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: Chemical Data Reporting under the Toxic Substances Control Act (TSCA section 8(a))¹

EPA ICR No.: 1884.10 OMB Control No.: 2070-0162

EPA Form No. 7740-8

Docket ID No. EPA-HQ-OPPT-2017-0648

1(b) Short Characterization/Abstract

This information collection request (ICR) addresses the paperwork requirements contained in the most recent Chemical Data Reporting (CDR) rule (40 CFR Part 711) under the Toxic Substances Control Act (TSCA). Under TSCA section 8(a) (15 USC 2607), the Environmental Protection Agency (EPA) is authorized to collect certain information on chemical substances manufactured (including imported) or processed in the United States. The CDR was formerly known as the Inventory Update Rule (IUR).

The CDR collection provides chemical manufacture, processing, and use information that helps EPA identify what chemicals the public may be exposed to as consumers or in commercial and industrial settings. The data also helps EPA assess routes of potential exposure to those chemicals. EPA has used the CDR rule to collect basic manufacturing information for selected chemical substances on the TSCA Inventory eight times beginning in 1986. More recent collections, beginning in 2006, included additional information relating to the manufacture, processing, and use of those chemical substances. The reporting requirements have been modified through rulemaking, with the most recent major changes occurring in 2011 when EPA promulgated the IUR Modifications Rule (76 FR 50815, August 16, 2011). The 2011 rule phased in some provisions; all changes were fully implemented with the 2016 CDR and are slated to continue for the next submission of data in 2020. The CDR collection is on a four-year reporting cycle and contains detailed manufacturing and processing information drawn from the principal reporting year; the rule also contains basic information on production volume, by year, for the three years prior to the principal reporting year (e.g., for the 2020 reporting cycle, the principal reporting year will be 2019; the three years prior will be 2016, 2017, and 2018). In addition, changes have been made to the list of chemical substances (see 40 CFR 711.6(b)(ii)(4)) that are partially exempt, most recently in 2016 (81 FR 17395, March 29, 2016).

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¹ The title of this ICR was previously: "Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting)." It was recently changed to reflect the 2011 name change, as this reporting is now routinely referred to as CDR.

Certain other changes to CDR were put in place following enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA on June 22, 2016. For example, the CDR certification statement was updated in June 2016 to be consistent with the revised statutory requirements. The requirement for substantiation of claims of confidential business information (CBI) at the time the claim is made is being implemented though a separate action, initiated in 2017 (82 FR 6522, January 19, 2017). EPA is providing questions to help submitters develop their substantiation of CBI at the time of claim. These changes and the reporting burden estimates associated with them have been incorporated into this ICR supporting statement.

The 2020 CDR data collection is expected to involve an average of approximately 5,662 respondents at an annual cost of \$57 million during the ICR period. The details of the paperwork burden and cost estimates are discussed in this document.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Under TSCA as amended by the Lautenberg Act in 2016, EPA is charged with protecting human health and the environment from potential chemical risks. EPA's Office of Pollution and Toxics (OPPT) carries out its responsibilities by, among other things, prioritizing chemicals for evaluation, conducting risk evaluations and, where necessary, taking risk management actions under TSCA, as well as by making non-confidential information publicly available in order to promote informed decision-making and transparency. CDR data helps the Agency to identify, assess, and control potential risks to human health and the environment posed by commercial chemical substances. TSCA section 8(a) authorizes the Administrator to promulgate rules to provide for the maintenance and collection of records from manufacturers (including importers) and processors of commercial chemical substances. Sections 8(a)(1) and (2) of TSCA also authorize the Agency to collect information on the chemical substance manufacturing (including importing) industry. EPA possesses broad discretion in determining the information to be reported under TSCA section 8(a). See Attachment 1.

Through the CDR regulation² (See Attachment 2), EPA collects basic exposure-related manufacturing, processing, and use information used by the Agency and others in a wide range of activities. The CDR data collection is on a four-year reporting cycle and mainly contains information drawn from the principal reporting year but also contains some information, by year, from the previous three years. The information collected enables EPA to better understand and interpret the state of U.S. chemical manufacturing, processing, and use, and further enhances EPA's ability to identify, evaluate, and manage potential chemical risks.

Under CDR, manufacturers (including importers) are required to report if, for any calendar year since the last principle reporting year (i.e., 2015 for the 2016 reporting cycle), a chemical substance was manufactured (including imported) at a site in production volumes of

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² The original IUR rule was codified at 40 CFR part 710. In its August 2011 amendments, EPA moved the CDR rule to 40 CFR part 711.

25,000 pounds or greater for most chemical substances. The reporting threshold is lower (2,500 pounds) for chemical substances that are the subject of certain TSCA actions, including:

- A rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6;
- An order issued under TSCA sections 5(e) or 5(f); or
- Relief that has been granted under a civil action under TSCA sections 5 or 7.

The CDR exposure-related data on manufacturing, processing, and use will enable EPA to conduct a more effective and efficient screening-level review of chemical substances to identify candidates for further evaluation or action. This is particularly important in light of EPA's requirement under TSCA, as amended by the Lautenberg Act, to identify chemicals in commerce as high priority or low priority for risk evaluation (TSCA section 6(b)).

Additionally, under TSCA section 14, claims of CBI (other than for production volume) must be substantiated at the time information is submitted to EPA, including as part of CDR (See 82 FR 6522, January 19, 2017). In order to make sure EPA can use CDR data most effectively, including sharing it with the public, TSCA necessitates the submission of CBI substantiation and EPA review of the legitimacy of CBI claims. For instance, the data that are claimed confidential should not already be publicly available and submitters should demonstrate that the disclosure of confidentially-claimed information would cause harm to a business' competitive position.

2(b) Practical Utility/Users of the Data

The reporting methods, including the reporting tool and electronic registration, help to ensure that the information reported to EPA is accurate and in compliance with the CDR requirements. In addition, the data elements reported have practical utility for users of the data within EPA and for the public.

e-CDRweb Reporting Tool

For the 2020 submission period, EPA will continue to require electronic reporting for all CDR submissions, including joint submissions and amendments. Persons submitting information under the CDR rule are required to use e-CDRweb, the Agency-provided, web-based tool to complete Form U (the CDR reporting form). The information is submitted electronically via the Internet, through EPA's Central Data Exchange (CDX). Users of CDX are required to register with the system, including submitting an authorized signature agreement to EPA.

CDX Registration

Each CDR submission must have an associated authorized official. The authorized official signs the certification statement and submits the CDR report via CDX. To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder") completes an electronic signature agreement (ESA) form. For identity authentication, the registrant will complete the ESA, and either submit the form electronically or mail to EPA. Once EPA receives the form, EPA will activate the registrant's CDX account and send a notification via email.

A company may need or desire to have more than one individual complete an electronic signature agreement, so that more than one person can add information to an original CDR submission. Persons submitting supplemental information for a CDR submission on behalf of a company need to register with CDX by signing an ESA. The company official can authorize an unlimited number of agent or support registrants and agent or support registrants can work with an unlimited number of company officials. An agent registrant has abilities very similar to those of the authorized official, but the agent does not have the abilities to submit completed forms and assign agent or support registrants. A support registrant is more limited in their abilities, but they can enter and edit submission information. An agent or support registrant may be an employee of the company, an outside consultant for the company, or an authorized representative agent for the company. While this individual is not able to sign the certification statement required for the initial CDR submission, they are able to provide additional information, if needed, using CDX.

Data Elements for CDR Submissions

The CDR information collection is the only mechanism through which EPA routinely collects basic information on commercial chemical substances listed on the TSCA Inventory, including production volume and other manufacturing (including importing), processing, and use exposure-related data. EPA will use the information collecting in the following ways:

- 1) U.S. parent company, site, and technical contact information: EPA requires that company information be provided for the U.S. parent company associated with the reporting site. Consistent use of parent company names makes for more meaningful comparisons of data, especially for protecting information claimed as confidential when there are multiple sites for the same parent company. Site information is important because EPA and stakeholders need to know where chemical manufacturing (including import) occurs. EPA uses the technical contact information to contact submitters in the event of questions about the submission.
- 2) Manufacturing-related information:
 - a) The production volume of a manufactured (including imported) chemical substance used at the reporting site: This data element identifies whether a chemical substance is used on site. Either domestically manufactured or imported chemical substances can be reported as used at the reporting site. This information is related to potential exposures associated with the on-site volumes, and provides the Agency with information for exposure assessments and other data analyses.
 - b) The production volume for each of the years since the last principal reporting year: Manufacturers (including importers) need to report production volume information for the principal reporting year (the year before the collection; i.e., for 2020 the principal reporting year would be 2019) and for each of the calendar years since the last report (i.e., 2016, 2017, 2018), if a chemical substance was manufactured (including imported) at a site in excess of the relevant production volume threshold (25,000 pounds or 2,500 pounds if subject to certain TSCA actions) for any of the four calendar years. Examples of how EPA will use these data include: chemical prioritization efforts; chemical manufacturing, processing, and use trend analyses; and assessment of Agency and public programs.
 - c) Whether an imported chemical substance is physically at the reporting site: Imported chemical substances may never physically be located at the reporting site because, upon

- import, they are shipped directly to another site. This data element enables the Agency and others to better assess manufacturing-related potential exposures, thereby enabling information for screening-level analyses and other uses of the CDR data.
- d) The production volume directly exported and not domestically processed or used: This data element allows EPA to identify the completeness of the reported processing and use information by indicating the proportion of the production volume potentially covered by the reported processing and use information. CDR processing and use information is required only for domestic use situations and is not required for any volumes directly exported. This data element informs the exposure profile for the U.S. public.
- e) *The number of workers exposed:* This data element allows EPA to identify the number of workers reasonably likely to be exposed to each reportable chemical substance during manufacture at each site. This exposure-related information allows OPPT to screen chemical substances based on the potential for risk in order to protect human health.
- f) The maximum concentration of a chemical: This data element provides maximum concentration measured by percentage of weight of a reportable chemical substance at the time it is reacted on-site to produce a different chemical substance or as it leaves the site. This data element provides information relevant to the exposure profile of a chemical substance.
- g) Whether a manufactured (including imported) chemical substance is being recycled, remanufactured, reprocessed, or reused: This data element provides information relevant to the exposure profile of a chemical substance and indicate efficiencies within the chemical manufacturing industry.
- h) *The physical form of a chemical:* This data element provides information needed for the Agency to understanding potential routes of exposure to the chemical substance, which is dependent in part on the physical form of the chemical substance.
- 3) Processing and use information: Data elements that relate to processing and use help EPA, and other agencies to readily screen and prioritize chemicals for the purpose of identifying potential human health and environmental effects. For example, the data are used in exposure and risk screening, testing and/or priority setting, and exposure estimates required by TSCA section 4; for EPA monitoring activities of newly manufactured substances that have completed pre-manufacture notification (PMN) review under TSCA section 5(a); and to measure potential human and environmental exposure which helps inform chemical risk evaluations, such as those required under TSCA section 6. Each data element corresponds to a data point necessary for basic risk screening.
 - a) Industrial processing and use data: These data elements identify how the chemical is processed or used in an industrial setting, including the function of the chemical substance in any formulation or product. The industrial data elements include the type of process or use operation (TPU), the industrial sector (IS) and the industrial function category (IFC). Both IS and IFC codes were designed to consolidate information based on potential exposure-related scenarios, thereby reducing the number of choices available to the respondent, streamlining the reporting process, and making the data easier to use. Also included in this industrial processing and use section are data elements for percent production volume, number of sites, and number of workers. These data elements help to characterize the potential exposures associated with the TPU, IS, and IFC data elements.

- b) Consumer and commercial use data: These data are reported separately from the industrial data and are used to determine exposure potential based on uses by consumer and commercial populations. The specific data elements include product category; whether the application is intended for consumer or commercial populations (or both), including specifically for use by children, and characterizing data elements (percent production volume, maximum concentration, and number of commercial workers). This information allows EPA and the public to better understand the consumer and commercial uses of CDR chemicals, including what is in children's products, thereby enabling the Agency to better characterize chemical exposures related to children's health.
- 4) Special considerations for Joint Submitters when Chemical Identity is Unknown: In certain situations, CDR submitters are allowed to report the information jointly with the supplier(s) of the chemical substance for which the submitter is reporting. For example, importers may not know the specific chemical identity of the imported TSCA chemical substance because the foreign supplier chooses to keep the information confidential. In addition, a manufacturer may not know the specific chemical identity of the substance being manufactured because the supplier of a reactant used to manufacture the substance chooses to keep the information confidential. In such situations, the manufacturer (including importer) is still responsible for ensuring that the CDR information is submitted to EPA and may do so by submitting a joint report.

In the case of an imported substance, the U.S.-based importer, as the primary submitter, initiates and completes the majority of the required information on Form U, and provides a trade name in Part II.2.A.4 of Form U to identify the chemical substance. Using e-CDRweb (the electronic reporting tool), the primary submitter then contacts the foreign supplier, as the secondary submitter, to notify them of the need to report the specific chemical identity information directly to EPA in the joint submission section (Part IV) of Form U. Because signatures are required by each party of a joint submission, each party must register with CDX, complete their own company information sections on Form U, and submit their respective portions of the same report electronically to EPA. The secondary submitter will not be able to access the information provided by the primary submitter and vice versa. EPA combines information provided separately by the primary and secondary submitters, thereby providing a complete picture of the CDR data for the subject chemical substance without breaching confidentiality.

EPA collects certain data to enable the joint submission and to combine information from the two parties. These data will be used in the following ways:

- a) Joint submission information (primary submitter): The primary submitter provides a trade name or other designation in place of the specific chemical identification and the secondary company contact information (name, address, email address). This information is used by the electronic reporting tool to contact the secondary submitter and by EPA to connect the information from both parts of the submission.
- b) Secondary company identification information (secondary submitter): These data identify the secondary submitter's company name and the complete mailing address of the

- company. The information helps ensure that the company information is provided consistently and is used to associate the secondary submitter's company with the primary submitter's company and site plant.
- c) Technical contact information (secondary submitter): The company's technical contact information provides EPA with the name and complete mailing address of the person who will be able to answer questions that EPA may have about the reported chemical substance.
- d) *Trade product identification information (secondary submitter)*: These data identify chemicals associated with the primary submitters supplied trade product name, and include the associated chemical name and Chemical Abstract Services (CAS) Registry Number. If the product contains multiple chemicals, the secondary submitter includes also the percent of formulation for each chemical substance. The trade product information is the portion that is considered confidential by the secondary submitter, and will be used as discussed in sections 2(b)(2) and 2(b)(3) of this document.
- 5) CBI Substantiation: Most CDR data can be claimed as CBI when the CDR reporting form is submitted to EPA. As required under TSCA as amended by the Lautenberg Act, substantiation for CBI claims must be submitted at the time the claim is made, except for CBI claims for production volume information (excludes percent production volume). The e-CDRweb electronic reporting tool is the mechanism for submitting substantiation information. For certain data elements, submitters must answer EPA substantiation questions related to whether the information is publicly known and whether public knowledge of the information would hurt a business' competitive position. EPA provides additional questions for chemical identification that is claimed CBI.

Uses of CDR Data

This collection of information is key to strengthening EPA's TSCA program, by providing exposure-related data needed to develop an understanding of chemical risks. Past improvements of the CDR collection during the last three reporting cycles resulted in data that are more transparent, more useful, and in a more useable format. An increased quality and reliability of the data, faster access to the data, and an increased amount of data for the public have vastly expanded the usefulness of the CDR data.

CDR data provide basic exposure information which helps EPA fulfill its environmental protection mandate. For example, CDR data:

- Provide a "current picture" of a chemical, industry, or use by reporting information not otherwise available for chemicals listed on the TSCA Inventory.
- Enable more effective screening of chemicals, their uses, and potential exposures so EPA can prioritize efforts.
- Provide information useful for measuring the progress of regulatory or voluntary programs.
- Allow EPA to identify industry trends.

Although EPA has used CDR data for past efforts, changes to TSCA by the Lautenberg Act make the data even more important for statutorily-required Agency prioritization activities. TSCA section 6 now requires EPA to develop and use a process to designate the priority of chemical substances, and that the process:

...shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed. [TSCA section 6(b)(1)(A)]

CDR data will be important for characterizing the exposure potential, potentially exposed or susceptible subpopulations, the conditions of use, and the production volume or significant changes in the production volume of chemical substances being considered for priority designation for risk evaluation.

Also, CDR data are used in risk evaluation (including scope development and exposure assessment) to:

- aid in characterizing the life cycle of the chemical (from manufacture, processing, use, and recycling activities)
- identify existing conditions of use based on industrial processing and use reporting as well as reporting on the use of a CDR chemical in commercial and consumer products
- identify potentially exposed or susceptible subpopulations (e.g. number of workers, use in children's products)
- estimate releases and exposures associated with conditions of use

Specific examples of CDR data used in risk evaluation:

- In 2012 (and updated in 2014), EPA screened all existing chemicals to identify candidates for assessment over the next several years. The screening process used to identify these chemicals is detailed in the TSCA Work Plan Chemicals Methods

 Document. This process used CDR data to develop an exposure score, which included identifying if children were likely to be exposed, determining the potential for release when TRI data were not available, identifying the production volume and number of sites, and developing rankings based on the industrial processing and use and on the consumer/commercial uses. Ultimately, 345 chemical substances or chemical compound categories were screened, from which 90 in 2014 were identified as the TSCA Work Plan Chemicals, or chemicals the Agency identified as high priority for risk assessment.
- The 2014 TSCA Work Plan will continue to inform future prioritization of chemicals for risk evaluation under TSCA as amended by the Lautenberg Act.
- In 2016, EPA announced the <u>first 10 chemicals</u> for risk evaluation, as required by TSCA. As part of this process, EPA <u>published the scope of each risk evaluation</u> to be conducted. These scope documents utilized CDR data to identify potential exposures,

- conditions of use and potentially exposed or susceptible subpopulations that the Agency expects to consider during the risk evaluation.
- OPPT develops Emission Scenario Documents (ESDs) used by the Organisation for Economic Cooperation and Development (OECD) and industry-specific generic scenarios for use in developing occupational exposure and environmental release estimates of chemicals for specific use scenarios. CDR data are used in generic scenario / ESD development to:
 - identify types of chemicals commonly used and their functions in the industry of interest
 - o estimate number of potentially exposed workers per site
 - o develop estimates of exposure levels and releases.

Other offices in EPA rely on CDR data:

- ORD (Office of Research and Development) uses CDR data in the development of lifecycle inventories (LCIs) to:
 - o aid in characterizing the life cycle of the chemical
 - o develop standardized emission/release estimates (i.e., per 1 kg chemical) during chemical production
- OW (Office of Water) uses CDR data in the development of effluent guidelines to:
 - o identify facilities in industry sectors of interest for development of new effluent guidelines
 - o identify chemicals of interest and their associated processing and use activities (part of Annual Effluent Guideline Review Reports)
- OECA (Office of Enforcement and Compliance Assurance) uses CDR data to:
 - o analyze chemical manufacturing production volume trends over time and correlate production with facility discharges to evaluate potential noncompliance and define compliance assistance efforts

Other Federal Agencies use CDR data:

- Occupational Safety and Health Administration (OSHA):
 - o uses the production and use information to better understand worker exposure and industries where exposure may occur (FR Doc No: 2014-24009)
- Centers for Disease Control and Prevention (CDC)
 - o the Agency for Toxic Substances and Disease Registry (ATSDR) uses CDR data to develop toxicological profiles
- National Institute of Health (NIH)
 - o uses CDR data for exposure and use information published in the Hazardous Substances Data Bank (HSDB)

Following the 2016 amendment of TSCA by the Lautenberg Act, states are expected to have increased access to TSCA data and to have more opportunity to contribute to EPA's risk evaluation processes for chemicals in commerce. While this process is being put into place, states have identified their current uses of CDR data:

- State chemical risk evaluation processes
- Emergency Response Planning/Community Right to Know
- State OSHA/worker health and safety
- Facility Siting and Permitting (most likely air and water permits)
- Compliance and enforcement for disposal/releases/mismanagement
- Pollution Prevention Planning and Implementation
- Technical Assistance Programs
- Development of Policy and Legislation

CDR data are also made public by the Agency via the online ChemView database, public releases of information on chemicals of interest (such as those prioritized for risk evaluation under TSCA (82 FR 31592, July 7, 2017), and documents posted publicly by EPA that highlight key information about the most current reporting period.

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

3(a) Non-Duplication

The data included in this information collection (i.e., production volume, chemical manufacture, exposure, and processing and use data) are not collected comprehensively or systematically at the national level by any other entities.

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

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on October 1, 2018 (83 FR 36928, July 31, 2018) (FRL-9980-28). EPA received three comments from: Richard Starr, Manager, Regulatory and Technical Affairs, American Chemistry Council (ACC); Jared Rothstein, Senior Manager, Regulatory Affairs, Society of Chemical Manufacturers & Affiliates (SOCMA); and David Wawer, Executive Director, Color Pigments Manufacturers Association (CPMA) during the comment period. Copies of the public comment(s) and of EPA's response to the public comment(s) appear in Attachment 4.

3(c) Consultations

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions via e-mail to the following individuals from stakeholders representing the potential respondent group:

Mike Walls, Vice President Regulatory and Technical Affairs American Chemistry Council Inc. 700 2nd Street N.E. Washington, D.C. 20002

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E-mail: mike_walls@americanchemistry.com

Kathleen Stanton, Senior Director Technical and Regulatory Affairs American Cleaning Institute 1331 L Street N.W., Suite 650 Washington, D.C. 20005

Tel: (202) 662-2513

E-mail: kstanton@cleaninginstitute.org

Derek Swick, Senior Policy Advisor Regulatory and Scientific Affairs American Petroleum Institute 1220 L Street N.W. Washington, D.C. 20005-4070

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David Wawer, Executive Director Color Pigments Manufacturers Association 1400 Crystal Drive, Suite 630 Arlington, VA 22202 Tel: (571) 348-5130

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Steve Bennet, Vice President Scientific Affairs Household and Commercial Products Association 1667 K Street N.W., Suite 300 Washington, D.C. 20006

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E-mail: moedritzerm@socma.com

EPA received responses to its solicitation for consultations from: Tatiana Letcheva (CPMA), Jared Rothstein (SOCMA), and Richard Starr (ACC). A copy of the responses and a copy of EPA's consultation e-mail are included in Attachment 5.

3(d) General Guidelines

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

The record retention period of this collection is five years, as specified in 40 CFR 711.25, exceeding the PRA maximum of three years. This is necessary to ensure companies retain records long enough to facilitate their completion of Form U (EPA Form 7740-8) every four years, and to allow EPA's enforcement activities to overlap two CDR reporting cycles. Based on changes to TSCA from the Lautenberg Act, CBI claims remain intact for up to 10 years after submission and are renewable.

3(e) Confidentiality

CBI claims limit public access to the CDR data. EPA recognizes that some information submitted to the Agency is legitimately confidential business information, and EPA reviews CBI data in its mission to protect human health and the environment, in accordance with TSCA section 14(f) and (g).

Submitters may claim information reported to EPA under this rule as confidential if such information would reveal the submitter's trade secrets or proprietary information as defined by TSCA section 14 and existing regulations promulgated by EPA under TSCA. EPA has long-established procedures for properly handling, storing, processing, and disposing of TSCA CBI. Transfers of this information to others, such as states, tribes, and emergency responders, as

allowed under TSCA section 14(d), can be made only if the other entity agrees to adhere to all relevant TSCA confidentiality provisions and policies. EPA will maintain standard CBI procedures to protect any confidential, trade secret, or proprietary information from disclosure in accordance with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

3(f) Sensitive Questions

This collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The regulated community consists of companies manufacturing (including importing) certain chemical substances listed on the TSCA Inventory and regulated under the TSCA section 8(a) CDR regulation. In general, the industry segments that compose the regulated community for the rule are those that produce or import chemical substances. Most respondents expected to be subject to this ICR have previously reported CDR information. The Agency's previous experience with CDR collections has shown that the majority of the respondents affected by this collection activity are from the following NAICS code categories:

- 325 Chemical Manufacturing
- 324 Petroleum and Coal Product Manufacturing

The subsectors identified above represent the designation of sites that likely would be subject to CDR reporting. However, this list does not include all potentially affected entities. Other types of entities not listed in this unit could also be subject to reporting.

Generally, TSCA section 8(a) excludes small manufacturers (including importers) from reporting. EPA defines small manufacturers (including importers) for purposes of CDR and certain other reporting in 40 CFR 704.3. See also section 5(c) below.

4(b) Information Requested

(i) Reporting Threshold for Certain Regulated Chemicals

The threshold for reporting to CDR is a production volume of 25,000 pounds at a single site for any calendar year since the previous principal reporting year. The reporting threshold is 2,500 pounds for certain chemical substances that are:

- The subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6,
- The subject of an order issued under TSCA sections 5(e) or 5(f),
- The subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

Chemical substances subject to these particular TSCA actions are of demonstrated high interest to the Agency. The lower reporting threshold helps to ensure the availability of current

information on those chemical substances manufactured above 2,500 pounds when the Agency has expressed a concern in the form of regulatory action. EPA will use the CDR data associated with these regulated chemical substances to monitor chemical substance production and compliance with the rules.

(ii) Data elements, including recordkeeping requirements

The CDR data elements are related to, or indicative of three components of exposure. These components are: (1) the number of ecosystems or size of human populations potentially exposed, (2) the potential human or environmental exposure concentrations, and (3) the frequency and duration of potential exposures. The data enhances EPA's ability to evaluate each of these components of exposure. Respondents are required to submit certain "known or reasonably ascertainable" manufacturing, processing, and use exposure-related information.

Using e-CDRweb, individuals report the data elements as follows:

- Authorized company official's e-mail address. The e-mail address of the company official authorized to sign and submit the CDR Form U.
- *U.S. parent company name and address*. The name, Dun & Bradstreet number, and mailing address of the U. S. parent company.
- *Manufacturing site*. The site name; Dun & Bradstreet number and the physical address of the manufacturing site.
- *Technical Contact Information*. The individual name, the company name, and address of the technical contact. Sites are able to provide one contact for the site or one for each chemical.
- Manufacturing information. The production volume for each of the years since the last principal reporting year. For the principal reporting year only: the volume of the reported chemical substance used at the reporting site; whether an imported chemical substance is physically at the reporting site; the production volume directly exported and not domestically processed or used; the number of workers likely to be exposed at the site; the maximum concentration, measured by percentage of weight; whether the manufactured (including imported) chemical substance is being recycled, reused, reprocessed, or remanufactured and the physical form(s) of the chemical substance, and the associated percent production volume of each physical form.
- Processing and use information. Respondents are to report this information for all reported chemical substances, unless the chemical substance is specifically partially exempted.
 - o *Industrial processing and use data*. Submitters must report their type(s) of industrial process or use, sector(s), industrial function category(ies), percentage(s)

- of production volume, number(s) of sites, and number(s) of workers reasonably likely to be exposed.
- o *Consumer and commercial use data*. Submitters must indicate the product category(ies); whether the use is consumer, commercial, or both; whether the chemical is used in products intended for children; and for each product category: the percent production volume, the maximum concentration, and number of commercial workers reasonably likely to be exposed to the chemical.
- *CBI substantiation*. All of the data elements described in the Manufacturing Information section and Processing and Use Information section may be claimed CBI. Substantiation of the CBI claim must accompany the claim unless the claim is for production volume.

Joint Submissions when Chemical Identity is Unknown. Joint submissions are allowed only in those instances where a supplier will not disclose to the submitter the specific chemical name of the imported TSCA Inventory chemical substance or of a reactant used to manufacture the TSCA Inventory substance. This may happen, for example, when a company is importing a mixture under a trade name, and the foreign supplier does not want to reveal the components in the mixture. (See Special Considerations for Joint Submitters when Chemical Identity is Unknown in section 2(b) of this document.) In addition to signing the certification statement and completing Parts I, II, and III, primary respondents will report on data elements in Part II, Blocks 2.A.5 through 2.A.12, on Form U as follows:

• *Joint submission information*. Trade name of the chemical substance being reported, secondary respondent name, and complete mailing address (city, state/province, zip code, and country (if applicable)).

Secondary submitters register with CDX as secondary authorized submitter or a secondary support registrant. The secondary submitter will provide the primary company's information and the trade product name, supplied to them by the primary submitter to initiate Part IV of Form U. The secondary submitter reports the following data elements:

- Certification. The company official must certify by signature and date that to the best of his/her knowledge and belief: 1) all information entered on Form U has been completed in compliance with the regulatory requirements; and 2) any confidentiality claims are true and correct as to that information for which they have been asserted.
- *Secondary company information.* The secondary company name and complete mailing address (city, state, zip code, and country (if applicable)).
- Secondary technical contact information. The technical contact name, phone number, complete mailing address (city/town, state/province, zip code, and country (if applicable)), and e-mail address.

- *Primary company information sent to secondary company.* Trade name and the Unique Identifier for Joint Submissions number provided by the primary submitter and sent to the secondary submitter.
- *Trade product information*. The trade product name; the chemical name, CAS Registry Number, and percentage of each component of the product.

(iii) Submitter Activities/Information Collections (ICs)

EPA identified the following ICs in the currently-approved ICR for activities that submitters would complete when complying with the rule:

- CDX Registration Activities
- Prepare and Submit Report, and Maintain Records.

Table 1: Information Collections (ICs) for CDR Reporting

Activity	Description	Related IC(s) included in this
V	•	ICR Renewal
CDX Registration	Before submitting a TSCA Form U, new submitters	CDX Registration Activities
and e-Signature	and experienced submitters with new employees must	
	register with CDX. In addition, registrants must	
	complete an Electronic Signature Agreement form,	
	which is signed, dated, and either submitted	
	electronically or mailed back to EPA.	
Preparation and	Staff must collect all of the required information and	Prepare and Submit Report, and
Submission of	submit relevant information for each of the reportable	Maintain Records.
Reports	chemicals substances at that site in an electronic	
	submission of the Form U. The information must be	
	gathered, reviewed, and submitted to EPA. This task	
	includes any research necessary to identify the correct	
	information, the act of completing the submission, and	
	associated review. Therefore, the list of activities	
	included in this IC are (as described in this ICR	
	Supporting Statement): rule familiarization (for new	
	reporters only), compliance determination, form	
	completion, and recordkeeping.	
Recordkeeping	Respondents must keep records supporting their	Prepare and Submit Report, and
	submissions for five years.	Maintain Records

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

5(a) Agency Activities

The Agency develops and maintains the electronic tool used to collect and verify data. Other activities routinely conducted by EPA related to the processing, analysis and storage of the information collected under this rule include the following:

- Review and verify submissions;
- Answer submitter questions and provide any necessary technical assistance;
- Process submissions for inclusion in CDR database;
- Review requests for confidentiality in the submissions;
- Maintain the database; and
- Distribute the data.

5(b) Collection Methodology and Management

All manufacturers (including importers), except for those defined as "small manufacturers" by EPA's regulations, are required to submit information on every substance subject to the regulation (40 CFR 711) that they manufacture (including import) in quantities that meet or exceed the CDR thresholds. However, a person who otherwise qualifies as a small manufacturer is required to report any chemical substance that is the subject of a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6, or is the subject of an order in effect under TSCA section 5(e), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7. The collection will occur every four years. The next CDR collection will occur in 2020.

(i) Collection Methodology

Submitters are required to submit information associated with this data collection electronically via the Internet using e-CDRweb and CDX.

In addition to the notice of reporting requirements contained in the CDR rule published in 2011, potential submitters will be notified of the need to report in three ways: (1) make available guidance describing CDR reporting requirements at chemical industry conferences and meetings, and through web and list serve announcements, (2) send email notices to previous CDR submitters, and (3) publish articles in the trade press. The requirement to report is based on the CDR regulations; potential submitters that do not receive a notification as listed above or who do not read published articles are still required to report. Reporting materials, including a non-submission version of the Form U and a variety of instructions documents (Instruction Manual, Q&As, Case Studies, Fact Sheets), are available on EPA's CDR website. Submitters also can obtain these materials from the TSCA Hotline. Submitters obtain the e-CDRweb reporting tool (which enables the completion of the Form U for submission) as part of the CDX electronic webbased registration process, as described in section 4 of this document. The e-CDRweb reporting tool enables the user to complete Form U for submission to EPA.

EPA will receive all CDR submissions electronically. The CDX registration process, required for all submitters, will provide a user ID, which the submitter will use to access e-CDRweb.

Information quality control and validation begins with the e-CDRweb reporting tool, which is programmed to help the submitter provide the information required, in the correct format, as required by the CDR rule.

To aid persons subject to this information collection, the Agency's TSCA and CDX Hotlines are available to answer questions regarding the CDR requirements or submission process. When Hotline staff is unable to answer questions, the submitter is referred to OPPT's Information Management Division (IMD) or Chemical Control Division (CCD), as appropriate. Submitters can also email their questions to the e-CDRweb mail site at eCDRweb@epa.gov. Other Divisions within OPPT or the Office of Environmental Information (OEI) are used as necessary.

(ii) Data Management

This section describes the Agency tasks required for efficiently processing submissions under the CDR. The tasks for which the Agency is responsible are presented under four main categories: database systems development, guidance document development, Form U processing, and additional tasks. The task descriptions presented below generally do not change from collection to collection.

CDR data is stored in a database managed by EPA. Once updated, the CDR database is then available to EPA technical reviewers to search or export into their various analytical modeling systems and databases. The CDR database is also available for quick screening and other direct uses. The Agency makes publicly available as much information as possible, within the confines of protecting CBI.

- <u>Database Systems Development and Maintenance</u> The Agency develops and maintains adequate information systems in place to support the database that serves as the primary data storage medium for CDR collections. File servers with appropriate backup are used to contain the CDR databases.
- <u>Instructions Document Development</u> The Agency develops guidance, instructions, case studies, and other information to assist submitters in submitting data and complying with CDR requirements. The documents are updated for each CDR cycle.
- Form U Processing The Agency is responsible for processing CDR Form U submissions. This includes developing standard operating procedures and documentation for all stages in the CDR life cycle, tracking submissions, implementing quality assurance and control, maintaining files and databases, information security, disseminating data, and training staff. EPA receives CDR submissions over the Internet, using CDX.
- Additional Activities The Agency develops various supporting documents associated
 with the reporting tool and makes them available on the Internet. In addition, the Agency
 provides the TSCA Hotline with standardized responses for frequently asked questions;
 preparing mailings, mailing lists, and labels; and develops outgoing information
 materials.

5(c) Small Entity Flexibility

The CDR regulation provides flexibility to small entities, which includes small businesses, governmental jurisdictions, and not-for-profit organizations. While there is some reporting to CDR by small government jurisdictions, there is a very low likelihood of requiring reporting by small governmental jurisdictions, or small not-for-profit organizations. Instead, affected small entities are generally small businesses. Small manufacturers (including importers),

in accordance with TSCA section 8(a) and 40 CFR Sections 711.9, are generally exempt and therefore are generally not subject to any of the reporting or recordkeeping requirements. A manufacturer (including importer) is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than \$40 million for the principal reporting year and (2) its total production and/or importation of the chemical substances for the principal reporting year, does not exceed 100,000 pounds (45,000 kilograms) at an individual site owned and controlled by the firm. If the firm's total annual sales when combined with those of its parent company (if any) are less than \$4 million for the principal reporting year, the firm is considered small regardless of the production volume. The *Economic Analysis for the Final Inventory Update Reporting Modifications Rule* determined that the impact on these companies is, on average, significantly less than one percent of revenues (EPA, 2011).

5(d) Collection Schedule

The submission period/schedule follows the requirements of 40 CFR 711.20. The submission period for the next collection in 2020 will be from June 1, 2020 to September 30, 2020.

Activity	Timeline
Public outreach efforts: articles in industry press,	2018-2020
meetings with regulated community, and information on	
the CDR website	
Email to 2020 CDR e-mailing list and other stakeholders	Early 2020
with instructions for obtaining the reporting form and	
initiating reporting	
Open period for submitting 2020 CDR Forms	June 1, 2020, to September 30, 2020

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This section presents the burden and cost estimates for industry and the Agency. Respondents submit the CDR Form U in accordance with a four-year reporting cycle, with the last year of the cycle termed the "principal reporting year," but the information reported reflecting the previous four years. For example, the 2020 CDR refers to the four-year collection of data from calendar years 2016, 2017, 2018, and 2019 with the principal reporting year of 2019. The Form U requires reporting on a "per site" basis for each of the reportable chemicals at that site. Therefore, each site subject to CDR requirements is considered a respondent that will submit one Form U (response) containing one or more chemical reports. Respondents are comprised of both new CDR submitters and experienced submitters who have responded in previous CDR/IUR reporting cycles. Estimates cover the three-year ICR renewal period (provided also on an annual basis) and are presented herein in 2016 dollars.

6(a) Estimating Respondent Burden

For the 2020 reporting cycle (as previously in the 2016 reporting cycle), manufacturers (including importers) must submit a Form U for each site at which 25,000 pounds or more (or

2,500 pounds or more, if applicable) was manufactured for a chemical substance in *any* calendar year in the principal reporting year and the previous three years. Estimates are presented according to the full reporting cycle first (Tables 2-14) and then converted to a basis for the ICR period (Table 15).

Burden estimates were derived originally from a survey conducted by EPA in 1996 (under OMB Control No. 2070-0034) to assess the potential burden associated with the IUR, as amended at that time. The survey was distributed to previous IUR respondents selected from the IUR database. Burden estimates were updated for a 2005 amendment to the rule as described in *Economic Analysis of IUR Modifications Final Rule* (US EPA, 2005).³ Burden estimates for additional new reporting elements were developed for the 2012 and 2016 CDR submission periods in the final rule, as derived and described in the *Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule* (US EPA, 2011b). Last, in this ICR renewal, burden estimates are provided for updated requirements for CBI substantiation under the changes introduced by the Lautenberg Act.⁴

For the analysis in this section, the respondent is defined as a manufacturing site. There is one response per respondent, as one Form U per site accommodates multiple chemical reports in the same submission. Activities for preparing and submitting a Form U include rule familiarization (for new reporters only), compliance determination, and form completion. Additionally, recordkeeping is required. Last, for those not already registered in CDX, individuals must complete CDX registration, including e-signature. Activity descriptions are as follows:

- Rule Familiarization (for new reporters) —Site staff new to reporting must become familiar with all requirements. This entails reading the rule, understanding the reporting and administrative requirements, and determining what tasks are required in order to meet reporting requirements.
- Compliance Determination Site staff must determine whether reporting is required for a chemical substance manufactured (including imported) at a particular site, based on the chemical substance's production volume and the applicability of certain reporting exemptions. This activity requires that the site determine whether the production volume of a chemical substance has met or exceeded the applicable threshold (25,000 lbs or 2,500 lbs annually) in any of the four years of the reporting period.
- Form Completion Site staff must provide information from the principal reporting year for most of their Form U reporting requirements. In addition, they must provide only production volume from the previous three years. Form U consists of: Part I site identification information; Part II chemical specific manufacturing (including import) data (production volumes, etc.); and Part III chemical specific processing and use information (see Section 2(b) for detailed data element-specific

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³ The economic analysis for the 2005 Amendments assumed a 15 percent reduction in burden for the completion of Part III because submitters were no longer required to report use and downstream processing information for exports.

⁴ In preparation for providing estimates of this ICR renewal, corrections to baseline activity-level unit burdens are made and explained in Section 6(g) of this document.

- descriptions).⁵ Note that certain chemicals are specifically exempted from being required to submit Part III. Additionally, some sites will not have information to submit in Part III (not applicable). For circumstances in which a chemical is only addressed in Parts I and II, the chemical report is termed a "partial report."
- *CDX Registration and e-Signature* Before submitting Form U, respondents not already registered must register with CDX. In addition, respondents must complete an Electronic Signature Agreement form, which is signed, dated, and either submitted electronically or mailed back to EPA.

Table 2 summarizes unit burdens according to activity. However, the activity-level burdens are not incurred evenly for the Form U submission. Therefore, the submission-level burden must be estimated on the basis of the conditions of the average submission. The unit burden per submission, which is a roll-up of activity level unit burdens, is derived in Table 3. On average, sites submit 7.5 chemical reports. However, 22% of chemical reports do not include data for Part III of the Form U (i.e., partial reports). Moreover, certain data elements are of high impact but relatively low frequency and are therefore pro-rated (% joint submission reports, % CBI for substantiation). The "Adjusted Unit Burden" column in Table 3 accounts for these effects, yielding the unit burden by activity in the context of the average submission, per observed CDR reporting characteristics.⁶

As derived in Table 3, the industry average Form U per-response burden, including rule familiarization, compliance determination, form completion, and recordkeeping for experienced reporters is estimated at 483.63 hours per four-year reporting cycle. This estimate reflects average reporting conditions of 7.5 chemicals per submission with 22% of chemical reports consisting of partial reports.

Table 2. Activity-Level Unit Burdens per Four-Year Reporting Cycle, Experienced Reporters

Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity-Level Unit Burden (hours)
1	Rule Familiarization	Per site	0.000	0.000	0.000	0.000
2	Compliance Determination	Per site	2.000	4.500	0.000	6.500
3	Recordkeeping	Per site	0.750	1.500	0.750	3.000
	Form Completion					
		Part I. Site	Identification Inf	formation		
4	Certification	Per site	1.010	0.850	0.000	1.860

⁵ Part IV of the Form U is completed by a secondary submitter in the context of a joint submission involving a primary submitter and a secondary submitter (see Section 2(b) for additional details). For purposes of this analysis, burden and costs associated joint submissions by two or more respondents completing one Form U is considered roughly equivalent and of the same burden and cost as completion of a singular submission that does not involve joint reporting.

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⁶ Information used in Table 4 to estimate universe characteristics for the average submission are obtained from 2016 CDR data (US EPA, 2017c).

Table 2. Activity-Level Unit Burdens per Four-Year Reporting Cycle, Experienced Reporters

	Experienced Reporters									
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity-Level Unit Burden (hours)				
5	Parent Company Information (Company Name, Address, D&B Number, Mailing Address)	Per site	0.002	0.006	0.000	0.008				
6	Site Identification (Site Name, D&B Number, Address, Mailing Address)	Per site	0.004	0.010	0.000	0.014				
	Part i	I. Site Identificati	on Information C	hemical Report L	evel					
7	Technical Contact Information (Name, Phone, Mailing Address, Email, Country)	Per chemical	0.002	0.004	0.000	0.006				
		Part II. M	anufacturing Info	ormation						
8	Chemical Substance Identification	Per chemical	0.000	0.083	0.000	0.083				
9	Chem ID CBI Substantiation ¹	Per chemical	0.950	1.925	0.000	2.875				
10	Joint Submission Information	Per chemical	0.012	0.000	0.000	0.012				
11	Activity, Production Volume for Principal Reporting Year	Per chemical	0.450	1.820	0.000	2.270				
12	Whether imported chemical substance is physically at reporting site	Per chemical	0.020	0.090	0.000	0.110				
13	Production Volume used onsite	Per chemical	0.040	0.160	0.000	0.200				
14	Volume exported	Per chemical	0.200	0.820	0.000	1.020				
15	Total Number of Workers	Per chemical	0.470	1.140	0.000	1.610				
16	Maximum Concentration, Physical Form, Percent Volume of Production	Per chemical	0.860	2.230	0.000	3.090				
17	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.	Per chemical	0.020	0.090	0.000	0.110				
18	Production Volume for each of the Years since Last Principal Reporting Year	Per chemical	0.600	2.460	0.000	3.060				
19	Non-Chem ID CBI Substantiation (Part II) ²	Per chemical	0.320	0.850	0.000	1.170				
		Part III Proc	essing and Use I	nformation						
	Industrial Processing and Use E	xposure-Related I	Data							
20	Determination of Applicability (includes "Type of Process or Use")	Per chemical	0.230	0.810	0.000	1.040				
21	Sector	Per chemical	0.320	0.750	0.000	1.070				
22	Industrial Function Category	Per chemical	1.650	3.530	0.000	5.180				

Table 2. Activity-Level Unit Burdens per Four-Year Reporting Cycle, Experienced Reporters

Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity-Level Unit Burden (hours)
23	Percent of Production Volume	Per chemical	4.220	8.000	0.000	12.220
24	Total Number of Processing and Use Sites	Per chemical	2.820	7.310	0.000	10.130
25	Total Number of Potentially Exposed Workers	Per chemical	3.060	12.340	0.000	15.400
	Consumer and Commercial Use	Exposure-Relate	d Data			
26	Determination of Applicability (includes "Consumer or Commercial or both")	Per chemical	0.200	0.750	0.000	0.950
27	Identification of Production Category/Use by Children	Per chemical	0.200	0.670	0.000	0.870
28	Percent of Production Volume	Per chemical	0.360	1.010	0.000	1.370
29	Maximum Concentration by Category	Per chemical	0.280	1.090	0.000	1.370
30	Number of Commercial Workers Reasonably Likely to be exposed	Per chemical	3.060	12.340	0.000	15.400
31	Non-Chem ID CBI Substantiation (Part III) ³	Per chemical	0.320	0.830	0.000	1.150

General Notes

- Sources include: US EPA, 2011a; US EPA, 2015a; US EPA, 2017b; Abt Associates 2016; and best professional judgment (BPJ)
- This table contains estimates for information provided by primary submitters in the Form U Parts I, II, and III. For purposes of
 this analysis, burden and costs associated with joint submissions by two or more respondents completing one Form U is
 considered roughly equivalent and of the same burden and cost as completion of a single submission that does not involve
 joint reporting. For this reason, the information provided in Form U Part IV by secondary submitters in the context of joint
 submission(s) is not estimated.
- Updated estimates to reflect changes to CBI substantiation requirements are presented in Items 9, 19, and 31 with further detail in footnotes below.

Table Footnotes

- ¹ Estimate revised to reflect requirements of the Lautenberg Act. Burden is estimated using recommended CBI substantiation questions in the template posted on the EPA web site (US EPA 2017a), based on US EPA (2017b) and BPJ.
- ² Estimate revised to reflect requirements of the Lautenberg Act. Burden is estimated using recommended CBI substantiation questions in the template posted on the EPA web site (US EPA 2017a), based on US EPA (2017b) and BPJ. CBI non-chem ID substantiation in Part II applies to: 2.B.1: CBI for Company Identification, 2.B.2: CBI for Site Identification, 2.B.3: CBI for Technical Contact Information.
- ³ Estimate revised to reflect requirements of the Lautenberg Act. Burden is estimated using recommended CBI substantiation questions in the template posted on the EPA web site (US EPA 2017a), based on US EPA (2017b) and BPJ. CBI non-chem ID substantiation in Part III applies to all entries in 3.A. Industrial Processing and Use and all entries in 3.B. Consumer and Commercial Use (all entries).

Table 3: Submission Burden per Four-Year Reporting Cycle, Experienced Reporters

Item#	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity Level Unit Burden (hours)	Proportion of Affected Chemical Reports ¹	Adjusted Unit Burden
1	Rule Familiarization	Per Site	0.000	0.000	0.000	0.000	N/A	0.000
2	Compliance Determination	Per Site	2.000	4.500	0.000	6.500	N/A	6.500
3	Recordkeeping	Per Site	0.750	1.500	0.750	3.000	N/A	3.000
		Pa	art I. Site Identific	cation Information				
4	Certification	Per Site	1.010	0.850	0.000	1.860	N/A	1.860
5	Parent Company Information (Company Name, Address, D&B Number, Mailing Address)	Per Site	0.002	0.006	0.000	0.008	N/A	0.008
6	Site Identification (Site Name, D&B Number, Address, Mailing Address)	Per Site	0.004	0.010	0.000	0.014	N/A	0.014
		Part I. Site Ide	entification Inform	mation Chemical Re	port Level			
7	Technical Contact Information (Name, Phone, Mailing Address, Email, Country)	Per chemical	0.002	0.004	0.000	0.006	1.000	0.006
		ı	Part II. Manufactu	ring Information				
8	Chemical Substance Identification	Per chemical	0.000	0.083	0.000	0.083	1.000	0.083
9	Chem ID CBI Substantiation	Per chemical	0.950	1.925	0.000	2.875	0.014	0.040
10	Joint Submission Information	Per chemical	0.012	0.000	0.000	0.012	0.017	0.0002
11	Activity, Production Volume for Principal Reporting Year	Per chemical	0.450	1.820	0.000	2.270	1.000	2.270
12	Whether imported chemical substance is physically at reporting site	Per chemical	0.020	0.090	0.000	0.110	1.000	0.110
13	Production Volume used on-site	Per chemical	0.040	0.160	0.000	0.200	1.000	0.200
14	Volume exported	Per chemical	0.200	0.820	0.000	1.020	1.000	1.020
15	Total Number of Workers	Per chemical	0.470	1.140	0.000	1.610	1.000	1.610
16	Maximum Concentration, Physical Form, Percent Volume of Production	Per chemical	0.860	2.230	0.000	3.090	1.000	3.090
17	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused	Per chemical	0.020	0.090	0.000	0.110	1.000	0.110

Table 3: Submission Burden per Four-Year Reporting Cycle, Experienced Reporters

Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity Level Unit Burden (hours)	Proportion of Affected Chemical Reports ¹	Adjusted Unit Burden
18	Production Volume for each of the Years since Last Principal Reporting Year	Per chemical	0.600	2.460	0.000	3.060	1.000	3.060
19	Non-Chem ID CBI Substantiation (Part II)	Per chemical	0.320	0.850	0.000	1.170	0.480	0.562
		Par	t III Processing a	nd Use Information	1			
	Industrial Processing and Use Exposure-Related Data							
20	Determination of Applicability (includes "Type of Process or Use")	Per chemical	0.230	0.810	0.000	1.040	0.780	0.811
21	Sector	Per chemical	0.320	0.750	0.000	1.070	0.780	0.835
22	Industrial Function Category	Per chemical	1.650	3.530	0.000	5.180	0.780	4.040
23	Percent of Production Volume	Per chemical	4.220	8.000	0.000	12.220	0.780	9.532
24	Total Number of Processing and Use Sites	Per chemical	2.820	7.310	0.000	10.130	0.780	7.901
25	Total Number of Potentially Exposed Workers	Per chemical	3.060	12.340	0.000	15.400	0.780	12.012
	Consumer and Commercial Use Exposure-Related Data							
26	Determination of Applicability (includes "Consumer, Commercial or both")	Per chemical	0.200	0.750	0.000	0.950	0.780	0.741
27	Identification of Production Category/Use by Children	Per chemical	0.200	0.670	0.000	0.870	0.780	0.679
28	Percent of Production Volume	Per chemical	0.360	1.010	0.000	1.370	0.780	1.069
29	Maximum Concentration by Category	Per chemical	0.280	1.090	0.000	1.370	0.780	1.069
30	Number of Commercial Workers Reasonably Likely to be exposed	Per chemical	3.060	12.340	0.000	15.400	0.780	12.012
31	Non-Chem ID CBI Substantiation (Part III)	Per chemical	0.320	0.830	0.000	1.150	0.090	0.104
	Subtotal Parts I, II, III - Single Chemical Form Completion							64.850
	Subtotal Parts I, II, III – Average Multi -Chemical Form Co	mpletion (7.5	chemicals) ²					474.13

Table 3: Submission Burden per Four-Year Reporting Cycle, Experienced Reporters

Item#	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity Level Unit Burden (hours)	Proportion of Affected Chemical Reports ¹	Adjusted Unit Burden
	Total, Average Multi-Chemical Preparation and Submissi form completion, and recordkeeping	on—includes	rule familiarizat	ion, compliance det	termination,			483.63

General Note:

• See Table 2 for details regarding new CBI substantiation requirements and treatment of joint submissions (i.e., data from Form U Part IV).

Table Footnotes:

¹Unit burdens are pro-rated according to occurrence as measured in 2016 CDR (US EPA, 2017c) for % joint submission for Joint Submission Information, % CBI pertaining to Chem ID, Part II and Part III CBI Substantiation, and % full reports for all of Part III. See also Table 12.

²The average number of chemicals per site submission overall is measured at 7.5 chemicals per site, using 2016 CDR information (US EPA, 2017c). Multi-chemical form completion entails performing activities of items 4 through 6 once (per site), and activities of items 7 through 31 for 7.5 times (once per chemical).

Reporting burden for new reporters is based on estimates for experienced reporter burden and EPA experience regarding the additional effort undertaken by new reporters. New reporters must undergo rule familiarization in addition to all the same activities as experienced reporters. Additionally, for the activities of form completion, new reporters are estimated to take 1.26 times longer than experienced reporters. As derived in Table 4, the industry average Form U perresponse burden, including recordkeeping for new reporters is estimated at 630.90 hours per four-year reporting cycle. The result reflects average reporting conditions of 7.5 chemicals per submission, with 22% of chemical reports that are partial reports.

Table 4: Submission Unit Burden per Four-Year Reporting Cycle, New Reporters as Derived using the First Time Filer Factor (FTF)

	Experienced Reporters	New Reporters ¹	Overall ²
Activity	Unit Burden per Submission (Hours)	Unit Burden per Submission (Hours)	Unit Burden per Submission (Hours)
Rule Familiarization	0.00	24.00	3.60
Compliance Determination	6.50	6.50	6.50
Recordkeeping	3.00	3.00	3.00
Average Multi-Chemical Form Completion (7.5 chemicals)	474.13	597.40	492.62
Total	483.63	630.90	505.72

General Notes

- Estimates are for a multi-chemical submission of 7.5 chemicals per site, as observed overall in 2016 CDR (US EPA, 2017c)
- The estimate for new reporter Rule Familiarization burden consists of seven hours of Managerial labor and 17 hours of Technical labor. Compliance Determination and Recordkeeping for new reporters are estimated at the same levels as for experienced reporters.

Table Footnotes:

¹The estimate for new reporter Form Completion is derived using this ICR renewal's experienced reporter estimate and a First Time Factor of 1.26 based on the ratio of unadjusted activity level estimates, for new and experienced reporters, per corrections (see Section 6(g) of this report).

² Overall unit burden is based on 15% new reporting sites (see discussion in Section 6(d)).

CDX activities include CDX registration and electronic signature. Unlike CDR Form U submissions, the response unit is per registration rather than per submission. Respondents may be new reporters or new employees at sites with experience reporting. Not all new reporters necessarily need to conduct CDX activities, as the same registration and e-signature apply to multiple EPA reporting functions. As shown in Table 5, unit burden for CDX activities is

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⁷ As presented in Section 6(g), for form completion the ratio is 1.26 to one for new reporter burden compared to experienced reporter burden, based on unadjusted activity-level unit burdens and the average multi-chemical submission of 7.5 chemicals per site.

estimated at 0.53 hours per registrant for those who are not already registered. Similarly, unit cost for CDX registration activities total \$41.55 per registrant.

Table 5: CDX Registration for e-Reporting Respondent Unit Burden and Cost (2016\$)

Respondent Activities	Managerial Burden (Hours)	Technical Burden (Hours)	Clerical Burden (Hours)	Total Burden (Hours)	Average Wage Rate	Unit Cost
CDX Registration	0	0.18	0	0.18	\$78.40	\$14.11
CDX Electronic Signature	0	0.35	0	0.35	\$78.40	\$27.44
CDX Registration and e-Signature Total	0	0.53	0	0.53	\$78.40	\$41.55

General Notes

• Source: US EPA, 2015b

See Table 6 for wage rate information.

6(b) Estimating Submitter Cost

Wage Rates for managerial, technical, and clerical labor are derived and presented in Table 6. Thereafter, unit cost per submission are derived in Table 7, similar to the method used for burden in Table 3, with the average submission conditions of 7.5 chemicals per site and 22% of reports consisting of partial reports, and pro-rating applied (% joint submission reports, % CBI for substantiation).

Table 6: Industry Wage Rates (2016\$)

			Wage	Fringe Benefit	Fringes as % Wage	Over- head % wage ²	Fringe + Overhead Factor ³	Hourly Loaded Wages ⁴
Labor Category	Data Series ¹	Date	(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

Table Footnotes

¹ Employer Costs for Employee Compensation Supplementary Tables: December 2006 – December 2016 (U.S. Bureau of Labor Statistics, 2017).

² An overhead rate of 17% is used based on assumptions in Wage Rates for Economic Analysis of the Toxics Release Inventory Program (Rice, 2002b), and the Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (US EPA, 2002a).

³ The inflation factor of "1" in the formula for calculating the fringe + overhead factor means wage data are not escalated to reflect inflation.

⁴ Wage data are rounded to the closest cent in this analysis.

Table 7: Submission Cost per Four-Year Reporting Cycle, Experienced Reporters

Item#	Activity	Unit of Analysis	Adjusted Unit Burden ¹	Activity Average Wage Rate	Adjusted Unit Cost (\$2016)
1	Rule Familiarization	Per Site	-	N/A	N/A
2	Compliance Determination	Per Site	6.500	\$79.90	\$519.35
3	Recordkeeping	Per Site	3.000	\$68.58	\$205.74
	Part I. Site Identific	ation Inform	ation		
4	Certification	Per Site	1.860	\$81.04	\$150.73
5	Parent Company Information (Company Name, Address, D&B Number, Mailing Address)	Per Site	0.008	\$79.62	\$0.64
6	Site Identification (Site Name, D&B Number, Address, Mailing Address)	Per Site	0.014	\$79.79	\$1.12
	Part I. Site Identification Inforn	nation Chemi	ical Report Le	vel	
7	Technical Contact Information (Name, Phone, Mailing Address, Email, Country)	Per chemical	0.006	\$80.02	\$0.48
	Part II. Manufactu	ring Informa	tion		
8	Chemical Substance Identification	Per chemical	0.083	\$78.40	\$6.51
9	Chem ID CBI Substantiation	Per chemical	0.040	\$80.01	\$3.20
10	Joint Submission Information	Per chemical	0.0002	\$83.26	\$0.02
11	Activity, Production Volume for Principal Reporting Year	Per chemical	2.270	\$79.36	\$180.15
12	Whether imported chemical substance is physically at reporting site	Per chemical	0.110	\$79.28	\$8.72
13	Production Volume used on-site	Per chemical	0.200	\$79.37	\$15.87
14	Volume exported	Per chemical	1.020	\$79.35	\$80.94
15	Total Number of Workers	Per chemical	1.610	\$79.82	\$128.51
16	Maximum Concentration, Physical Form, Percent Volume of Production	Per chemical	3.090	\$79.75	\$246.43
17	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused	Per chemical	0.110	\$79.28	\$8.72
18	Production Volume for each of the Years since Last Principal Reporting Year	Per chemical	3.060	\$79.35	\$242.81
19	Non-Chem ID CBI Substantiation (Part II)	Per chemical	0.562	\$79.73	\$44.81
	Part III Processing a	nd Use Infor	mation		
	Industrial Processing and Use Exposure-Related Data				
20	Determination of Applicability (includes "Type of Process or Use")	Per chemical	0.811	\$79.47	\$64.45
21	Sector	Per chemical	0.835	\$79.85	\$66.67

Table 7: Submission Cost per Four-Year Reporting Cycle, Experienced Reporters

Item#	Activity	Unit of Analysis	Adjusted Unit Burden ¹	Activity Average Wage Rate	Adjusted Unit Cost (\$2016)
22	Industrial Function Category	Per chemical	4.040	\$79.95	\$323.00
23	Percent of Production Volume	Per chemical	9.532	\$80.08	\$763.32
24	Total Number of Processing and Use Sites	Per chemical	7.901	\$79.75	\$630.10
25	Total Number of Potentially Exposed Workers	Per chemical	12.012	\$79.37	\$953.39
	Consumer and Commercial Use Exposure-Related Data				
26	Determination of Applicability (includes "Consumer, Commercial or both")	Per chemical	0.741	\$79.42	\$58.85
27	Identification of Production Category/Use by Children	Per chemical	0.679	\$79.52	\$53.99
28	Percent of Production Volume	Per chemical	1.069	\$79.68	\$85.18
29	Maximum Concentration by Category	Per chemical	1.069	\$79.39	\$84.87
30	Number of Commercial Workers Reasonably Likely to be exposed	Per chemical	12.012	\$79.37	\$953.39
31	Non-Chem ID CBI Substantiation (Part III)	Per chemical	0.104	\$79.75	\$8.29
	Subtotal Parts I, II, III - Single Chemical Form Completion		64.85	\$79.65	\$5,165.16
	Subtotal Parts I, II, III – Average Multi -Chemical Form Completion (7.5 chemicals) ²		474.13	\$79.61	\$37,747.52
	Total, Average Multi-Chemical Preparation and Submis includes rule familiarization compliance determination completion, and recordkeeping	483.63	\$79.55	\$38,472.61	

General Notes

 See Table 2 for details regarding new CBI substantiation requirements and treatment of joint submissions (i.e., data from Form U Part IV).

Table Footnotes

¹ Unit burdens are pro-rated according to occurrence as measured in 2016 CDR (US EPA, 2017c) for % joint submission for Joint Submission Information, % CBI pertaining to Chem ID, Part II and Part III CBI Substantiation, and % full reports for all of Part III.

EPA estimates the industry average Form U per-response cost, including recordkeeping, for experienced reporters at \$38,472.61 per four-year reporting cycle. For new reporters, a wage rate is applied to the hours in Table 4 to produce the results in Table 8.8 The average per-response cost for new reporters is estimated at \$50,202.34 per four-year reporting cycle. The

⁸ Per the simplified method for new reporters' burden estimates presented in 6(g), the same weighted average wage rates as used to estimate experienced reporters' cost are applied.

²The average number of chemicals per site submission overall is measured at 7.5 chemicals per site, using 2016 CDR information (US EPA, 2017c). Multi-chemical form completion entails performing activities of items 4 through 6 once (per site), and activities of items 7 through 31 for 7.5 times (once per chemical).

results for experienced and new reporters reflect average reporting conditions of 7.5 chemicals per submission, with 22% of chemical reports consisting of partial reports.

Table 8: Submission Unit Cost per Four-Year Reporting Cycle, New Reporters as Derived using the First Time Filer Factor (FTF)

		Experienced Reporters		New Reporters	
Activity	Average Wage Rate	Unit Burden per Submission (Hours)	Unit Cost per Submission (2016\$)	Unit Burden per Submission (Hours)	Unit Cost per Submission (2016\$)
Rule Familiarization	\$79.82	-	\$0.00	24.00	\$1,915.68
Compliance Determination	\$79.90	6.50	\$519.35	6.50	\$519.35
Recordkeeping	\$68.58	3.00	\$205.74	3.00	\$205.74
Average Multi-Chemical Form Completion (7.5 chemicals)	\$79.61	474.13	\$37,747.52	597.40	\$47,561.57
Total			\$38,472.61		\$50,202.34

General Notes

- Estimates are for a multi-chemical submission of 7.5 chemicals per site, as observed overall in 2016 CDR (US EPA, 2017c).
- The estimate for new reporter Rule Familiarization burden consists of seven hours of Managerial labor and 17 hours of Technical labor. Compliance Determination and Recordkeeping for new reporters are estimated at the same levels as for experienced reporters.
- The estimate for new reporter Form Completion Unit Cost is based on unit burden in Table 4 (derived using a First Time Factor-FTF of 1.26 —see Table 4 and Section 6(g)).
- The wage rate from the experienced reporters' analysis for Form Completion is assumed to be the same as the wage rate for new reporter Form Completion (see Section 6(g) for additional information).

6(c) Estimating Agency Burden and Cost

EPA is responsible for the following activities associated with administering the CDR rule:

- Document receipt and tracking;
- Quality control of data, including protection of CBI;
- Backup systems operation;
- Data processing;
- Systems development;
- Contract oversight and management;
- Publication of materials and creating pdfs of forms; and
- Operation of the TSCA Hotline to handle CDR-related calls.

Note that costs related to EPA activities that involve using the data are not included.

(i) EPA Staff Activities

Of the tasks listed above, Agency personnel are responsible for 1) quality control of data; and 2) data processing, systems development, and contract oversight and management. Contractors perform the other activities, as described below.

EPA estimates the total burden of completing Agency tasks to be one full-time equivalent program staff member for quality control of data, and one full-time equivalent IT staff member for data processing, systems development, and contract oversight and management, per-reporting cycle.

EPA labor costs are based on annual federal wage rates, as presented in Table 9. As in the previous ICR renewal, a GS-12 Step 3 is assumed for program staff hours and a GS-13 Step 3 is assumed for IT staff hours.

Labor	Data Source for Wage	Wage (\$/hour)	Fringe Benefit	Fringes as % wage	Overhead as % wage	Fringe + Overhead Factor	Loaded Wage (\$/hr)
Category	Information	(a)	(b)	(c) = (b) / (a)	(d)	(e) = (c) + (d) + 1	(f) = (a) * (e)
EPA program staff	Annual federal staff cost: OPM Washington- Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-12 Step 3 pay rates ¹	\$39.61	Included in 60% overhead	N/A	60% ²	1.6	\$63.38
EPA IT staff	Annual federal staff cost: OPM Washington- Baltimore-Northern Virginia, DC-MD-PA-VA-WV area, GS-13 Step 3 pay rates ¹	\$47.10	Included in 60% overhead	N/A	60% ²	1.6	\$75.36

Table 9: Agency Wage Rate (2016\$)

Table Footnotes

Unit Burden and cost associated with EPA staff activities per a four-year reporting cycle are the same as in the previous ICR and presented in Table 10. The cost associated with quality control of data is performed by program staff and is dependent on the number of reports received. The cost of activities performed by IT staff, including systems development, and contract oversight and management, are fixed costs and are not dependent on the number of reports submitted to EPA.

¹ Source: Pay & Leave: Salaries & Wages Table 2016-DCB. U.S. Office of Personnel Management. (2017).

² The 60 percent fringes-and-overhead rate is from an EPA guide, *Instructions for Preparing ICRs* (US EPA, 2009).

Table 10: EPA Staff Unit Burden and Cost of Processing Report and Fixed Cost per Four-Year Reporting Cycle

Activity	Unit of Analysis	Agency Burden per Activity (Hours)	Agency Cost per Activity (2016\$) ¹
Quality Control of Data for Part I	Per Site	0.0019	\$0.12
Quality Control of Data for Part II	Per Chemical Report	0.0054	\$0.34
Quality Control of Data for Part III	Per Chemical Report	0.0063	\$0.40
Review of Electronic Signatures	Per CDX Registration	0.0081	\$0.51
Systems development, and contract oversight and management	Per Reporting Cycle	2,080	\$156,749

General Notes

Sources include: US EPA, 2015a

Table Footnotes

¹ Based on Labor rates (see Table 7) for (1) Quality Control activities and Review of e-Signatures by Program Staff GS12 Step 3; and (2) Systems development, and contract oversight and management for IT Staff GS13, Step 3.

(ii) Contractor Activities

Agency costs also include payment for extramural tasks completed by contractors (this category includes costs to EPA, but not burden hours). Contractor activities include document receipt, tracking, data review, maintaining backup systems, publication of materials, making pdfs of Form Us, and managing the TSCA Hotline, as presented in Table 11. With the exception of document receipt, tracking, and data review, all contractor costs are fixed and are not dependent on the number of reports received. All variable and fixed costs are taken from the last published ICR and are inflated from 2012 to 2016 dollars with an inflation factor calculated using the Employment Cost Index (ECI), seasonally adjusted, for management, professional, and related occupations in private industry (BLS, 2017).

Table 11: Unit Cost of Contractor Activities for Four-Year Reporting Cycle, per report

Activity	Cost 2012\$	Cost ¹ 2016\$
Variable Costs		
Document receipt, tracking, and data review for Part I	\$0.10	\$0.11
Document receipt, tracking, and data review for Part II	\$0.28	\$0.31
Document receipt, tracking, and data review for Part III	\$0.32	\$0.35
Total Cost of Document receipt, tracking, and data review, per single chemical full report	\$0.70	\$0.77

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Activity	Cost 2012\$	Cost ¹ 2016\$		
Fixed Costs				
Maintaining and Operating Back Up Systems	\$63,385	\$69,723.50		
Publication of materials and making a pdf of all Form U's	\$5,921	\$6,513.10		
Managing the TSCA Hotline	\$47,898	\$52,687.80		
Total Fixed Cost	\$117,204	\$128,924.40		

General Notes

• Sources include: US EPA, 2015a and BLS, 2017b.

Table Footnotes

¹ The inflation rate of 1.01 is calculated as the Employment Cost Index (ECI) for 2016 divided by the ECI for 2012.

6(d) Bottom-Line Industry Burden and Cost Estimates

This section describes the estimated social burden and cost of paperwork over the three-year ICR period. The next CDR submission period will occur in 2020 for chemical substances manufactured (including imported) during the calendar years 2016-2019. Even though reporting occurs only once every 4 years, EPA recognizes that activities associated with the submission are performed over the entire course of the reporting cycle. This section first provides burden and cost estimates for the four-year CDR reporting cycle for industry and the Agency, followed by a summary of estimates that apply for the three-year ICR renewal period.

Respondent Tally

Table 12 presents the expected numbers of sites, chemicals, and chemical reports for the 2020 reporting cycle based on information from the recent 2016 CDR submission period (US EPA, 2017c). EPA expects similar counts for the next CDR reporting cycle, as the reporting thresholds to CDR have not changed. As in 2016, when a site exceeds the threshold in any of the four years of the reporting cycle, they must report to CDR. Note that as in 2016 CDR, the 2020 CDR requires that certain chemical substances be subject to lower thresholds. Table 12 also provides an estimate for the universe of CDX registrations, based on 25% of the count of firms submitting the Form U. As stated in Section 6(a), not all new reporters necessarily need to conduct CDX activities, as the same registration and e-signature apply to multiple EPA reporting functions. However, given that the CDR information collection involves a relatively large number of submitters and thereby greater potential for turnover, the estimate of registrations for CDR is greater than typical estimates for other EPA programs. The 25% basis is derived using the percentage for new reporter sites at 15% plus an additional 10% to account for employee turnover within all firms.

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⁹ These chemicals are termed "subject to TSCA Action," and include chemical substances: subject to TSCA sections 5(a)(2), 5(b)(4), or 6; a consent agreement developed under the procedures of 40 CFR part 790; an order issued under section 5(e) or 5(f) of TSCA; or relief that has been granted under a civil action under TSCA sections 5 or 7, as listed in Appendix B of the *Instructions for the 2016 TSCA Chemical Data Reporting* (US EPA, 2016).

As stated above, EPA assumes that the burden for experienced submitters is reduced due to efficiencies achieved through familiarity with the reporting process. Therefore, the respondent tally must distinguish between new and experienced reporters. New reporters are entering the CDR reporting universe with all relevant chemical reports exceeding thresholds for the first time. EPA estimates that on average 15% of CDR sites are new to CDR for a given four-year reporting cycle.¹⁰

Table 12: Universe of Respondent Sites, Chemical Reports, and CDX Registration

Form U Submissions Universe				
Submitters/Sites	Chemical Reports	Chemicals		
5,662	42,466	8,717		
Overall Submitter Characteristics,	% of Chemical Rep	orts1		
Characteristic				
Chemicals per Report		7.50		
% of Partial Reports		22.0%		
% Joint Reporters	1.7%			
% CBI Chem ID	1.4%			
% CBI Non Chem ID Pt II	48.0%			
% CBI Non Chem ID Pt III	9.0%			
CDX Registrations Universe				
Туре				
CDX Registrations ²	1,416			
Table Footnotes ¹ Information on submissions is based on observations in 2016 CDR (US EPA, 2017c). ² CDX registrations, as estimated based on 25% of the count for firms submitting the Form U.				

Total Industry Burden/Cost. Estimates of the reporting burden and cost per four-year reporting cycle are shown in Table 13, broken down by experienced and new reporters for Form U submission, and by registrants for CDX registration activities. Total burden and cost is estimated at 2,864,095 hours and \$227,837,292, respectively per four-year reporting cycle. These estimates translate to annual burden and cost for the ICR period of 716,024 hours and \$56,959,323, respectively per year (see Table 15).

¹⁰ To estimate the proportion of new reporters in a given reporting cycle, EPA evaluates the dynamics of reporters' production volume levels and whether threshold levels are exceeded, on a year-by-year basis. For sites transitioning from a status in which none of the chemicals exceed threshold to a status in which one or more chemicals exceed threshold, an annual rate of 209 unique sites per year is observed, yielding the overall four-year count of 836 new sites reporting. In sum, 15% of total sites are estimated as new reporting sites for the CDR reporting cycle.

Table 13. Respondent Total Burden and Cost for a Four-Year Reporting Cycle

			Form U Sul	omitters			
	Experience	ed Reporters	New Re	eporters1	Total Bu	ırden (Hours) and Cost
IC: Prepare and Submit Report, and Maintain Reports	Unit Burden per Average Submission (Hours)	Respondents (Number of Sites)	Unit Burden per Average Submission (Hours)	Respondents (Number of Sites)	Total Burden (Hours)	Average Wage Rate	Total Costs (2016\$)
Rule Familiarization	0.00	4,813	24.00	849	20,376	\$79.82	\$1,626,412
Compliance Determination	6.50	4,813	6.50	849	36,803	\$79.90	\$2,940,560
Recordkeeping	3.00	4,813	3.00	849	16,986	\$68.58	\$1,164,900
Average Multi- Chemical Form Completion (7.5 chemicals)	474.13	4,813	597.40	849	2,789,180	\$79.61	\$222,046,620
Total	483.63	4,813	630.90	849	2,863,345		\$227,778,492
			CDX Regis	strants			
IC: CDX Registration Activities		Registrants ²	Hours per	Registration	Total Burden (Hours)	Average Wage Rate	Total Costs (2016\$)
CDX Registration and e-Signature		,416	0	.53	750	\$78.40	\$58,800
Total Industry Bu	urden (four-year i	reporting cycle)			2,864,095		\$227,837,292
			Unive	rse			
Total Number of Respondents ²	Total Number of Responses (Form U plus CDX)	Total Number of Site-Level Form Us		per of Form U al Reports	Total	Number of C	hemicals
5,662	7,078	5,662	42	,466		8,717	
Table Footnotes						- 	

Table Footnotes

Agency Tally

Table 14 presents the Agency costs associated with the CDR reporting requirements for a four-year reporting cycle. EPA applied unit cost to report counts for Parts I, II, and III where applicable to calculate the total burden and cost. EPA estimates total burden and cost at 2,540 hours and \$340,143, respectively per four-year reporting cycle. These estimates translate to annual burden and cost for the ICR period of 635 hours and \$85,036, respectively per year (see Table 15).

¹ New Reporters' submissions are measured at 15% of sites; new reporters and experienced reporters are assumed to have the same characteristics (per overall universe, as reported in Table 12). Analyses using 2016 CDR data (US EPA 2017c) show that the assumption produces final total estimates that are slightly overstated (by about 5%).

² Registrant counts are included in counts of Form U submission respondent counts because CDX registrants constitute a subgroup of Form U submission respondents.

Table 14: Total Burden and Cost of Agency Activities, per Reporting Cycle

				Cost per Activity	Total Cost
Activity	Staff	Form U Section	Affected Universe	(2016\$)	(2016\$) ¹
Variable Burdens and	d Costs				
		Part I	5,662 Sites	\$0.11	\$622.82
Submission Receipt and Tracking; Data Review	Contractor	Part II	42,466 Full and Partial Chemical Reports	\$0.31	\$13,164.46
Neview		Part III	33,123 Full Chemical Reports	\$0.35	\$11,593.22
		Part I	5,662 Sites	\$0.12	\$679.44
		Part II	42,466 Full and Partial Chemical Reports	\$0.34	\$14,438.44
Quality Control	EPA Program Staff	Part III	33,123 Full Chemical Reports	\$0.40	\$13,249.39
		Electronic Signature Agreements	1,416 CDX Registrations	\$0.51	\$721.91
Total Variable Burde	n and Cost				\$54,470.00
Printing and Publish	ing Forms and Mate	erials			
Data Processing, Systems Development; Contract Oversight and Management	EPA IT Staff	N/A	N/A	N/A	\$156,748.80
Back Up Systems Operations and Maintenance	Contractor	N/A	N/A	N/A	\$69,723.50
Publishing Forms and Materials	Contractor	N/A	N/A	N/A	\$6,513.10
Managing the TSCA Hotline	Contractor	N/A	N/A	N/A	\$52,687.80
Total Fixed Burden a	nd Cost				\$285,673.20
Total Agency Burder	and Cost				\$340,143.20
Table Footnotes ¹ Based on Labor rates (:	see Table 7) for Progra	m Staff GS12 Step 3; fo	r IT Staff GS13, Step 3.		

Total Burden and Cost - ICR Period

Table 15 presents the bottom line totals for Industry and Agency Burden/Cost, including average annual, and ICR Renewal Period totals.

Table 15. Annual Average and Total Burden and Cost for the ICR Renewal Period

	CDR F	Reporting	g Cycle E	Burden		R Cycle and ewal Period		ewal Period 3 - Nov '21)
Burden Category	2016	2017	2018	2019	Annual Average Burden	Annual Average Cost	Total Burden	Total Cost
Industry Burden CDX Registration and								
e-Signature	750				188	\$14,700	564	\$44,100
Form U Submission: Prepare and Submit Report, and Maintain Records ¹	2,863,345				715,836	\$56,944,623	2,147,508	\$170,833,869
Industry Burden, Total		2,864,09	5		716,024	\$56,959,323	2,148,072	\$170,877,969
Agency Burden, Total		2,54	0		635	\$85,036	1,905	\$255,108
Table Footnotes 1 Includes rule familiarizati	on (new	reporters), compli	ance dete	ermination, form co	ompletion, and recor	dkeeping	

Reasons for Change in Burden

6(e)

There is a decrease of 73,179 hours in the total estimated burden compared with that approved by OMB. This decrease reflects a combination of program changes and adjustments. Program changes involve updated CBI substantiation requirements as a result of the 2016 amendments to TSCA (-4,877 hours); and adjustments involve methodology corrections (-184,158 hours) and an increase in the estimated number of respondents (+106,102 hours). Refer to Table 16 for further detail.

Table 16: Reasons for the Change in Burden

Information Collection	Previ	ious ICR	(1) Changes to the Counts of Reporters ¹ Unit Total		(2) Methodology Corrections and Updates ²		(3) Changes to CBI Substantiation Requirements		ICR Renewal		
<u>(IC)</u>	Unit	Total			Unit	Total	Unit	Total	Unit	Total	
CDX Registration	2.67	516		69	-2.14	-397			0.53	188	
Prepare and Submit Report, and Maintain Records	158.02	788,687		106,033	-32.44	-183,761	.86	4,877	126.44	715,836	
TOTAL		789,203	106,102			-184,158		4,877	77 716,024		

General Notes

• All unit and total burden estimates are reported in hours and are on an annual basis.

Table Footnotes

¹ From 4,991 sites in 2012 CDR to 5,662 sites in 2016 CDR.

² For CDX activities, methodology is changed to align unit burdens with other TSCA information collections. For Form U submissions, pro-rating is implemented for certain low occurrence activities, based on observations in 2016 CDR (US EPA 2017c).

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6(f) Burden Statement

The respondent burden for this collection of information is estimated to average 126.44 hours per year for the average multi-chemical submission of 7.5 chemicals per site with 22% of reports consisting of partial reports and 15% of sites as new reporters. This estimate includes time spent on rule familiarization (for new reporters), compliance determination, form completion, and recordkeeping. In addition, for CDX activities the average per-response burden is estimated at 0.53 hours per registration for those respondents not already registered in CDX. Burden is defined in 5 CFR 1320.3(b). An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR Part 9, and are displayed either by publication in the Federal Register or by other appropriate means, such as 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-2017-0648, which is available for online viewing at www.regulations.gov, or in-person viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the EPA West Building, Room 3334, 1301 Constitution Ave., N.W., Washington, DC. The 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 the 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, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0648 and OMB Control No. 2070-0162, to both EPA and OMB as follows:

- To EPA online using http://www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.
- To OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

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

6(g) Additional Tables

This section provides details from corrections made in November 2017 that are used to revise activity-level unit burdens for experienced reporters, as well information for a simplified

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method for estimating submission-level burden for new reporters. Tables 17A and 17B provide corrections to activity-level burdens for experienced and new reporters, respectively.

From this point forward, separate activity level unit burdens and unit costs for new reporters will not be maintained. Instead, a simplified methodology will be used. For new reporter unit burdens, a first-time factor (FTF) will be applied to experienced reporter estimates of Form Completion burden to translate to an estimate of Form Completion for new reporters. Using the estimates in Tables 17A and 17B, the FTF for a single chemical submission is 1.25 hours of new reporter burden per hour of experienced reporter burden. Applying the method to a multi-chemical submission involving 7.5 chemicals yields an FTF of 1.26, which is used for the estimates in previous sections of this report.

Additionally, for unit costs for new reporters, rather than using detailed activity-level unit costs based on activity-level unit burdens, the wage rate from the experienced reporters' analysis for Form Completion is assumed to be the same as the wage rate for new reporter Form Completion.

Table 17A: Experienced Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	vious ICR Activ	ity-Level Unit	Burdens				Corrected ICR Activity-Level Unit Burdens				
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)
1 ¹	Rule Familiarization	Per site	2.000	2.000	0.000	4.000	1 ¹	Rule Familiarization	0.000	0.000	0.000	0.000
21	Compliance Determination	Per site	0.000	2.500	0.000	2.500	21	Compliance Determination	2.000	4.500	0.000	6.500
3	Recordkeeping	Per site	0.750	1.500	0.750	3.000	3	Recordkeeping	0.750	1.500	0.750	3.000
					F	orm Completion	on					
					Informati	ion						
4	Certification	Per site	1.010	0.850	0.000	1.860	4	Certification	1.010	0.850	0.000	1.860
52	Company Information (Company Name, Technical Contact, Address, D&B Number, Mailing Address)	Per site	0.004	0.010	0.000	0.014	52	Parent Company Information (Company Name, Address, D&B Number, Mailing Address)	0.002	0.006	0.000	0.008
6	Plant Site Identification (Plant Name, D&B Number, Address, Mailing Address)	Per site	0.004	0.010	0.000	0.014	6	Site Identification (Site Name, D&B Number, Address, Mailing Address)	0.004	0.010	0.000	0.014
	Subtotal, Part I					1.888		Subtotal, Part I				1.882
								Part I. Site Identification	Information Ch	emical Report L	evel	
							7 2	Technical Contact Information (Name, Phone, Mailing Address, Email, Country)	0.002	0.004	0.000	0.006
					Part II. Ma	anufacturing Ir	nformatio					
73	Chemical Substance Identification, Upfront CBI Substantiation	Per chemical	0.610	1.160	0.000	1.770	83	Chemical Substance Identification	0.000	0.083	0.000	0.083
							93	Chem ID CBI Substantiation	0.610	1.079	0.000	1.687
							104	Joint Submission Information	0.012	0.000	0.000	0.012

Table 17A: Experienced Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	vious ICR Activ	ity-Level Unit	Burdens				Corrected ICR Activity-Level Unit Burdens					
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	
85	Site-Limited, Activity, Production Volume (2015)	Per chemical	0.450	1.820	0.000	2.270	115	Activity, Production Volume for Principal Reporting Year	0.450	1.820	0.000	2.270	
9	Whether imported chemical substance is physically at reporting site	Per chemical	0.020	0.090	0.000	0.110	12	Whether imported chemical substance is physically at reporting site	0.020	0.090	0.000	0.110	
10	Production Volume used on-site	Per chemical	0.040	0.160	0.000	0.200	13	Production Volume used on-site	0.040	0.160	0.000	0.200	
11	Volume exported	Per chemical	0.200	0.820	0.000	1.020	14	Volume exported	0.200	0.820	0.000	1.020	
12	Total Number of Workers	Per chemical	0.470	1.140	0.000	1.610	15	Total Number of Workers	0.470	1.140	0.000	1.610	
13	Maximum Concentration, Physical Form, Percent Volume of Production	Per chemical	0.860	2.230	0.000	3.090	16	Maximum Concentration, Physical Form, Percent Volume of Production	0.860	2.230	0.000	3.090	
14	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.	Per chemical	0.020	0.090	0.000	0.110	17	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.	0.020	0.090	0.000	0.110	
15	Production Volume for each of the Years since Last Principal Reporting Year (2012-2014)	Per chemical	0.600	2.460	0.000	3.060	18	Production Volume for each of the Years since Last Principal Reporting Year	0.600	2.460	0.000	3.060	
166	Plant Site Upfront Substantiation	Per chemical	0.410	0.660	0.000	1.070	196	Non-Chem ID CBI Substantiation (Part II)	0.410	0.660	0.000	1.070	
	Subtotal, Part II	Per chemical				14.310		Subtotal, Part II	14.3				
					Part III Proc	essing and Us	e Informa	ation					
	Industrial Processing and	Use Exposure-Rel	ated Data					Industrial Processing and	essing and Use Exposure-Related Data				
177	Determination of Applicability	Per chemical	0.230	0.810	0.000	1.040	20 ⁷	Determination of Applicability (includes "Type of Process or Use")	0.230	0.810	0.000	1.040	

Table 17A: Experienced Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	evious ICR Activ	ity-Level Unit	Burdens				Corrected	ICR Activity-L	evel Unit Burd	lens		
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	
18	Sector	Per chemical	0.320	0.750	0.000	1.070	21	Sector	0.320	0.750	0.000	1.070	
19	Industrial Function Category	Per chemical	1.650	3.530	0.000	5.180	22	Industrial Function Category	1.650	3.530	0.000	5.180	
20	Percent of Production Volume	Per chemical	4.220	8.000	0.000	12.220	23	Percent of Production Volume	4.220	8.000	0.000	12.220	
21	Total Number of Processing and Use Sites	Per chemical	2.820	7.310	0.000	10.130	24	Total Number of Processing and Use Sites	2.820	7.310	0.000	10.130	
22	Total Number of Potentially Exposed Workers	Per chemical	3.060	12.340	0.000	15.400	25	Total Number of Potentially Exposed Workers	3.060	12.340	15.400		
	Consumer and Commerci	ial Use Exposure-R	elated Data					Consumer and Commerci	ial Use Exposure	Pelated Data			
238	Determination of Applicability	Per chemical	0.200	0.750	0.000	0.950	26 ⁸	Determination of Applicability (includes "Consumer, Commercial or both")	0.200	0.750	0.000	0.950	
24	Identification of Production Category/Use by Children	Per chemical	0.200	0.670	0.000	0.870	27	Identification of Production Category/Use by Children	0.200	0.670	0.000	0.870	
25	Percent of Production Volume	Per chemical	0.360	1.010	0.000	1.370	28	Percent of Production Volume	0.360	1.010	0.000	1.370	
26	Maximum Concentration by Category	Per chemical	0.280	1.090	0.000	1.370	29	Maximum Concentration by Category	0.280	1.090	0.000	1.370	
27	Number of Commercial Workers Reasonably Likely to be exposed	Per chemical	3.060	12.340	0.000	15.400	30	Number of Commercial Workers Reasonably Likely to be exposed	3.060	12.340	0.000	15.400	
28	Upfront Substantiation for Processing and Use Information CBI Claims	Per chemical	0.210	0.430	0.000	0.640	Non-Chem ID CBI Substantiation (Part III) 0.210 0.430 0.000				0.000	0.640	
	Subtotal, Part III					65.640		Subtotal, Part III 6					

General Notes:

- Sources include: US EPA, 2011a; US EPA, 2015a; US EPA, 2017b; Abt Associates 2016; and best professional judgment (BPJ).
- For corrections that only involve a revision to the item description, see comparison across the row.
- Dark grey areas indicate that there is no corresponding unit burden estimate on the other half of the table.

Table Footnotes

¹ In the previous ICR, rule familiarization is estimated for both new and experienced reporters. In order to adhere to conventional practices by which rule familiarization is incurred by new reporters only, the estimates associated with experienced reporters'; rule familiarization are moved to compliance determination, increasing that total estimate by four hours. For consistency in the estimates for compliance determination across new and experienced reporters, the same treatment is applied to new reporters, reducing rule familiarization by four hours and increasing compliance determination by four hours.

² Technical contact information may be entered on a chemical-per-chemical basis. The previous ICR's estimate for "Company Information (Company Name, Technical Contact, Address, D&B Number, Mailing Address" is split to remove Technical Contact information so the activity could be moved to *Part I. Site Identification Information - Chemical Report Level.* The estimate for technical contact information was determined based on information from similar TRI estimates and BPJ (US EPA, 2011a).

³ In preparation for revisions to update CBI substantiation estimates, the previous ICR's estimate for "Chemical Substance Identification, Upfront CBI Substantiation" was split to remove CBI Substantiation to a separate activity. The estimate for Chemical Identification is obtained from Abt Associates (2016) as used in (US EPA, 2017b).

⁴ Estimates added to account for data elements in Part II Section A (2.A.5 - 2.A.12) including Trade Name, Other Information, Secondary Company Name, Secondary Company Address and Country, and email address (same for new and experienced reporters), based on BPJ. The same estimates are used for experienced and new reporters.

⁵ Previous ICR's descriptor "site limited" is dropped because the site-limited designation (checkbox) was removed and replaced with "% site-limited" as of 2012 CDR.

⁶ In the previous ICR, the only Part II data element included in the estimate for CBI substantiation is "plant site." In preparation for revisions to update CBI substantiation estimates (to include all applicable data elements in Part II), the description is changed to accommodate the revision's broader treatment (2.B.1: CBI for Company Identification, 2.B.2: CBI for Site Identification, 2.B.3: CBI for Technical Contact Information). Note that estimates under "Corrected Activity-Level Burdens" are the same as in the previous ICR, with above-stated revisions applied in Table 3.

⁷ For Part III Section A, the "Type of Process or Use" information is not explicitly listed and is therefore assumed to be included in the item, "Determination of Applicability."

8 In Part III Section B, the "Consumer or Commercial or both" information is not explicitly listed and is therefore assumed to be included in the item, "Determination of Applicability."

Table17B: New Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	evious ICR Activ	vity-Level Unit	Burdens			Corrected ICR Activity-Level Unit Burdens					
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)
11	Rule Familiarization	Per site	9.000	19.000	0.000	28.000	1 ¹	Rule Familiarization	7.000	17.000	0.000	24.000
21	Compliance Determination	Per site	0.000	2.500	0.000	2.500	21	Compliance Determination	2.000	4.500	0.000	6.500
3	Recordkeeping	Per site	0.750	1.500	0.750	3.000	3	Recordkeeping	0.750	1.500	0.750	3.000
	Form Completion							Form Completion				
	Part I. Site Identification	Information						Part I. Site Identification	Information			
4	Certification	Per site	1.010	0.850	0.000	1.860	4	Certification	1.010	0.850	0.000	1.860
5 ²	Company Information (Company Name, Technical Contact, Address, D&B Number, Mailing Address)	Per site	0.020	0.040	0.000	0.060	5 ²	Parent Company Information (Company Name, Address, D&B Number, Mailing Address)	0.011	0.023	0.000	0.034
6	Plant Site Identification (Plant Name, D&B Number, Address, Mailing Address)	Per site	0.020	0.060	0.000	0.080	6	Site Identification (Plant Name, D&B Number, Address, Mailing Address)	0.020	0.060	0.000	0.080
73	Information for Joint Submissions	Per site	0.010	0.000	0.000	0.010						
	Subtotal, Part I	Per site				2.010		Subtotal, Part I				1.974
								Part I. Site Identification	Information Cl	hemical Report Le	evel	
								Technical Contact Information (Name, Phone, Mailing Address, Email, Country)	0.009	0.017	0.000	0.026
	Part II. Manufacturing In	formation						Part II. Manufacturing In	formation			
84	Chemical Substance Identification, Upfront CBI Substantiation CHI Substance Identification						84	Chemical Substance Identification	0.000	0.083	0.000	0.083
							94	Chem ID CBI Substantiation	0.610	1.079	0.000	1.687

Table17B: New Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	vious ICR Activ	rity-Level Unit	Burdens			Corrected ICR Activity-Level Unit Burdens						
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	
95	Accession Number Request	Per chemical	0.010	0.010	0.000	0.020							
							10 ³	Joint Submission Information	0.012	0.000	0.000	0.012	
106	Site-Limited, Activity, Production Volume (2015)	Per chemical	0.560	2.280	0.000	2.840	116	Activity, Production Volume for Principal Reporting Year	0.560	2.280	0.000	2.840	
11	Whether imported chemical substance is physically at reporting site	Per chemical	0.030	0.110	0.000	0.140	12	Whether imported chemical substance is physically at reporting site	0.030	0.110	0.000	0.140	
12	Production Volume used on-site	Per chemical	0.050	0.200	0.000	0.250	13	Production Volume used on-site	0.050	0.200	0.000	0.250	
13	Volume exported	Per chemical	0.250	1.030	0.000	1.280	14	Volume exported	0.250	1.030	0.000	1.280	
14	Total Number of Workers	Per chemical	0.590	1.430	0.000	2.020	15	Total Number of Workers	0.590	1.430	0.000	2.020	
15	Maximum Concentration, Physical Form, Percent Volume of Production	Per chemical	1.070	2.790	0.000	3.860	16	Maximum Concentration, Physical Form, Percent Volume of Production	1.070	2.790	0.000	3.860	
16	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.	Per chemical	0.030	0.110	0.000	0.140	17	Whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.	0.030	0.110	0.000	0.140	
17	Production Volume for each of the Years since Last Principal Reporting Year (2012-2014)	Per chemical	0.760	3.080	0.000	3.840	18	Production Volume for each of the Years since Last Principal Reporting Year	0.760	3.080	0.000	3.840	
18 ⁷	Plant Site Upfront Substantiation	Per chemical	0.510	0.830	0.000	1.340	19 ⁷	Non-Chem ID CBI Substantiation (Part III)	0.510	0.830	0.000	1.340	
	Subtotal, Part II	Per chemical				17.950		Subtotal, Part II				17.492	
	Part III Processing and U	Jse Information						Part III Processing and Use Information					
	Industrial Processing and	Use Exposure-Rei	ated Data					Industrial Processing and Use Exposure-Related Data					
198	Determination of Applicability	Per chemical	0.280	1.010	0.000	1.290	208	Determination of Applicability (includes "Type of Process or Use")	0.280	1.010	0.000	1.290	

Table17B: New Reporters Activity-Level Unit Burden Correction, November 2017

	Pre	evious ICR Activ	rity-Level Unit	Burdens			Corrected ICR Activity-Level Unit Burdens							
Item #	Activity	Unit of Analysis	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)	Item #	Activity	Managerial Burden (hours)	Technical Burden (hours)	Clerical Burden (hours)	Activity- Level Unit Burden (hours)		
20	Sector	Per chemical	0.400	0.940	0.000	1.340	21	Sector	0.400	0.940	0.000	1.340		
21	Industrial Function Category	Per chemical	2.070	4.670	0.000	6.740	22	Industrial Function Category	2.070	4.670	0.000	6.740		
22	Percent of Production Volume	Per chemical	5.270	10.000	0.000	15.270	23	Percent of Production Volume	5.270	10.000	0.000	15.270		
23	Total Number of Processing and Use Sites	Per chemical	3.520	9.140	0.000	12.660	24	Total Number of Processing and Use Sites	3.520	9.140	0.000	12.660		
24	Total Number of Potentially Exposed Workers	Per chemical	3.830	15.430	0.000	19.260	25	Total Number of Potentially Exposed Workers	3.830	15.430	0.000	19.260		
	Consumer and Commerci	ial Use Exposure-R	Pelated Data					Consumer and Commerci	al Use Exposure	e-Related Data	Related Data			
25 ⁹	Determination of Applicability	Per chemical	0.250	0.940	0.000	1.190	26 ⁹	Determination of Applicability (includes "Consumer, Commercial or both")	0.250	0.940	0.000	1.190		
26	Identification of Production Category/Use by Children	Per chemical	0.250	1.680	0.000	1.930	27	Identification of Production Category/Use by Children	0.250	1.680	0.000	1.930		
27	Percent of Production Volume	Per chemical	0.450	1.260	0.000	1.710	28	Percent of Production Volume	0.450	1.260	0.000	1.710		
28	Maximum Concentration by Category	Per chemical	0.340	1.360	0.000	1.700	29	Maximum Concentration by Category	0.340	1.360	0.000	1.700		
29	Number of Commercial Workers Reasonably Likely to be exposed	Per chemical	3.830	15.430	0.000	19.260	30	Number of Commercial Workers Reasonably Likely to be exposed	3.830	15.430	0.000	19.260		
30	Upfront Substantiation for Processing and Use Information CBI Claims	Per chemical	0.260	0.430	0.000	0.690	31	Non-Chem ID CBI Substantiation (Part III)	0.260	0.430	0.000	0.690		
	Subtotal, Part III	Per chemical				83.040		Subtotal, Part III				83.040		

General Notes

- Sources include: US EPA, 2011a; US EPA, 2015a; US EPA, 2017b; Abt Associates 2016; and best professional judgment (BPJ).
- For corrections that only involve a revision to the item description, see comparison across the row.
- Dark grey areas indicate that there is no corresponding unit burden estimate on the other half of the table.
- In the previous ICR's CDX registration activities are included as part of new reporter burden, However, in this ICR, CDX burden is estimated in separate analysis because registrations affect both new and experienced reporters per OPPT convention for Section 5 and e-TSCA reporting initiatives. The activity-level estimates in hours are revised as follows:

	Prev	ious ICR per Ne	ew Reporter		ICR R	enewal per CD)	K Registration	
Activity	Managerial Burden	Technical Burden	Clerical Burden	Total	Managerial Burden	Technical Burden	Clerical Burden	Total
CDX Registration	0.18	0.73	0	0.92	0	0.18	0	.18
CDX E-Signature Agreement	0.75	1	0	1.75	0	0.35	0	.35
Total				2.67				.53
Source	EPA, 2015b					EPA 2017b		

Table Footnotes

- ¹ In the previous ICR, rule familiarization is estimated for both new and experienced reporters. In order to adhere to conventional practices by which rule familiarization is incurred by new reporters only, the estimates associated with experienced reporters'; rule familiarization are moved to compliance determination, increasing that total estimate by four hours. For consistency in the estimates for compliance determination across new and experienced reporters, the same treatment is applied to new reporters, reducing rule familiarization by four hours and increasing compliance determination by four hours.
- ² Technical contact information may be entered on a chemical-per-chemical basis. The previous ICR's estimate for "Company Information (Company Name, Technical Contact, Address, D&B Number, Mailing Address" is split to remove Technical Contact information so the activity could be moved to *Part I. Site Identification Information Chemical Report Level.* The estimate for technical contact information was determined based on information from similar TRI estimates and BPJ (US EPA, 2011a).
- ³ Estimates modified to account for data elements in Part II Section A (2.A.5 2.A.12) including Trade Name, Other Information, Secondary Company Name, Secondary Company Address and Country, and email (same for new and experienced reporters), based on best professional judgment. Same estimates are used for experienced and new reporters.
- ⁴ In preparation for revisions to update CBI substantiation estimates, the previous ICR's estimate for "Chemical Substance Identification, Upfront CBI Substantiation" was split to remove CBI Substantiation to a separate activity. The estimate for Chemical Identification is obtained from Abt Associates (2016) as used in (US EPA, 2017).
- ⁵ Previous ICR's estimate for "Accession Number Request" is dropped due evidence at EPA that requests are rarely submitted. This activity has largely been replaced by electronic SRS searches. (included in the activity for "Chemical Substance Identification.")
- ⁶ Previous ICR's descriptor "site limited" is dropped because the site-limited designation (checkbox) was removed and replaced with "% site-limited" as of 2012 CDR.
- ⁷ In the previous ICR, the only Part II data element included in the estimate for CBI substantiation was "plant site." In preparation for revisions to update CBI substantiation estimates (to include all applicable data elements in Part II), the description is changed to accommodate revisions' broader treatment (2.B.1: CBI for Company Identification, 2.B.2: CBI for Site Identification, 2.B.3: CBI for Technical Contact Information). Note that estimates under "Corrected Activity-Level Burdens" are the same as in the previous ICR, with above-stated revisions applied in Table 3.
- ⁸ For Part III Section A, the "Type of Process or Use" information is not explicitly listed and is therefore assumed to be included in the item, "Determination of Applicability."
- 9 In Part III Section B, the "Consumer or Commercial or both" information is not explicitly listed and is therefore assumed to be included in the item, "Determination of Applicability."

7. ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this rule related Information Collection Request (ICR) under the docket identification number <u>EPA-HQ-OPPT-2017-0648</u>. These attachments are available for online viewing at http://www.regulations.gov or otherwise accessed as described in the sections below.

Attachment 1: Toxic Substances Control Act, Section 8 - 15 USC 2607.

Available online at https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act.

Attachment 2: TSCA Chemical Data Reporting Requirements - 40 CFR 711.

Available online at https://www.ecfr.gov/cgi-bin/text-idx?SID=72e46806befb5032729dc4d209702813&mc=true&node=pt40.33.7 11&rgn=div5.

Attachment 3: CDR Form U (EPA Form 7740-8) – Representative Form U, excluding

substantiation questions

In the docket.

Attachment 4: CDR Form U Substantiation Questions – Screen Shots

In the docket.

Attachment 5: e-CDRweb User Guide – Primary Authorized Official

In the docket.

Attachment 6: e-CDRweb User Guide – Primary Support

In the docket.

Attachment 7: e-CDRweb User Guide – Secondary Authorized Official

In the docket.

Attachment 8: e-CDRweb User Guide – Secondary Support

In the docket.

Attachment 9: Instructions for Reporting: 2016 TSCA Chemical Data Reporting

In the docket.

Attachment 10: Public Comments Received and EPA Response to Comments.

In the docket.

Attachment 11: Consultations Message Sent by EPA to Potential Respondents.

In the docket.

8. REFERENCES

- Abt Associates. 2016. Estimated Burden Associated with Searching for Chemicals on the TSCA Inventory List.
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