EPA conducts inspections to review the records of TSCA section 8(b) submitters to ensure that the information submitted in a notice was correct and that the submitter provided the notice for chemical substances in U.S. commerce during the time periods specified under TSCA section 8(b).

Users of these data are primarily EPA employees located primarily in the Office of Pollution Prevention and Toxics (OPPT) within the Office of Chemical Safety and Pollution Prevention (OCSPP). Other EPA employees in the Regional Offices and the Office of Enforcement and Compliance Assurance (OECA), including the Core TSCA Regional Coordinator Inspectors, may use these data for compliance monitoring and enforcement purposes.

3. NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

There is no duplication of these activities because EPA is the only federal agency that is required to manage the TSCA Inventory and the information collection activities covered

² See 85 FR 13062, March 6, 2020 (FRL-10005-48) <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0320-0055>.

by this ICR are not duplicated by any other EPA program. The information submitters provide cannot be obtained elsewhere.

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

EPA sought public comment on the information collection activities covered by this ICR in the context of the proposed rule³ and a supplemental proposed rule⁴ that revised the reporting activities and provided revised burden and cost estimates. EPA addressed the comments received in the context of the final rule and accompanying Response to Comment document, and the revised incremental burden was submitted to OMB for review and approval as a rule related addendum to the existing approved ICR that is identified under OMB Control No. 2070-0210 (EPA ICR No. 2594.03). Those documents are available in the rulemaking docket at <http://www.regulations.gov> under Docket ID No. EPA-HQ-OPPT-2018-0320.

At this point the retrospective activities and burdens are complete, and this ICR only covers the ongoing activities associated with Form B, including the revised CBI substantiation requirements as contained in 40 CFR part 710.

3(c) Consultations

Given the two rule-related opportunities for public comment associated with the rulemaking that was just finalized in March 2020, EPA did not conduct additional consultation under 5 CFR 1320.8(d)(3). However, EPA intends to consult with potential respondents and information users about specific aspects of the ongoing reporting and recordkeeping in this ICR as an integral part of implementing those requirements.

3(d) Effects of Less Frequent Collection

This ICR involves a one-time reporting requirement, and a less frequent collection would not fulfill the statutory mandate because manufacturers and processors are required to notify EPA before re-introducing inactive substances into U.S. commerce so that EPA can designate such substances as active on the TSCA Inventory.

3(e) General Guidelines

This collection of information is consistent with OMB guidelines under 5 CFR 1320.6 except with respect to the maintenance of records by respondents. The record retention period is five years, as specified in TSCA section 8(b)(9)(B) and 40 CFR 710.53, which exceeds the recommended maximum recordkeeping of three years.

A five-year recordkeeping requirement is also necessary to carry out an effective program and is consistent with the five-year statute of limitations under 28 U.S.C. 2462 held applicable to all Agency enforcement actions, including administrative proceedings under TSCA. See 3M Company vs. Browner, 17 F.3d 1453 (DC Cir. 1994).

3(f) Confidentiality

Respondents may claim information submitted under this ICR as CBI under TSCA and

³ Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Proposed Rule. Federal Register, 84 FR 16826, April 23, 2019 (FRL-9992-05).

⁴ Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Revisions to the CBI Substantiation Requirements; Supplemental notice of proposed rulemaking. Federal Register, 84 FR 60363, November 8, 2019 (FRL-10001-44).

its implementing regulations. As amended in 2016, TSCA section 8(b) requires the respondents to substantiate claims for specific chemical identities for chemicals reported as “active” in U.S. commerce.

The Agency’s policies and requirements related to the TSCA Inventory allow public involvement while preserving confidentiality. TSCA section 14(a) prohibits, except in limited circumstances, the disclosure of trade secret information. Persons will be reporting chemical identity information in NOAs based on a list of TSCA Inventory chemical substances posted in EPA’s Substance Registry System. This list does not contain confidential chemical identity information. In reporting a confidential substance, persons will select a substance listed with a generic chemical name and an EPA-assigned accession number. Although no confidential chemical identity information will be included in NOAs, persons are required to reassert claims to maintain the confidentiality of chemical substances as listed on the confidential portion of the TSCA Inventory.

The 2016 amendments to TSCA include new provisions that impact procedures for how confidential business information claims can be made and the Agency’s obligations to review and make determinations concerning the validity of the claims. Persons submitting NOAs that claim reported information CBI must follow the general requirements of TSCA section 14 for making such claims, as modified by the specific provisions under TSCA section 8(b). TSCA section 14(c) requires that submitters claiming CBI must provide a specific statement attesting to the basis for the CBI claims. TSCA also requires that all submissions containing information claimed as CBI must also include substantiations in support of the CBI claims. With the exception of existing claims on chemical identity (as stated in TSCA section 8(b)), substantiations are required at the time of notification.

Based on its experience, EPA expects that information included in NOAs, specifically submitter information (company name and contact information), will likely be claimed CBI. The Agency has developed an elaborate system to prevent unauthorized disclosure of CBI. This system includes procedures for logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters, procedures for photocopying and transmitting CBI, and a stand-alone CBI local area computer network. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures have been instituted to restrict access to computerized CBI. 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.

Any information being sent via CDX is transmitted using secure technologies to protect CBI. EPA-provided reporting application, termed e-NOA, 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 to the e-NOA software, and the corresponding private key is sent to EPA’s New Chemical System (NCS). The

encryption remains while the submission is transmitted via CDX to NCS. The file can be decrypted only with the NCS's 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 protection will occur for all correspondence going back to the submitter. The NCS and e-NOA 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 e-NOA software.

3(g) Sensitive Questions

The information collection activities covered by this ICR do not involve sensitive questions as described by the PRA and OMB implementing regulations.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

Potential respondents to the information collection activities covered by this ICR are expected to include entities that manufacture (defined by statute to include import) or process chemical substances that are regulated under TCSA. These entities are typically identified under North American Industrial Classification System (NAICS) codes 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products). Although such entities are generally companies, respondents can include anyone who engages in the covered activities. For purposes of the ICR, respondent is used interchangeably with company and entity.

4(b) Information Requested

Under 40 CFR 710, respondents are required to notify the Agency by submitting a Notice of Activity (NOA) Form B (EPA Form No. 9600-06) for chemical substances designated as "inactive" on the TSCA Inventory before they are to be reintroduced into U.S. commerce. EPA reviews the information provided and designates the chemical substance as "active" for the TSCA Inventory.

Required reporting information includes the following:

- Chemical identity of the substance;
- Anticipated date that the chemical substance is to be reintroduced into U.S. commerce;
- Name and address of the submitting company;
- Name and address of the authorized official for the submitting company who will be signing the NOA;
- Name and telephone number of a technical contact person;
- Clear indication of what information, if any, is to be considered confidential; and
- Substantiation of confidentiality claims.

This information must be submitted to EPA using the NOA Form B. Submitters are required to submit electronically using the e-NOA software to generate a finalized submission. Manufacturers (includes importers) and processors must provide the NOA to EPA prior to anticipated reintroduction of a chemical substance into U.S. commerce but not more than 90 days prior.

4(c) Respondent Activities

The following respondent activities represent the information collections (ICs) that are covered by this ICR.

(i) Register with EPA's CDX and Complete the Electronic Signature Agreement

Although completed during the initial reporting in 2017, which was covered in the previous ICR period, EPA recognizes that there may be some ongoing CDX registration related activities, either due to new respondents or for updating the CDX registration and e-Signature. EPA is therefore including this ICR and related burden estimates again in this ICR.

EPA is providing two different variations of the e-NOA software, one with encryption and one without encryption. The e-NOA software with encryption, available on EPA's CDX website, accommodates electronic submission through CDX. The e-NOA software without encryption is available through EPA's TSCA New Chemicals Program website. Both variations of the e-NOA software are available free of charge as Internet downloads. The e-NOA software without encryption is also available on optical discs provided by the Agency upon request.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") downloads two forms: the Electronic Signature Agreement and the Verification of Company Authorizing Official form. Registration enables CDX to perform two important functions: authentication of identity and verification of authorization. Within the "Electronic Signature Agreement" form, the Authorized Official (AO) agrees to certain CDX security conditions. On the "Verification of Company Authorizing Official" form, the AO designates himself/herself as the AO and attests to the completeness and accuracy of the submitted information.

There is a third form generated by CDX that the AO needs to fill out if the AO wants to authorize other persons to submit support documents on his or her behalf, including a paid employee of the company, an outside consultant for the company, or an authorized representative agent for the company. This form is entitled, "Authorization and Verification for Submitter by Company Authorizing Official." On this form, the AO designates various persons to submit support documents on his or her behalf, and attests to the completeness and accuracy of the submitted information. Persons designated by the AO to submit on his or her behalf must also sign this form along with the Electronic Signature Agreement form, in order to be "linked" to the AO by EPA and therefore be able to submit support documents via CDX on the AO's behalf.

When these forms are received, EPA activates the submitter's registration in CDX and sends an e-mail notification confirming registration.

(ii) Submit the TSCA Section 8(b) Notice (Form B)

The required activities related to submission include the following:

Compliance Determination. The burden associated with compliance determination involves the respondent first determining whether reporting is required for chemical substance(s) that they intend to manufacture (including import) and/or process, which is based on whether the chemical substance is designated as “inactive” on the TSCA Inventory. Compliance determination burden is assumed to occur on a per-chemical basis, and this review may involve using the Substance Registry Services (SRS) search in the NOA submission software or searching the TSCA inventory from EPA web site.

Form Completion/Submission. In all cases, respondents use the e-NOA software to:

- **generate** the submission materials for TSCA section 8(b) notices;
- **populate** the submission materials with the relevant information; and
- **submit** the completed Form B to EPA.

A sample Form B is provided in Attachment C.

Respondent activities to finalize and submit TSCA section 8(b) notices depend on the chosen submission method. The e-NOA software requires users to complete a finalization process before preparing the information for submission to EPA. During the finalization step, the e-NOA software checks that all legally required information is included and provides warnings for certain kinds of missing, incomplete or incorrect data.

After the e-NOA finalization step is complete, the e-NOA software prompts respondents to log-in to CDX. Respondents simply transmit the information to EPA online by clicking on the e-NOA software’s “send” button.

(iii) CBI Substantiation

Respondents may claim information submitted under this ICR as CBI under TSCA and its implementing regulations. As amended in 2016, TSCA section 8(b) requires the respondents to substantiate claims for specific chemical identities for chemicals reported as “active” in U.S. commerce.

Substantiation of a CBI claim for specific chemical identity must be provided by not later than 30 days after the notice is submitted (TSCA section 8(b)(5)(B)(ii)(II)), but may be provided at the time of submission of the NOA Form B. Substantiation of CBI claims for all other data elements must be provided at time of notification. Procedures and requirements associated with making and substantiating CBI are specified in 40 CFR part 710. See also additional discussion in unit 3(e).

(iv) Recordkeeping

Under 40 CFR 710.53, submitters must keep documentation of the information provided to EPA in a TSCA section 8(b) notice for five years from the date of submitting the notice.

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

5(a) Agency Activities

In processing TSCA section 8(b) notices, the Agency will perform the following

activities:

- Review NOA submissions;
- Analyze submissions for confidentiality and provide appropriate protection for confidential data;
- Acknowledge receipt of submissions and notify respondents of any submission errors or deficiencies;
- File and store submissions to Agency data systems;
- Update the TSCA Inventory based on notices received;
- Provide technical assistance to respondents; and
- Conduct site and record inspections and perform related compliance monitoring functions.

5(b)Collection Methodology and Management

All NOA forms must be generated using the e-NOA software and submitted electronically via CDX. The data being transmitted electronically via CDX are encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for efficient data transmittal to Agency data systems. The Agency requires all section 8(b) notices to be submitted electronically via CDX.

An electronic signature is required for TSCA section 8(b) notices submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process.

All e-NOA software users need to perform the “finalization” step in generating a document. During the “finalization” step, the e-NOA software checks that all legally required information is included, provides warnings where necessary, and saves data in a read-only format acceptable to the Agency. Section 8(b) notices in which data have not undergone the “finalization” step are determined incomplete. This step is necessary to allow for an accurate and efficient transfer of data to EPA data systems. The word, “finalized,” is in the file name and the name ends with “tsca.” The “finalized” file (folder) contains the CBI and non-CBI data in XML format that are non-editable. The CBI and non-CBI attachments are also in this folder in their native format. Attachments must be submitted in one of EPA’s approved formats for the Agency to be able to open the files.

All information sent via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The e-NOA software facilitates the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also allows submitters to share a draft notice within their company during the creation of a notice and to save a copy of the final file for future use. A “Profiler,” available in the software, also allows for certain information to be kept on file by the submitter to avoid the burden associated with re-entering the same information into a new form.

The Agency also benefits from receiving electronic submissions. Data systems are populated electronically, minimizing the potential for human error. Agency personnel are also able to communicate efficiently with submitters electronically. Because companies register with EPA to submit their data electronically to the Agency via CDX, the Agency in turn communicates electronically with submitters via CDX. The electronic means of communication provides significant time and resource efficiencies for both parties.

Additionally, to aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA regulatory requirements. When TSCA Hotline staff members are unable to answer questions regarding TSCA section 8(b), the questions are referred to OPPT staff for appropriate resolution.

5(c) Small Entity Flexibility

The reporting and recordkeeping requirements associated with TSCA section 8(b) are applicable to all affected entities, regardless of the size of the business. However, EPA provides specialized assistance to respondents, particularly to small entities. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers and processors of chemical substances. This office has established a TSCA Hotline to assist businesses complying with TSCA rules. It provides material such as copies of documents explaining requirements (rules and guidance), advisories, and other information on request.

Moreover, EPA has taken certain steps to minimize for all respondents the reporting burden associated with complying with this collection. For example, the information technology used by EPA includes chemical substances on the TSCA Inventory using the EPA Substance Registry System. This list allows submitters to select their reportable chemical substances from the list rather than manually entering each substance. Additionally, submitters are able to report multiple chemical substances in one session; upon completion of a session, each chemical substance will be transmitted in one NOA submission.

Finally, EPA provides the services and other personnel to assist persons with reporting questions and notice preparation prior to submission. TSCA Inventory personnel routinely respond to TSCA section 8(b) inquiries that pertain to the full scope of TSCA section 8(b) regulations.

5(d) Collection Schedule

There is no applicable collection schedule. Submission of information under this ICR occur once per chemical substance on an as-needed basis that is initiated by the respondents.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This analysis presents the burden and cost estimates for affected entities and covers submissions of the Notice of Activity (NOA), Form B (EPA Form No. 9600-06). The respondent activities discussed in unit 4(c) are summarized in Table 1 along with the related Information Collection (IC) category that corresponds to each respondent activity.

Table 1. Respondent Activities and Related Information Collections (ICs)

Respondent Activity	Description	Title of Related IC(s)
Register with EPA's CDX and Complete the Electronic Signature Agreement [See Unit 4(c)(i)]	Respondents must register with CDX, unless already registered, and respondents may need to update that registration overtime to ensure that it is up to date when they need to use it.	CDX Registration and eSignature

Respondent Activity	Description	Title of Related IC(s)
Use the e-NOA Software to Prepare TSCA Section 8(b) Notice (Form B) [See Unit 4(c)(ii)]	When respondents determine to commence the manufacture or processing of a chemical substance identified as “inactive” on the TSCA Inventory, they must prepare & submit the NOA Form B to EPA. EPA must review & change status to “active” for the TSCA Inventory.	Prepare and Submit NOA Form B, and Maintain Records
CBI Substantiation [See Unit 4(c)(iii)]	Respondents must prepare and submit the required CBI substantiation.	CBI Substantiation
Recordkeeping [See Unit 4(c)(iv)]	Respondents must keep records supporting their submissions.	Recordkeeping

Several existing ICs are being deleted because the corresponding activities are complete.

6(a) Estimating Respondent Burden

This unit presents EPA’s estimates of the burden for the identified information collection activities to respondents in terms of the time required for facility personnel to perform the activities as described in unit 4(c), and summarized in Table 1.

From EPA’s perspective, the organizing reporting unit is a “notice.” A given notice typically submitted by a single firm pertains to a single chemical substance or multiple chemical substances. Burden and cost calculations are based on the assumption that EPA will receive approximately 20 notices involving multiple-chemicals annually for each year of reporting using Form B. A typical multiple-chemical submission is assumed to include 18 chemicals.

The overall unit burden experienced by firms is estimated by combining activity-level unit burdens at the appropriate scale (e.g., per firm or per chemical) to produce estimates for unit burden per submission, by firm. A summary of activity-level unit burdens is included in Table 2. In Table 3, activity burdens are combined to produce unit burdens associated with submissions for a number of reporting conditions. For firms submitting an NOA with multiple chemicals, it is assumed that on average there are 18 chemicals per submission (for basis, see EPA, 2017). Therefore, the estimated burden per firm is on the basis of 18 chemicals per submission.

Table 2. Activity-Level Unit Burdens

Description	Activity-Level Unit Burden (hours)	Unit of Analysis	Source
CDX registration or Updates	0.53	Per firm	2017 ICR
Compliance determination, without review of “Active Status” list	0.500	Per firm	Agency BPJ
Compliance determination, review of “Active Status” list only	0.083	Per chemical	Abt Associates (2016)
Nominal Single-Chemical Submission			
(1) Submitter Authorized Official Name and Address and Technical Contact Name and Telephone Number	0.014	Per firm	CDR ICR (EPA, 2015a)
(2) Technical Contact Name and Telephone Number	Included in (1) above	Per firm	CDR ICR (EPA, 2015a)

Description	Activity-Level Unit Burden (hours)	Unit of Analysis	Source
(3) NOA Certification	0.500	Per submission	Section 5 PMN estimates (summarized in EPA, 2016)
(4) Certifier E-mail	0.017	Per submission	Section 5 PMN estimates (summarized in EPA, 2016)
(5) Chemical Name	0.083	Per chemical	Abt Associates (2016)
(6) Chemical Identity (e.g., Chemical Abstract Service Registration Number - CASRN)	Included in (5) above	Per chemical	Abt Associates (2016)
(7) CBI Designations for Chemical Identity	Estimated at zero	Per chemical	Negligible level of burden
(8) Start Date of Manufacture, Import, and/or Process	0.017	Per chemical	Agency BPJ (similar to #4 above)
(9) CBI Designation for Start Date	Estimated at zero	Per chemical	Negligible level of burden
(10) Chemical Identity CBI Status Declaration: maintain or not maintain claim of confidentiality of the full chemical substance identity on the TSCA Inventory	0.002	Per chemical	TRI reporting (EPA, 2011)
(11) CBI Substantiation for Chemical Identity (applies to certain submissions) ⁵	1.340 where applicable	Per chemical	Agency BPJ
(12) CBI Substantiation for non-Chemical Identity data elements	0.960 where applicable	Per chemical	Agency BPJ
Date and Time Stamps	System-generated	Per submission	N/A
Recordkeeping	0.125	Per submission	Section 5 ICR for NOC (EPA, 2015b)

⁵ Burden and cost estimates pertaining to submissions that include CBI chemID claims for specific chemical identities include the burden associated with substantiation which is estimated at 1.34 hours per chemical-specific claim. As it is only expected that five percent of submissions will include CBI chemID claims, the average burden and cost per respondent as estimated in this document reflect five percent of the burden associated with full substantiation. The burden associated with this activity is inclusive of the additional estimated burden of 0.19 hours per chemical-specific claim that is required to provide answers for two additional substantiation questions related to reverse engineering.

Table 3. Unit Burden for Ongoing Reporting

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
<i>COMPLIANCE DETERMINATION</i> (Without Review of “Active Status” List)	Firm	0.000	0.500	0.000	0.500
<i>COMPLIANCE DETERMINATION</i> (Review of “Active Status” List Only)	Chemical	0.000	0.083	0.000	0.083
FORM COMPLETION FOR NOMINAL SINGLE-CHEMICAL SUBMISSION					
(1) Submitter Authorized Official Name, Company Name, and Mailing Address and Technical Contact Name and Telephone Number	Firm	0.000	0.010	0.004	0.014
(2) Technical Contact Name and Telephone Number	Firm				Included in (1) above
(3) NOA Certification	Submission	0.000	0.000	0.500	0.500
(4) Certifier E-mail	Submission	0.000	0.017	0.000	0.017
(5) Chemical Name ¹	Chemical	0.000	0.083	0.000	0.083
(6) Chemical Identity ¹	Chemical				Included in (5) above
(7) CBI Designations for Chemical Name and Chemical Identity	Chemical				Estimated at zero
(8) Start Date of Manufacture, Import, and/or Process	Chemical	0.000	0.017	0.000	0.017
(9) CBI Designation for Start Date	Chemical				Estimated at zero
(10) Chemical Identity CBI Status Declaration: maintain or not maintain claim of confidentiality of the full chemical substance identity on the TSCA Inventory	Chemical	0.000	0.002	0.000	0.002
(11) CBI substantiation for Chemical Identity ²	Chemical	0.000	0.045	0.022	0.067
(12) CBI Substantiation for non-Chemical Identity data elements ³	Chemical	0	0.211	0.106	0.317
Date and Time Stamps	Submission				System-Generated
SINGLE CHEMICAL SUBMISSION FORM COMPLETION		0.000	0.385	0.632	1.547
RECORDKEEPING					
Per NOA Submission	Firm	0.125	0.000	0.000	0.125
Average Annual Ongoing Unit Burden per Firm					
CDX Registration and Updates		0.0	0.53	0.0	0.53
Compliance Determination		0.000	1.994	0.000	1.994
Form Completion		0.000	6.471	2.808	9.279
Average Annual Ongoing Unit Burden per Firm without Recordkeeping					11.803

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
Recordkeeping		0.125	0.000	0.000	0.125
TOTAL					11.928
<p>General Note Sources for unit burden estimates are drawn from various Economic Analyses and ICR Supporting Statements. Additionally, Agency BPJ was employed to finalize results. For further detail, see Section 4.6 of <i>Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements</i> (EPA, 2017).</p> <p>Footnotes ¹The composite of 0.083 hours, or about 5 minutes reported here is the result of the assessment that providing CBI chemical identity and chemical name (accession number plus generic name) requires 0.083 hours, and that providing non-CBI chemical identity and chemical name (CASRN and TSCA Inventory name) requires 0.083 hours. Also note that 5% of CDR chemicals are reported as having CBI chemical identities. ²This unit burden is assumed to apply to only 5% of submissions, given that 5% of CDR chemicals are reported as having CBI chemical identities. Therefore, the value shown in the table is 5% of the full value unit burden per chemical reported in Table 2 at 0.045 hours of technical labor; 0.022 hours of managerial labor. ³This unit burden is assumed to apply to 33% of submissions, given that that 33% of CDR chemicals have CBI nonChemID data elements throughout the Form U. Specifically, the same incidence rate is assumed in this analysis for submissions in which the connection between the nonCBI chemical identity and the company information, etc. is claimed to be confidential. Therefore, the value shown in the table is 33% of the full value unit burden per chemical reported in Table 2 at 0.211 hours of technical labor; 0.106 hours of managerial labor.</p>					

For total industry burden and cost by activity, see 8 of this document.

6(b) Estimating Respondent Cost

Estimation of unit industry cost involves combining the unit industry burden identified in unit 6(a) with wage data obtained for December 2017 from the BLS (2018) and converted from raw wage rate and benefit data to loaded wage rates. Table 4 presents the resultant loaded wage rates for managerial, professional/technical, and clerical staff.

Table 4. Industry Wage Rates (2017 Dollars)

Labor Category	Data Series ^a	Wage (a)	Fringe Benefit (b)	Fringes as % Wage (c) =(b)/(a)	Overhead % wage ^b (d)	Fringe + Overhead Factor ^c (e)= (c)+ (d)+1	Hourly Loaded Wages (f)=(a)×(e)
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	\$46.59	\$22.16	47.6%	17%	164.6%	\$76.67
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	\$45.82	\$24.33	53.1%	17%	170.1%	\$77.94
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	\$20.49	\$11.02	53.8%	17%	170.8%	\$34.99

Industry unit costs are presented below in Table 5, in similar fashion to the industry unit burdens provided in Table 3.

Table 5. Unit Cost for Ongoing Reporting

Activity	Unit of Analysis	Clerical Cost (2017\$) (a)	Technical Cost (2017\$) (b)	Managerial Cost (2017\$) (c)	Total Cost (2017\$) (d)=(a)+(b)+(c)
COMPLIANCE DETERMINATION (Without Review of "Active Status" List)	Firm	\$0.00	\$38.97	\$0.00	\$38.97
COMPLIANCE DETERMINATION (Review of "Active Status" List Only)	Chemical	\$0.00	\$6.47	\$0.00	\$6.47
FORM COMPLETION FOR NOMINAL SINGLE-CHEMICAL SUBMISSION					
(1) Submitter Authorized Official Name, Company Name, and Mailing Address and Technical Contact Name and Telephone Number	Firm	\$0.00	\$0.78	\$0.31	\$1.09
(2) Technical Contact Name and Telephone Number	Firm				Included in (1) above
(3) NOA Certification	Submission	\$0.00	\$0.00	\$38.34	\$38.34
(4) Certifier E-mail	Submission	\$0.00	\$1.32	\$0.00	\$1.32
(5) Chemical Name ¹	Chemical	\$0.00	\$6.47	\$0.00	\$6.47
(6) Chemical Identity ¹	Chemical				Included in (5) above
(7) CBI Designations for Chemical Name and Chemical Identity	Chemical				Estimated at zero
(8) Start Date of Manufacture, Import, and/or Process	Chemical	\$0.00	\$1.32	\$0.00	\$1.32
(9) CBI Designation for Start Date	Chemical				Estimated at zero
(10) Chemical Identity CBI Status Declaration: maintain or not maintain claim of confidentiality of the full chemical substance identity on the TSCA Inventory	Chemical	\$0.00	\$0.16	\$0.00	\$0.16
(11) CBI Substantiation for Chemical Identity ²	Chemical	\$0.00	\$3.51	\$1.69	\$5.19
(12) CBI Substantiation for non-Chemical Identity data elements ³	Chemical	\$0.00	\$16.45	\$8.13	\$24.57
Date and Time Stamps	Submission				System-Generated
SINGLE CHEMICAL SUBMISSION FORM COMPLETION		\$0.00	\$30.01	\$48.46	\$78.46
RECORDKEEPING					
Per NOA Submission	Firm	\$4.37	\$0.00	\$0.00	\$4.37
Average Annual Ongoing Unit Cost per Firm					

Activity	Unit of Analysis	Clerical Cost (2017\$) (a)	Technical Cost (2017\$) (b)	Managerial Cost (2017\$) (c)	Total Cost (2017\$) (d)=(a)+(b)+(c)
CDX Registration & Updates		\$0.00	\$41.31	\$0.00	\$41.31
Compliance Determination		\$0.00	\$155.41	\$0.00	\$155.41
Form Completion		\$0.00	\$504.35	\$215.29	\$719.64
Average Unit Cost per Firm in Annual Ongoing Period					\$916.36
<i>Recordkeeping</i>		\$4.37	\$0.00	\$0.00	\$4.37
TOTAL					\$920.74

General Notes

Sources for Unit Burden estimates are drawn from various Economic Analyses and ICR Supporting Statements. Additionally, Agency BPJ was employed to finalize results. For further detail, see Section 4.6 of *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017).

Values may not sum due to rounding. Estimates are rounded to the nearest penny.

Footnotes

¹The composite of 0.083 hours, or about 5 minutes reported here is the result of that assessment that providing CBI chemical identity and chemical name (accession number plus generic name) requires 0.083 hours, and that providing non-CBI chemical identity and chemical name (CASRN and TSCA Inventory name) requires 0.083 hours. See Appendix B for further detail and reference. Also note that about 5% of CDR chemicals are reported as having CBI chemical identities.

²This unit burden is assumed to apply to only 5% of submissions, given that 5% of CDR chemicals are reported as having CBI chemical identities. Therefore, the value shown in the table reflects 5% of the full value associated with the unit burden per chemical reported in Table 2 at 0.045 hours of technical labor; 0.022 hours of managerial labor.

³This unit burden is assumed to apply to 33% of submissions, given that that 33% of CDR chemicals have CBI non-chemID data elements throughout the Form U. Specifically, the same incidence rate is assumed in this analysis for submissions in which the connection between the non-CBI chemical identity and the company information, etc. is claimed to be confidential. Therefore, the value shown in the table reflects 33% of the full value associated with the unit burden per chemical reported in Table 2 at 0.211 hours of technical labor; 0.106 hours of managerial labor.

6(c) Estimating Agency Burden and Cost

EPA is implementing new software and integration with CDX to facilitate form submission and processing. EPA is expanding the CISS database to incorporate the Form B submission, and is adding new tasks to manage NOA submissions and take care of routine TSCA inventory maintenance.

New ongoing agency costs associated with the information collection are associated with the following Agency activities:

- (1) Reviewing NOA submissions;
- (2) Analyzing submissions for confidentiality and providing appropriate protection for confidential data;
- (3) Acknowledging receipt of submissions and notifying respondents of any submission errors or deficiencies;
- (4) Filing and storage of submissions to Agency data systems;
- (5) Updating the TSCA Inventory based on notices received;
- (6) Providing technical assistance to respondents; and
- (7) Conducting site and record inspections and performing related compliance monitoring functions.

Estimates of Agency labor required to complete startup and ongoing tasks are discussed in Section 4.6 of the *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017). Agency burden is combined with wage data from Table 6 to estimate Agency cost as displayed in Table 7.

Table 6. Agency Wage Rate (2017 Dollars)

Labor Category	Data Source for Wage Information ^a	Wage (\$/hour) (a)	Fringe Benefit (b)	Fringes as % wage (c) = (b) / (a)	Overhead as % wage ^b (d)	Fringe + Overhead Factor ^c (e) = (c) + (d) + 1	Loaded Wage (\$/hour) (f) = (a) × (e)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Arlington, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates	\$51.48	Included in 60% overhead	N/A	60%	1.6	\$82.37

Footnotes
^a Source: Salaries & Wages for the locality of Washington-Baltimore-Arlington (Office of Personnel Management (OPM), 2017). All rates are rounded to the nearest cent.
^b The 60 percent fringes-and-overhead rate is from *Instructions for Preparing ICRs* (EPA, 2009).
^c The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

Table 7. Agency Burden and Cost for IT and Inventory Publication

Activity	Burden	Labor Cost	Non-Labor Cost	Total Cost (2016\$)
Annual Ongoing Reporting Period				
CDX and CISS	0.5 FTE	\$85,665	\$10,000	\$95,665
Management of NOA Submissions	19.80 hours × 20 submissions	\$32,619	\$0	\$32,619
TSCA Inventory Maintenance	0.5 FTE	\$85,665	\$10,000	\$95,665
TOTAL Annual Ongoing Costs				\$223,948

6(d) Estimating the Respondent Universe and Total Burden and Costs

Total industry burden and cost are estimated by combining industry unit burdens from Table 3 and industry unit costs from Table 5 with affected universe counts, as derived in the *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017). Total burden and total costs are then aggregated for all firms in the affected universe. Total industry burden and cost are presented in 8.

Table 8. Total Respondent Burden and Cost by Activity

IC Categories	Unit Burden (Hours per Firm)	Unit Costs (2017\$)	Submission Respondents (Number of Firms)	Total Burden (Hours)	Total Costs (2017\$)
CDX Registration and eSignature	0.53	\$41.31	10	5	\$207
Reporting (Form B)	10.887	\$845.13	20	218	\$16,903
CBI Substantiation	0.386	\$29.92	20	8	\$598
Recordkeeping	0.125	\$4.37	20	3	\$87
TOTAL			20	234	\$17,795
General Note					
Total burden and cost are estimated by combining unit burdens (Table 3) and costs (Table 5) with estimates of the potentially affected universe (as determined in Section 3 and Table 2 of <i>Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements</i> (EPA, 2017)).					
Values may not sum due to rounding. Unit costs displayed are rounded to the nearest penny. Total costs are calculated with unrounded unit costs and then rounded to the nearest dollar.					
Footnotes					
¹ Assumes the average firm includes 18 chemicals per submission, similar to characteristics of the general response universe, as observed in CDR in chemicals per parent company (see EPA, 2017).					

6(e) Bottom Line Burden Hours and Costs

The following tables display the annual burden and costs borne by respondents and EPA associated with submitting and processing NOAs.

Table 9. Total Annual Burden and Cost

Burden Category	Annual Average	
	Burden (hours)	Cost (2017\$)

Respondent Burden, Total	234	\$17,795
Agency Burden, Total	2,476	\$223,948
General Note		
Annual average burden and cost are rounded to the nearest hour and dollar, respectively. As the annual burden and cost estimates to not vary across years, the annual average burden and cost presented in this table are representative of the annual burden and cost estimates.		

6(f) Reason for Change in Burden

The total burden estimate reflects a decrease from an annual average burden of 1,174,916 hours currently approved in the existing ICR to an annual average burden of 234 hours. This net change is largely the result of the completion of several activities associated with the initial rule familiarization and one-time reporting activities (- 1,174,608 hours); a decrease in the estimated number of respondents that will need to register for CDX or otherwise update their CDX registrations (- 85 hours); and the addition of CBI substantiation burden associated with the 2020 rule amendments (+ 7 hours). This additional burden is only applicable to submissions that include CBI claims for specific chemical identities, which are expected to be five percent of submissions. This change is considered an adjustment.

6(g) Burden Statement

The respondent burden for this collection of information is estimated to average 234 hours per average response. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to approval under the Paperwork Reduction Act 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 this ICR under Docket ID No. EPA-HQ-OPPT-2020-0413, which is available for online viewing at <http://www.regulations.gov>. The telephone number for the EPA Docket Center Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. For information about the docket, visit <https://www.epa.gov/dockets>.

At any time, 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 the docket ID number provided above and OMB Control No. 2070-0201, to EPA and OMB as follows:

1. Submit comments to EPA using <http://www.regulations.gov> and following the online instructions, and
2. Submit comments to OMB using <http://www.reginfo.gov/public/do/PRAMain>. Find this particular ICR by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

7. REFERENCES

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- Williamson, T. (2016). Email from Tracy Williamson to Cody Rice and Laura Nielsen. October 26, 2016. RE: INV Rule - Internal Resources.

8. ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPPT-2020-0413**. These attachments are available for online viewing at <http://www.regulations.gov> or as otherwise described below.

Attachment A: 15 U.S.C. 2607 - Section 8(b) of the Toxic Substances Control Act. Available online at the U.S. House of Representatives' [U.S. Code website](#)

Attachment B: 40 CFR part 710. Available online at https://www.ecfr.gov/cgi-bin/text-idx?SID=829d5a211eef71fe36203ab1b7ebfbf&mc=true&tpl=/ecfrbrowse/Title40/40cfr710_main_02.tpl

Attachment C: EPA Form Notice of Activity Form B. Existing Form B is available in CDX, and a sample is in the docket.