# Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)

## EXECUTIVE SUMMARY

### Identification of the Information Collection – Title and Numbers

**Title:** Chemical Data Reporting under the Toxic Substances Control Act (TSCA)

**EPA ICR No.:** 1884.15

**OMB Control No.:** 2070-0162

**Docket ID No.:** EPA-HQ-OPPT-2013-0721

### 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 help 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 2020 when EPA promulgated the TSCA Chemical Data Reporting Revisions Under TSCA Section 8(a) rule (85 FR 20122, April 9, 2020) and the Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements under the Toxic Substances Control Act (TSCA) Section 8(a) (85 FR 31986, May 28, 2020). The 2020 CDR Revisions Rule phased in some provisions; all changes will be fully implemented with the 2024 CDR. The CDR collection is on a four-year reporting cycle and contains detailed manufacturing, processing, and use information drawn from the principal reporting year; as well as basic information on production volume, by year, for the three years prior to the principal reporting year.

OPPT uses the CDR data in its chemical substance risk-management efforts. Individual sites manufacturing (including importing) chemical substances will submit the required information. The information will be stored electronically for reference by EPA staff and

others. Within the constraints of confidentiality claims, the information will be made public through the Agency's website (https://www.epa.gov/chemical-data-reporting). Further discussion of how the information is used, stored, and collected is included in this document.

### Summary Total Burden and Costs

Table 1 provides the total estimated number of respondents, average burden per response, reporting and recordkeeping burdens, and the corresponding costs for reporting and recordkeeping activities required by this ICR.

**Table 1. Summary Table of Respondent Burden and Cost**

| Information Collection | Number of Respondents | Average Annual Burden Hours | Average Annual Costs |
|---|---|---|---|
| **Form U Submission: Prepare and Submit Report, and Maintain Records** | | | |
| Rule Familiarization | 5460 | 5,395 | $456,347 |
| Compliance Determination | 5460 | 10,107 | $857,206 |
| Recordkeeping | 5460 | 4,095 | $299,058 |
| Average Multi-Chemical Form Completion besides Function Category Data Elements (7.38 chemicals) | 5460 | 620,499 | $67,255,338 |
| Function Category Data Elements (7.38 chemicals per site) | 5460 | 89,259 | $9,733,679 |
| CDX Registration and eSignature | 1365 | 181 | $14,558 |
| **Respondent Totals** | | **729,465** | **$78,616,166** |
| **Total Agency** | **-** | **3,458** | **$822,928** |

## SUPPORTING STATEMENT

**1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate**

**the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

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 help 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 regulation[1] (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.

**2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.**

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. 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 several reporting cycles resulted in data that are more transparent, more useful, and provided 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:

[1] 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.

- 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.

TSCA section 6 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 first 10 chemicals for risk evaluation, as required by TSCA. As part of this process, EPA published the scope of each risk evaluation 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. EPA continues to develop scoping documents for additional chemicals, beyond the original 10 chemicals.
- 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,
    - estimate number of potentially exposed workers per site, and
    - 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 life-cycle inventories (LCIs) to:
    - aid in characterizing the life cycle of the chemical and
    - 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:
    - identify facilities in industry sectors of interest for development of new effluent guidelines and
    - 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:
    - 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):
  - 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):
  - the Agency for Toxic Substances and Disease Registry (ATSDR) uses CDR data to develop toxicological profiles.
- National Institute of Health (NIH):
  - 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, and
- 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. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.**

Submitters are required to submit information associated with this data collection electronically via the Internet using e-CDRweb reporting tool and EPA's Central Data Exchange (CDX) data portal.

**4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

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. There are a variety of sources for certain data elements, but the sources are either incomplete or incompatible.

**5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.**

The CDR regulation provides ample flexibility to small entities. Small manufacturers (including importers), in accordance with TSCA section 8(b), are exempted from the need to report unless their chemical is the subject of certain TSCA actions. A manufacturer (including importer) is considered a small business when, (1) for a particular chemical company, annual sales are $120 million and the chemical's production volume is greater than 100,000 lb or (2) the company's annual revenue is at least $12 million, regardless of the production volume. (40 CFR 704.3) A government may also be a manufacturer; when the government of a city, county, town, township, village, school district, or special district has a population of less than 50,000, it is considered small. (40 CFR 704.3) States and tribal governments are not considered small governments.

**6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

If data were collected less frequently there would be a significant loss of data to the agency and general public as there are no alternative data sets as comprehensive as CDR for the chemical manufacturing industry. Requiring this data collection every four years helps to increase the agency's ability to understand the chemical industry and monitor the production levels of chemical substances manufactured (including imported) in the United States. As chemical industry product lines and manufacturing in the United States change substantially from one submission period to the next, more current information enhances the agency's ability to make more accurate chemical substance risk assessment and management decisions in a timely and cost-effective manner.

**7. Explain any special circumstances that require the collection to be conducted in a manner:**

**a) requiring respondents to report information to the agency more often than quarterly;**

**b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

**c) requiring respondents to submit more than an original and two copies of any document;**

**d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**

**e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

**f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

**g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

**h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

This collection does not exceed any of the Paperwork Reduction Act 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 completion of Form U (EPA Form 7740-8) in the next collection, which is in four years and to allow EPA's enforcement activities to overlap CDR reporting cycles.

**8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.**

**Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.**

**Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

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 to several interested parties via email (See Attachment 6). The individual entities contacted were:

- Nipro PharmaPackaging Americas Corp.
- Arakawa Chemical (USA) Inc.
- Ube America, Inc.
- Vulcan Global Manufacturing Solutions Inc.
- Sika Corporation
- Univar Solutions Inc.
- O'Brien Industrial Holdings LLC
- Giant Cement Holding Inc.
- Livent Corporation

A copy of EPA's consultation to the above potential respondents and the two responses received are in Attachment 6 and are available in the docket.

EPA received two comments in response to the previously provided 60-day public review opportunity (86 FR 52457, September 21, 2021) (FRL-8768-01-OCSPP). One comment was a duplicate of a consultation response.

EPA's responses to the summarized comments are in Attachment 7.

Giant Cement Holding, Inc. (GCHI) and Arakawa Chemical (USA) Inc provided feedback, noting that requirements for CDR submissions were clear and the eCDRweb reporting tool was easy to use. Arakawa commented that the substantiation process was slightly more difficult than entering the data, but that the resources provided were adequate to complete this process.

The American Chemistry Council (ACC) provided comments in response to the public review opportunity. The ACC comments included, as an attachment, a letter previously provided to EPA summarizing experiences during the 2020 CDR submission period. Comments from ACC were supportive of the Agency's efforts to collect relevant information on chemicals in commerce (TSCA), but noted that, during the 2020 CDR submission period, ACC member companies reported spending about three times the amount of time as in previous years. ACC attributed this to issues associated with the eCDRweb reporting tool. ACC also suggested changes to some of the data elements and the CBI substantiation and process. and the CBI substantiation process. EPA has taken steps to address the items noted in the ACC comments. Specifics are provided in the comment summary and response in Attachment 7.

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

Not applicable.

**10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.**

Most CDR data can be claimed as confidential when the CDR reporting form is submitted to EPA. As required under TSCA, substantiation for confidentiality claims must be submitted at the time the claim is made, except for confidentiality claims for production volume information (excludes percent production volume). Submitters must substantiate their claims by answering a series of questions related to whether the information is publicly known and whether public knowledge of the information would hurt a business' competitive position. The e-CDRweb electronic reporting tool is the mechanism for submitting substantiation information.

Confidential business information (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).

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

**12. Provide estimates of the hour burden of the collection of information. The statement should:**

**a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

**b) If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**

**c) Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate**

**categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**

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 North American Index Classification (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.

Reporting Threshold

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), or
- The subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

Chemical substances subject to these 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.

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.

Table 2 provides the universe of respondent sites, chemical reports, and CDX registration based on analytical assumptions described in section 4.3.2 of the Economic Analysis for the CDR Revisions Rule and section 5.3.3 of the Economic Analysis for the Small Manufacturers Definition (SMD) Rule (EPA, 2020a,b)

**Table 2. Universe of Respondent Sites, Chemical Reports, and CDX Registration**

| **Form U Reporting Universe[1]** | | |
|---|---|---|
| **Sites** | **Chemical Reports** | **Chemicals** |
| 5,460 | 40,286 | 8,484 |
| **Overall Submitter Characteristics, % of Chemical Reports** | | |
| **Characteristic** | | **Value** |
| Chemicals per Report | | 7.38 |
| % of Partial Reports | | 21.92% |
| % Joint Reporters | | 1.72% |

| | |
|---|---|
| % CBI Chem ID | 1.44% |
| % Part II.A CBI Substantiation for Connection to Company ID, Site ID, and/or Technical Contact | 17.36% |
| % Part II.C CBI | 35.93% |
| % Part II.D CBI | 8.40% |
| **CDX Registrations Universe** | |
| **Type** | **Value** |
| CDX Registrations[2] | 1,365 |

Table Footnotes

[1] Sites, Chemical Reports, Chemicals and Chemicals per Report information are based on observations in 2016 CDR (US EPA, 2018), adjusting for the reduction in reporting associated with the 2020 rules (EPA, 2020a,b). Percent of reports etc, are estimated from the unadjusted 2016 CDR

[2] CDX registrations, as estimated based on 25% of the count for firms submitting the Form U.

Data elements

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.
- *Parent company name and address*. The name, Dun & Bradstreet number, and mailing address of the U. S. parent company and, if applicable, the foreign parent company.
- *Manufacturing site.* The site name; Dun & Bradstreet number and the physical address of the manufacturing site; the NAICS code associated with the site and an indication if the NAICS is associated with a volume that is

domestically manufactured, imported, or both. Sites are able to provide up to three NAICS codes.

- *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, 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.

    - *Industrial processing and use data.* Submitters must report their type(s) of industrial process or use, sector(s), function category(ies), percentage(s) of production volume, number(s) of sites, and number(s) of workers reasonably likely to be exposed.

    - *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 function of the chemical; 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.

*Special considerations for Co-Manufactured Chemicals when reported jointly by the Contracting and Producing Companies:* In certain circumstances, manufacturers may choose to report their co-manufactured chemical jointly, such that each party (i.e., the contracting company and the producing company) provides certain information directly to EPA. This is primarily done when one or both parties consider some of its information

as confidential. These special considerations do not apply when co-manufacturers chose to share their information with each other, resulting in the producing company report all information to EPA.

In the case of a jointly-reported co-manufactured chemical, the contracting company initiates the co-manufacture report by providing the chemical identity and the identity of the producing company and name (actual name, trade name, or other alias) used to identify the chemical substance in communications with the producing company. Using e-CDRweb (the electronic reporting tool), the contracting company then contacts the producing company to notify them of the need to report the manufacturing-related information directly to EPA as part of the producing company's Form U. Because signatures are required by each party of a co-manufactured chemical 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 contracting company will not be able to access the information provided by the producing company and vice versa. EPA combines information provided separately by the contracting and producing companies, 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:

- *Joint submission information (contracting company):* The contracting provides a trade name or other designation in place of the specific chemical identification and the producing company contact information (name, address, email address).
- *Producing company identification information:* These data identify the producing company's name and the complete mailing address of the company.
- *Technical contact information (producing company):* 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.

For the most part, the contracting company provides the chemical identity and processing and use information for the co-manufactured chemical, and the producing company provides the manufacturing-related data. For selected data, the information is provided by both companies due to differing knowledge bases among different co-manufacturers. In addition, for other data elements the terminology may be changed from what is used for a non-co-manufactured chemical; however, the intent of the information is unchanged. Specifically:

- *Production volume*

- *Contracted volume directly exported from producing site*
- *Contracted volume never physically at site*

*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. In addition to signing the certification statement and completing the above data elements, primary respondents will report on additional data 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 a Secondary 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 and the component's function.

Instructions, User Guides, Frequent Questions, and Other Guidance Documents

EPA provides a variety of guidance materials, including *Instructions for Reporting*, *Frequent Questions*, and other topic-specific guidance, that help the submitter understand their reporting obligations. Here is a list of the documents from the 2020 CDR. These documents will be updated, as needed, for the next CDR submission period in 2024.

- Instructions for the 2020 TSCA Chemical Data Reporting
- EPA CDR Sample Form U Printouts
- Summary of regulatory changes for the 2020 CDR submission period
- Case Studies for the 2020 Chemical Data Reporting
- Byproducts, Impurities, and Recycling Scenarios
- Frequent Questions
- Reporting Thresholds for 2020
- Chemical Substances that are the Subject of Certain TSCA Actions
- Help with Chemical Data Reporting: How to Search for Chemicals Subject to Certain TSCA Actions
- Reporting After Changes to Company Ownership or Legal Identity
- Importers
- Imported Articles
- Co-Manufactured Chemicals
- Non-Isolated Intermediates
- Kraft Pulp and Paper Process
- Byproducts Reporting for the Printed Circuit Board Industry
- Reporting for Electricity Generating Sites
- Reporting Manufactured Chemical Substances from Metal Mining and Related Activities
- Preparing and Submitting a Petition

Respondent burden and costs are generated by companies compiling and preparing the required information to be reported to EPA every 4 years. In addition to reporting every 4 years, sometimes companies need to update or correct information previously reported. Therefore, even in off reporting years, company efforts relating to activities

described in this ICR are not zero. The 3 years covered by this ICR begins following the previous ICR's expiration date of July 30, 2023 and continues through June 30, 2026. The burden and costs estimates draw partially from both the 2024 CDR reporting cycle and the 2028 reporting cycle. The full burden and cost for each reporting cycle is provided in Table 3. The fractional portions of those burdens and costs covered by this ICR are provided in Table 4.

**Table 3. Respondent Total Burden and Cost for Four Year Reporting Cycles**

| | Average Unit Burden and Cost[1] | | Universe | Total Burden and Cost | |
|---|---|---|---|---|---|
| **Form U Submitters** | | | | | |
| **IC: Prepare and Submit Report, and Maintain Reports** | **Unit Burden per Average Site (hours)** | **Unit Cost per Average Site (2020$)** | **Respondents (Number of Sites)** | **Total Burden (hours)** | **Total Cost (2020$)** |
| **2024 Cycle (Second Cycle)** | | | | | |
| Rule Familiarization | 3.952 | $334.32 | 5,460 | 21,578 | $1,825,387 |
| Compliance Determination | 7.404 | $627.99 | 5,460 | 40,426 | $3,428,825 |
| Recordkeeping | 3.000 | $219.09 | 5,460 | 16,380 | $1,196,231 |
| Average Multi-Chemical Form Completion besides Function Category Data Elements (7.38 chemicals) | 454.541 | $49,271.31 | 5,460 | 2,481,794 | $269,021,353 |
| Function Category Data Elements (7.38 chemicals per site) | 71.016 | $7,744.25 | 5,460 | 387,747 | $42,283,605 |
| **Total** | **539.913** | **$58,196.96** | **5,460** | **2,947,925** | **$317,755,401** |
| **2028 Cycle (Future Cycle)** | | | | | |
| Rule Familiarization | 3.952 | $334.32 | 5,460 | 21,578 | $1,825,387 |
| Compliance Determination | 7.404 | $627.99 | 5,460 | 40,426 | $3,428,825 |
| Recordkeeping | 3.000 | $219.09 | 5,460 | 16,380 | $1,196,231 |
| Average Multi-Chemical Form Completion besides Function Category Data Elements (7.38 chemicals) | 454.541 | $49,271.31 | 5,460 | 2,481,794 | $269,021,353 |
| Function Category Data Elements (7.38 chemicals per site) | 59.767 | $6,517.55 | 5,460 | 326,328 | $35,585,823 |
| **Total** | **528.664** | **$56,970.26** | **5,460** | **2,886,506** | **$311,057,619** |

Table Footnotes:

[1]Overall unit burden is based on about 15% new reporting sites except for the Function Category Data Elements in the second cycle, where the overall unit burden is based on 90% new reporting sites.

**Table 4. Respondent Annual and Total Burden and Cost for 3 Year ICR Period**

| Burden Category | CDR Reporting Cycle Burden (hours)[1] | | | | | | | | ICR Renewal Period (July '23 - June '26)[2] | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Second Reporting Cycle (2024 Cycle) | | | | Future Reporting Cycle (2028 Cycle) | | | | Annual Average Burden (hours) | Annual Average Cost (2020$) | Total Burden (hours) | Total Cost (2020$) |
| | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | | | | |
| *Reporter Burden* | | | | | | | | | | | | |
| CDX Registration and eSignature | | | | 723 | | | | 723 | 181 | $14,558 | 543 | $43,674 |
| Form U Submission: Prepare and Submit Report, and Maintain Records[3] | | | | 2,947,925 | | | | 2,886,506 | 729,304 | $78,601,628 | 2,187,912 | $235,804,883 |
| **Reporter Burden, Total** | | | | **2,948,646** | | | | **2,887,229** | **735,485** | **$78,616,186** | **$2,188,455** | **$235,848,557** |

Table Footnotes:

[1]EPA assumes that reporting activities for a CDR cycle begin on the first day of the calendar year following the previous cycle, at which point reporters have complete information for the first reporting year of the cycle. Because the CDR cycle is four years, EPA assumes that reporting activities for a CDR cycle end on the last day of the calendar year of the cycle. For example, reporting activities for the 2024 cycle begin on January 1, 2021 and end on December 31, 2024.

[2]ICR Renewal Period burden and cost are calculated as a prorated sum of Second Cycle and Future Cycle burden and cost. The ICR renewal period is comprised of 36 months (July 2023 through June 2026) with 18 months in the second four-year reporting cycle and 18 months in the subsequent future four-year reporting cycle.

[3]Includes rule familiarization (new reporters), compliance determination, form completion, and recordkeeping.

**13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).**

**a) The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

**b) If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing**

**economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

**c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

There are no operation and maintenance costs associated with this collection.

**14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.**

The 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 forms as they are received;
- Answer submitter questions and provide any necessary assistance;
- Process submissions for inclusion in CDR database;
- Maintain the database; and
- Distribute the data.

This section describes the Agency tasks required for efficiently processing submissions under 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 the Agency. 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.

- Database Systems Development and Maintenance -- The Agency is responsible for having 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. In addition, CDR data are tracked via the correspondence tracking system utilized by the Confidential Business Information Tracking System (CBITS) located within the Confidential Business Information Center (CBIC).

- Guidance Document Development -- The Agency is responsible for developing and maintaining guidance to assist submitters in complying with CDR requirements. The guidance documents usually are developed by a contractor with oversight by Agency personnel.

- 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 document life cycle, document receipt and tracking, data input, quality control, file and database maintenance, information security, CBI aggregation policy, data dissemination, and staff training.

- Additional Activities -- The Agency develops various supporting documents associated with the reporting tool and makes them available on the Internet. In addition, the Agency is responsible for providing the TSCA Hotline with standardized responses for frequently asked questions; preparing mailings, mailing lists, and labels; and developing outgoing information materials.

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

Table 5 provides the burden and cost per report for all EPA staff activities anticipated during this ICR period. The activities performed by the GS-13 level staff member, including systems development, and contract oversight and management, are fixed costs and are not dependent on the number of reports submitted to EPA. However, there are burden and costs which vary based on the number of CDR respondents or chemical reports. For this reason, Agency burden and cost are split into two categories, fixed and variable.

## Table 5. Annual Agency Burden and Cost

| Activity | Staff | Affected Universe | Unit Burden and Cost | | Total Burden and Cost | |
|---|---|---|---|---|---|---|
| | | | Burden per Activity (hours) | Cost per Activity (2020$) | Total Burden (hours) | Total Cost (2020$)[1] |
| **Variable Burdens and Costs** | | | | | | |
| Submission Receipt and Tracking; Data Review | Contractor | 5,460 Sites | N/A | N/A | N/A | $25,900 |
| Quality Control, except CDX Registration | EPA Staff | 40,286 Reports | 0.005 | $0.51 | 188 | $20,614 |
| Quality Control | Contractor | N/A | N/A | N/A | N/A | $25,000 |
| Quality Control, CDX Registration | EPA Staff | 1,365 CDX Registrations | 0.0081 | $0.89 | 11 | $1,215 |
| **Total Variable Burden and Cost** | | | | | **199** | **$72,729** |
| **Printing and Publishing Forms and Materials** | | | | | | |
| Data Processing, Systems Development; Contract Oversight and Management | EPA Staff | N/A | N/A | N/A | 2,080 | $228,070 |
| Development and maintenance of the electronic data collection tool (incl. electronic guidance) | Contractor | N/A | N/A | N/A | N/A | $162,000 |
| Back Up Systems Operations and Maintenance | Contractor | N/A | N/A | N/A | N/A | $161,000 |
| Publishing Forms and Materials | Contractor | N/A | N/A | N/A | N/A | $8,333 |
| Managing the TSCA Hotline | Contractor | N/A | N/A | N/A | N/A | $56,520 |
| Development of Reporting Instructions, webinars, group communications | EPA Staff | N/A | N/A | N/A | 1,179 | $129,276 |
| Development of Reporting Instructions | Contractor | N/A | N/A | N/A | N/A | $5,000 |
| **Total Fixed Burden and Cost** | | | | | **3,259** | **$750,199** |
| **Total Agency Burden and Cost** | | | | | **3,458** | **$822,928** |

Table Footnotes
[1] Based on Labor rates (see Table A-1) for Program Staff GS13 Step 5

### 15. Explain the reasons for any program changes or adjustments reported in hour or cost burden.

The respondent burden for this collection of information is estimated to average 135 hours per year for the average multi-chemical submission of 7.38 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.

There is an increase of 10,194 hours in the total estimated burden compared with that

currently approved by OMB. This increase reflects a combination of reporting requirement changes including changes to the information reported (+35,611 hours) and changes to the number of reporters (-25,417 hours) due to byproducts exemptions and a new small manufacturer definition, which were included in two ICR addendums approved by OMB in 2020 (one associated with the 2020 CDR Revisions Rule and the other with the 2020 8(a) SMD Update Rule). Refer to Error: Reference source not found for further detail.

**Table 6: Reasons for the Change in Annual Burden**

| Information Collection (IC) | Previous ICR | | Changes | | | | ICR Renewal | |
|---|---|---|---|---|---|---|---|---|
| | | | (1) Changes to the Counts of Reporters[1] | | (2) New and Modified Reporting Activities[2] | | | |
| | Unit | Total | Unit | Total | Unit | Total | Unit | Total |
| *Reporter Burden* | | | | | | | | |
| CDX Registration | 0.133 | 188 | | -7 | 0 | 0 | 0.133 | 181 |
| Form U Submission: Prepare and Submit Report, and Maintain Records[3] | 127.05 | 719,103 | | -25,410 | 6.5216 | 35,611 | 134.666 | 729,304 |
| **Reporter Burden, Total** | | **719,291** | | **-25,417** | | **35,611** | | **729,485** |

General Notes:

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

• The total burdens presented in this table may not equal the product of the unit burden and the reporting universe count of sites due to rounding.

Table Footnotes:

[1]From 5,660 sites in 2018 CDR ICR to an estimated 5460 sites in the 2022 CDR ICR. Note that the number of sites in the previous ICR has been adjusted from 5,662 to 5,660 to account for the removal of two test sites identified in the 2016 CDR after the preparation of the 2018 ICR renewal.

[2]New and modified reporting activities include new and modified reportable data elements, changes to CBI substantiation requirements, and the rule familiarization and compliance determination associated with the changes in the 2020 CDR Revisions Rule and the 2020 8(a) SMD Update Rule.

[3]Includes rule familiarization (new reporters), compliance determination, form completion, and recordkeeping.

**16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.**

After each collection, the CDR data are tabulated into a series of spreadsheets and an Access database, checked to ensure any data submitted as confidential are protected, and made public by directly posting on the CDR website and via the online ChemView database. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.**

Not applicable.

**18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act Submissions."**

EPA does not request an exception to the certification of this information collection.

## SUPPLEMENTAL INFORMATION

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0162). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 711. 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 public reporting and recordkeeping burden for this collection of information is estimated to be 135 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

To comment on 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, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPPT-2013-0721, which is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above.

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via http://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

All comments received by EPA 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.

For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

## REFERENCES

1. EPA, 2020a. Economic Analysis for the Final Rule on the TSCA Chemical Data Reporting (CDR) Revisions. Docket EPA-HQ-2018-0321-0118

2. EPA, 2020b. Economic Analysis for the Final Rule on the TSCA Section 8(a) Small Manufacturers Definition Update. Docket EPA-HQ-2018-0321-0141

3. EPA 2018. 2016 CDR Database

## LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through http://www.regulations.gov using Docket ID Number: EPA-HQ-OPPT-2013-0721.

| Attachment | Title |
|---|---|
| 1. | Statutory Authority |
| 2. | Implementing Regulation |
| 3. | Uses of Specific Data Elements |
| 4. | Wage Rates |
| 5. | CDX User Guide |
| 6. | CDR Screen shots |
| 7. | Consultation Email |
| 8. | Consultation Response from Arakawa |
| 9. | Summarized Comments and Responses |
| 10. | Form U EPA Form No. 9600-010 |
| 11. | Form U Primary Manufacturer Import EPA Form No.9600-011 |
| 12. | Form U. Primary Co-Manufacture EPA Form No 9600-012 |
| 13. | Form U Primary Co-Manufacturer Producing EPA Form No.9600-013 |
| 14. | Form U Secondary or Tertiary EPA Form No.9600-014 |
| 15. | Form U Secondary Notify Tertiary EPA Form No. 9600-015 |