Supporting Statement for a Request for OMB Review 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

EPA ICR No.: 2565.01 OMB Control No.: 2070-0201

Docket ID No.: EPA-HQ-OPPT-2016-0426

1(b) Short Characterization

This information collection request addresses the reporting and recordkeeping requirements under section 8(b) of the Toxic Substances Control Act (TSCA) associated with chemical substances on the TSCA Chemical Substance Inventory, as prescribed in the final rule entitled: "**TSCA Inventory Notification (Active-Inactive) Requirements**" and codified in 40 CFR Part 710.[1]

The Environmental Protection Agency (EPA) manages the TSCA Chemical Substance Inventory ("Inventory") under TSCA section 8(b). 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. On December 23, 1977, EPA promulgated a rule under TSCA section 8, to compile the TSCA Chemical Substance Inventory from chemical substances that had been in commerce since January of 1975. Since compiling the initial TSCA Inventory, TSCA section 5 requires that any person who proposes to manufacture (which includes import) a "new chemical," i.e., a chemical not listed on the TSCA Inventory, must provide a premanufacture notice (PMN) or an exemption application to the Agency at least 90 days prior to commencing manufacture of that chemical. The Agency regularly adds new chemical substances that have completed new chemical review requirements pursuant to TSCA section 5(a) and that have been manufactured or processed for non-exempt commercial purpose. EPA maintains the TSCA Inventory as the authoritative list of all the chemical substances reported to the Agency for inclusion on the Inventory.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act made several substantive amendments to TSCA. (see Attachment A). The 2016 amendments to TSCA section 8 require EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, EPA is establishing a 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 will use these notifications to

[1] Identified by FRL-9964-22 and RIN 2070-AK24, once published in the **Federal Register**, the final rule will be available in the docket identified above. As part of the rulemaking, EPA also prepared a report entitled "Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements" that is available in the docket.

distinguish active substances from inactive substances. EPA will include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. EPA is also establishing procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for non-exempt commercial purposes is expected to resume. After EPA deems the notice valid, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. EPA is establishing the procedures regarding the manner in which such retrospective and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.

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 and keep current the TSCA Inventory, the list of chemical substances manufactured or processed in the United States. TSCA sections 8(b)(4) and 8(b)(5), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, require additional responsibilities of the Agency in maintaining the TSCA Inventory; specifically, the Agency is to designate chemical substances on the Inventory as "active" or "inactive" in U.S. commerce.

Section 8(b)(4)(A)(i) requires EPA to promulgate a rule by June 22, 2017, which requires manufacturers to notify the Agency, by not later than 180 days after the date on which the final rule is published in the **Federal Register**, of each chemical substance on the TSCA Inventory that was manufactured for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016, the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Section 8(b)(4)(A)(ii) requires the Agency to designate a chemical substance on the Inventory as an active substance if the Agency receives notice for that substance under clause (i). Section 8(b)(4)(A)(iii) requires the Agency to designate chemical substances on the Inventory for which no notices are received under clause (i) as inactive substances.

TSCA section 8(b)(5)(A) requires EPA to maintain active and inactive designations for chemical substances on the TSCA Inventory.

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, section 8(b)(5)(B)(iii) requires the Agency to change the designation of the substance from inactive to active.

Copies of TSCA section 8(b) and of 40 CFR part 710 are available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2016-0426 and are available for online viewing at *www.regulations.gov* (also see Attachments A and B). The regulations may also be viewed online at the National Archives and Records Administration's

Electronic CFR Website at *https://www.ecfr.gov/cgi-bin/ECFR?page=browse*.

2(b) Use/Users of the Data

TSCA requires EPA to compile and keep current the TSCA Inventory, the list of chemical substances manufactured or processed in the United States for non-exempt commercial purposes, and to designate these substances on the Inventory as active or inactive in U.S. commerce. To designate chemical substances as active or inactive, the Agency needs to conduct an initial collection of data on the commercial activity for each substance on the Inventory. Because a company may at any time in the future, after the initial data collection, reintroduce into U.S. commerce a chemical substance designated as inactive on the Inventory, the Agency needs to also conduct future data collection for those chemical substances, to be notified that the substances' whose commercial activity is about to changes from inactive to active. Such notification is directly mandated by TSCA section 8(b)(5). Information collected is also essential to the Agency for compliance purposes. The information requirements for NOA reporting will assist in identifying cases in which submitters have mistakenly reported chemical substances based on their commercial activity status in the U.S. Finally, information collected will support EPA's responsibilities in routinely publishing non-confidential Inventory data.

EPA requires the use of two specific reporting forms, a Form A (EPA Form No. [tba][2]) and a Form B (EPA Form No. [tba]), for NOAs submitted for chemical substances on the TSCA Inventory in accordance with 40 CFR 710 (see Attachments D and E). The use of a standard form for commercial activity reporting leads to greater efficiency by assisting EPA in providing uniformity in recording data in EPA databases and on the Inventory, and by providing manufacturers a format to assure that required information is not inadvertently omitted in their submissions.

The recordkeeping requirements for NOAs 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 section 8(b).

Users of these data are EPA employees located primarily in the Office of Pollution Prevention and Toxics (OPPT) within the Office of Chemical Safety and Pollution Prevention (OCSPP). In particular, management and staff of existing chemicals programs within the various Divisions of OPPT will use this information to inform existing chemical prioritization. OCSPP employees in the Regional Offices, employees in the Office of Enforcement and Compliance Assurance (OECA) in Headquarters and in the Regions, and Core TSCA Regional Coordinator Inspectors may use these data for compliance monitoring and enforcement purposes.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER

[2] EPA maintains a form registry that will assign a unique identification number to these forms once they are finalized.

COLLECTION CRITERIA

3(a) Non-Duplication

EPA manages the TSCA Chemical Substance Inventory under TSCA 8(b). The Inventory is EPA's comprehensive list of confidential and non-confidential chemical substances manufactured or processed in the United States. EPA is the only federal agency that regularly collects information on chemical substances listed on the TSCA Inventory. Therefore, the information submitters provide in an NOA cannot be obtained elsewhere.

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

Along with public comment on the proposed rule, EPA provided a 60-day public comment period on the draft ICR that ended on March 14, 2017 (82 FR 4255, January 13, 2017). EPA received comments from 48 organizations during the comment period. Copies of the comments received are available in the docket and EPA's response to the comments are included as Attachment F.

3(c) Consultations

EPA has been regularly engaged in a continuing series of joint EPA/industry/public interest group meetings to exchange information related to the TSCA programs in general (which includes TSCA Inventory functions), and more recently has begun engaging in similar meetings to exchange information related to specific new requirements required by TSCA as amended in 2016. These recent meetings included EPA public meetings and meetings with individual companies, and may include upcoming professional meetings (e.g., the annual Global Chem Conference).

Comments were received as a result of early consultations from five organizations: the American Chemistry Council, the American Petroleum Institute, the Biotechnology Innovation Organization, the Color Pigments Manufacturers Association, and the Environmental Defense Fund. Formal comments were received from 48 organizations as a result of the public notice in the **Federal Register** (82 FR 4255, January 13, 2017).

3(d) Effects of Less Frequent Collection

The information collection includes an initial round of reporting from manufacturers, which is mandated under TSCA Section 8(b)(4). The information collection also includes the ongoing collection of follow-on notifications from manufacturers and processors to address those circumstances where substances designated as inactive may be later re-introduced into active commerce. The deadlines associated with initial reporting and associated follow-on notifications are specified by statute. Delaying collection would limit EPA's ability to meet its obligations under 8(b)(4) and manufacturers and processors' ability to meet their obligations under section 8(b)(5). Manufacturers must submit a NOA for chemical substances in U.S. commercial during the time periods specified under section 8(b)(4); the timing of follow-on notifications is determined by submitters' statutory obligations to submit those notifications,

under section 8(b)(5). Information is initially provided to the Agency on an as-needed basis, according to the initial reporting requirements to collect data on active chemical substances, i.e., chemical substances on the TSCA Inventory that were active in U.S. commerce during the 10-year time period ending on June 21, 2016. Subsequent reporting would only be required for inactive substances, i.e., chemical substances on the Inventory for which EPA received no notice during the initial reporting period and that are reintroduced into U.S. commerce at a date after the initial reporting period closes. As subsequent notification occurs over time changing designations from inactive to active, fewer notification are expected.

3(e) General Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.6 except with respect to the maintenance of records by respondents for more than three years. EPA believes a five-year recordkeeping requirement is needed to carry out an effective program. The five-year recordkeeping requirement 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). Therefore, EPA requires respondents to retain records for more than three years.

3(f) Confidentiality

The required NOA information may be considered by the submitter to be a trade secret, proprietary, or confidential business information (CBI). However, TSCA mandates that EPA require the submission of such information because it is essential for maintaining the individual chemical substance listings on the TSCA Inventory. Because unique, individual chemical substances are listed on the Inventory, the Agency requires specific chemical identity information for each listing to properly maintain on the TSCA Inventory. Additionally, the Agency is required by TSCA section 8(b) to routinely publish non-confidential data on each chemical substance on the TSCA Inventory. Congress included this provision to provide the public with information on chemical substances in U.S. commerce.

The Agency's policies allow public involvement while preserving confidentiality. TSCA section 14(a) prohibits, except in limited circumstances, the disclosure of trade secret information. Under 40 CFR part 2, when the specific chemical identity data are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in Federal Register notices and the publications of the TSCA Inventory. 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 non-CBI substance, persons will select a substance listed with a Chemical Abstracts Service Registry Number (CASRN) and a Chemical Abstracts (CA) Index name. 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 to 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

Information requirements under TSCA section 8(b) do not include questions of a sensitive nature.

3(h) Maximizing Electronic Technology

The Government Paperwork Elimination Act (GPEA, Pub. L. 105-277) requires that, when practicable, federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (70 FR 59848, October 13, 2005) provides that any requirement in Title 40 of the Code of Federal Regulations to submit a report directly to the Agency can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a notice that electronic document submission is available for that requirement.

In light of GPEA and CROMERR, EPA published on January 5, 2010, a final rule entitled "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (75 FR 773) amending the TSCA section 5 notification regulations to phase out paper-based submissions and facilitate the introduction and use of electronic reporting. In addition, EPA published on December 4, 2013, a final rule entitled "Electronic Reporting Under the Toxic Substances Control Act" (78 FR 72818) which extended the TSCA section 5 electronic reporting requirements to certain documents relating to TSCA section 5 notices submitted to the Agency prior to April 6, 2010 (i.e., the effective date of the "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations"). These actions require manufacturers and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit TSCA section 5 notices to the Agency. These include Premanufacture Notices (PMNs) (40 CFR 720), Significant New Use Notices (SNUNs) (40 CFR 721), exemption applications and notices (40 CFR 720 and 723.50), biotechnology notices for genetically modified microorganisms (40 CFR 725), Notices of Commencement of Manufacture or Import (NOCs) (40 CFR 720.102) and other support documents. The rule required under TSCA section 8(b)(4)(A) will extend TSCA electronic reporting requirements to documents submitted under the requirements of sections 8(b)(4)(A)(i) and 8(b)(5)(B)(i) (see Attachment C). These include Notices of Activity (NOAs) (40 CFR 710) which include an NOA form A for section 8(b)(4)(A)(i) reporting, to commence June 22, 2017, and an NOA form B for subsequent reporting under 8(b)(5)(B)(i) (see Attachments D and E).

EPA introduced CDX reporting in two phases over a two-year period. From April 6, 2010 through April 6, 2011, the Agency allowed submissions via CDX, optical disc, and paper. Regardless of the delivery method, the Agency required that all submissions be generated with new electronic-PMN "e-PMN" computer software. As of April 6, 2011, paper submissions were no longer accepted for any new notices and support documents (including NOCs). Disc-based submissions (e.g., CDs and data DVDs) for all new notices and support documents were no longer accepted as of April 6, 2012. As of April 6, 2012, all submitters are required to submit electronically via CDX using the e-PMN software. As of March 4, 2014 (i.e., the effective date of the "Electronic Reporting Under the Toxic Substances Control Act" regulations), all submitters are required to submit NOCs and all support documents via CDX using the e-PMN software. The Agency incorporated this phased approach because it allowed submitters to gain experience in using the e-PMN software and the submission delivery system. See *epa.gov/opptintr/newchems/epmn/epmn-index.htm* for information on e-PMN reporting and the use of CDX.

In addition, EPA published a direct final rule entitled "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting" on July 20, 2015, which provides the user community with new methods for accessing the e-PMN software, new procedures for completing the electronic-PMN (e-PMN) and other forms, changes to the CDX registration process, adds the requirement to submit "bona fide intents to manufacture" electronically, and changes to the procedure for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by the Agency under 723.50. These changes were intended to further streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA. EPA believes that submitters now have sufficient experience in using the electronic software and system, and coupled with the recent changes to streamline the electronic reporting process, the Agency is requiring submitters to submit NOAs electronically via CDX using the e-NOA software, effective June 22, 2017.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

This information collection affects companies that manufacture or process chemical substances. These companies are typically found in NAICS major groups 325 (Chemical Manufacture) and 324 (Petroleum and Coal Products). The per-response reporting unit, or unit of analysis, is "notices." A given notice typically submitted by a single firm may pertain to a single or multiple chemical substances.

4(b) Information Requested

(i) Data Items - Reporting Requirements

Retrospective Notices of Activity - Under 40 CFR 710, EPA requires persons to notify the Agency by submitting a Notice of Activity (NOA) for chemical substances on the TSCA Inventory that were in commerce during the 10-year period ending on June 21, 2016. Required reporting information includes the following:

- Chemical identity of the substance;
- 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.

These NOAs must be submitted to EPA using the NOA Form A (EPA Form [tba]). Submitters are required to submit electronically using the e-NOA software to generate a finalized submission using Form [tba]. Manufacturers (includes importers) must provide the NOA to the Agency not later than 180 calendar days after the publication of the TSCA Inventory Notification (Active-Inactive) Requirements Final Rule. Within a few months after the 180-day submission period for manufacturers closes, EPA will publish a draft Inventory

with substances reported by manufacturers designated as active. Processors can provide the NOA to the Agency not later than 420 calendar days after the publication of the TSCA Inventory Notification (Active-Inactive) Requirements Final Rule. Substantiation of a CBI claim for specific chemical identity must be provided at a time to be determined by a rule that the Administrator is required to promulgate not later than one year after the date the Agency compiles the list of active substances (TSCA section 8(b)(4)(B)(iii)), but may be provided at the time of submission of the NOA Form A. Substantiation of CBI claims for all other data elements must be provided at time of notification.

Forward-looking Notices of Activity - Under 40 CFR 710, EPA requires persons to notify the Agency by submitting a Notice of Activity (NOA) for chemical substances on the TSCA Inventory that were not reported to the Agency during the initial reporting and that are to be reintroduced into U.S. commerce after June 22, 2016 (i.e., after the period addressed by initial reporting). 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.

These NOAs must be submitted to EPA using the NOA Form B (EPA Form [tba]). Submitters are required to submit electronically using the e-NOA software to generate a finalized submission using Form [tba]. 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. 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.

(ii) Data Items - Recordkeeping Requirements

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.

(iii) Respondent Activities

In responding to the reporting and recordkeeping requirements outlined in this document, respondents will engage in the following activities:

- Read regulatory requirements and provisions;
- Determine which provisions are applicable to their activities;
- Gather information necessary to meet the requirements;

- Substantiate any claims of confidential business information;
- Register with CDX;
- Use the e-NOA software;
- Submit information to EPA, as necessary;
- Comply with any restrictions EPA may impose upon completion of review of their submission; and
- Maintain any necessary records.

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

5(a) Agency Activities

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. 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) Information Requested

a. Data items, including recordkeeping requirements

Data items are approved under OMB Control Numbers [tba] and [tba].

b. Respondent Activities - Register with EPA's CDX and Complete the Electronic Signature Agreement

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.

c. Respondent Activities - Use the e-NOA Software to Prepare TSCA Section 8(b) Notices

In all cases, respondents use the e-NOA software to:

- ***generate*** the submission materials for TSCA section 8(b) notices, including forms (i.e., the NOA Form A [tba] and the NOA Form B [tba]); and,
- ***populate*** the submission materials with the relevant information.

d. Respondent Activities - Finalize and Submit

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.

<u>Using e-NOA Software to Submit Electronically to EPA via CDX</u>

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.

5(c) 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(d) Small Entity Flexibility

The reporting and recordkeeping requirements associated with TSCA section 8(b) are applicable to all affected entities, regardless of size of 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 small businesses complying with TSCA rules. It provides material such as copies of Federal Register notices, 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 in 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 of TSCA Inventory 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(e) Collection Schedule

Does not apply. Submission of information under this collection is on an as-needed basis, initiated by the submitters.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This analysis presents the burden and cost estimates for affected entities, and covers submissions of Notices of Activity (NOAs). Table 1 provides a list of general activities required for compliance with the regulation by manufacturers (including importers) and processors. Table 1 also provides a cross-walk of the related Information Collection category that corresponds to each activity. Burden and cost calculations are based on the assumption that EPA will receive approximately 1,685 NOA submissions during Start-Up Reporting in the first year, and 20 NOA submissions annually for each year of Ongoing Reporting. For both Start-Up and Ongoing Reporting, the typical submission is assumed to include 18 chemicals, as reported in *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017).

Table 1. Cross-Walk between Industry Activities and Related Information Collections (ICs)

Activity	Description	Related IC(s) included in this ICR Renewal
Preparation and Submission of Reports	Staff must collect all of the information, required by submissions. This ICR covers the NOAs submitted during Start-Up Reporting and for Annual Ongoing Reporting. The information must be gathered, reviewed, and submitted to EPA. This activity involves any research necessary to identify the correct information and the act of completing the submission review.	Prepare and Submit Report, and Maintain Records
Recordkeeping	Respondents must keep records supporting their submissions.	Prepare and Submit Report, and Maintain Records
CDX Registration	The information collection requires that submitters register with CDX in order to submit electronic records and completing an Electronic Signature Agreement form, including a CROMERR certification, which is signed, dated, and submitted electronically back to EPA.	CDX Registration Activities

6(a) Estimating Respondent Burden

This section presents the burden of this information collection activity to respondents in terms of the time required for facility personnel to perform the activities outlined in Section 3 of this document. 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. This section details the activity-level unit burdens grouped by type of activity. For additional details see the *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017). Note that there are two types of reporting within the ICR period. Start-Up Reporting occurs within the first year, and Ongoing Reporting occurs during the last two years.

The required activities are described below. Table 3 provides the detailed estimates.

***Rule Familiarization*.** The burden associated with rule familiarization involves becoming familiar with the full requirements of the rule, which includes reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which reporting requirements will be met for each chemical substance. This level of activity would apply to all entities within the affected universe during Start-Up Reporting, regardless of whether a NOA is submitted.

***Compliance Determination*.** The burden associated with compliance determination involves first reviewing files to determine whether reporting is required for chemical substance(s) manufactured (including imported) and/or processed by a particular company. Additionally, compliance determination burden is required on a per-chemical basis in order to review the list of active chemicals as they appear on the TSCA Inventory. 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.

CDX Registration and e-Signature. If not already registered, submitters are required to register with CDX in order to submit electronic records and completing an Electronic Signature Agreement form, including a CROMERR certification, which is signed, dated, and submitted electronically back to EPA.

Form Completion/Submission. A NOA submission for one chemical will include the data elements discussed below and also summarized in Table 3. Some items are firm-specific and only require one entry per submission; some items are chemical-specific and may be submitted once or for multiple chemicals.

1. **Submitter Information** includes Authorized Official Name and Address and Technical Contact Name and Address.
2. **CBI Designations** for Submitter Information are part of the submission.
3. **NOA Certification** is a required component of the NOA submission.
4. **Certifier e-mail Address** is required with certification and e-signature.

5A and 6A **Non-CBI Chemical Name and Chemical Identity**: For non-CBI chemicals, the NOA submitter is required to submit the TSCA Inventory Chemical Name and Chemical Abstract Services Registry Number (CASRN). The submitter may locate this information via SRS, or alternatively, select from a pick list during the electronic submission.

5B and 6B **CBI Chemical Name and Chemical Identity**: For CBI chemicals, the NOA submitter is required to submit the Generic Chemical Name. CBI chemID's chemical identification consists of an Accession Number. The submitter may locate this information via SRS, or alternatively, select from a pick list during the electronic submission.

7. **CBI Designation** for Chemical Name and Chemical Identity is part of the submission.
8. **Start Date** (per chemical for Ongoing Reporting) is the anticipated date of the start of manufacture, importation, or processing.
9. **CBI Designation** for Start Date is part of the submission.
10. **Chemical Identity CBI Status Declaration** involves selecting one of two conditions: to maintain the CBI claim or to not maintain the claim of confidentiality of the full chemical substance identity on the TSCA Inventory.
11. **CBI Substantiation for Chemical Identity** applies for certain submissions. As part of the NOA, submitters may provide chemID CBI substantiation in association with the indication that

they seek to maintain the CBI claim. The chemID CBI substantiation questions are as follows:

A. APPLICABLE TO ANY CBI CLAIM

(1) Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)?
If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).
If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

(2) Will disclosure of any information likely result in substantial harm to your business's competitive position?
If you answered yes, please describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.
If, for example, it is not publicly known that the submitter manufacturer, imports or processes the reported chemical, describe with specificity the harmful effects that would result if this information were made available to the public. If you are claiming technical contact name or name of authorized official as CBI, describe with specificity the harmful effects that would result if this information were made available to the public.
If you are claiming multiple information elements as CBI, please provide information for EACH element you identified above.

(3) To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.
(1) Non-disclosure agreement required prior to access.
(2) Access is limited to individuals with a need-to-know.
(3) Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).
(4) Other internal control measure(s). *If yes, please explain below.*

(4) Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public?
If you answered yes, please explain why the information should be treated as confidential.

(5) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If so, please indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

(6) Has EPA, another federal agency, or court made any made any confidentiality determination regarding information associated with this substance?

If you answered yes, please explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

B. APPLICABLE ONLY TO CHEMICAL IDENTITY CBI CLAIMS

(1) Are you providing a substantiation at this time to maintain a specific confidential chemical identity as CBI?
If you answered yes, please respond to questions below and in Section A.
If you answered no, please leave all questions below blank. You must substantiate by the deadline established in a forthcoming Review Plan, to be promulgated at a later date in accordance with TSCA section 8(b)(4)(C).

(2) Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States?
If you answered yes, please explain why the information should be treated as confidential.

C. CERTIFICATION

I certify that, for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that:

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

[Electronic signature]

12. **CBI Substantiation for non-Chemical Identity Data Elements (**Applies for certain submissions). As part of the NOA, relevant submitters are required to provide CBI substantiation for non-chemID data elements, including: Name and company name of authorized official; Mailing address for authorized official; Name of technical contact; Telephone number for technical contact; and start date (up to five elements). The non-chemID CBI substantiation questions are as follows:

A. APPLICABLE TO ANY CBI CLAIM

(1) Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)?
If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).
If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

(2) Will disclosure of the information likely result in substantial harm to your business's competitive position?
If you answered yes, please describe with specificity the substantial harmful effects that would likely result to your competitive position if the CBI element is made available to the public.

If, for example, it is not publicly known that the submitter manufactures, imports or processes the reported chemical, describe with specificity the harmful effects that would result if this information were made available to the public. If you are claiming technical contact name or name of authorized official as CBI, describe with specificity the harmful effects that would result if this information were made available to the public.

If you are claiming multiple information elements as CBI, please provide information for EACH element you identified above.

(3) To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.

(1) Non-disclosure agreement required prior to access.

(2) Access is limited to individuals with a need-to-know.

(3) Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).

(4) Other internal control measure(s). *If yes, please explain below.*

(4) Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public?

If you answered yes, please explain why the information should be treated as confidential.

(5) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If so, please indicate the number of years (between 1-10 years) or specific date/occurrence after which the claim is withdrawn.

(6) Has EPA, another federal agency, or court made any made any confidentiality determination regarding information associated with this substance?

If you answered yes, please explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

B. APPLICABLE ONLY TO CHEMICAL IDENTITY CBI CLAIMS

[not applicable]

C. CERTIFICATION

I certify that, for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that:

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

[Electronic signature]

Recordkeeping. Submitters must keep records supporting their submissions for five years. Recordkeeping requirements for NOAs are necessary for EPA compliance and enforcement purposes.

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 a NOA for one chemical (i.e., Processors during Phase II of Start-Up Reporting), the nominal single-chemical submission estimates apply for either Start-Up or Ongoing Reporting. For firms submitting a NOA with multiple chemicals, it is assumed that on average there are 18 chemicals per firm submission(for basis, see EPA, 2017). Therefore, the estimates for "Start-Up Typical Average Unit Burden per Firm" and "Annual Ongoing Unit Burden per Firm" are on the basis of 18 chemicals per submission. Note that the average burdens do not include CDX registration and e-Signature, as these activities coincide with a different unit of analysis (per registration) and constitute only a small part of the overall burden estimate.

Table 2. Activity-Level Unit Burdens

Description	Activity-Level Unit Burden (hours)	Unit of Analysis	Source
Rule familiarization	4.000	Per firm	CDR ICR (EPA, 2015a)
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)
CDX Registration	0.180	Per CDX registration (individuals in firms)	Section 5 ICR (EPA, 2015b)
CDX e-Signature	0.350	Per CDX registration (individuals in firms)	Section 5 ICR (EPA, 2015b)
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)
(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)

Description	Activity-Level Unit Burden (hours)	Unit of Analysis	Source
(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 (applies only to Annual Ongoing Reporting)	0.017	Per chemical	Agency BPJ (similar to #4 above)
(9) CBI Designation for Start Date (applies only to Annual Ongoing Reporting)	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)	1.150 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
Miscellaneous			
Recordkeeping	0.125	Per submission	Section 5 ICR for NOC (EPA, 2015b)

Table 3. Unit Burden for Start-Up and Annual Ongoing Conditions

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
CDX REGISTRATION [1]	Registration	0.000	0.180	0.000	0.180
CDX e-SIGNATURE [1]	Registration	0.000	0.350	0.000	0.350
RULE FAMILIARIZATION	Firm	0.000	2.000	2.000	4.000
COMPLIANCE DETERMINATION (Without Review of "Active Status" List)	Firm	0.000	0.500	0.000	0.500
COMPLIANCE DETERMINATION (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 [2]	Chemical	0.000	0.083	0.000	0.083
(6) Chemical Identity [2]	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 (applies only to Annual Ongoing Reporting)	Chemical	0.000	0.017	0.000	0.017
(9) CBI Designation for Start Date (applies only to Annual Ongoing Reporting)	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 [3]	Chemical	0.000	0.039	0.019	0.058
(12) CBI Substantiation for non-Chemical Identity data elements[4]	Chemical	0	0.211	0.106	0.317
Date and Time Stamps	Submission				System-Generated
SINGLE CHEMICAL SUBMISSION FORM COMPLETION, Start-Up Period		0.000	0.362	0.629	**0.991**

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
SINGLE CHEMICAL SUBMISSION FORM COMPLETION, Annual Ongoing Period		0.000	0.379	0.629	**1.008**
RECORDKEEPING					
Per NOA Submission, Start-Up and Annual Ongoing Periods	Firm	0.125	0.000	0.000	0.125
START-UP TOTAL, Unit Burden for Nominal Single Chemical					**5.699**
ANNUAL ONGOING TOTAL, Unit Burden for Nominal Single Chemical (Note: No Rule Familiarization)					**1.716**
AVERAGE UNIT BURDEN ACCORDING TO MULTI-CHEMICAL SUBMISSION					
Start-Up Period					
Rule Familiarization		0.000	2.000	2.000	4.000
Compliance Determination		0.000	1.994	0.000	1.994
Form Completion		0.000	6.057	2.754	8.811
Typical Average Unit Burden per Firm without Recordkeeping [5]					14.805
Recordkeeping		0.125	0.000	0.000	0.125
TOTAL, Typical Average Unit Burden per Firm [5]					**14.930**
Annual Ongoing Period					
Rule Familiarization		N/A	N/A	N/A	
Compliance Determination		0.000	1.994	0.000	1.994
Form Completion		0.000	6.363	2.754	9.117
Average Annual Ongoing Unit Burden per Firm without Recordkeeping [5]					11.111
Recordkeeping		0.125	0.000	0.000	0.125
TOTAL, Average Annual Ongoing Unit Burden per Firm [5]					**11.236**

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 *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017).

Footnotes

[1] New CDX registrations and e-signatures are expected due to: (1) firms that have not had experience with CDX, and (2) personnel turnover in firms that have experience with CDX.

[2] The 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.

Activity	Unit of Analysis	Clerical Burden (hours) (a)	Technical Burden (hours) (b)	Managerial Burden (hours) (c)	Total Burden (hours) (d) = (a) + (b) + (c)
[3] This 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 0.039 hours of technical labor; 0.019 hours of managerial labor.					
[4] This 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.					
[5] An average firm is expected to report 18 chemicals per submission, as similarly observed for CDR as chemicals per parent company.					

For total industry burden and cost by activity and reporting period, see Table 8 of this document in Section 6(d).

6(b) Estimating Respondent Cost

Estimation of unit industry cost involves combining the unit industry burden identified in Section 6(a) with wage data obtained for December 2016 from the BLS (2017) 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 (2016 Dollars)

Labor Category	Data Series [a]	Date	Wage	Fringe Benefit	Fringes as % Wage	Overhead % wage [b]	Fringe + Overhead Factor [c]	Hourly Loaded Wages
			(a)	*(b)*	*(c) =(b)/(a)*	*(d)*	*(e)=(c)+(d)+1*	*(f)=(a)×(e)*
Managerial	BLS ECEC, Private Manufacturing industries, "Mgt, Business, and Financial"	Dec-16	$50.09	$24.65	49%	17%	1.66	$83.26
Professional / Technical	BLS ECEC, Private Manufacturing industries, "Professional and related"	Dec-16	$45.66	$24.98	55%	17%	1.72	$78.40
Clerical	BLS ECEC, Private Manufacturing industries, "Office and Administrative Support"	Dec-16	$20.29	$10.52	52%	17%	1.69	$34.26

Footnotes
[a] Source: *Employer Costs for Employee Compensation Historical Supplementary Tables: December 2006 – December 2016* (BLS, 2017).
[b] An overhead rate of 17% is used based on assumptions in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002) and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (EPA, 2002).
[c] The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

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 Start-Up and Annual Ongoing Conditions

Activity	Unit of Analysis	Clerical Cost (2016$) (a)	Technical Cost (2016$) (b)	Managerial Cost (2016$) (c)	Total Cost (2016$) (d)=(a)+(b)+(c)
CDX REGISTRATION [1]	Registration	$0.00	$14.11	$0.00	$14.11
CDX e-SIGNATURE [1]	Registration	$0.00	$27.44	$0.00	$27.44
RULE FAMILIARIZATION	Firm	$0.00	$156.80	$166.52	$323.32
COMPLIANCE DETERMINATION (Without Review of "Active Status" List)	Firm	$0.00	$39.20	$0.00	$39.20
COMPLIANCE DETERMINATION (Review of "Active Status" List Only)	Chemical	$0.00	$6.51	$0.00	$6.51
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	$0.33	$1.11
(2) Technical Contact Name and Telephone Number	Firm				Included in (1) above
(3) NOA Certification	Submission	$0.00	$0.00	$41.63	$41.63
(4) Certifier E-mail	Submission	$0.00	$1.33	$0.00	$1.33
(5) Chemical Name [2]	Chemical	$0.00	$6.51	$0.00	$6.51
(6) Chemical Identity [2]	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 (applies only to Annual Ongoing Reporting)	Chemical	$0.00	$1.33	$0.00	$1.33
(9) CBI Designation for Start Date (applies only to Annual Ongoing Reporting)	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 [3]	Chemical	$0.00	$3.06	$1.58	$4.64
(12) CBI Substantiation for non-Chemical Identity data elements [4]	Chemical	$0.00	$16.54	$8.83	$25.37

Activity	Unit of Analysis	Clerical Cost (2016$) (a)	Technical Cost (2016$) (b)	Managerial Cost (2016$) (c)	Total Cost (2016$) (d)=(a)+(b)+(c)
Date and Time Stamps	Submission				System-Generated
SINGLE CHEMICAL SUBMISSION FORM COMPLETION, Start-Up Period		**$0.00**	**$28.38**	**$52.37**	**$80.75**
SINGLE CHEMICAL SUBMISSION FORM COMPLETION, Annual Ongoing Period		**$0.00**	**$29.71**	**$52.37**	**$82.08**
RECORDKEEPING					
Per NOA Submission, Start-Up and Annual Ongoing Periods	Firm	$4.28	$0.00	$0.00	$4.28
START-UP TOTAL, Unit Cost for Nominal Single Chemical					**$454.06**
ANNUAL ONGOING TOTAL, Unit Cost for Nominal Single Chemical (Note: No Rule Familiarization)					**$132.07**
AVERAGE UNIT COST ACCORDING TO MULTI-CHEMICAL SUBMISSION					
Start-Up Period					
Rule Familiarization		$0.00	$156.80	$166.52	$323.32
Compliance Determination		$0.00	$156.38	$0.00	$156.38
Form Completion		$0.00	$474.97	$229.34	$704.31
Typical Average Unit Cost per Firm in Start-Up Period [5]					**$1,184.01**
Recordkeeping		$4.28	$0.00	$0.00	$4.28
TOTAL, Typical Average Unit Cost per Firm [5]					**$1,188.29**
Annual Ongoing Period					
Rule Familiarization		N/A	N/A	N/A	
Compliance Determination		$0.00	$156.38	$0.00	$156.38
Form Completion		$0.00	$498.91	$229.34	$728.25
Average Unit Cost per Firm in Annual Ongoing Period [5]					**$884.63**
Recordkeeping		$4.28	$0.00	$0.00	$4.28
TOTAL, Average Annual Ongoing Unit Cost per Firm [5]					**$888.91**

Activity	Unit of Analysis	Clerical Cost (2016$) (a)	Technical Cost (2016$) (b)	Managerial Cost (2016$) (c)	Total Cost (2016$) (d)=(a)+(b)+(c)
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 *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017).					
Footnotes					
[1] New CDX registrations and e-signatures are expected due to: (1) firms that have not had experience with CDX, and (2) personnel turnover in firms that have experience with CDX.					
[2] The 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.					
[3] This 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 0.039 hours of technical labor; 0.019 hours of managerial labor. [4] This 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.					
[5] An average firm is expected to report 18 chemicals per submission, as similarly observed for CDR as chemicals per parent company reported.					

6(c) Estimating Agency Burden and Cost

The implementation of EPA capacity to receive and process NOAs will involve new costs in the start-up year and on an ongoing basis. EPA will implement new software and integration with CDX to facilitate form submission and processing. Additionally, the CISS database must be expanded to incorporate the new type of submission. Last, new tasks will be added 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 tasks:

(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 in Table 6 to estimate Agency cost, as shown in Table 7.

Table 6. Agency Wage Rate (2016 Dollars)

Labor Category	Data Source for Wage Information	Wage ($/hour)	Fringe Benefit	Fringes as % wage	Overhead as % wage	Fringe + Overhead Factor [c]	Loaded Wage ($/hour)
		(a)	(b)	(c) = (b) / (a)	(d)	(e) = (c) + (d) + 1	(f) = (a) × (e)
EPA staff	Annual federal staff cost: OPM Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 5 pay rates [a]	$50.04	Included in 60% overhead	N/A	60% [b]	1.6	$80.06

Footnotes
[a] Source: Salaries & Wages for the locality of Washington-Baltimore-Arlington (OPM, 2016).
[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$)
Start-Up Reporting Period				
CDX and CISS Expansion	2 FTE	$333,050	$185,000	$518,050
Management of NOA Submissions	19.80 hours × 1,685 submissions	$2,671,042	$0	$2,671,042
TSCA Inventory Setup	2 FTE	$333,050	$100,000	$433,050
TOTAL Start-Up Period Costs				**$3,622,142**
Annual Ongoing Reporting Period				
CDX and CISS	0.5 FTE	$83,262	$10,000	$93,262
Management of NOA Submissions	19.80 hours × 20 submissions	$31,704	$0	$31,704
TSCA Inventory Maintenance	0.5 FTE	$83,262	$10,000	$93,262
TOTAL Annual Ongoing Costs				**$218,228**

General Notes

1. Sources: Agency BPJ (Williamson, 2016), NOC estimate for "review of NOC forms" (EPA, 2015b), and wage rate in Table 6.
2. All FTE hours are associated with a labor cost based on wage rate for GS-13 Step 5 of $80.06 per hour and assumes 2,080 working hours per year (see Table 6).
3. An average firm is expected to report 18 chemicals per submission, as similarly observed for CDR as chemicals per parent company reported (see EPA, 2017).

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).[3] Total burden and total costs are then aggregated for all firms in the affected universe. Total industry burden and cost are presented in Table 8.

[3] See Section 3 and Table 2 of the *Burden and Cost Report*. The number of firms is based on the number of firms in the affected universe that must undergo rule familiarization as well as the subgroup of those firms that actually submit responses to EPA.

Table 8. Total Industry Burden and Cost by Activity and Reporting Period

Reporting Group	Unit Burden (Hours per Firm)	Unit Costs (2016$)	Rule Familiarization (Number of Firms)	Submission Respondents (Number of Firms)	Total Burden (Hours)	Total Costs (2016$)
PHASE I START-UP: INITIAL REPORTING FOR MANUFACTURERS AND IMPORTERS (APPROXIMATELY JUNE-DECEMBER 2017)						
Rule Familiarization	4.000	$323.32	4,957		19,828	$1,602,697
Compliance Determination	1.994	$156.38		1,220	2,433	$190,784
Form Completion	8.811	$704.31		1,220	10,749	$858,258
Recordkeeping	0.125	$4.28		1,220	153	$5,222
Total Phase I Start-Up [1]				***1,220***	***33,163***	***$2,657,961***
PHASE II START-UP: INITIAL REPORTING PERIOD FOR PROCESSORS (APPROXIMATELY JAN-JUN 2018)						
Group 1 – Additional Manufacturers and Importers Reporting (After Phase I)						
Rule Familiarization	4.000	$323.32	365		1,460	$118,012
Compliance Determination	1.994	$156.38		365	728	$57,079
Form Completion	8.811	$704.31		365	3,216	$257,073
Recordkeeping	0.125	$4.28		365	46	$1,562
Group 1 Subtotal [1]				***365***	***5,450***	***$433,726***
Group 2 - Processors						
Rule Familiarization	4.000	$323.32	283,993		1,135,972	$91,820,617
Compliance Determination	0.583	$45.71		100	58	$4,571
Form Completion	0.991	$80.75		100	99	$8,075
Recordkeeping	0.125	$4.28		100	13	$428
Group 2 Subtotal [2]				***100***	***1,136,142***	***$91,833,691***

Reporting Group	Unit Burden (Hours per Firm)	Unit Costs (2016$)	Rule Familiarization (Number of Firms)	Submission Respondents (Number of Firms)	Total Burden (Hours)	Total Costs (2016$)
Total Phase II Start-Up				**465**	**1,141,592**	**$92,267,417**
CDX Registration and e-Signature (Phase I and II Combined) [3]	0.530	$41.55		169	90	$7,022
TOTAL START-UP REPORTING				**1,685**	**1,174,845**	**$94,931,400**
ANNUAL ONGOING REPORTING (APPROXIMATELY POST JUNE 2018)						
Rule Familiarization	N/A	N/A				
Compliance Determination	1.994	$156.38		20	40	$3,128
Form Completion	9.117	$728.25		20	182	$14,565
Recordkeeping	0.125	$4.28		20	3	$86
TOTAL ANNUAL ONGOING REPORTING [1]				**20**	**225**	**$17,779**

General Note
Total industry 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 *Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements* (EPA, 2017).

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).

[2] Assumes the average firm includes one chemical per submission, given the nature of the submission.

[3] Total reflects assumption that the number of CDX registrations is 10% of the count of affected firms in the start-up period.

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 as a result of this information collection for the period of this initial ICR period.

Table 9. Annual Burden of the TSCA Inventory Notification Requirements – Initial ICR

Burden Category	Burden Hours			
	Year 1	Year 2	Year 3	Annual Average over the ICR Period
Industry Burden				
CDX Registration	90	0	0	30
NOA Submissions (includes respondents undergoing only rule familiarization in Year 1)	1,174,543	222	222	391,662
Recordkeeping	212	3	3	73
Industry Burden, Total	**1,174,845**	**225**	**225**	**391,765**
Agency Burden, Total	**41,683**	**2,476**	**2,476**	**15,545**

Table 10. Summary of Burden and Cost of the TSCA Inventory Notification Requirements

	Total Burden Hours	Annualized Average BURDEN over the ICR Period	Total Annual Costs	Annualized Average COSTS over the ICR Period
Industry				
Total Start-Up (for year one)	1,174,845	391,765	$94,932,400	$31,655,986
Total Ongoing (subsequent years)	225		$17,779	
Agency				
Total Start-Up (for year one)	41,683	15,545	$3,622,142	$1,352,866
Total Ongoing (subsequent years)	2,476		$218,228	

6(f) Reason 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 a reporting requirement on regulated entities. As such, the change being implemented in this ICR period is the addition of new burden and cost for first year implementation, as presented in Table 9 and Table 10. The annualized average burden to industry for this ICR period is 391,765 hours per year (total burden / 3 year approval period for ICR).

6(g) Burden Statement

The industry burden for this collection of information is estimated to average 14.930 hours per typical response during the start-up year and 11.236 hours per average response for annual ongoing reporting (second and third years of the ICR period). In both reporting periods, the average submission by a firm is assumed to contain information for 18 chemicals. Additionally, a burden of 0.530 hours per CDX registration is estimated for submitters not already registered with CDX. Burden is defined in 5 CFR 1320.3(b). 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-2016-0426, which is available for online viewing at *http://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-2016-0426 and OMB Control No. 2070-0201, to both (1) EPA online using http://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 20460, and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

7 REFERENCES

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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-2016-0426**. These attachments are available for online viewing at *www.regulations.gov* or otherwise accessed as described in section 6(f) of the supporting statement.

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

Attachment B: **40 CFR part 710**. [Final Rule] Also available online at the National Archives and Records Administration's Electronic CFR website

Attachment C: **Instruction Manual for TSCA Section 8(b) Reporting**. Also available online at http://www.epa.gov/oppt/newchems/pubs/tscaman2.pdf

Attachment D: **EPA Form [tba] – Notice of Activity Form A.** Also available online at http://epa.gov/oppt/newchems/pubs/NOAA.htm

Attachment E: **EPA Form [tba] - Notice of Activity Form B.** Also available online at http://epa.gov/oppt/newchems/pubs/NOAB.pdf

Attachment F: **Public Comments Received and EPA Responses to Proposed Rule.** See Response to Comment document in the docket.