ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704, 711, and 712

[EPA–HQ–OPPT–2018–0321; FRL–9982–16]

RIN 2070–AK33

TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Toxic Substances Control Act (TSCA) section 8(a) Chemical Data Reporting (CDR) requirements and the TSCA section 8(a) size standards for small manufacturers. The current CDR rule requires manufacturers (including importers) of certain chemical substances listed on the TSCA Chemical Substance Inventory (TSCA Inventory) to report data on chemical manufacturing, processing, and use every 4 years. EPA is proposing several changes to the CDR rule to make regulatory updates to align with new statutory requirements of TSCA, improve the CDR data collected as necessary to support the implementation of TSCA, and potentially reduce burden for certain CDR reporters. Proposed updates to the definition for small manufacturers, including a new definition for small governments, are being made in accordance with TSCA section 8(a)(3)(C) and impact certain reporting and recordkeeping requirements for TSCA section 8(a) rules, including CDR. The definitions may reduce burden on chemical manufacturers by increasing the number of manufacturers considered small. Overall, these regulatory modifications may better address EPA and public information needs by providing additional information that is currently not collected; improve the usability and reliability of the reported data; and ensure that data are available in a timely manner.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0321, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susan Sharkey, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8789; email address: *sharkey.susan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute at 15 U.S.C. 2602(9) to include import) chemical substances, including chemical users or processors who may manufacture byproduct chemical substances, and are therefore subject to either of the following: (1) Reporting under the TSCA Chemical Data Reporting (CDR) requirements at 40 CFR part 711 or (2) TSCA reporting and recordkeeping requirements at 40 CFR part 704 or other TSCA reporting requirements which reference the small manufacturer standards at 40 CFR 704.3. Any use of the term ''manufacture'' in this document will encompass ''import,'' the term ''manufacturer'' will encompass ''importer,'' and the term ''chemical substance'' will encompass ''byproduct chemical substance,'' unless otherwise stated.

The regulated community consists of entities that produce domestically or import into the United States chemical substances listed on the TSCA Inventory. The Agency's previous experience with TSCA section 8(a) collections has shown that most respondents affected by this collection activity are from the following North American Industrial Classification System (NAICS) code categories:

- NAICS 325—Chemical Manufacturing; and
- NAICS 324—Petroleum and Coal Product Manufacturing.

In addition to the anticipated respondents from the NAICS listed previously, the regulated community consists of manufacturers of byproducts that are required to report under certain TSCA section 8(a) rules, including CDR. Byproduct manufacturers may be listed under a different primary activity for a site, such as NAICS codes 22, 322, 327310, 331, and 3344 representing, utilities, paper manufacturing, cement manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing, respectively.

The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions at 40 CFR 711.8. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Section 8(a)(1) of TSCA authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may reasonably require (15 U.S.C. 2607). TSCA section 8(a) generally excludes small manufacturers and processors of chemical substances from the reporting requirements established in TSCA section 8(a). However, EPA is authorized by TSCA section 8(a)(3)(A)(ii) to require TSCA section 8(a) reporting from small manufacturers and processors with respect to any chemical substance that is the subject of a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6; that is the subject of an order in effect under TSCA sections 4 or 5(e); that is subject to a consent agreement under TSCA section 4; or that is the subject of relief granted pursuant to a civil action under TSCA section 5 or 7.

TSCA section 8(a)(3)(B) authorizes the EPA Administrator, after consultation with the Administrator of the Small Business Administration (SBA), to prescribe by rule the standards for determining the manufacturers and processors which qualify as small manufacturers and processors. Pursuant

to TSCA section 8(a)(3)(C), on November 30, 2017, EPA determined that revision of the standards is warranted (82 FR 56824).

TSCA section 8(a)(5) requires the EPA Administrator, to the extent feasible, to not require unnecessary or duplicative reporting and minimize the cost of compliance for small manufacturers.

TSCA section 14 imposes requirements for the assertion, substantiation and review of confidential business information (CBI) claims.

C. What action is the Agency taking?

In this action, EPA is proposing several amendments to the current CDR rule requirements. These amendments, described in more detail in Unit III., include:

- Changing requirements for making confidentiality claims, including to identify when upfront substantiation is required, update the substantiation questions, and identify data elements that cannot be claimed as confidential to align with the Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments);
- Replacing certain processing and use codes (industrial function and commercial/consumer product use) with codes based on the Organisation for Economic Co-operation and Development's (OECD) functional use and product and article use codes, including adding reporting of the OECD-based functional use codes for consumer and commercial use information;
- Adding the requirement to report the NAICS code(s) for the site of manufacture;
- Modifying the requirement to indicate whether a chemical is removed from the waste stream and recycled, remanufactured, reprocessed, or reused with the requirement to indicate whether a chemical is removed from the waste stream and recycled;
- Adding a requirement to identify the percent total production volume of a chemical substance that is a byproduct;
- Requiring that the secondary submitter of a joint submission report the chemical specific function along with the percentage of the chemical in the imported product;
- Adding a voluntary data element to provide a public contact;
- Modifying the definition of ''parent company'' to clarify the definition, add the requirement to report a foreign parent company, when applicable, and codify reporting scenarios;
- Simplifying the reporting process for co-manufacturers by enabling a multi-reporter process for reporters to separately report directly to EPA within the e-CDRweb reporting tool;
- Allowing reporting in specified metal categories for inorganic byproducts;
- Adding exemptions for specifically identified byproducts that are recycled in a site-limited, enclosed system and for byproducts that are manufactured as part of non-integral pollution control and boiler equipment; and
- Clarifying regulatory text by removing outdated text, consolidating exemptions, and making other improvements.

Additionally, EPA is proposing an amendment to update the size standards definition for small manufacturers for reporting and recordkeeping requirements under TSCA section 8(a). Further details of this amendment are in Unit IV.

EPA is also giving notice of some aspects of the amendments to TSCA from the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments) that may impact, more broadly, TSCA submitters. For example, under TSCA section 14(e)(1)(B), the Agency is charged with implementing a ten year ''sunset'' provision for confidentiality claims.

Because the small manufacturer size standard under TSCA section 8(a) impacts the CDR rule more than other TSCA section 8(a) reporting rules at this time, EPA included these two actions as one proposed rule. However, EPA recognizes that the changes made to the small business definition will impact current and future TSCA section 8(a) reporting rules and intends to finalize these amendments as two separate actions.

EPA is taking other, non-regulatory steps to minimize the burden on all reporters, including small entities, by improving the reporting application and database to be user-friendly and dynamic, consisting of straightforward questions that include fill-in-the-blank (number) fields, check boxes, and drop-down menus. In addition, EPA is replacing the current pre-formatted Form U with a customized report based on the actual information submitted by a site through e-CDRweb, the electronic reporting tool. Although these changes are not discussed further in this proposal, they are an important component of the effort to reduce burden and modernize the data collection system. EPA is adding an addendum to the current CDR rule ICR (OMB Control Number 2070–0162) for the regulatory changes proposed in this document. In addition to the changes outlined in this proposed rule, if needed, EPA will provide a second addendum to this ICR to address non-regulatory changes. As was done for previous CDR collections, EPA will provide industry with the opportunity to test and comment on the updated e-CDRweb prior to the 2020 CDR submission period. EPA anticipates holding a webinar to introduce the revised e-CDRweb to the regulated community directly following the finalization of the CDR Revisions rule. During the webinar, EPA will issue a general invitation to interested parties to participate in a short testing period of the revised e-CDRweb. EPA will open the testing period within 4 months after this proposal is finalized, and currently anticipates that testing will occur in the February to March 2020 timeframe. Because of resource constraints, the testing period will be limited to 25 participants. For additional information, contact the person under **FOR FURTHER INFORMATION CONTACT**. Also, information will be posted on the CDR website (*https://www.epa.gov/chemical-data-reporting*).

D. Why is the Agency taking this action?

EPA is proposing revisions to the CDR rule for three primary reasons: Align with amendments to TSCA from the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments), improve the CDR data collected as necessary to support the implementation of TSCA, and reduce burden for CDR reporters pursuant to TSCA section 8(a)(5).

The 2016 Amendments to TSCA changed requirements associated with confidentiality claims, including identifying the data elements eligible for confidentiality claims and when substantiation of claims is required. EPA is proposing revisions to the CDR rule to address these changes.

EPA is proposing to modify the definition for small manufacturers, as a result of the 2016 Amendments revision of TSCA section 8(a)(3)(C), which requires EPA, after consultation with the Administrator of the SBA, to review the adequacy of the standards for determining which manufacturers and processors qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). EPA published a determination that revision of the TSCA section 8(a) size standards for small manufacturers as warranted in a **Federal Register** Notice published November 30, 2017 (82 FR 56824). EPA's determination, supporting documents, and comments received can be found at *regulations.gov* under docket number EPA–HQ–OPPT–2016–0675. This proposed change may reduce burden for some manufacturers

that would be considered small manufacturers under CDR and other TSCA section 8(a) rules relying on the small manufacturer definition in 40 CFR part 704.3.

EPA is also proposing to make some changes to the CDR data reporting so the information collected is tailored to better meet the Agency's overall information needs and aligned with specific needs for prioritization and risk evaluation under TSCA section 6. TSCA section 2 specifies that ''adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures'' (TSCA section 2(b)(1)). These proposed changes include the addition of data elements, such as a site-specific NAICS code and how much of a chemical is a byproduct; modification to multi-reporter submission requirements, including adding a process for jointly reporting co-manufactured chemicals; and changes to current data elements, such as codes used for reporting processing and use information. In addition, proposed changes to the parent company reporting requirements would increase EPA's ability to protect confidential information while better enabling EPA to make information publicly available and the addition of a voluntary public contact would direct inquiries from the public to a designated individual rather than to the technical contact. These changes would help to meet the Agency's requirement under TSCA section 26(h), in carrying out TSCA sections 4, 5, and 6, to make scientific decisions consistent with the best available science, improve the CDR data collected as necessary to support the implementation of TSCA, and improve EPA's ability to effectively provide public access to the information. Furthermore, these changes would meet the Agency's objective to obtain new and updated information relating to potential exposures to a major subset of chemical substances listed on the TSCA Inventory.

At the same time, EPA is interested in reducing burden on industry while maintaining the Agency's ability to receive the information it needs to understand exposure to these chemicals (TSCA section 8(a)(5)). EPA used experiences from the 2016 CDR submission period, concerns identified by users of CDR information, and burden-reduction suggestions made as part of public comment opportunities, including public comments solicited in conjunction with Executive Order 13777, *Enforcing the Regulatory Reform Agenda* (EPA–HQ–OA–2017–0190 and 82 FR 17793, April 13, 2017) and as part of the renewal of the Information Collection Request (ICR) (EPA–HQ–OPPT–2017–0648 and 83 FR 36928, July 31, 2018). In addition, EPA identified ways to reduce burden specifically for manufacturers of inorganic byproducts as part of an extensive negotiated rulemaking effort, which included participation by all stakeholder groups, and subsequent public comment period in 2017 (EPA–HQ–OPPT–2016–0597 and 82 FR 47423, October 12, 2017). Taking into account these experiences and stakeholder input, EPA is proposing the following changes to reduce burden: The new ability to alternatively report inorganic byproducts within defined metal categories, the introduction of two new exemptions related to byproducts, a revised approach to reporting for co-manufactured chemicals, and the harmonization of function and product codes with those used by other countries.

Additionally, EPA has received comments that modernizing the CDR data collection and public access to the database would reduce reporting burden and facilitate ease of use by reporters and the public (81 FR 90843; EPA–HQ–OPPT–2016–0597 and Refs. 1, 2, and 3). These comments were used to develop this proposal and to inform other, non-regulatory changes that EPA plans to make to the reporting process.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs and benefits of revising CDR reporting requirements and modifying standards for small manufacturers in CDR and other TSCA section 8(a) reporting. Some aspects of the proposal increase burden and cost while other aspects decrease burden and result in cost savings. Overall, EPA estimates that the combined impact of all the proposed amendments would decrease the total burden and result in a cost savings to industry and government reporters. These analyses, which are available in the docket (Refs. 4 and 5), are discussed in Units III. and IV. and are briefly summarized here.

1. *CDR revisions economic impacts summary.* The proposed amendments are estimated to result in an overall net decrease in burden with associated cost savings. The estimated changes include increases in rule familiarization, compliance determination, and form completion. The future cycle burden and costs or cost savings are listed by type of change:

- For changes to modify or add reportable data elements (*e.g.,* processing and use codes, NAICS codes, byproduct percentage, chemical function, public contact, and parent company—discussed in Units III.B. and III.C.), the incremental burden is expected to increase by 45,000 hours with an associated cost increase of $3.5 million.
- For changes to claiming confidentiality (discussed in Unit III.A.), the incremental burden is expected to decrease by 340 hours with an associated cost savings of $0.03 million.
- For changes to add byproducts exemptions (discussed in Unit III.D.), the incremental burden is expected to decrease by 68,000 hours with an associated cost savings of $5.2 million.
- For changes to implement consolidated category reporting for certain inorganic metals (discussed in Unit III.D.), the incremental burden is expected to decrease by 13,000 hours with an associated cost savings of $1.0 million.
- For changes that affect CDR reporting eligibility (targeted to certain sites with varying reductions to the number of chemicals reported per site), the incremental burden is expected to result in a net decrease by 81,000 hours with associated cost savings at $6.3 million. There are increases in burden and costs for several requirements, such as the need to assess whether exemptions apply (compliance determination) and the need to familiarize oneself with modifications to the rule (rule familiarization), estimated at 3,000 hours with an associated cost of $0.24 million. However, the changes to form completion in the aggregate are estimated to result in an overall net decrease in burden and cost savings due to decreases in the number of sites reporting and or the number of chemical reports from a site. These decreases are due to the proposed byproduct exemptions (discussed in Units III.D.2. and III.D.3.) and consolidated category reporting (discussed in Unit III.D.1.).

In sum, the overall incremental impacts to industry and government reporters result in a net decrease in burden and cost savings. Estimates include rule familiarization, compliance determination, and CDR form completion (Ref. 4). Note that estimated changes to recordkeeping burden and cost are negligible and estimated at zero. An estimated 5,660 sites are expected to report during the next CDR submission period in 2020. The total incremental burden reduction and cost savings are estimated at a 36,000 hour reduction and $2.79 million cost savings. On an annualized basis using a 3 percent and

a 7 percent discount rate over a 10-year period, the annualized incremental cost savings is estimated at $0.66 million and $0.65 million per year, respectively (Ref. 4).

2. *TSCA section 8(a) small manufacturer definition economic impacts summary.* The proposed modified standards for small manufacturers would affect TSCA section 8(a) rules, including CDR. These rules use the TSCA section 8(a) small manufacturer definition to identify the entities exempted from reporting or for other reduced reporting requirements. The impact from the proposal is focused on the CDR rule and may impact whether a site is required to report or the number of chemicals a site would report. There is no measurable impact to other TSCA section 8(a) rules either because EPA has not received any chemical reports for the rule for an extended period of time or because the rule uses a different definition that is not being changed by this proposal (see Unit IV.A. for a more detailed discussion). The proposed definition, discussed in detail in Unit IV., results in a cost savings.

a. *Impact of proposed small manufacturer definition.* The proposal is estimated to eliminate reporting entirely for 93 industry sites and reduce reporting by eliminating the need to report at least one chemical for additional 129 industry sites (Ref. 5). This reduction in reporting is in addition to the sites already not reporting because they meet the current small manufacturer definition.

Under this proposed definition, incremental future cycle burden reductions and cost savings are estimated at 64,000 hours and $5.0 million, respectively, over a four-year CDR reporting cycle (Ref. 5). On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields net annualized incremental cost savings of $1.2 million and $1.2 million per year, respectively (Ref. 5). This proposal also includes a small government exemption (described in this unit).

b. *Impact of proposed small government definition.* The following government entities report under CDR: Seven municipalities, one county-level public utility district, and one tribal entity. Under the proposed small government definition, four government entities would be exempted from the need to report. The burden and cost savings associated with the exempted entities, in future reporting cycles, are included in the estimates for the proposed definition with incremental future cycle burden reduction and cost savings estimated at 500 hours and $39,000 respectively, over a four-year CDR reporting cycle (Ref. 5).

3. *Total economic impacts summary for proposal.* The amendments in this proposal may affect the number of reports submitted during a submission period and the burden to prepare a report. EPA estimates that the combined impact of all the proposed amendments would decrease the total burden and cost to industry associated with CDR reporting. Tables 1A and 1B present the summaries of burden and cost impacts, respectively, for the proposed CDR revisions and TSCA section 8(a) small manufacturer definition update. In the tables, estimates are presented for the CDR four-year first cycle and in the future cycle. In the first cycle, higher burdens and costs are incurred, because all reporters need to familiarize themselves with the changes and may take longer to complete reporting activities. After the first cycle, and for future cycles, experienced reporters (85%) are familiar with the changed requirements. In addition to estimates that cover the four-year CDR cycle, Tables 1A and 1B present annual estimates. These annual estimates are the four-year estimates divided by four. EPA acknowledges that activities may be spread unevenly across the four years. On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields a net annualized incremental cost savings of $1.85 million and $1.83 million per year, respectively, for the overall proposed rule.

TABLE 1A—SUMMARY OF ECONOMIC IMPACTS, BURDEN REDUCTIONS

	Number of affected sites	First cycle		Future cycles	
		Four-year cycle	Annual	Four-year cycle	Annual
		Burden reduction (hours)	Burden reduction (hours)	Burden reduction (hours)	Burden reduction (hours)
CDR Revisions	5,660	31,306	7,827	36,005	9,001
8(a) Small Manufacturer Exemption [1]	5,627	56,162	14,040	64,295	16,074
Small Government Exemption [2]	33	454	113	504	126
Net Incremental Change	5,660	87,922	21,980	100,804	25,201

General Note: Annual estimates are based on changes applied evenly across the four-year cycle. However, due to rounding issues, results may not be readily derived using this table.

Footnotes:

[1] Under the proposed exemptions, incremental changes represent the net change due to the proposed rule and therefore include sites and chemical reports that are exempted. Note that sites and reports can be entirely affected or undergo a split effect, with a portion of the site's chemical reports exempted.

[2] Four small governments are identified to qualify for the small government exemption under the proposed small government exemption.

TABLE 1B—SUMMARY OF ECONOMIC IMPACTS, COST SAVINGS

	Number of affected sites	First cycle		Future cycles	
		Four-year cycle	Annual	Four-year cycle	Annual
		Cost savings (2017$)	Cost savings (2017$)	Cost savings (2017$)	Cost savings (2017$)
CDR Revisions	5,660	$2,428,630	$607,157	$2,792,871	$698,218
8(a) Small Manufacturer Exemption [1]	5,627	4,357,362	1,089,341	4,988,270	1,247,068
Small Government Exemption [2]	33	35,132	8,783	39,025	9,756
Net Incremental Change	5,660	6,821,124	1,705,281	7,820,166	1,955,042

General Note: Annual estimates are based on changes applied evenly across the four-year cycle. However, due to rounding issues, results may not be readily derived using this table.

Footnotes:

[1] Under the proposed exemptions, incremental changes represent the net change due to the proposed rule and therefore include sites and chemical reports that are exempted. Note that sites and reports can be entirely affected or undergo a split effect, with a portion of the site's chemical reports exempted.

[2] Four small governments are identified to qualify for the small government exemption under the proposed small government exemption.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.*

II. Background

A. What is the Chemical Data Reporting (CDR) rule?

The CDR rule requires U.S. manufacturers of certain chemicals listed on the TSCA Inventory to report to EPA every four years the identity of chemical substances manufactured for all years since the last principal reporting year. For example, for the 2020 submission period, the principal reporting year is 2019 and the last principal reporting year for the 2016 submission period was 2015. Reporting during the 2020 submission period covers the manufacture of chemicals in 2016, 2017, 2018, and 2019. To help minimize reporting burden, detailed information is required only for the principal reporting year (*i.e.,* 2019), including a breakout of the production volume to provide separate volumes for domestically manufactured and imported amounts. Generally, reporting is required for substances whose production volumes are 25,000 pounds or more at any single site during any of the calendar years since the last principal reporting year. However, a lower threshold applies for chemical substances that are the subject of certain TSCA actions (see 40 CFR 711.8(b)). The CDR regulation generally excludes several groups of chemical substances from its reporting requirements, *e.g.,* polymers, microorganisms, naturally occurring chemical substances, certain forms of natural gas, and water (see 40 CFR 711.5 and 711.6). For the 2016 CDR, EPA received Form U's from 5,660 sites with an associated 42,464 chemical reports, providing information on 8,717 unique chemicals.

Persons domestically manufacturing or importing chemical substances are required to report information such as company name, site location and other identifying information, production volume of the reportable chemical substance, and exposure-related information associated with the manufacture of each reportable chemical substance, including the physical form and maximum concentration of the chemical substance, the number of potentially exposed workers at the reporting site and certain processing and use information (40 CFR 711.15). The processing and use information that is currently required includes: Process or use category; NAICS code; industrial function category; percent production volume associated with each process or use category; number of sites; number of potentially exposed industrial or commercial workers; and consumer/commercial information such as use category, use in or on products intended for use by children, and maximum concentration. Under CDR, submitters report information to the extent that it is ''known to or reasonably ascertainable'' (40 CFR 711.15), which means ''all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know'' (40 CFR 711.3, referencing 40 CFR 704.3). Reported information can be claimed as confidential (40 CFR 711.30).

B. How are the CDR data used by EPA?

EPA uses the data reported pursuant to the CDR rule to support health, safety, and environmental protection activities related to chemical manufacturing and use. Manufacturing, processing and use information about chemicals in commerce helps EPA understand exposure to these chemicals and screen and prioritize chemicals to identify potential human health and environmental effects. EPA uses the data reported under the CDR rule to support many activities under TSCA and to provide overall support for EPA and other federal, state, local, and tribal health, safety, and environmental protection activities (Ref. 6 and 83 FR 36928, July 31, 2018 (EPA–HQ–OPPT–2017–0648)).

CDR provides basic exposure-related data which EPA uses in a wide variety of its activities, from choosing the chemicals EPA will focus on for prioritization and assessment activities to informing response actions, such as to hurricanes and other disasters. For example, in accordance with TSCA section 6(b)(1)(A), EPA is required to consider ''the conditions of use or significant changes in conditions of use of the chemical substance, and the

volume or significant changes in the volume of the chemical substance manufactured or processed.'' CDR provides information directly pertaining to the conditions of use, such as the number of sites, the number of workers reasonably likely to be exposed, and how and why the chemical is used, based on the CDR processing and use information. In addition, CDR provides the production volume, the production volume over time, and changes in the volumes under different conditions of use. Such information is expected to contribute to improved understanding of the chemical, including during the prioritization process. For example, EPA used the 2012 and 2016 CDR data to assist in identifying current uses and production volumes and, inversely, uses that are no longer ongoing, to help determine the scope of the risk evaluations for the first 10 chemicals being reviewed under amended TSCA. EPA grouped uses for these chemicals based on CDR categories such as industrial, commercial, and consumer use. Additionally, the problem formulations for the first 10 chemicals, which were published in June 2018, used CDR data to identify the number of sites where exposure may occur and approximate workers who may be exposed to the chemicals. For example, in the *Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tertrachloro),* EPA used CDR data to identify conditions of use for Perchloroethylene (Ref. 7). CDR data will continue to inform future prioritization, risk evaluation, and risk management work under TSCA.

For another example, to help prepare EPA and others to respond to hurricane disasters that occurred in 2018, EPA prepared information about chemicals expected to be in the affected areas from data sources such as CDR.

In 2012, EPA published its TSCA Work Plan for Chemical Assessments. CDR data were used extensively in the development of this Work Plan. Using CDR data collected during the 2012 CDR submission period, EPA updated the exposure rankings for the chemicals initially screened as part of the original Work Plan and, in 2014, published a revised Work Plan (2014 Work Plan). TSCA requires that at least 50 percent of all chemical substances undergoing risk evaluation (High-Priority designations) come from the 2014 Work Plan, until the Work Plan chemical list is exhausted.

The Interagency Testing Committee (ITC), an independent advisory committee to the EPA Administrator, uses CDR data when updating the Priority Testing List (PTL). The ITC designates or recommends chemicals to the PTL that the Agency may prioritize when requiring testing under TSCA section 4 or collecting information under TSCA sections 8(a) or 8(d). In making those determinations, production volumes reported to CDR are used to identify the opportunity for exposure to a particular chemical.

OECD member countries develop Emission Scenario Documents (ESD). EPA is an active participant of the OECD Task Force and regularly works on the development of ESDs that are reviewed by the Task Force and added to the published series of ESDs. ESDs developed by EPA cover both occupational exposures and environmental releases due to EPA's review responsibilities under TSCA. In a separate and related effort, EPA has regularly developed industry-specific generic scenarios which are similar to an OECD ESD, as tools to assist in the assessment of the many types of uses for new chemicals reviewed under TSCA. CDR data are used to identify the chemicals commonly used in specific industries, estimate the number of potentially exposed workers, and develop estimates of exposure and releases that support the development of these documents and scenarios.

Additional examples of how EPA uses CDR data include use by the Office of Research and Development to characterize the life cycle of chemicals for life cycle inventories, to develop conceptual models, and to develop standardized emission and release estimates from chemical production. The Office of Water uses CDR data to identify facilities in specific industry sectors while developing effluent guidelines and to identify chemicals of interest and their associated processing and use activities for Effluent Guidelines Annual Review Reports.

C. What are the current standards for small manufacturers and processors?

In 1988, EPA established the general TSCA section 8(a) small manufacturer definition for use in other rules issued under TSCA section 8(a), which are codified at 40 CFR 704.3. These are the current standards that apply to CDR:

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

1. *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

2. *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

3. *Inflation index.* EPA must use the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of the rule (*i.e.,* 40 CFR 704), whichever is later. EPA shall provide **Federal Register** notification when changing the total annual sales values.

Pursuant to authority under TSCA section 8(a)(3)(B), certain TSCA section 8(a) rules codify slight variations of the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 (see, *e.g.,* 40 CFR 704.45). There is no general small processor standard, and EPA is not proposing one in this action. However, other rules issued under TSCA section 8(a) establish analogous standards for small processors in those particular rules. See Unit IV.A. for additional discussion.

III. Detailed Discussion of the Proposed Modifications to CDR

A. Changes to Claiming Confidentiality

EPA is proposing changes to requirements related to claiming CDR data as confidential to be consistent with the new statutory requirements in TSCA section 14. TSCA requires the Agency to review and make determinations regarding the validity of confidential claims for information submitted to EPA. EPA estimates that this proposed change would result in a decrease in burden, which is explained in detail in Table 4–14 in the Economic Analysis (Ref. 4).

New statutory provisions that are pertinent to reporting under CDR include the following:

- Under TSCA section 14(c)(3), all claims of confidentiality must be substantiated at the time the information is submitted to EPA, except for those types of information exempt under TSCA section 14(c)(2).
- The submitter must provide a statement supporting the claim, as described in TSCA section 14(c)(1)(B) and must certify that the statement is true and correct, as described in TSCA section 14(c)(5).
- TSCA section 14(b)(3)(B) limits confidentiality claims for reported use information that customarily would be shared with the general public or within an industry or industry sector.
- Under TSCA section 14(e)(1)(B), confidentiality claims on information not described in TSCA section 14(c)(2) expire after ten years, unless a request for extension is submitted and granted.

The proposed amendments to the CDR rule address these new provisions, with the exception of the TSCA section 14(e)(1)(B) CBI expiration provision which while it will impact all TSCA submissions filed after June 22, 2016 does not distinctively impact the CDR data collections.

This preamble discussion also includes information about other provisions of TSCA relating to actions EPA must take, but that do not impact the regulatory text or require specific submitter actions.

1. *Substantiations.* EPA interprets TSCA section 14(c)(3) as requiring substantiations of non-exempt CBI claims at the time the information claimed as CBI is submitted to EPA (82 FR 6522, January 19, 2017). The Agency is proposing to amend the CDR substantiation provisions to require substantiation for all confidentiality claims except for those types of information exempt from substantiation under TSCA section 14(c)(2), which are described later in this unit. Submission of substantiations at the time of assertion of confidentiality enables EPA to fulfill its obligation under TSCA section 14(g) to review all confidentiality claims for specific chemical identity, plus a representative subset (comprising at least 25 percent) of all other non-exempt confidentiality claims.

EPA is proposing revisions to the current substantiation questions in 40 CFR 711.30 and the addition of new substantiation questions to address data elements which, prior to amended TSCA, did not require substantiation at the time of submission. The questions are in the proposed regulatory text at the end of this notice. In addition, Appendix B of the CDR Revisions EA (Ref. 4) provides a summary of the questions prior to the 2016 TSCA Amendments and those that are being proposed in this action (Ref. 4). These questions would facilitate the Agency's implementation of TSCA section 14 and the requirement to review and approve, approve in part, deny in part, or fully deny requests for confidentiality. These CDR-specific questions are designed to encourage thoughtful consideration of the need for confidential treatment, improve the consistency of EPA's review of the responses, and reduce the need for multiple discussions between EPA and the submitter regarding the substantiations that may otherwise hinder the Agency's ability to timely fulfill its review obligations under TSCA.

The questions have been carefully drafted to elicit the required information to allow for a CBI review and determination, without imposing an unnecessary burden. A set of standard questions, set forth in proposed 40 CFR 711.30(b), would apply to all non-exempt CBI claims. These questions generally ask about the impact of disclosure on the submitter's competitive position, whether the information has been made available to others, and the controls used to protect the confidential information. These are similar in concept to questions under the current CDR at 40 CFR 711.30. Additional questions are targeted to specific data elements. For chemical substance identity confidentiality claims, the additional substantiation questions, set forth in proposed 40 CFR 711.30(c), are substantively the same as exist under the current CDR at 40 CFR 711.30(b). An additional question for company, site, and technical contact identity is set forth in proposed 40 CFR 711.30(d). Although substantively the same as exists for site identity substantiations in the current CDR at 40 CFR 711.30(c), it is newly applied to company name and technical contact confidentiality claims. Additional questions for processing and use information are set forth in proposed 40 CFR 711.30(e) and are substantively the same as exist in the current CDR at 40 CFR 711.30(d).

a. Exceptions to the substantiation requirements. TSCA section 14(c)(2) identifies certain information that shall not be subject to substantiation requirements under this rule. This includes:

- Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
- Marketing and sales information;
- Information identifying a supplier or customer;
- In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
- Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
- Specific production or import volumes of the manufacturer or processor; and
- Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA section 5.

EPA believes that the only data elements collected under CDR that may be subject to the TSCA section 14(c)(2) limit on substantiation requirements are: (1) Production volume and (2) supplier information associated with joint submissions, such as supplier identity and details of the full composition of a mixture. However, these two data elements may still be subject to substantiation and CBI review under the circumstances described in TSCA section 14(f).

i. Regarding production volume. EPA is proposing to not require substantiation at the time the claim of confidentiality is made for five production volume data elements (*e.g.,* the volume domestically manufactured in 2019, the volume imported in 2019, and the total production volume for each of the three years 2016 through 2018). For each reported chemical, total production volume is reported for each of the years since the last principal reporting year, except for the current principal reporting year when the production volume is reported as domestically manufactured and imported volumes. As an example, for the 2020 CDR submission period, production volume is collected for the calendar years 2016, 2017, and 2018. For calendar year 2019, the production volume is reported as domestically manufactured and imported volumes. EPA believes that these five data elements are exactly the kinds of specific production or import volumes identified in TSCA section 14(c)(2)(F).

ii. Regarding information associated with a joint submission. Joint

submissions are necessary under limited circumstances. Currently these circumstances are: (1) A company imports a chemical or a mixture under a trade name and the substance identity, or individual components, are not known to the importer or (2) a manufacturer cannot provide the entire chemical identity of a chemical substance it manufactures because the chemical substance is manufactured using a reactant having an identity that the reactant supplier claims as confidential. In these circumstances, the supplier has identified that it will not disclose to the manufacturer (or importer) or does not, itself, know the chemical identity.

A joint submission is a submission started by a primary submitter, typically an importer. The primary submitter provides the trade name of the subject chemical substance or mixture, the name and address of the supplier, and other information as appropriate. Given the requirements of amended TSCA, EPA proposes to require that the primary submitter identify whether the supplier information, including the supplier identity and chemical substance name (trade name) is confidential. Substantiation of the confidentiality claims for this information is not required at the time of submission under the proposed rule because EPA believes it is exempt from substantiation as ''[i]nformation identifying a supplier'' under TSCA section 14(c)(2)(C).

The secondary submitter of the joint submission provides their company name and location, a technical contact, trade name, and chemical identity(ies) and percentage of each chemical substance in the composition of the substance or mixture represented by the trade name. In addition, as explained in Unit III.B.5., EPA proposes to collect the function of each chemical in the mixture. Given the requirements of amended TSCA, EPA is proposing to provide the ability for the secondary submitter to specifically identify whether this information is claimed as confidential. Except for the percentage composition information, which is generally exempt from substantiation pursuant to TSCA section 14(c)(2)(D), all other reported data elements are subject to substantiation at the time the information is submitted.

b. Chemical identity. Only chemical substances listed on the confidential portion of the TSCA Inventory (the Inventory) can be claimed as confidential. This provision is not new and is reflected in the current CDR rule at 40 CFR 711.30(b). Such a confidentiality claim applies to the specific identity of the chemical substance as it is listed on the confidential portion of the Inventory. CDR reported chemical identities, including generic chemical names, that are listed on the public portion of the Inventory cannot be claimed as confidential and would be made publicly available. EPA included this discussion for clarification purposes only and is not proposing any changes to this approach.

c. Connection between company, site, or technical contact identity and chemical-specific information. EPA is proposing to require assertion and substantiation of a claim of confidentiality at the time of submission, on a chemical-specific basis, for the linkage between company or technical contact identity and chemical substance information. This is the same as is currently required under 40 CFR 711.30(c) for site identity, when on a chemical-specific basis, one must claim the linkage between the site identity and the chemical substance information as confidential by asserting and substantiating the claim at the time of submission. There would likely be instances where a confidentiality claim for a company name would not be appropriate, but one for site identity or technical contact might be appropriate.

d. Benefits of proposed changes to CBI substantiation. The reduced amount of information subject to confidentiality limitations will facilitate greater interagency and public sharing of data and will decrease the number of inappropriate or unnecessary claims of confidentiality, which will increase the transparency and public accessibility of the CDR. Clarification of which data elements can be claimed as confidential will improve the consistency of EPA's review of CBI substantiation information and will decrease the need for multiple conversations between EPA and reporters about substantiation responses, thus reducing burden for the Agency and for reporters.

2. *Certification.* The authorized official submitting confidentiality claims must certify all claims for confidentiality are true and correct, and all information submitted to substantiate such claims is true and correct. As required by TSCA sections 14(c)(1)(B) and 14(c)(5). EPA combined these requirements into a single certification statement, which was implemented in the CDR electronic reporting tool in June 2016. EPA is proposing to codify the language of the certification statement in the CDR rule (see the proposed regulatory text for 40 CFR 711.30(h)).

3. *Processing and use data not protected from disclosure.* TSCA section 14(b)(3)(B), as amended by the 2016 Amendments, prohibits confidentiality claims for the following submitted information: ''a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.''

This statutory provision directly impacts and limits confidentiality claims for certain CDR processing and use data. Thus, EPA proposes to codify in the regulatory text that the following data elements cannot be claimed as confidential because they constitute general descriptions of processes and uses that customarily would be shared with the general public or within an industry or industry sector:

- *Certain Industrial processing and use data elements.* The data elements which directly relate to how the chemical is used or processed, *i.e.,* the type of process or use; the industrial sector; and the industrial function (40 CFR 711.15(b)(4)(i)(A), (B), and (C)).
- *Certain Consumer and Commercial use data elements.* The data elements which directly relate to how the chemical is used, *i.e.,* the product category (§ 711.15(b)(4)(ii)(A)); whether the chemical is used in commercial or consumer products (§ 711.15(b)(4)(ii)(B)); whether the chemical is likely to be used in children's products (§ 711.15(b)(4)(ii)(C)); and the function of the chemical in the consumer or commercial product (the function is a proposed data element—see Unit III.B.5. for additional information).

For the purposes of this proposal, EPA believes that other CDR processing and use data elements do not offer a ''general description'' and therefore do not fall within the limits of TSCA section 14(b)(3)(B). Under this proposal, submitters may continue to assert claims of confidentiality for the following processing and use data elements:

- *Certain Industrial Processing and use data elements.* Percent production volume, number of sites, and number of workers (§ 711.15(b)(4)(i)(D), (E), and (F)).
- Certain Consumer and Commercial use data elements. Percent production volume, maximum concentration, and number of commercial workers (§ 711.15(b)(4)(ii)(D), (E), and (F)).

4. *Time duration of confidentiality claims.* In accordance with TSCA section 14(e)(1)(B), non-exempt confidentiality claims are initially protected from disclosure for a period of 10 years from the date of submission and confidentiality assertion, assuming all other relevant requirements of the statute are met. Information on confidential business information under TSCA is available on EPA's website at *https://www.epa.gov/tsca-cbi.* One of the proposed new substantiation questions asks whether the submitter anticipates that the claim's duration would last less than the 10-year statutory time frame. Respondents would indicate when the claim would no longer be needed, and EPA would incorporate the release date into its data system, enabling the information to be made publicly available at that time.

B. Modifications to Reportable Data Elements

1. *Processing and use codes.* The CDR rule requires manufacturers to report industrial, consumer, and commercial processing and use information for chemical substances manufactured during the principal reporting year. EPA is proposing multiple changes to the data elements comprising this processing and use information. Specifically, EPA is proposing to replace the CDR industrial function and commercial/consumer product use codes with OECD function, product, and article use categories and to add OECD function categories for commercial/consumer products. EPA is listing these codes in the CDR instructions, rather than codifying them in the CFR, which would enable EPA to limit the codes to just those considered relevant for CDR reporting, with a catch-all ''non-TSCA'' code for the OECD codes that do not fit under TSCA. EPA would then be able to update the Instructions prior to each CDR submission period to align with any changes to the OECD codes.

EPA did not develop burden estimates associated with replacing the current CDR codes with ones based on the OECD codes because such an estimate heavily relies on the e-CDRweb user interface which will feature burden-reducing guided data entry. The addition of the function categories for commercial/consumer products is a new data element whose addition could potentially result in an increase in burden (not estimated at this time). For additional information, see section 4.1.3.2 in the Economic Analysis (Ref. 4).

The OECD Internationally Harmonized Functional, Product, and Article Use Categories were developed through the OECD Working Party on Exposure Assessment (Task Force on Exposure Assessment) under the leadership of the EPA, based on a review of current functional use and product categories from the United States, Canada, and the European Union; bilateral discussions with the European Chemicals Agency (ECHA); and multiple reviews from task force members. The OECD categories are described in the document ''Internationally Harmonised Functional, Product and Article Use Categories'' (referred to herein as the OECD Category Document) (Ref. 8).

Harmonizing CDR use codes with the OECD codes would expand the utilization of applicable use and exposure-related information from international sources to support EPA risk evaluation and risk assessment activities for new and existing chemicals. Additionally, this harmonization would provide industry with international uniformity in use and exposure information reporting, enabling industry to better streamline their different country-specific reporting requirements.

EPA has received requests to harmonize CDR data categories and descriptions with other countries to the extent possible. In particular, industry stakeholder groups such as the American Chemistry Council have expressed a desire to harmonize with Canadian and OECD data collections in order to provide common global terminology and preciseness in risk evaluation (Ref. 9). EPA worked closely with Canada in the development of the current CDR processing and use codes, and both EPA and Canada were involved in the development of the OECD Harmonized codes.

Under CDR, there are two main categories of use codes: Function use codes and product use codes. The function of a chemical combined with the type of product that the chemical is used in provides an exposure scenario with unique characteristics. These exposure scenarios are necessary for implementation of TSCA for the prioritization of the chemical and for further consideration for the development of exposure and risk evaluations.

a. *Function codes (industrial and consumer/commercial).* EPA currently requires the reporting of function categories for chemical substances used in industrial products but does not require the reporting of a chemical substance's function for commercial/consumer products. EPA is proposing to require reporting of function use categories for both industrial and commercial/consumer products and to adopt the OECD functional use categories.

Function codes are based on the intended physical or chemical characteristic for when a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used (*e.g.,* as an abrasive, a catalyst, or an elasticizer). EPA uses information regarding the function of a chemical substance in combination with the industrial sector and processing or use operation to identify an exposure scenario or the type of application in which a chemical would be used (such as solvents for cleaning and degreasing). Understanding the exposure scenarios or the type of application of the chemical would inform assessment of the potential route, duration, frequency and magnitude of exposure.

During screening and risk evaluation activities, EPA evaluates how the chemical substance is manufactured, processed, distributed in commerce, used, and disposed of. Currently, CDR requires the reporting of consumer and commercial product categories but does not require the reporting of chemical function within the product category. The lack of functional use information for consumer and commercial applications has restricted EPA's ability to provide more complete evaluations or more realistic characterizations of exposure for consumer and commercial applications; instead, EPA relies in many cases on scenarios using potentially conservative assumptions. (Ref. 10) The addition of information on the function of the chemical in combination with the consumer or commercial product category would improve EPA's ability to consider exposures to consumers and in commercial applications, providing a more accurate and real-world understanding of the uses of chemical substances throughout their life cycle.

As explained in the OECD Category Document, the OECD product and article use categories are intended to focus on the end-use application of chemicals within products and articles, rather than upstream manufacturing and processing. However, the functional use categories cover the life cycle and describe the specific function that a chemical provides when used in the formulation of a product or article, or when used within an industrial process. While the function of a chemical may be the same across its life cycle, certain functions may only be appropriate for consideration in an industrial setting,

while others may be relevant for a consumer or commercial setting.

Adopting the OECD functional use codes would provide greater detail by expanding the function categories from the 35 codes currently used by CDR to 117 codes. For example, the broad current CDR category *Adhesives and Sealants* corresponds to four categories under the OECD harmonized codes in this proposal: *Adhesion/Cohesion Promoters, Binders, Flux Agents,* and *Sealants (Barrier).* In this proposed rule, not all of the OECD harmonized codes would be adopted to CDR because some are for uses not covered by TSCA (*e.g.,* in the circumstances where, because of a chemical's particular use, it is not a ''chemical substance'' under TSCA section 3(2)(B)(vi)). The current CDR codes contain a catch-all ''non-TSCA code'' for uses that are not covered under TSCA. Under this proposed rule, EPA would continue to provide the same non-TSCA code as a blanket code for these applications, such as for a food or cosmetic (other than soap), when the chemical is reportable to CDR because the chemical is also used in a way that falls under the jurisdiction of TSCA. EPA is interested in receiving comments on whether all of the OECD harmonized codes should be listed so that the codes are an exact match, even if the uses are not covered by TSCA. Would the exact match make it easier for submitters to report information under CDR and other reporting requirements using the OECD harmonized codes?

EPA is listing these codes in the CDR instructions discussed in Unit III.B.1. Additional details about the proposed function categories, how they are related to the OECD functional use categories, and a crosswalk with the current CDR function codes are in the supplemental document *Technical Support Document: Harmonizing CDR Functional and Product codes with OECD Functional, Product, and Article Codes* (Ref. 11).

b. Commercial/consumer product codes. CDR currently requires the reporting of product category codes for manufactured chemical substances that have consumer or commercial uses. The current product codes consist of both article and other non-article products; they correlate to the OECD Product and Article Use Categories described in the OECD Category document (Ref. 8). The OECD Category document uses the term ''product'' to mean consumable liquids, aerosols, semi-solids, or solids that are used a given number of times before they are depleted and the term ''articles'' to generally mean solids, polymers, foams, metals, and woods, all of which are always present within indoor environments for the duration of their useful life, which may be several years (Ref. 8). These terms were developed for the OECD Category document because, for the purposes of exposure assessment, products and articles are treated differently. Formulations, anticipated use patterns, and available approaches to estimate exposure are different, and certain chemicals may only be added to articles, others only used to formulate products, and others could be used for both. Because of these differences, OECD provides separate lists of product and article use categories. EPA is proposing to adopt the OECD codes and to consolidate the separate OECD lists into one list to be consistent with the current CDR approach of listing the article and other non-article products in one list of CDR Product Categories.

CDR product categories are broader than the OECD categories. Using the OECD categories would provide a specificity that would be more helpful to EPA in carrying out its responsibilities under TSCA. For example, a broad CDR category is *Fuels and Related Products,* which, under the OECD product codes, is divided into three categories: *Cooking and Heating Fuels, Fuel Additives, and Vehicular or Appliance Fuels* (Ref. 11). Under this proposal, the current 33 consumer/commercial product categories would be replaced by 98 categories. For a listing of the proposed product categories, see Appendix D of the Instructions for Reporting (Ref. 12). Under TSCA, the definition of ''chemical substance'' excludes certain uses such as pesticide, tobacco, food, and other specifically listed uses. Some of the OECD harmonized product categories cover the TSCA-excluded uses; those particular codes were not adopted in CDR. The current CDR codes contain a catch-all ''non-TSCA code'' for uses that are not covered under TSCA. Under this proposed rule, EPA would continue to provide the same ''non-TSCA'' code as a blanket code for these applications. EPA is interested in receiving comments on whether all of the OECD harmonized codes should be listed, even if the uses are not covered by TSCA, to make it easier for submitters to report information under CDR and in response to other reporting requirements using the OECD harmonized codes. Additional details about the proposed product categories, how they are related to the OECD product and article categories, and a crosswalk with the current CDR product codes are in the supplemental document *Technical Support Document: Harmonizing CDR Functional and Product codes with OECD Functional, Product, and Article Codes* (Ref. 11).

2. *NAICS codes for manufacturers.* EPA is proposing to require submitters to report the 6-digit NAICS code that best describes the manufacturing activities conducted at the reporting site. The NAICS was developed under the direction and guidance of the Office of Management and Budget (OMB) as the standard for use by Federal statistical agencies in classifying business establishments for the collection, tabulation, presentation, and analysis of statistical data. NAICS is based on a production-oriented concept, meaning that it groups establishments into industries according to similarity in the processes used to produce goods or services (62 FR 17288). Use of the standard provides uniformity and comparability in the presentation and understanding of data. EPA estimates that this proposed change would result in a slight increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

EPA would use the NAICS code information in its analysis of the reported manufacturing-related information to better analyze the data by industry sector. EPA's insight into particular industry sectors has been limited without this particular data element. For example, during the 2017 negotiated rulemaking, participants asked EPA to analyze specific industries to determine if there was overlap in reporting among different Agency programs and to determine if EPA could trace the life cycle of some chemical substances from their manufacture through their use and to their disposal (Refs. 13 and 14). NAICS codes would have better enabled EPA to fulfill the requests because many other EPA programs, such as the Toxics Release Inventory (TRI), require the reporting of NAICS codes. By adding the site's NAICS code as a required data element for CDR, EPA would be better able to use information from CDR in conjunction with TRI data to support implementation of TSCA.

Because reporting under CDR is done by the site that is conducting the manufacturing activity, the site is expected to be sufficiently knowledgeable to be able to determine the appropriate NAICS code. EPA believes sites would be able to identify a single NAICS code per site; however, the Agency is interested in comments on whether the CDR reporting tool should enable the reporting of multiple NAICS codes based on each chemical substance, similar to how the technical contact is reported.

a. Relationship to processing and use industrial sector codes. For processing and use information, often conducted at sites other than the manufacturing site, submitters currently report an industrial sector (IS) code instead of the NAICS codes. The IS codes divide the entire range of NAICS codes into sectors such that there is a sector corresponding to any NAICS code. Initially, submitters reported NAICS codes when describing the industrial processing and use of their reported chemicals. In the 2011 Inventory Update Reporting (IUR) Modifications final rule, EPA replaced the NAICS codes with the industrial sector codes. (76 FR 50816, August 16, 2011; EPA–HQ–OPPT–2009–0187–0393). Respondents to the 2006 IUR, the predecessor to the CDR, submitted 342 unique 5-digit NAICS codes. So many codes made it difficult for EPA to group chemical substances based on industrial processing and use scenarios. In all, the 2006 IUR database has 2,330 unique combinations of processing or use codes, NAICS codes, and industrial function categories. This large number of unique combinations increased the difficulty and time required by EPA to sort and classify chemical substances because EPA either would need to develop exposure scenarios for each unique combination or determine the three-code combinations that have similar exposure scenarios and can be grouped. The use of the IS codes for the 2012 and subsequent CDR reporting cycles has reduced the number of unique combinations, thereby increasing the usability of the data and reducing the associated reporting burden.

EPA believes that the manufacturing of chemicals incorporates a narrower range of NAICS codes than the processing and use of chemicals. Therefore, identifying the more specific NAICS code for the manufacturing site is not expected to result in the large number of combinations experienced in 2006 for the processing and use information.

b. Improving outreach and reporting assistance. EPA would also use the NAICS codes to improve outreach and reporting assistance for manufacturers in specific industry sectors. For the 2016 submission period, EPA developed industry sector-specific Fact Sheets for the printed circuit board, metal mining, and electricity-generating sectors (Refs. 15, 16, and 17). Each Fact Sheet addressed reporting requirements specific to that industry, including the use of specific and unique examples designed to better illustrate the sector's reporting requirements. EPA expects to continue this practice for other industries, and having NAICS codes available in the CDR dataset would facilitate expansion of this outreach.

3. *Modifying recycled information.* Currently, CDR submitters identify whether their reportable chemical substance is *recycled, remanufactured, reprocessed, reused, or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream.* EPA is proposing to modify this data element by removing the terms ''remanufactured, reprocessed, reused'' as this may be interpreted and applied too broadly to obtain the information of interest for this collection. These terms are also not necessarily synonymous with ''recycle'' in all scenarios. It is EPA's intention that this data element identify the chemical substances that would otherwise be disposed of as a waste, and EPA believes the revised phrase ''recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream'' best describes this intention. This proposed change is also intended to reduce confusion, and thus burden, and provide greater specificity as to what this data element requires. For example, the term ''reused'' might cause the site to consider the need to report other chemical substances that it simply purchased and used if the site found a way to reuse that substance. Such reporting would be erroneous, because a site is only required to report a substance that it manufactures, not that it has merely purchased. However, if a manufactured (including imported) substance is reused instead of being disposed of as a waste, then that would be reported. EPA does not anticipate a change in burden associated with this proposed change. See section 4.1.3 of the Economic Analysis for additional information (Ref. 4). EPA is soliciting public comments on modifying this data element to better capture recycling in CDR.

EPA is soliciting comment on whether submitters should identify the percentage of total production volume of their chemical substance that is recycled instead of only designating whether recycling occurred, the burden associated with providing such an estimate, and any difficulties industry might encounter in estimating such a percentage (either to the nearest 10 percent or more accurately). EPA believes that the percent production volume for a chemical substance that is being recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream would be information relevant to the exposure profile of a chemical substance and indicates efficiencies within the chemical manufacturing industry. EPA is interested in the exposures from these activities. In addition, information about whether certain types of industries recycle or whether certain types of chemicals are recycled and if such recycling is increasing or decreasing provides information about changes in the manufacturing environment that inform EPA's TSCA activities. Collecting specific percentages about recycling could give EPA a better understanding of the recycling reporting universe and provide EPA the opportunity to grant more targeted reporting exemptions and burden reduction activities in future reporting cycles.

4. *Percent byproduct.* EPA is proposing to add the requirement to report the *percent total production volume for a chemical substance that is a byproduct.* EPA believes this data element would provide information to better understand the manufacturing of byproduct chemical substances and the impact of current or potential future exemptions to reporting. EPA is interested in this change in order to increase transparency by identifying important submitter subpopulations and their representations in CDR with respect to production volume. EPA estimates that this proposed change would result in an increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

Information about byproduct reporting has been of particular interest due to requirements of the 2016 amendments to TSCA to conduct a negotiated rulemaking for manufacturers of inorganic byproducts. During the deliberations of the negotiated rulemaking committee, EPA was unable to specifically identify, from the CDR data, chemical substances manufactured as byproducts or byproduct manufacturers who would be impacted by changes to the reporting requirements. With the addition of this data element, EPA will be able to identify those manufacturers that recycle portions of their substances or only report to CDR due to their byproduct production. EPA would consequently be better able to understand a larger spectrum of potential exposure scenarios, by improving understanding of the connection between manufacturing and downstream activities for the purposes of substance life cycle assessments and risk evaluation. In addition, EPA would use this information to inform future decisions about potential changes to CDR requirements.

There are situations where the same chemical substance is manufactured both as a primary chemical substance and a byproduct. While this is rare, it is a known occurrence. For example, when commercial stearic acid is manufactured, it is known to contain significant amounts of palmitic acid and oleic acid as byproducts. Such a producer would also be likely to separately manufacture palmitic acid and/or oleic acid as primary chemical products. In this situation, if the palmitic acid that is manufactured as a byproduct is used for a reportable commercial purpose, its volume would be reported along with the volume of palmitic acid that is separately manufactured at the same site and its volume would be counted as the byproduct portion when calculating the percent manufactured as a byproduct. It is important to recognize that an overproduction of the primary manufactured substance does not meet the regulatory definition of a byproduct, and thus is not considered a byproduct for the purposes of CDR, and should not be counted as such when calculating the percent manufactured for this data element.

Reporting in percentages. As with other percentage production volume reporting requirements in the CDR regulation, EPA is proposing to require that the percentages for the percent byproduct be rounded to the nearest 10 percent, unless the percentage is less than 5 percent. EPA would allow the reporting of more specific percent production volumes. In situations where the percentages account for less than 5 percent of the submitter's total production volume for the reportable chemical substance, the submitter would not round off to zero if the production volume attributable to that amount is greater than or equal to 25,000 lbs. (or in an amount of 2,500 lbs. or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)). In such cases, submitters would report the percentage of production volume attributable to that portion to the nearest 1 percent of production volume. This exception to the general rounding off rule is being proposed to differentiate situations where no portion or a very low portion of the chemical substance is a byproduct, to ensure that adequate manufacturing information would be reported for the larger production volume chemical substances. The 25,000 lbs. (or 2,500 lbs.) level was selected for consistency with the current threshold for reporting under CDR. EPA is interested in receiving comment on whether reporting the percent production volume to the nearest 10 percent or 1 percent for 5 percent or below is a lower burden than simply reporting to the nearest 1 percent for any percentage. EPA is interested in the difficulty that industry might encounter in estimating a percentage rounded to the nearest ten percent or a more accurate percentage of byproduct that is produced in the manufacturing process and what challenges industry may encounter in calculating this estimate. EPA is also interested in the burden estimate associated with calculating this data element. EPA is also interested in receiving general comment on the reporting requirements in this proposed rule, including on the effort required by a submitter to provide the percent production volume that is a byproduct.

5. *Chemical specific function for imported mixtures.* EPA is proposing to require the secondary submitter of a joint submission to report the chemical-specific function along with information on chemical composition of the imported product or mixture. A joint submission is most typically used when a substance or a mixture is imported and the supplier does not provide to the importer the specific chemical identity of the substance or substances that comprise the mixture. See Unit III.A. for additional information about joint submissions. Currently, the importer identifies the function of the imported product. In some circumstances, the function of the imported product can be correctly applied to the specific chemical substance. However, in the circumstance where the imported product is a multi-component mixture, applying the function of the imported product to each component of the mixture can result in identifying a function for an individual chemical substance that is not appropriate. For example, a dye or a fragrance that is part of a cleaning mixture should not be identified as a cleaner, but rather as a dye or a fragrance. Providing the appropriate function for the component of the mixture would inform the assessment process by improving the understanding of the conditions of use for a chemical (*e.g.,* formulation, use rate, etc.). EPA does not anticipate a change in burden associated with this proposed change because the burden associated with reporting the function of the chemical for the secondary submitter is already captured in the baseline burden. See section 4.1.3 of the Economic Analysis for additional information (Ref. 4).

6. *Public contact.* EPA is proposing to enable the reporting of a public contact for each CDR submission as a voluntary data element. Currently, a technical contact familiar with the information provided in the form is required to be reported. The public contact would be in addition to the technical contact and would be an individual who may be contacted by the general public with questions related to the publicly available information reported by the company under CDR. This person has been designated by the site or company to handle public inquiries. The addition of a public contact to handle public inquiries is modeled after TRI's approach to the public contact, albeit on a voluntary basis, and would include the contact's name, phone number, and email address. Because the public contact is intended to be made available to the public, this voluntary data element would not be able to be claimed as confidential. EPA is interested in receiving comment on whether it would be helpful to have a public contact available. EPA estimates that this proposed change would result in a slight increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

Difference between public contact and technical contact. Submitters to CDR are already required to supply, and may claim as confidential, a technical contact(s) who should be a person able to answer technical questions about the reported chemical substance(s). Typically, a person located at the manufacturing site is best able to answer such questions. The public contact, which would be voluntarily reported, is intended to be a more general, public-facing company representative who would be available to answer questions the public might ask the company.

7. *Parent company identity.* EPA is proposing three changes associated with reporting the parent company under CDR: (1) To add the requirement to report a foreign parent company in addition to reporting the highest-level U.S. parent company when the ultimate parent company is located outside of the United States; (2) to remove the definition of U.S. parent company from 40 CFR 711.3 and replace it with a new definition for parent company; and (3) to add a requirement for reporters to report legal name(s) and to follow a naming convention for providing the parent company name(s), the details of which would be provided in the CDR Instructions (see 40 CFR 711.35). As a whole, EPA believes these changes would increase the usefulness of the CDR data by improving consistency in reporting, better enabling EPA to protect information claimed as confidential, and reducing the after-reporting quality control effort for both EPA and

submitters. EPA estimates that the proposed addition of a foreign parent company would slightly increase the burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4). EPA did not estimate the burden reduction associated with the reduced need to contact companies for quality control purposes after data submission.

Currently, sites required to report to CDR must report their U.S. parent company, which is defined to mean the highest-level company located in the United States that directly owns at least 50 percent of the voting stock of the manufacturer (see 40 CFR 711.3). The site must report its U.S. parent company name, address, and Dun and Bradstreet D–U–N–S® (D&B) number (see 40 CFR 711.15(b)(2)(i)).

Proposed change to definition of U.S. parent company. EPA is proposing to replace the definition of *U.S. parent company* from 40 CFR 711.3 with a new definition for *parent company* that includes both U.S. and foreign parent companies and provides guidelines for different company structures. In developing this definition, EPA considered solely using the definition of ''parent company'' already found in 40 CFR 704.3, but decided to propose the specifically listed guidelines in the regulatory text for clarity and consistency with other programs. Please review the proposals in the following paragraphs. EPA is requesting comment on this approach.

Proposed reporting of foreign parent company. In some situations, the highest-level parent company is outside of the United States. EPA is proposing that sites also identify the highest-level worldwide parent company, when applicable, and therefore is also adding the requirement to report the *foreign parent company* under 40 CFR 711.15. Under this proposal, reporters would continue to report their U.S. parent company, but also report their foreign parent company if the situation applies.

Including the foreign parent company would increase the ability of EPA to protect information claimed as confidential. Currently, some confidential information may be inadvertently disclosed due to challenges in identifying connections between sites when the parent companies are outside of the United States. EPA takes such relationships into account when aggregating confidential information. By reporting the foreign parent company, EPA would be able to better identify company groupings for data aggregation and, ultimately, protection of information claimed as confidential.

This modification would be responsive to industry concerns expressed during the 2016 CDR submission period with not being able to report their ''true'' parent company when that company is outside of the United States. In many cases, sites know the foreign corporation's name more readily than the U.S. parent company's name.

As opposed to relying exclusively on the foreign parent company (where applicable), EPA is retaining the U.S. parent company reporting requirement to allow EPA to align future CDR collections with historical data; inclusion of the U.S. parent company for 2020 reporting would enable EPA to correlate with past reporting cycles and potentially to increase consistency in reporting among sites associated with the same parent company. Including both the U.S. and the foreign parent companies would provide data users greater flexibility when combining CDR data with data from other sources, some of which are limited to only U.S. information.

Application of parent company definition to different situations. EPA recognizes that there are a variety of ownership situations for manufacturers reporting under CDR. The scenario-specific information listed in this document is based on the guidelines included in the proposed definition and contains additional examples illustrating the application of the proposed parent company definition and reporting requirements. The guidelines include how to populate the U.S. and a foreign parent company data elements. EPA is interested in receiving comments on whether the guidelines and these examples encompass the representative range of scenarios for reporting under CDR, and whether the guidelines included in the proposed definition are sufficient. The examples are as follows:

(1) If the site is entirely owned by a single U.S. company that is not owned by another company, then that single company is the U.S. parent company and there is no foreign parent company.

(2) If the site is entirely owned by a single U.S. company that is, itself, owned by another U.S.-based company (*e.g.,* it is a division or subsidiary of a higher-level company), the highest-level company in the ownership hierarchy is the U.S. parent company. If there is a higher-level parent company that is outside of the United States, the highest-level foreign company in the ownership hierarchy is the foreign parent company.

(3) If the site is owned by more than one company (*e.g.,* company A owns 40 percent, company B owns 35 percent, and company C owns 25 percent of the site), the highest-level U.S. company with the largest ownership interest in the site is the U.S. parent company. Under this scenario, this would be either company A itself (if it doesn't have a U.S.-based parent company), company A's parent, or, if it exists, a single parent company that owns both company B and company C, in which case that single parent company would have the largest ownership interest. If there is a higher-level foreign company in the site's ownership hierarchy, that company is the foreign parent company. There may be the situation where the highest U.S. company is company A's parent company but a foreign company owns both company B and company C. In this situation, the foreign parent company would be the highest-level parent company that owns companies B and C and the U.S. parent company would be the parent company of company A.

(4) If the site is ultimately owned by a 50:50 joint venture or a cooperative, the joint venture or cooperative is its own U.S. parent company. If the site is owned by a U.S. joint venture or cooperative, the highest level of the joint venture or cooperative is the U.S. parent company. If the site is owned by a joint venture or cooperative outside the United States, the highest level of the joint venture or cooperative outside the United States is the foreign parent company.

(5) If the site is entirely owned by a foreign company (*i.e.,* without a U.S.-based subsidiary within the facility's ownership hierarchy), the highest-level foreign parent company is the facility's foreign parent company. In this situation, the U.S. parent company would be the site itself.

(6) If the site is a federally owned, the highest-level federal agency or department is the U.S. parent company.

(7) If the site is owned by a non-federal public entity, that entity (such as a municipality, State, or tribe) is the U.S. parent company.

Proposed use of naming convention. EPA is also proposing to require sites to follow the CDR instructions regarding standardized conventions for the naming of a parent company. These naming conventions address common formatting discrepancies, such as punctuation, capitalization, and abbreviations (*e.g.,* ''Corp'' for ''Corporation''). The use of these naming conventions would reduce the number of inconsistencies with the *Parent Company Name* data field, and thereby would increase the reliability and usability of the data and reduce the associated reporting burden due to the

Agency's need to request corrections from reporting companies.

C. Changes to Reporting Process for Co-Manufactured Chemicals

EPA is proposing to change the method manufacturers use to report co-manufactured chemicals. A co-manufacturing relationship occurs when a chemical substance, manufactured other than by import, is produced exclusively for another person who contracts for such production. To be considered a co-manufacture situation, the producing company produces the chemical substance exclusively for another person (the contracting company) under contract for that production. If the chemical substance is produced for other purposes, then the situation fails this first test of ''co-manufacturing.'' For example, if a company manufactures a chemical for speculative purposes based on expectations of the market, the company is not operating in a co-manufacturing situation. In addition, the other person contracting the manufacture (*i.e.,* the contracting company) specifies the identity of the chemical substance, the total amount produced, and the basic technology for the plant process. This is the second test of ''co-manufacturing.'' To be considered co-manufacturers, both of these tests must be met. See 40 CFR 711.3 (definition of ''manufacture''). Although this proposed change reduces co-manufacturer confusion and addresses other industry concerns, EPA estimates that it would have a minimal impact on the burden and therefore did not include an estimate in the analysis. See section 4.1.3.2 in the Economic Analysis for additional information (Ref. 4).

EPA is avoiding the use of the term toll manufacturer for this proposal and future guidance to add clarity for the co-manufacturing situation. In instructions, guidance, and other communication with submitters, EPA may previously have referred to co-manufacturing as toll manufacturing, and more specifically to the two parties as the contracting manufacturer and the toll manufacturer. Because EPA does not specifically define the term ''toll manufacturer,'' EPA now believes the use of this term may be open to mis-interpretation and it would be clearer to use terms associated with the CDR definition of manufacturer in 40 CFR 711.3. Additionally, EPA believes the chemical industry often refers to toll manufacturing in a more general manner, where both of the tests included in the CDR definition for manufacture are not met. These tests are: (1) The chemical substance is produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process.

Current reporting requirements. Under the current CDR rule, the contracting company and the producing company are jointly responsible for reporting and submitting to CDR. Only one report may be submitted per reportable chemical and per production site. In order to report, the contracting company and the producing company must work together and identify who will submit the report they are both responsible for, to prevent duplicate reporting and ensure both parties have met their reporting obligations.

Pursuant to the CDR definition of ''site'' at 40 CFR 711.3, the site reported is the site of physical manufacture (*i.e.,* the producing company's site). This is true irrespective of whether it is the producing company or the contracting company who completes the report. If both parties fail to report, both the contracting company and producing company are liable.

The companies must designate a single technical contact for the specified chemical(s), who can be an employee of either the contracting company or the producing company (or a consultant). This technical contact should be knowledgeable about the specific chemical and should be the best equipped to answer questions about the certain chemical.

Submitters have identified multiple concerns with the current reporting process for co-manufacturers. Current issues associated with using this method for reporting include:

- The contracting company and producing company are unsure who should be primarily or solely responsible for CDR reporting and are concerned regarding the shared liability.
- The producing company has information (such as the number of workers likely to be exposed) that the contracting company does not have, and the contracting company has information (such as information about the processing and use of the chemical substance) that the producing company does not have. However, when currently completing the CDR chemical report, one company may not be willing to share information it considers confidential with the other company.
- In situations where the producing company is reporting for additional chemical substances, the current co-reporting requirement may result in the need to submit multiple CDR reports for the producing company's site. This created a complicated situation that required special handling and increased confusion and burden for the submitter.

Proposed reporting methodology. EPA is proposing to change the reporting mechanism for co-manufacturers by developing a multi-submitter process, similar to that used by importers, where the contracting company is the primary submitter and the producing company is the secondary submitter. When evaluating the co-manufacturing reporting process, EPA considered industry's desire for a flexible reporting mechanism and the need to protect the confidential information of both the contracting company and the producing company. These considerations were made apparent through documented correspondence between EPA and reporters to the 2016 CDR who were either a contracting company or a producing company regarding issues with the co-manufacturing mechanism. EPA also met with representatives from reporting companies to discuss the co-manufacturing mechanism and the challenges related to coordinating a dual effort between the contracting companies and producing companies during the 2016 reporting period (Ref. 18).

In response, EPA is proposing a new methodology for the 2020 and future reporting cycles. Under this new reporting methodology, the contracting company (as the primary submitter) would have the responsibility to initiate a co-manufacture report that would prompt the reporting requirements for the producing company (as the secondary submitter). The contracting company would start the chemical report for the co-manufactured chemical, identifying the chemical substance and the producing company. The contracting company would then initiate the co-manufacture report using e-CDRweb to send a notification to the producing company. Additionally, the contracting company is responsible for completing the volume manufactured (40 CFR 711.15(b)(3)) and the processing and use-related section (40 CFR 711.15(b)(4)). Upon receipt of the email, the producing company will have the information needed to begin its portion of the co-manufacture report, which would include the manufacturing-related data elements from 40 CFR 711.15(b)(3), including the production volume.

Although the manufacturing information section includes the chemical identity field, it is EPA's belief, based on the two tests for a co-manufacturing situation in which the contracting company specifies the

chemical to be manufactured and the process to be used, that the contracting company would be best situated to complete the chemical identity field. EPA also believes that both parties should report the volume manufactured because both are responsible for reporting other data elements and an associated percent production volume. To ensure the percent production volume is correctly interpreted by both data reporters and data users, the basis for that percent production volume must be known. EPA is interested in receiving comments on whether this split in the data elements is reflective of the knowledge of each party in the co-manufacturing relationship.

This improved reporting mechanism would protect the confidentiality of both the producing company and contracting company by ensuring that the contracting company would not require any potentially confidential information from the part of the producing company. This method also would eliminate confusion between the two involved parties by designating the contracting company as the primary submitter responsible for initiating the reporting process. As with current reporting, both parties would remain liable for reporting the co-manufactured chemical because each party has a portion of the information required under CDR. In addition, this co-manufacture reporting procedure enables the use of one Form U per site, because the contracting company indicates the producing company's site without starting a separate Form U and the producing company completes an independent report for any other, non-co-manufactured chemicals in its own site report.

Alternative reporting methodologies. EPA considered alternatives to the proposed approach for reporting in a co-manufacturing situation. The first alternative would require the producing company (instead of the contracting company) to initiate the reporting and to be primarily liable for reporting. In this alternative, the producing company would initiate reporting via a co-manufacture report and provide the exposure information from the manufacturing site. Using e-CDRweb, the producing company would notify the contracting company of the need to provide the remainder of the information. EPA does not favor this option at this time because it believes that the contracting company is likely to be more knowledgeable about the chemical identity and other information required by CDR and therefore better able to complete the reporting requirements.

The second alternative would be to retain the current reporting mechanism (described in *Current reporting requirements)* where the contracting company and the producing company are jointly responsible for reporting and submitting under CDR. This alternative could include the addition of an indication that the chemical is being co-manufactured and, for the contracting company, the addition of the producing company site location. As is currently the case, only one report may be submitted per reportable chemical and per production site; therefore, the contracting company and the producing company must determine who is responsible to submit the one report to prevent duplicate reporting, and work together to provide a single complete report.

EPA requests comments on the proposed reporting methodology where the contracting company is the primary submitter and on the two alternative reporting scenarios (where the producing company is the primary submitter or retaining the current reporting mechanism without a primary or secondary submitter) for improving the reporting process for co-manufacturing situations. In addition to comments on the general approaches, EPA is interested in comments on the information that should be included on each portion of the co-manufacturing report (for the proposed and first alternative).

Definition of site. EPA is proposing to modify the definition of *site* by replacing the term *toll manufacturer* with the term *producing company.* This change would make terminology consistent between the definitions of *site* and *manufacture.*

Relationship of co-manufacturing to imports. As with the current CDR rule, a co-manufactured chemical substance cannot be an import. Rather, the chemical substance produced via an arrangement with a foreign supplier results in an imported chemical substance, and the U.S. importer alone, as the reporting manufacturer, is responsible for reporting that substance.

D. Reporting of Byproducts

EPA is proposing three changes that directly impact manufacturers of byproduct substances, including inorganic byproducts, to: (1) Allow reporting in metal categories for inorganic byproducts; (2) exempt specifically listed byproducts that are recycled in a site-limited manner; and (3) exempt byproducts manufactured in pollution control and boiler equipment when that equipment is non-integral to the primary manufacturing process. Byproducts are defined at 40 CFR 704.3 to mean a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s). In developing these proposals, EPA relied on information gathered during the negotiated rulemaking process (EPA–HQ–OPPT–2016–0597 and 81 FR 90843, December 15, 2016) and from other public comments (EPA–HQ–OA–2017–0190 and 82 FR 17793, April 13, 2017), with the intent to develop proposals for addressing burden for these byproduct manufacturers while maintaining the information needed by EPA, as described in Unit I.C.

1. *Alternative reporting in metal compound categories for inorganic byproducts.* EPA is proposing to allow, but not require, CDR reporting within defined metal compound categories for certain elemental metals and inorganic metal compounds that are produced as inorganic byproducts. Manufacturers of these inorganic byproducts would have the option to combine and report multiple inorganic byproduct metal substances, that otherwise would be reported individually as listed on the TSCA Inventory, into one or more specifically-listed categories (*e.g.,* Chromium & Chromium Compounds).

If the manufacturer has multiple inorganic byproduct chemical substances to report, they would be able to choose to report some byproduct substances in categories and other different byproduct substances as specific substances. However, the manufacturer would not be able to bifurcate the production volume of the same byproduct chemical substance and report a portion in a category and another portion as a specific chemical substance unless the bifurcation is due to having different metal elements present in the byproduct. Some substances would be required to be reported as listed on the TSCA Inventory and not as part of these metal compound categories, because they are of particular interest to EPA. They are described later in this unit.

EPA believes this proposed method of reporting in categories would simplify reporting and ease reporting burden for manufacturers whose inorganic byproduct metal-containing substances have chemical compositions that are non-specific and difficult to identify, while also providing information that meets EPA's needs. Additionally, because manufacturers would retain the ability to report to CDR by specific substances contained on the TSCA Inventory (as is currently required), manufacturers of these byproduct

substances would have the flexibility to report these substances in the manner that they prefer.

Inorganic metal substances that are manufactured as products and not as byproducts would be ineligible to report within a metal category because these non-byproduct substances are intended products and should be more easily identifiable by their manufacturers.

EPA has the explicit authority under TSCA section 26(c) to take any actions authorized or required by TSCA with respect to categories of chemical substances, and the Agency has experience assessing chemicals in categories under TSCA. For an example of how EPA could use information reported in metal compound categories, see the Antimony Trioxide (ATO) Risk Assessment conducted in 2014 (Ref. 19). Because ATO is not specifically listed on the TRI, releases reported under the broader category of antimony compounds were used as a surrogate to evaluate the potential for aquatic exposures.

The proposed defined inorganic metal compound categories are designed in part to allow CDR reporting to align more closely with those chemical substances and compound categories on the 2014 Update to the TSCA Work Plan for Chemical Assessments.

TRI also uses a similar option of reporting under compound categories, many of which are metals. EPA recognizes that many companies report to both statutory programs and is interested in aligning TRI and CDR to the extent possible and reasonable given the differing purposes of the two rules.

The proposed CDR metal categories list is comprised of the following categories from the 2014 Update to the TSCA Work Plan for Chemical Assessments and from TRI (Refs. 20 and 21). In the future, EPA may modify, by rulemaking, the metal categories list as more chemicals are evaluated as part of the existing chemical program:

- Antimony & Antimony Compounds
- Arsenic & Arsenic Compounds
- Barium & Barium Compounds
- Beryllium & Beryllium Compounds
- Cadmium & Cadmium Compounds
- Chromium & Chromium Compounds
- Cobalt & Cobalt Compounds
- Copper & Copper Compounds
- Lead & Lead Compounds
- Manganese & Manganese Compounds
- Mercury & Mercury Compounds
- Molybdenum & Molybdenum Compounds
- Nickel & Nickel Compounds
- Selenium & Selenium Compounds
- Silver & Silver Compounds
- Thallium & Thallium Compounds
- Vanadium & Vanadium Compounds
- Zinc & Zinc Compounds

To better characterize which substances would be reportable within these metal compound categories, EPA is proposing to use the definition of inorganic chemical substances that was originally part of the IUR (51 FR 113, June 12, 1986). For the purposes of this rule, inorganic substances would be defined to mean those substances that do not contain carbon or contain carbon only in the form of carbonato [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups (*e.g.,* thiocarbonato (=CS3-xOx, where x = 0–2), thiocyanato (-SCN), or isothiocyanato (-NCS)). It should be noted that EPA does not consider organometallics to be inorganic chemical substances, and therefore such substances would not be reportable under metal compound categories. Examples of organometallic substances listed on the TSCA Inventory are: Ferrocene, benzoyl- (CASRN 1272–44–2), Plumbane, tetraethyl- (CASRN 78–00–2), Stannane, tetrabutyl- (CASRN 1461–25–2), Mercury, dimethyl- (CASRN 593–74–8), and Cobalt, di-.mu.-carbonylhexacarbonyldi-, (Co-Co) (CASRN 10210–68–1).

As an example of how to use this inorganic metal compound category reporting method, a manufacturer who is domestically producing Copper chloride, Copper hydroxide, and Copper sulfide as byproduct substances would have the option to report all of these inorganic byproducts under a single report of Copper and Copper compounds, aggregating their volumes. If reporting by category, the manufacturer in this example would first assess if it meets the threshold for reporting by combining the production volumes for all three substances (Copper chloride, Copper hydroxide, and Copper sulfide). If the combined threshold for *any* of the years since the last principal reporting year is 25,000 lbs. or greater, the manufacturer has met the reporting threshold for the copper compound category (*e.g.,* for 2020 CDR, consider the production volumes for 2016, 2017, 2018, and 2019), which would prompt the need for the manufacturer to report for that category of chemicals (Ref. 22).

In terms of reporting, however, EPA is proposing that only the *weight* of the parent metal portion of the metal category compound would be reported (for example, if reporting by categories, 34,000 pounds of Copper chloride (CuCl2) (CASRN 7447–39–4) would be reported based on 16,072 pounds in the category ''copper and copper compounds'') (Ref. 22). This approach is proposed because it is similar to the methodology used by TRI (Ref. 23). Although the type of threshold prompting the need to report would be similar to that for reporting in categories under TRI, it is important to note that reporting under CDR is for amounts manufactured (and imported), while reporting under TRI is for amounts released. It is also important to recognize that this method is different than reporting under CDR using a TSCA-listed chemical substance identity.

EPA is interested in obtaining comment on the proposal to allow reporting of inorganic substances in metal compound categories, including the methodology for how to report using categories. Specifically, EPA is interested in receiving comments on deviating from the standard approach used for CDR of reporting the volume of substance manufactured and instead using the approach of reporting the weight of the metal in the compounds when reporting by the metal category. Would it be more appropriate to report the full weight of the chemical substance instead of the metal weight? Are submitters likely to report using this approach?

Exclusions from category reporting. EPA is also proposing to require various substances to be reported as listed on the TSCA Inventory and not as part of these metal compound categories. Such substances are of particular interest to EPA, and would include:

- Substances that have been individually identified on the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 20): specifically, *Carbonic acid, barium salt (1:1)* (CASRN 513–77–9) (referred to as Barium carbonate);
- Substances that are the subject of certain TSCA actions as listed in 40 CFR 711.6, including TSCA section 5(a)(2) Significant New Use Rules (SNURs), TSCA section 5(b)(4) rules, TSCA sections 4, 5(e) and 5(f) orders, TSCA section 6 rules, TSCA section 4 test rules, Enforceable Consent Agreements (ECAs) developed under the procedures of 40 CFR part 790, and TSCA section 5 or 7 civil actions. Note that lists of subject chemicals can be identified using the eCDRweb reporting tool or separately from EPA's Substance Registry Services (SRS) website (*https://www.epa.gov/srs*). Instructions for determining subject chemicals are provided on the CDR website and in CDR guidance.
- Chemical substances undergoing prioritization or risk evaluation under TSCA section 6. While the current list

of chemical substances undergoing risk evaluation is comprised of ten chemicals that are not inorganic metal-containing compounds (Ref. 24), EPA may initiate risk evaluations for inorganic metal-containing chemicals in the future, which would exclude those chemical substances from being able to be reported to CDR under a metal compound category.

For example, consider reporting within the chromium category. There is a TSCA section 6 action (40 CFR 749.68) that covers several hexavalent chromium-based water treatment chemicals. Those covered substances (*e.g.,* Chromic acid (H2Cr2O7), sodium salt (1:2) (CASRN 10588–01–9), Chromic acid (H2CrO4) (CASRN 7738–94–5), and Chromium trioxide (CrO3) (CASRN 1333–82–0)) would not be reportable within the chromium category, even if they were manufactured as byproducts. However, other chromium substances, containing Chromium not in the hexavalent oxidation state (*e.g.,* Chromium chloride (CrCl3) (CASRN 10025–73–7), Chromium hydroxide (Cr(OH)3) (CASRN 1308–14–1), and Chromium oxide (Cr2O3) (CASRN 1308–38–9)), if manufactured as byproduct substances, would be able to be reported within the Chromium compound category.

2. *Specific site-limited recycled byproducts.* EPA is proposing to exempt specifically identified byproducts that are recycled on-site from two industries. Portland cement manufacturers that produce *Flue dust, portland cement* (CASRN 68475–76–3) (referred to as cement kiln dust), and manufacturers using the Kraft pulping process to produce *Sulfite liquors and Cooking liquors, spent* (CASRN 66071–92–9) (often comprised of what is referred to as black liquor) and *Carbonic acid calcium salt (1:1)* (CASRN 471–34–1) (referred to as calcium carbonate) would, under certain scenarios, be exempted from the need to report these byproduct substances. These byproducts would be exempted from reporting only when (1) they are recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured and (2) when the site is reporting under CDR the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.

Based on information provided by these two industries, these byproduct substances are directly recycled in physically enclosed systems in a site-limited manner (see definition of ''Site-limited'' at 40 CFR 711.3). For the purposes of CDR, EPA considers an enclosed system to be a system of equipment directly connected to the production process that is designed, constructed, and operated in a manner which prevents emissions, or the release of any chemical substance into the facility or environment during the production process. Such emissions, including fugitive emissions, could lead to exposures to workers, the public, or the environment. For an enclosed system, exposure and release could only occur due to loss of integrity or failure of the manufacturing process equipment or control systems.

To meet the EPA enclosed system scenario, any equipment that the byproduct is present in at any point during the process sequence, such as tanks, reaction vessels, reactors, processing units (*e.g.,* a drum filter), and/or connecting lines, must: (1) Be of high structural integrity and contained on all sides, (2) pose no foreseeable potential for escape of constituents to the facility or environment during normal use, and (3) be connected directly by pipeline or similarly enclosed device to a production process. Also, any transfers or holding steps occurring in this system must be necessary to the recycle process and must take place within physically enclosed equipment that meet the aforementioned criteria. For example, hard piping or completely sealed (*i.e.,* welded) equipment would meet these criteria if connected directly to other enclosed equipment, preventing potential releases including fugitive emissions.

EPA recognizes that there may be some potential for exposures and releases (*e.g.,* through non-routine cleaning of equipment, or maintenance operations) associated with such enclosed, site-limited systems, but believes the potential exposures and releases related to such systems are less than the potential exposures and releases associated with recycling systems that are not enclosed. Likewise, systems that transfer the byproduct to a different site for recycling or other use are expected to have higher levels of potential exposures and releases. For example, on-site recycling systems that rely on open troughs for moving material have an increased opportunity for exposures due to dusting or splashing as compared to the use of an enclosed pipe for moving material from one part of the manufacturing process to another.

Based on 2016 CDR data, the sites reporting under CDR within these two industries have reported chemicals that are related to these byproducts because they are subsequently manufactured from the byproducts or from other substances via the same overall manufacturing process. EPA therefore would collect exposure-related information about the manufacturing site for these two industries.

This proposed exemption is only for the volumes of the byproduct substance, listed at 40 CFR 711.10(c)(2)(i) (as proposed), that are recycled in a site-limited manner in physically enclosed systems of the same overall manufacturing process. Volumes that are used for a commercial purpose distinct from their manufacture as a byproduct remain reportable. Also, volumes that are removed from the enclosed systems, such as those that are stored in an open tank or pit, or stored in any non-connected tank or vessel, are excluded from this exemption and remain reportable.

Portland cement industry—Cement kiln dust. The Portland Cement Association (PCA) suggested that EPA should eliminate reporting requirements for cement kiln dust (CKD) that is temporarily stored before reintroduction into the Portland cement manufacturing process (Refs. 25 and 26). PCA suggested that their manufacture and recycling of cement kiln dust is similar to non-isolated intermediates, which are currently exempted from the need to report under CDR by 40 CFR 711.10(c)(4)(viii). However, EPA's existing policy with respect to non-isolated intermediates excludes storage in tanks or other vessels (*e.g.,* shipping containers) even if the vessels are part of an enclosed system.

There are circumstances where the cement kiln dust is stored for a period of time in a tank that is connected in an enclosed system with the other operating equipment. Because the cement kiln dust is stored, it cannot meet the requirements of the non-isolated intermediate exemption and therefore would need to be considered for reporting under CDR (Refs. 25 and 26).

EPA agrees that, based on the information provided by PCA, relevant portions of CKD processing meet the definition of enclosed as described for this proposed exemption; however it does not meet the non-isolated intermediate exemption. In addition, the recycling operation uses the CKD to manufacture clinker (which consists of Portland cement), which is reported under CDR by its component substances and therefore would supply the Agency with exposure information from a similar production process. Based on

CDR data submitted for the most recent principal reporting year (2015), EPA estimates that approximately 23 million lbs of CKD might meet the criteria established in this exemption. This is the amount of CKD that was reported as recycled and used on-site (out of the approximately 1.1 billion lbs total manufactured domestically in 2015).

Kraft pulping cycle—black liquor and calcium carbonate. The American Forest & Paper Association (AF&PA) provided EPA with extensive information about the Kraft pulping cycle and chemicals manufactured as part of that cycle. Most recently, AF&PA and other industry representatives communicated with EPA by petitioning for full exemption from CDR for four manufactured Kraft pulping cycle chemicals, by submitting comments in response to **Federal Register** notices related to the negotiated rulemaking, and by meeting with EPA to view and discuss a video providing an in-depth explanation of the Kraft pulping cycle (Refs. 27, 28, 29, and 30).

AF&PA identified that the Kraft pulping cycle begins with the production of black liquor as a byproduct of pulping in the production of paper, and the black liquor is subsequently used to manufacture green liquor. Calcium oxide and green liquor are used to manufacture white liquor, which results in the production of calcium carbonate as a byproduct. The calcium carbonate is recycled to produce calcium oxide. From the information provided, EPA believes that both black liquor and calcium carbonate are byproducts that are recycled in site-limited, enclosed systems. Based on CDR data submitted for the most recent principal reporting year (2015), EPA estimates that approximately 382 billion lbs of black liquor and calcium carbonate together might meet the criteria established in this exemption. This is the amount of black liquor and calcium carbonate that was reported as recycled and used on-site (out of the approximately 386 billion lbs total manufactured domestically in 2015). The other substances in the cycle are intentionally manufactured substances and would therefore continue to be reportable under CDR. Because the sites would be reporting these other substances, their production of black liquor and calcium carbonate would meet the requirements for this proposed exemption.

Changes to the list of exempted processes and related byproduct substances. EPA is proposing a petition process for the public to request changes to the list of exempted manufacturing processes and related byproduct substances. The initial exempted substances were selected based on information provided directly to EPA as part of the negotiated rulemaking-related activities and through other communications with these industries, as described elsewhere in this unit. Because there may be other manufacturing processes and related byproduct substances that meet the criteria for this exemption (as identified at the beginning of this unit) or EPA's interest in these byproduct substances may change, EPA may amend the list of byproduct substances and processes that have been proposed as part of this exemption. The Agency may do this on its own initiative or in response to a request from the public, based on EPA's determination of whether the manufacturing process and related byproduct substance described meet the criteria explained in this unit.

Any person would be able to request that EPA amend the manufacturing process and related byproduct substance exempted list. EPA is proposing to model the procedure to request amendments after the one described in 40 CFR 711.6(b)(2)(iii) to amend the list of partially exempted chemical substances for which the processing and use information is of low current interest. The proposed procedure would require a written request that identifies the process and byproduct chemical substance in question, including a written rationale for the request that provides sufficient specific information, including cites and relevant documents, to demonstrate to EPA that the byproduct substance(s) and manufacturing process(es) in question either would or would not meet the criteria for this exemption.

EPA is proposing to consider the following factors when evaluating a request to amend the list of exempted manufacturing processes and related byproduct substances: (1) Whether the byproduct substance is recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured; (2) whether the site is reporting under CDR other chemical substances, in particular a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process; (3) whether EPA has a current interest in the byproduct substance; and (4) whether the byproduct substance must have already been reported under CDR or would be expected to be reported if not exempted by this exemption.

Regarding the second consideration, EPA expects to be able to ascertain typical exposure scenarios for the process based on information for other substances that are reported at the facility in the same or similar manufacturing process. If no other substances are reported, EPA would not have any exposure-related information about the manufacturing site.

Regarding the third consideration, EPA may have a current interest in a byproduct substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an ECA developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA sections 4, 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7. As noted earlier, lists of subject chemicals can be identified using the eCDRweb reporting tool or separately in EPA's Substance Registry Services (SRS). Instructions for determining subject chemicals are provided on the CDR website and in CDR guidance. EPA may also have a current interest in a byproduct substance that is undergoing risk evaluation, is being considered for prioritization, or that has particular uses or attributes that are of interest. This list is not exhaustive. For example, EPA may have a current interest for other reasons, including activities under other statutes, such as the Resource Conservation and Recovery Act (RCRA).

If a request related to a particular byproduct substance and process is resubmitted, any subsequent request would need to clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request. EPA would issue a written response to each request within 120 days of receipt of the request. As needed, the Agency would initiate rulemaking to revise the list of exempted byproduct substances. To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, requests would be required to be submitted to EPA no later than 12 months prior to the start of the next principal reporting year. EPA is interested in comments that may improve the proposed process for requesting amendments to the manufacturing process and related byproduct substance exempted list.

3. *Byproducts generated by specified non-integral processes.* EPA is also proposing to exempt byproducts manufactured in certain equipment via processes that are not integral to the production process. An integral process

is the portion of the manufacturing process that is chemically necessary or provides primary operational support for the production of the intended product. For the purposes of this exemption, certain associated processes that are not chemically required to produce the intended product would be considered non-integral. These may be required due, for example, to other regulations or the need to generate heat or electricity on-site, but not specifically necessary for the manufacture of the intended product. In this proposal, byproducts manufactured due to the use of pollution control equipment and boilers that generate heat or electricity on-site, when such equipment is not part of the main production process, would be exempted from reporting under CDR.

The site must continue to report chemical substances that are subsequently manufactured from these byproducts. The production of byproducts in equipment that is integral to the production processes remain subject to reporting as well, unless otherwise exempted. For example, utilities that produce electricity as a product may be using boilers as part of their production of electricity, and therefore those boilers are considered equipment integral to the production process. Thus, byproducts produced by these electric utility boilers would continue to be subject to reporting. Another example, reverberatory furnaces, which may function similarly to some boilers, can have a chemical processing function such as smelting. This and similar equipment, when used in such scenarios, would be considered integral to the main production process and any resultant manufactured byproduct substances would continue to be subject to reporting.

Examples of non-integral pollution control equipment include flue gas desulfurization and selective catalytic reduction systems. Under this proposed exemption, if a byproduct substance produced from this equipment is recycled for a non-exempted commercial purpose, the byproduct would be exempted from reporting under CDR. However, any chemical substance manufactured from the otherwise exempted byproduct would be subject to reporting unless otherwise exempted or the manufactured volumes are below the reporting threshold. EPA is interested in receiving comments on other examples of non-integral pollution control equipment, including descriptions of potential byproducts that could be produced in such equipment.

In reviewing how the CDR information is used, EPA believes the information about byproducts produced from the identified non-integral equipment is generally less critical to be obtained via CDR than information about byproducts produced from integral equipment for risk evaluations conducted under TSCA. Release from pollution control equipment can often be obtained through national inventories such as TRI. Among other tools, EPA uses generic scenarios, including OECD-approved Emission Scenario Documents, to develop environmental release assessments. The generic scenarios can be used in combination with information from CDR to develop estimates of facility releases. These Emission Scenario Documents do not include emissions from non-integral equipment; thus, CDR data from such equipment are generally not needed to support these environmental release assessments. EPA is interested in comments that may improve the approach proposed for this exemption.

E. General Regulatory Text Updates

EPA is also proposing to make other general updates to the regulatory text in 40 CFR part 711 that have been identified subsequent to the CDR rule's original promulgation in 2011. The general updates to the regulatory text include removing outdated text, consolidating byproduct-related exemption text, and simplifying and clarifying language throughout the regulatory text.

1. *Removing outdated regulatory text.* EPA is proposing to remove regulatory text specific to the 2012 CDR submission period. This text is no longer relevant because the submission period was completed more than five years ago and all phased-in reporting requirements from the change from the IUR to CDR have been fully in effect since the 2016 reporting cycle.

2. *Consolidating byproduct exemption regulatory text.* EPA is proposing to consolidate regulations regarding byproduct exemptions that affect reporting under the CDR rule into 40 CFR 711.10, such that all the CDR reporting exemptions regarding manufacturer activities are in one place. EPA expects such consolidation would make it easier for manufacturers to determine whether all or only some of their manufacturing activities are required to be reported under CDR, or whether all or some of their manufacturing activities are exempted from the need to be reported. Specifically, EPA is proposing that new exemptions proposed in this notice and language from 40 CFR 720.30(g) and (h) that is currently incorporated by reference would be replicated in 40 CFR 711.10(c). EPA intends to continue to interpret the replicated language in the same way as it has been interpreted under CDR, which for the most part aligns with how it has been interpreted under the TSCA section 5 Pre-Manufacture Notice (PMN) program. However, there are differences between the two programs that may result in different applications of the exemptions covered by this replicated regulatory text, and listing all exemptions in the CDR regulations instead of cross-referencing to the PMN regulations would allow for flexibility in the future as EPA continues to further analyze the CDR reporting exemptions.

3. *Simplifying and clarifying regulatory text.* EPA is proposing to change or add regulatory text to simplify or clarify regulatory requirements throughout 40 CFR part 711. These proposed changes are in addition to changes necessary for proposals discussed elsewhere in this notice, and include revisions to:

- 40 CFR 711.1(a) to remove the discussion about compiling and keeping current the TSCA Inventory, including the discussion about adding new chemicals to the Inventory. This discussion is unnecessary for an understanding of the scope of the CDR rule.
- 40 CFR 711.1(c) to include a statement about TSCA section 11 subpoena authority, as a reminder that EPA has this authority for compliance purposes.
- 40 CFR 711.3 definitions for *e-CDRweb, Manufacture,* and *Site* for clarification purposes.
- 40 CFR 711.6(a)(4) to reverse the order of ''certain forms of natural gas'' and ''water'' for clarification purposes.
- 40 CFR 711.10 to remove duplicative wording and add clarity to the requirements.
- 40 CFR 711.15(a) to add clarity to the reporting requirements.
- 40 CFR 711.35(c)(1) to update references.

IV. Detailed Discussion of the Proposed Modifications to Small Manufacturer Definition and Size Standards

EPA is proposing modifications to the TSCA section 8(a) small manufacturer size standards, as required, following EPA's determination on November 30, 2017 that revision to the current size standards is warranted (82 FR 56824). The proposed standards would apply to small manufacturers for TSCA section 8(a) rules, including CDR, unless a different standard is identified in the regulatory text of a particular rule. EPA

is also proposing a TSCA section 8(a) definition for small government entities.

Initially, when TSCA was implemented in the 1970's, EPA took a case-by-case approach to the definition of small manufacturers and processors and established individual size standards for each TSCA section 8(a) rule. EPA then developed a general 8(a) small manufacturer definition and size standards. These standards, finalized in the **Federal Register** of November 16, 1984 (49 FR 45425), have not been changed, although variations have been used for selected chemical-specific rules. See Unit II.C. of this action for additional information, including a description of the current standard.

A. Scope and Content of the Proposed Small Manufacturer Definition Update

For the TSCA section 8(a) small manufacturer definition update, EPA is proposing to update the current definition based on inflation. EPA is interested in public consideration of this approach and is soliciting comments regarding the extent to which this approach would reduce the reporting burden for those small manufacturers with fewer available resources, while ensuring Agency information needs are still met.

The proposed modification to the TSCA section 8(a) small manufacturer size standards are based on a number of factors, including: (1) Information gathered during meetings with the Small Business Administration, including the Office of Advocacy, regarding its definition of small business (Ref. 31); (2) preliminary comments and suggestions from representatives of the chemical industry, nongovernmental organizations, and state, local, and tribal governments submitted when EPA published its final determination that a revision to the standards is warranted (82 FR 56824, November 30, 2017); (3) review of various alternative exemption criteria; and (4) comments received on EPA's User Fees for the Administration of the Toxic Substances Control Act proposed rule (TSCA Fees Rule) (83 FR 8212, February 26, 2018). Documentation of these meetings, comments, and the analysis can be found in the dockets for the determination (EPA–HQ–OPPT–2016–0675), the proposed TSCA Fees Rule (EPA–HQ–OPPT–2016–0401), and this proposal (EPA–HQ–OPPT–2018–0321).

The proposed definition would be applicable to chemical manufacturers (including importers), but not to chemical processors. Because the scope of EPA's analysis of the proposed definition is focused on impacts to the CDR, in which reporting is required by manufacturers and not processors, EPA believes it is best to continue the past practice to develop definitions, as applicable, for small processors on a rule-by-rule basis. In addition, EPA has reviewed the existing TSCA section 8(a) rules that contain definitions for small processors. Because EPA has not received any reports under those rules for at least ten years, EPA believes that applying this proposed definition to processors would have no impact (Ref. 32). EPA welcomes comment on whether the proposed definition should be expanded to include processors.

All data in this preamble represent impacts to the manufacturing portion of the chemical industry, as evaluated for the CDR. The proposed definition is as follows:

Proposed small manufacturer definition: EPA is proposing to base the update of the current two-standard definition at 40 CFR 704.3 on inflation by adjusting the sales standard level for the first part from $40 million to $110 million and for the second part from $4 million to $11 million. Under this proposal, EPA would use the same definition for all manufacturers, except for small governments as discussed in this unit. The impacts of this option are provided in Unit I.E.2. The definition under this proposal would read:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Under CDR, sites that meet the small manufacturer requirements are exempted from the need to report either for the full site (based on the second standard) or for particular chemical substances (based on the first standard), unless the chemical substance the site is manufacturing (including importing) is the subject of one of certain TSCA actions: A rule proposed or promulgated under TSCA sections 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 sections 5 or 7. As part of this proposal, EPA is proposing to add TSCA section 4 orders to the list of certain TSCA actions. The authority to issue section 4 orders was added to TSCA when the statute was amended in 2016.

The current small manufacturer definition at 40 CFR 704.3 includes an inflation index to provide direction for determining the need to update the two standards comprising the definition (see Unit II.C.). For future inflation adjustments, EPA is proposing to use the Gross Domestic Product (GDP) deflator, or implicit price deflator, instead of the Produce Price Index (PPI) for Chemical and Allied Products when determining the need to adjust the total annual sales values. EPA is making this proposal because the types of small manufacturers subject to TSCA section 8(a) reporting requirements are broader than those defined by the PPI for Chemicals and Allied Products, which covers only Chemicals and Allied Products. The GDP deflator is less volatile and is broader than the PPI for Chemicals and Allied Products, and therefore EPA believes it is a better measure for considering an update to the revenue size standards in the proposed definition.

EPA estimates that the proposed definition would eliminate reporting entirely for 93 industry sites and would reduce reporting by eliminating the need to report at least one chemical for an additional 129 industry sites (Ref. 5). Overall, 888 chemical reports from industry sites would no longer be submitted to CDR. In sum, the use of the inflation adjustment definition results in a reduction of 2 percent of sites, an overall reduction of 2 percent of chemical reports, and a reduction of 0.07 percent of total volume reported (Ref. 5).

Proposed small governments definition. In addition to the proposed update to the definition for small manufacturers, EPA is proposing a definition for small governments. Currently, there is no small government definition in TSCA section 8(a). During the 2016 CDR reporting period, EPA became aware that the governments were reporting under CDR. Examples of governments considered to be manufacturers include a publicly owned water treatment facility that manufactures ozone onsite for water treatment, or a municipal landfill that

captures methane gas to be sold. EPA is proposing a small government definition to reduce the reporting burden for governments that may lack necessary resources. EPA proposes to use the same definition for small governments as the Regulatory Flexibility Act (5 U.S.C. 601(5)): A small governmental jurisdiction is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. States and tribal governments are not considered small governments. EPA is interested in comment on whether this definition should be changed for TSCA section 8(a) purposes to also include Tribal governments.

EPA estimates 33 government sites report under CDR in a four-year cycle. Under the proposed definition of small governments, reporting would be eliminated entirely for four government sites with an associated six chemical reports.

Application of standards. The size standards in this proposed rule would apply to all manufacturers of chemical substances subject to TSCA section 8(a) reporting and recordkeeping rules, unless the Agency specifically provides otherwise in a particular TSCA section 8(a) rule. Rules with different definitions than the current small manufacturer definition at 40 CFR 704.3 are: the nanoscale rule at 40 CFR 704.20; certain chemical-specific rules at 40 CFR 704.43 (Chlorinated Naphthalenes) and 40 CFR 704.102 (Hexachloronorbornadiene); and the Preliminary Assessment Information Rule (PAIR) at 40 CFR 712. Because of an inadvertent error there is currently no applicable definition of ''small manufacturer'' in 40 CFR 704.104 (Hexafluoropropylene oxide); EPA is proposing a correction, as discussed later in this unit.

Nanoscale materials. On January 12, 2017, EPA finalized the TSCA section 8(a) reporting and recordkeeping rule for nanoscale materials, which specified a separate small manufacturer definition (82 FR 3641). The nanoscale materials rule at 40 CFR 704.20 specifies the following definition: Small manufacturer or processor means any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million. In November 2017, when EPA determined that the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 warranted revision, EPA did not make a determination as to whether the definition in the nanoscale materials rule warranted revision. After further evaluation and consideration, EPA has determined that the size standard in the nanoscale materials rule definition does not warrant revision.

In the process of making this determination, EPA evaluated the effect of adjusting the small manufacturer size standard for nanoscale materials for inflation and found that it would cause no measurable impact on the number of reports received. Furthermore, since the first reports for nanoscale materials, which would make up a large portion of reported information, are due within one year after the final effective date of the rule and before any newly proposed small manufacturer definition would take effect, EPA does not want to complicate the process or potentially confuse regulated entities who are in the process of compiling the required information.

Certain chemical-specific TSCA section 8(a) rules. In addition to the nanoscale rule, there are eight chemical-specific rules listed in 40 CFR 704 subpart B. Five of those rules refer to the current TSCA section 8(a) small manufacturer definition listed in 40 CFR 704.3 and therefore would be impacted by the proposed approach for updating the standards. These impacted five rules are: §§ 704.25 (11-Aminoundecanoic acid); 704.33 (P-tert-butylbenzoic acid (P–TBBA), p-tert-butyltoluene (P–TBT) and p-tert-butylbenzaldehyde (P–TBB)); 704.45 (Chlorinated terphenyl); 704.95 (Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis-(EDTMPA) and its salts); and 704.175 (4,4′-methylenebis(2-chloroaniline) (MBOCA)). One of the chemical-specific rules in 40 CFR 704 subpart B, 40 CFR 704.104 (Hexafluoropropylene oxide), only includes a rule-specific small processor definition and not a small manufacturer definition. Upon review, EPA finds this to be an inadvertent error. As originally promulgated, 40 CFR 704.104 included the small manufacturer standard via the cross reference in 40 CFR 704.104(c)(2) to the exemption provisions in 40 CFR 704.5 which was lost when the exemptions at 40 CFR 704.5 were amended and the necessary corresponding change was not made at 40 CFR 704.104(c)(2) (52 FR 41297, October 27, 1987 and 53 FR 51717, Dec. 22, 1988). As such, EPA is including in this proposal a technical correction to address this error.

Two of the chemical-specific rules, namely 40 CFR 704.43 (Chlorinated Napthalenes) and 40 CFR 704.102 (Hexachloronorbornadiene) have their own rule-specific small manufacturer definitions. EPA is not proposing to change the definitions for these two rules because it has been over ten years since EPA has received any reports under these rules. EPA therefore believes a change to the small manufacturer definitions for these rules would have no impact. However, EPA is interested in comment on whether the small manufacturer definitions for these two rules should be changed.

PAIR rule. EPA is proposing to update the current small manufacturer definition in the PAIR rule at 40 CFR 712.25. EPA promulgated the TSCA section 8(a) PAIR rule in June 1982, to collect information to identify, assess and manage human health and environmental risks from chemical substances, mixtures, and categories listed on the rule. The 1982 PAIR small manufacturer definition predates the current 40 CFR 704.3 small manufacturer definition and has not been updated. It states: A manufacturer is qualified as small if both of the following criteria are met: (1) Total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period; [and] (2) Total production of the listed substance for the reporting period was below 45,400 kilograms (100,000 pounds) at the plant site. EPA is proposing to use the small manufacturer definition in 704.3 for the PAIR rule.

B. Agency Objectives

Industry compliance with TSCA reporting and recordkeeping requirements involves the expenditure of time, money, and personnel resources. These costs have particular impact on companies that have limited financial and personnel resources, such as smaller firms. Such manufacturers tend to have fewer administrative personnel and less capability for data compilation and recordkeeping than larger firms.

However, while recognizing the burdens on smaller firms, EPA is required to make risk management decisions based on reasonably available information, such as that collected through CDR. The information collection authority of TSCA section 8(a) reflects congressional recognition of EPA's need for sufficient data from the chemical industry. EPA has concluded that if a firm produces a subject chemical in substantial quantities, it is inappropriate to exempt that company from TSCA section 8(a) reporting requirements. Production data is valuable to EPA as an indicator of chemical exposure and high volume chemical production reflects a greater potential for environmental release. For this reason, EPA is maintaining the annual production or importation

volume modifier of 100,000 pounds for the first part of the proposed updated small manufacturer definition.

EPA also has the authority to develop new size standards separate from the general 8(a) small manufacturer definition in this proposed rule. Such development would be done in appropriate cases when the Agency finds that the general TSCA section 8(a) small manufacturer definition is not suitable for a new specific TSCA section 8(a) rule. However, when changing the definition for a specific rule, EPA must follow full notice and comment rulemaking procedures with regard to the amended definition and size standards.

EPA has an additional objective for the general TSCA section 8(a) small manufacturer definition and size standards. The standards should not prevent TSCA section 8(a) rules from providing information that is representative of firms of different sizes. Large and small firms have varying amounts of capital available, and therefore may utilize different production processes, techniques, and equipment. Different methods of production may cause the potential for chemical exposure to vary among large and small firms. It is important for the Agency to be able to monitor these differences. To ensure that EPA would receive information from a representative portion of manufacturers regulated under TSCA section 8(a), the structure of the definitions and levels of the size standards have been designed to allow the Agency to obtain production, use, and exposure data from a variety of firms.

A final objective for the standards is that they be easily analyzed and applied by both industry and the Agency. EPA is proposing exemption criteria that represent readily available data. These data enable identification of companies which would be likely to qualify for a small manufacturer exemption. The standards could also be easily enforced because the selected criteria would enable EPA to monitor compliance with the exemption.

C. Agency Approach and Methodology

In developing the size standards proposed in this rule, EPA examined the utility of several possible criteria for ''small'' as possible measures of chemical exposure potential and the resources available to manufacturers.

EPA looked at criteria for ''small'' used by other agencies, reviewed other ''small'' manufacturer definitions used by EPA, and reexamined criteria used for past rules under TSCA section 8(a), with specific focus on the recently finalized TSCA section 8(a) nanoscale materials rule (82 FR 3641, January 12, 2017). EPA considered the possible utility of parameters that have not been used previously, such as market share and net profit. EPA also relied on the input of industry representatives documented in the docket for the final determination that a revision to the standards is warranted and from SBA in meetings with EPA staff (82 FR 56824/EPA–HQ–OPPT–2016–0675–0022 and Ref. 31).

No parameter or set of parameters can meet EPA objectives and requirements perfectly. The various types of parameters considered, and their possible levels, are only approximations of company resources or EPA's information needs. EPA reviewed industry comments from the determination, as well as considerations factored into the development and evaluation of the original definitions, in selecting standards which best meet the Agency's requirements. EPA also took into consideration the comments on the TSCA Fees Rule (83 FR 8212, February 26, 2018), regarding the definition of small manufacturer. The following unit describes EPA's evaluation of possible alternative definitions.

D. Evaluation of Alternative Criteria for Small Manufacturer Definitions and Analysis of Selected Options

In the definitions used in the past by other Federal agencies, as well as at EPA under TSCA, there is no single definition of a ''small'' business. The definitions and size standards differ according to context and purpose. Identified broad categories include (1) benefits distribution, (2) data analysis and reporting, and (3) regulation and information collection (where flexibility is sought in balance with program objectives) (Ref. 5).

When establishing its size standards, SBA examines various industry characteristics such as average firm size, degree of competition within an industry, start-up costs and entry barriers, and distribution of firms by size. SBA also evaluates federal market factors including a small business's share in total industry's receipts. For more details, please see the ''SBA's Standards Methodology'' white paper, available at *www.sba.gov/size.* The SBA size standards are industry-specific mostly based on either average annual revenue or number of employees, for reference please see the SBA size standards at 13 CFR 121.202. In order for an entity to be classified as a small business for federal contracting and other small business programs, its enterprise level revenue or number of employees (including all affiliates) shall not exceed the size standard for the applicable industry. These size thresholds are determined at the 6-digit North American Industry Classification System (NAICS) levels. SBA's employee-based size thresholds range from 100 to 1,500 employees to account for differences among NAICS codes.

The size standards are intended to reflect the degree of competition within individual industries. SBA size standards vary by industry type to reflect the unique competitive characteristics of different industries. In some cases, SBA uses a revenue standard, or defines a business size in terms of assets. In other cases, the size standard is based on the number of employees. Within the chemical industry, the values assigned to the employment standards vary considerably among different industry groupings, which are represented using NAICS codes (Ref. 5).

For purposes of data analysis and reporting, Bureau of the Census (Census) uses a size standard of employee number at 500 to separate small businesses into their own subgroup for data reporting. Similarly, the U.S. Department of Agriculture's (USDA) Economic Research Service (ERS) identifies small farms at less than $350,000 farm income for reporting and research purposes. The purpose of these small business definitions is to identify companies whose paperwork burden can be lessened without substantial impact on the agencies' information bases (Ref. 5). Similarly, but to a much greater extent, small business definitions developed in regulatory contexts involve detailed program-specific balancing considerations. For example, the Occupational Safety and Health Administration (OSHA) defines a small business as having 10 employees or fewer for their Fire Protection in Shipyards regulations (Ref. 5).

Not unlike other federal agencies with similar purposes, EPA has separate definitions for ''small'' manufacturers, producers, processors, waste generators, and facilities under different statutes or regulations, including the National Primary Drinking Water Regulations, National Pollutant Discharge Elimination System Permit Regulations, RCRA laws, and the TRI. Each definition was created to meet individual programmatic needs or statutory requirements; it is therefore difficult to draw comparisons across the different definitions. For more information on the different ''small'' entity definitions used by other federal agencies and EPA, see Tables B–2 and B–3 in the Economic Analysis (Ref. 5).

When EPA first established the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 (49 FR 45425, November 16, 1984), EPA considered a number of possible parameters for the size standards, including: (1) Total annual company profit, (2) total company assets, (3) total annual company sales, (4) annual chemical sales, (5) number of company employees, (6) annual production volume per chemical, and (7) market share. When EPA reevaluated the size standards (82 FR 56824, November 30, 2017), the Agency considered the initial parameters again and additionally considered (8) barriers to entry, (9) start-up or expansion costs, (10) average firm size as a factor of employment and sales, (11) industry competition and concentration, (12) growth trends, and (13) technological changes, which were suggested by SBA's Office of Advocacy during the comment period and SBA consultation as part of EPA's determination process for reviewing whether revision to the current size standards for small manufacturers and processors was warranted (82 FR 56824, November 30, 2017).

To consider these parameters for this proposed rule, EPA explored SBA's approach to defining small businesses: A manufacturer (including importer) is defined as small in accordance with the size standards identified by NAICS codes at 13 CFR 121.201. EPA considered adopting an SBA-based size-standard in combination with various production volume modifiers such as 25,000; 50,000; and 100,000 pounds. For example, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 50,000 pounds, the manufacturer (including importer) would not qualify as small for purposes of reporting on the production or importation of that substance at that site.

EPA examined the impact of the various SBA-related definitions and the inflation adjusted definition on the number of reports, including by subcategories of particular interest to EPA such as TSCA Work Plan chemicals and by overall production volume. Details are in Table 2–1 of the Economic Analysis (Ref. 5). Any of the revised small manufacturing definitions considered resulted in fewer retained reports. Some of the definitions resulted in the addition of reports that are currently exempted. Details are in Tables 5–15 and 5–16 of the Economic Analysis (Ref. 5).

Comparing the options by the amount of overall production volume reported provides another insight into the impacts. Under the SBA-based size standards with production volume modifiers of 50,000 and 100,000 pounds, 38 million and 96 million pounds would be exempted, respectively. In comparison, under the inflation adjusted option, 13.7 billion pounds would be exempted. When compared to the baseline production volume, these would result in the retention of reporting on 99.93 percent (inflation adjusted), 99.9998 percent (SBA-based size-standard with a production-volume modifier of 50,000 pounds) and 99.9995 percent (SBA-based size-standard with a production-volume modifier of 100,000 pounds). In addition, under the inflation adjusted option the average report exempted 15.5 million pounds, whereas under the SBA-based size standards with production volume modifiers of 50,000 and 100,000 pounds, the average report exempted 23,000 pounds and 37,000 pounds, respectively. More details are in Tables 5–15 and 5–16 of the Economic Analysis (Ref. 5).

After analyses, the agency determined that adopting SBA's definition with the various production volume modifiers would likely result in loss of information for TSCA implementation, such as information on TSCA Work Plan chemicals. Given the impacts on losses to the CDR information necessary for the TSCA program coupled with the inherently higher complexity of an SBA-based definition (system involving a mix of revenue and employment bases with levels of size standards varying according to NAICS), EPA chose to propose the inflation adjustment option. EPA is, however, interested in comments on adopting the SBA standard (or an SBA-like standard) for small manufacturers, with an alternative production volume modifier, instead of the proposed definition. Details of SBA's standard can be found at 13 CFR 121.201 and on their website (Ref. 33). Details of EPA's analysis, options considered, and conclusions are summarized in detail in the Economic Analysis (Ref. 5).

Proposed definition: EPA adjusted the current size standards at 40 CFR 704.3 to account for inflation, resulting in an increase of the total annual sales from $40 million to $110 million for the first standard while maintaining the requirement that annual production or importation volume not exceed 100,000 pounds, and resulting in an increase of the total annual sales from $4 million to $11 million for the second standard. This proposed definition would reduce the amount of information reported under CDR, resulting in a decrease of 2 percent of chemical reports submitted, 2 percent of sites reporting, and 1.4 percent of total chemicals reported from the baseline conditions of the current definition. The baseline conditions are described in the Economic Analysis (Ref. 5). In future cycles, this proposed definition would reduce overall reporting burden by an estimated −64,295 hours and result in a $4,988,270 cost savings over a four-year CDR reporting cycle (Ref. 5). See also Unit I.E.2.

EPA's full analysis of the costs, cost savings, and benefits of this proposed definition is presented in detail in the Economic Analysis (Ref. 5). EPA welcomes comments on this proposal and on the other options and size standards EPA considered for evaluating the revised definition. In particular, EPA is seeking comments on an alternative definition for a small manufacturer (*e.g.,* an employment-based size standard varied by industry or a combination of employment-based and revenue-based varied by industry, such as the SBA standard with a 50,000 pound production volume modifier described previously in this unit of the preamble) which meets EPA's goal to minimize loss of chemicals and site reporting while maximizing reporting burden reductions for small businesses. A description on the SBA definition and a listing of other Federal government definitions for small business, including the employment-based definition used for the final TSCA Fees Rule (83 FR 52694, October 17, 2018), is provided in Appendix B of the Economic Analysis (Ref. 5).

V. Request for Comment

EPA requests comment on all changes and other topics described in this proposed rule, and the Economic Analyses prepared in support of this proposed rule (Refs. 4 and 5). EPA encourages all interested persons to submit comments on the issues identified in this Notice and to identify any other relevant issues as well. This input will assist the Agency in developing final rules that successfully addresses information needs while minimizing potential reporting burdens associated with the rule. EPA requests that commenters making specific recommendations include supporting documentation where appropriate.

EPA is also interested in receiving comment on whether reporting production volumes in ranges instead of to two significant figures would reduce burden for submitters while continuing to provide the information needed by EPA for implementation of TSCA. The current requirement to report to two

significant figures is, in essence, the reporting of a midpoint of a range. For example, if reporting 120,000 pounds, the actual production volume would be between 115,000 and 124,999 pounds. If reporting in ranges would reduce burden, should the ranges apply to a subset of reporters (such as inorganic chemicals or byproduct chemical substances), for lower production volumes only, as is done in TRI, (such as under 25,000 pounds), or to all? EPA is also interested in how a reporter would determine the percentage production volume required for physical form and processing and use information when reporting the underlying production volume in ranges.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA (2017). Public Webinar to Obtain Feedback on Improving CDR; Outreach meeting. Attended by the public, reporters to CDR, and EPA. Washington, DC. May 1, 2017.
2. EPA (2017). CDR Outreach meeting with Earthjustice and Other NGOs. Attended by Earthjustice, Safer Chemicals Healthy Families, Environmental Health Strategy Center, and EPA. Washington, DC. July 17, 2017.
3. EPA (2017). CDR Outreach meeting with Environmental Defense Fund (EDF). Attended by EDF and EPA. Washington, DC. July 19, 2017.
4. EPA (2018). *Economic Analysis for the Proposed Rule on TSCA Chemical Data Reporting (CDR) Revisions—(RIN 2070–AK33).* Office of Pollution, Prevention, and Toxics. Washington, DC. August 2018.
5. EPA (2018). *Economic Analysis for the Proposed Rule on TSCA Section 8(a) Small Manufacturer Definition Update (RIN 2070–AK33).* Office of Pollution, Prevention, and Toxics. Washington, DC. August 2018.
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14. EPA (2017). Meeting Summary of Public Organizational Planning Meeting for the Chemical Data Reporting (CDR) Inorganic Byproducts Negotiated Rulemaking. EPA–HQ–OPPT–2016–0597–0036.
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18. EPA (2018). CDR—Co-Manufacturing and Other Reporting Mechanics; Internal meeting. Attended by representatives of American Chemistry Council (ACC) and EPA. Washington, DC. February 12, 2018.
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26. EPA (2017). Chemical Data Reporting; Requirements for Inorganic Byproduct Chemical Substances; Notice of Public Meeting; Cancellation and Public Input Opportunity; Comment from PCA. EPA–HQ–OPPT–2016–0597–0085.
27. EPA (2006). Response Letter from Jim Willis (Director, Chemical Control Division) to Dr. John L. Festa (Senior Scientist, AF&PA), U.S. EPA, October 2006.
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29. EPA (2017). CDR Outreach Meeting—Overview of CDR Reporting for Pulping Chemicals; Internal meeting. Attended by representatives of AF&PA and EPA. Washington, DC. March 30, 2017.
30. EPA (2017). CDR Outreach Meeting—Kraft Chemical Looping Process Educational Video Presentation; Internal meeting. Attended by representatives of AF&PA and EPA. Washington, DC. July 13, 2017.
31. EPA (2018). Four Meetings with SBA—updating the Small Manufacturer Definition; Internal meetings. Attended by representatives of SBA and EPA. Washington, DC. April 19, May 15, and September 11, 2018.
32. EPA (2018). Email from Loraine Passe, Chief, Chemical Information and Testing Branch, CCD to Tyler Lloyd, ECB, CCD, Subject: Small Manufacturer Update and Small Processor Definition; Internal communication. Washington, DC. July 16, 2018.
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34. EPA (2019). Information Collection Request Proposed Addendum to Chemical Data Reporting under the Toxic Substances Control Act (TSCA section 8(a)) EPA ICR No. 1884.11; OMB Control Number 2070–0162. March 2019.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

The EPA prepared two economic analyses of the potential costs, cost savings, and benefits associated with this action. A copy of these economic analyses, entitled *Economic Analysis for the TSCA Chemical Data Reporting Revisions Rule* (Ref. 4) and *Economic Analysis for Proposed Rule on the TSCA Section 8(a) Small Manufacturer Definition Update* (Ref. 5), are available in the docket and is briefly summarized in Unit I.E.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

The CDR revisions and TSCA section 8(a) small manufacturer definition update are part of an action that is expected overall to be a deregulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017).

C. Paperwork Reduction Act (PRA)

For CDR, the information collection requirements in 40 CFR part 711 related to the submission of Form U's are already approved by OMB under the PRA, 44 U.S.C. 3501 *et seq.* That information collection request (ICR) has been assigned EPA ICR No. 1884.11 and OMB Control No. 2070–0162. Because this proposed rule involves new or revised information collection activities that require additional OMB approval, EPA has prepared an addendum to the currently approved ICR (Ref. 34 and 83 FR 36928, July 31, 2018 (EPA–HQ–OPPT–2017–0648). You can find a copy of the ICR addendum in the docket for this proposed rule (EPA–HQ–OPPT–2018–0321), and it is briefly summarized here.

The ICR addendum quantifies the burdens associated with the proposed CDR revisions and TSCA section 8(a) small manufacturer definition update (RIN 2070–AK33). EPA is proposing revisions to the CDR rule for three primary reasons: Align with amended TSCA, increase the usefulness of the CDR data collected, and reduce burden for CDR reporters pursuant to TSCA section 8(a)(5). The CDR data 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.

The PRA mandates that federal agencies estimate the recordkeeping and reporting burden of a rule. In this context, the term ''burden'' is interpreted as the total time, effort, or financial resources expended by individuals to generate, maintain, retain, disclose, or provide information to or for a federal agency. It includes the time regulated entities need to review instructions and to develop, acquire, install, and use technology and systems to collect, validate, verify, and disclose information. It also includes time taken to adjust existing ways to comply with any previously applicable instructions and requirements and to train personnel to respond to the information collection task.

For CDR, users submit data to EPA using a Form U on a four-year reporting cycle for the ''principal year'' and for the years since the previous principal reporting year (currently three years). Completion of the Form U involves 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) on one or more chemicals. Sites are subject to CDR reporting requirements when annual chemical production volume is at or above reporting thresholds (typically 25,000 lbs, but 2,500 lb for certain reporters) in any calendar year in the principal reporting year and the previous three years. 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 CDR reporting form include rule familiarization, compliance determination, form completion, and recordkeeping.

The changes covered by the proposed CDR revisions fall in to the following categories:

- Co-manufacturer reporting;
- Modifications and additions to reportable data elements;
- Changes to claiming confidentiality; and
- Byproduct provisions.

The changes proposed for the TSCA section 8(a) small manufacturer definition update are as follows:

- *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any) are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 100,000 pounds, the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under the second standard of this definition.
- *Second Standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

These changes are described in further detail in the CDR ICR Addendum (Ref. 34). Table 2 summarizes the changes to reporting under this proposed definition.

TABLE 2—CDR ICR ADDENDUM SUMMARY—ANNUAL BURDEN AND COST

Respondents/affected entities:	Entities potentially affected by this ICR include companies manufacturing (including importing) chemical substances listed on the TSCA Inventory and regulated under TSCA section 8.
Respondent's obligation to respond:	Respondents are obligated to report to EPA.
Estimated number of respondents:	5,660.
Frequency of response:	The collection occurs every four years. The next CDR collection will occur in 2020.
Estimated annual incremental burden:	25,201 hours.
Estimated annual cost:	$1,955,042.

For TSCA section 8(a) reporting outside of CDR, including the TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) or any of the chemical specific TSCA section 8(a) rules, EPA does not estimate incremental burden and cost either because EPA has not received any chemical reports under the rule for an extended period of time, or because the rule uses a different definition that is not being changed by this proposal.

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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your 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 EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov,* Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than May 28, 2019. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I certify that this action will not have a significant adverse economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in two Economic Analyses (Refs. 4 and 5).

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as:

1. A small business, as defined by the SBA's regulations at 13 CFR 121.201;

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and not dominant in its field.

The regulated community does not include small not-for-profit organizations. Additionally, no small governments are expected to be adversely affected by the proposed rule; in fact, the proposal creates an exemption for small governments. Therefore, the focus of the RFA analysis is on small businesses.

The existing CDR rule, at 40 CFR 711.9, generally exempts from reporting small businesses, defined at 40 CFR 704.3 as entities with annual sales of less than $40 million and less than 100,000-pound production of any given chemical substance at a site; or annual sales of less than $4 million. Note that under the proposed rule, as under current regulations, a small business would be ineligible for the exemption if it produces any chemical substance that is the subject of a regulation proposed or promulgated under TSCA sections 4, 5(b)(4), or 6; that is the subject of an order in effect under TSCA sections 4 or 5(e); that is subject to a consent agreement under TSCA section 4; or that is the subject of relief that has been granted pursuant to a civil action under TSCA sections 5 or 7. A small business may also report voluntarily.

For purposes of the economic analysis covering the CDR revisions portion of the proposed rule (Ref. 4), this small manufacturer exemption is assumed to be unchanged. Conversely, for the TSCA section 8(a) small manufacturer definition update portion of the rule (Ref. 5), reporting requirements on the Form U are assumed to be unchanged with changes to the exemption as the focus of the Economic Analysis (Ref. 5). Further discussions in this unit summarize results from each economic analysis, and then provide the synthesized overall conclusion.

1. *CDR revisions.* EPA analyzed potential small business impacts from this proposed rule for purposes of the small entity analysis using the SBA size standards which are either revenue or employment based, depending on the industry sector. EPA estimates that 732 small parent entities would potentially be affected by the CDR revisions portion of the proposed rule. Based on estimated maximum compliance costs annualized over a 10-year period and average revenue data for parent entities, EPA estimates that the cost-to-sales ratio of the proposed rule would be less than one percent for 728 (99.45 percent) of small parent entities subject to the rule. An additional two small parent entities are expected to incur cost impacts between one and three percent, and two small parent entities are expected to incur cost impacts above three percent (Ref. 4). Per EPA guidance, even if impacts are greater than one percent, as long as the number of entities is fewer than 100 and less than 20 percent of total small entities, the proposed rule is determined to not result in a significant impact on a substantial number of small entities. Therefore, EPA concludes that compliance costs associated with CDR revisions portion of the proposed rule are not expected to have a significant economic impact on a substantial number of small entities (no SISNOSE).

2. *TSCA section 8(a) small manufacturers definition update.* The TSCA section 8(a) small manufacturer definition update proposed definition is as follows:

- First standard, A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any) are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 100,000 pounds, the manufacturer or importer will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under the second standard of this definition.
- Second Standard. A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Under the proposed definition, the only change from the current TSCA section 8(a) small manufacturer definition is to increase levels for revenue size standards. As a result, EPA expects that no currently exempt small manufacturers would become newly subject to any current TSCA section 8(a) rules under this proposed definition, because all manufacturers that are currently exempt would remain exempt under this proposal. Moreover, the proposed rule would allow exemptions for certain current reporters, thereby eliminating their reporting burden. However, a small amount of incremental burden is incurred for rule familiarization.

As done for the CDR revisions portion of the proposed rule, EPA analyzed potential small business impacts for purposes of the small entity analysis using the SBA size standards which are either revenue or employment based, depending on the industry sector. For the small manufacturer definition update, EPA estimates that 732 small parent entities would potentially be affected by the proposed rule. Based on estimated compliance costs annualized over a 10-year period and average

revenue data for parent entities, EPA estimates that the cost-to-sales ratio of the small manufacturer definition update portion of the proposed rule would be less than 1% for all of these small parent entities (100 percent) (Ref. 5). Per EPA guidance, if impacts are less than 1%, a certification that the rule will not result in a significant (economic) impact on a substantial number of small entities can be made no matter the number of small entities affected. Therefore, the Agency concludes that the small manufacturer definition update portion of the proposed rule would not affect a significant number of small entities (no SISNOSE). Also note that there are no adverse small entity impacts to small government entities because under the post-change conditions all entities defined as small for purposes of small government assessment are the same entities that are newly eligible to take the small government exemption and eliminate their CDR reporting burden entirely.

3. *CDR rule overall.* Note that the two EAs' analyses cover overlapping groups, from which results from each analysis can be synthesized to reach an overall conclusion that the overall compliance costs associated with the proposed rule would not have a significant impact on a substantial number of small entities (overall no SISNOSE).

EPA continues to be interested in the potential impacts of this proposed rule on small entities and welcomes comments on issues related to such impacts.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and would not significantly or uniquely affect small governments. According to the information derived using the 2016 CDR, there are government entities that report to CDR, including: seven municipalities, one county-level public utility district, and one tribal entity. However, under the proposed changes, four of the municipalities would be exempt, with the remaining entities incurring a minimal average incremental burden and cost per site at about 3 hours and $262 per year, respectively. Consequently, impacts would not exceed $100 million for all governments. Additionally, under the proposed small government definition, four government entities would be exempt from TSCA section 8(a) reporting requirements (Ref. 5).

In sum, the proposed rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA.

F. Executive Order 13132: Federalism

This action would not have federalism implications. It would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action would not have tribal implications because it is not expected to have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). According to the information presented in the economic analysis for the TSCA section 8(a) small manufacturer definition update (Ref. 5), there is one tribal entity that reported during the 2016 CDR collection. Under the proposed rule, this entity is estimated to incur a minimal average incremental burden and cost per site at about 1 hour and $103 per year, respectively. Consequently, EPA has concluded that the impacts of the proposed rule would not significantly nor uniquely affect the communities of tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997), requires that federal agencies examine the impacts of each regulatory action on children for any economically significant regulation (as defined by Executive Order 12866) that the Agency has reason to believe may disproportionately affect children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it would not establish an environmental standard intended to mitigate health or safety risks. Nevertheless, the information obtained by the reporting required by this proposed rule would be used to inform the Agency's decision-making process regarding chemical substances to which children may be disproportionately exposed. This information would also assist the Agency and others in determining whether the chemical substances covered in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

Because this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The Agency believes that the rule would improve the information collected under CDR and better assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by the CDR. Because the CDR is an information collection requirement, the information that would be improved through the proposed rule would enable the Agency to target educational, regulatory, or enforcement activities towards industries or chemical substances that pose the greatest risks and/or to target programs for geographic areas that are at the highest risk. Thus, the information to be gathered under the proposed rule would help EPA make decisions that would benefit potentially at-risk communities, some of which may be disadvantaged.

The proposed rule is directed at manufacturers (including importers) of chemical substances. All consumers of these chemical products and all workers who come into contact with these chemical substances could benefit if data regarding the chemical substances' health and environmental effects were developed. Therefore, it would not appear that the costs and the benefits of the proposed rule would be disproportionately distributed across different geographic regions or among different categories of individuals.

List of Subjects

40 CFR Part 704

Environmental protection, Toxic substances control act, Reporting and recordkeeping requirements.

40 CFR Part 711

Environmental protection, Toxic substances control act, TSCA chemical data reporting and recordkeeping requirements.

40 CFR Part 712

Environmental protection, Toxic substances control act, Chemical information rules.

Dated: April 12, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, EPA proposes to amend 40 CFR parts 704, 711 and 712 as follows:

PART 704—[AMENDED]

■ 1. The authority citation for part 704 to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Section 704.3 is amended by:
■ a. Revising the definition of ''small manufacturer or importer''.
■ b. Adding in alphabetical order the definition for ''small government''.

The additions and revisions read as follows:

§ 704.3 Definitions.

* * * * *

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

* * * * *

Small manufacturer means a manufacturer (including importer) that meets either of the following standards:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

(3) *Inflation index.* EPA will make use of the Gross Domestic Product deflators, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Gross Domestic Product deflator has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA will provide notification in the **Federal Register** when changing the total annual sales values.

* * * * *

■ 3. Section 704.104 is amended by revising paragraph (c)(2) to read as follows:

§ 704.104 Hexafluoropropylene oxide.

* * * * *

(c) * * *

(2) Persons described in § 704.5 (a) through (f).

* * * * *

PART 711—[AMENDED]

■ 4. The authority citation for part 711 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 5. Section 711.1 is amended by revising paragraph (a) and (c) to read as follows:

§ 711.1 Scope and compliance.

(a) This part specifies reporting and recordkeeping procedures under section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(a)) for certain manufacturers (including importers) of chemical substances. TSCA section 8(a) authorizes the EPA Administrator to require reporting of information necessary for the administration of TSCA.

* * * * *

(c) TSCA section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. Section 16 of TSCA provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8(a) information and to otherwise restrain any violation of TSCA section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.) TSCA section 11 allows for inspections to assure compliance and the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary.

* * * * *

■ 6. In section 711.3:
■ a. Revise the definition for *e-CDRweb;*
■ b. Revise the definition for *Manufacture;*
■ c. Revise paragraph (1) of the definition for *Site;*
■ d. Remove the definition for *U.S. parent company.*
■ e. Add alphabetically the definitions for *Inorganic chemical substance* and *Parent company.*

The additions and revisions read as follows:

§ 711.3 Definitions.

* * * * *

e-CDRweb means the electronic, web-based tool provided by EPA for the completion of Form U and submission of the CDR data.

* * * * *

Inorganic chemical substance means any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups.

* * * * *

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. A chemical substance is co-

manufactured by the person who physically does the manufacturing and the person contracting for such production when that chemical substance, manufactured other than by import, is:

(1) Produced exclusively for another person who contracts for such production, and

(2) That other person dictates the specific chemical identity of the chemical substance and controls the total amount produced and the basic technology for the manufacturing process.

* * * * *

Parent company means the highest-level company(s) of the site's ownership hierarchy as of the start of the submission period during which data are being reported according to the following instructions. The U.S. parent company is located within the United States while the foreign parent company is located outside the United States:

(1) If the site is entirely owned by a single U.S. company that is not owned by another company, that single company is the U.S. parent company.

(2) If the site is entirely owned by a single U.S. company that is, itself, owned by another U.S.-based company (*e.g.,* it is a division or subsidiary of a higher-level company), the highest-level company in the ownership hierarchy is the United States parent company. If there is a higher-level parent company that is outside of the United States, the highest-level foreign company in the ownership hierarchy is the foreign parent company.

(3) If the site is owned by more than one company (*e.g.,* company A owns 40 percent, company B owns 35 percent, and company C owns 25 percent), the highest-level U.S. company with the largest ownership interest in the site is the U.S. parent company. If there is a higher-level foreign company in the ownership hierarchy, that company is the foreign parent company.

(4) If the site is owned by a 50:50 joint venture or a cooperative, the joint venture or cooperative is its own parent company. If the site is owned by a U.S. joint venture or cooperative, the highest level of the joint venture or cooperative is the U.S. parent company. If the site is owned by a joint venture or cooperative outside the United States, the highest level of the joint venture or cooperative outside the United States is the foreign parent company.

(5) If the site is entirely owned by a foreign company (*i.e.,* without a U.S.-based subsidiary within the site's ownership hierarchy), the highest-level foreign parent company is the facility's foreign parent company.

(6) If the site is federally owned, the highest-level federal agency or department is the U.S. parent company.

(7) If the site is owned by a non-federal public entity, that entity (such as a municipality, State, or tribe) is the U.S. parent company.

* * * * *

Sites * * *

(1) For chemical substances manufactured under contract, *i.e.,* by a co-manufacturer, the site is the location where the chemical substance is physically manufactured.

* * * * *

■ 7. Section 711.6 is amended by revising the section heading, the introduction paragraph and the first sentence in paragraph (a)(4) to read as follows.

§ 711.6 Chemical substances for which information is not required.

The following groups or categories of chemical substances are exempted from some or all of the reporting requirements of this part, with the following exception: A chemical substance described in paragraph (a)(1), (a)(2), or (a)(4), or (b) of this section is not exempted from any of the reporting requirements of this part if that chemical substance is the subject of a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA sections 4, 5(e), or 5(f), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

* * * * *

(a) * * *

(4). *Water and certain forms of natural gas.*

* * * * *

■ 8. Section 711.8 is amended by revising paragraph (a) and (b) to read as follows:

§ 711.8 Persons who must report.

* * * * *

(a) *Persons subject to recurring reporting*—Any person who manufactured (including imported) for commercial purposes 25,000 lb (11,340 kg) or more of a chemical substance described in § 711.5 at any single site owned or controlled by that person during any calendar year since the last principal reporting year.

* * * * *

(b) *Exceptions.* Any person who manufactured (including imported) for commercial purposes any chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6, or is the subject of an order in effect under TSCA sections 4, 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7 is subject to reporting as described in § 711.8(a), except that the applicable production volume threshold is 2,500 lb (1,134 kg).

■ 9. Section 711.9 is revised to read as follows:

§ 711.9 Persons not subject to this part.

A person described in § 711.8 is not subject to the requirements of this part if that person qualifies as a small manufacturer or small government as those terms are defined in 40 CFR 704.3. Notwithstanding this exclusion, a person who qualifies as a small manufacturer or small government is subject to this part with respect to any chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, or is the subject of an order in effect under TSCA sections 4 or 5(e), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

■ 10. Section 711.10 is revised to read as follows:

§ 711.10 Activities for which reporting is not required.

A person described in § 711.8 is not subject to the requirements of this part with respect to any chemical substance described in § 711.5, when:

(a) The person manufactured or imported the chemical substance solely in small quantities for research and development.

(b) The person imported the chemical substance as part of an article.

(c) The person manufactured the chemical substance in any of the following manners:

(1) Any byproduct if its only commercial purpose is for use by public or private organizations that (i) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)

(2) Byproduct substances listed in subparagraph (i) for the following manufacturing processes, when recycled or otherwise used within a site-limited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was generated, and when the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled

byproduct or manufactured in the same overall manufacturing process:

(i) *List of processes and related byproduct substances.*

(A) Portland Cement Manufacturing (*i.e.,* CASRN 68475–76–3, Flue dust, portland cement).

(B) Kraft Pulping Process (*i.e.,* CASRN 66071–92–9, Sulfite liquors and Cooking liquors, spent; and CASRN 471–34–1, Carbonic acid calcium salt (1:1)).

(ii) *Amendments.* EPA may amend the exemptions list in paragraph (c)(2)(i) of this section on its own initiative or in response to a request from the public based on EPA's determination of whether the byproduct substance and process described meet the criteria explained in paragraph (c)(2) of this section, based on the considerations listed in paragraph (c)(2)(ii)(B) of this section.

(A) Any person may request that EPA amend the chemical substance list in paragraph (c)(2)(i) of this section. Your request must be in writing and must be submitted to the address provided in 40 CFR 700.17(a). Please label your request as follows: Attention: TSCA Chemical Data Reporting—Byproduct Exemption Request. Requests must identify the manufacturing process and byproduct chemical substance in question, as well as its CASRN or other chemical identification number as identified in § 711.15(b)(3)(i), and must contain a written rationale for the request that provides sufficient specific information, addressing the considerations listed in (c)(2)(ii)(B) of this section, including cites and relevant documents, to demonstrate to EPA that the byproduct substance and process in question either does or does not meet the criteria explained in paragraph (c)(2) of this section. If a request related to a particular byproduct substance and process is resubmitted, any subsequent request must clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request. EPA will issue a written response to each request within 120 days of receipt of the request and will maintain copies of these responses in a docket that will be established for each reporting cycle.

(B) *Considerations.* In making its determination of whether this exemption should apply to a particular manufacturing process and related byproduct substance, EPA will consider the totality of information available for the process and related byproduct substance in question, including but not limited to, one or more of the following considerations:

(*1*) Whether the byproduct substance is recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured.

(*2*) Whether the site is reporting under CDR other chemical substances, in particular a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.

(*3*) Whether EPA has a current interest in the byproduct substance.

(*4*) That the byproduct substance must have already been reported under CDR or would be expected to be reported if not exempted by this exemption.

(C) As needed, the Agency will initiate rulemaking to make revisions to the list of substances in paragraph (c)(2)(i) of this section.

(D) To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, requests must be submitted to EPA no later than 12 months prior to the start of the next principal reporting year.

(3) A quantity of the byproduct that is manufactured solely in the following equipment when it is not integral to the chemical manufacturing processes of the site:

(i) Pollution control equipment.

(ii) Boilers used to generate heat or electricity for that site.

(4) The chemical substances described in this section: (Although they are manufactured for commercial purposes under TSCA, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(i) Any impurity.

(ii) Any byproduct which is not used for commercial purposes.

(iii) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(iv) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(v) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(vi) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(vii) Any chemical substance which results from a chemical reaction that occurs when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(viii) Any nonisolated intermediate.

■ 11. Section 711.15 is revised to read as follows.

§ 711.15 Reporting information to EPA.

Any person who must report under this part, as described in § 711.8, must submit the information described in this section for each chemical substance described in § 711.5 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year (*e.g.,* for the 2020 submission period, consider calendar years 2016, 2017, 2018, and 2019, because 2015 was the last principal reporting year). The principal reporting year for each submission period is the previous calendar year (*e.g.,* the principal reporting year for the 2020 submission period is calendar year 2019). For all submission periods, a separate report must be submitted for each chemical substance at each site for which the submitter is required to report. A submitter of information under

this part must report information as described in this section to the extent that such information is known to or reasonably ascertainable by that person.

(a) *Reporting information to EPA.* Any person who reports information to EPA must complete a Form U using the e-CDRweb reporting tool provided by EPA at the address set forth in § 711.35. The submission must include all information described in paragraph (b) of this section. Persons must submit the chemical reports on a separate single Form U for each site for which the person is required to report. The e-CDRweb reporting tool is described in the instructions available from EPA at the website set forth in § 711.35.

(b) *Information to be reported.* The information described in paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section must be reported for each chemical substance manufactured (including imported) in an amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year. The requirement to report information described in paragraph (b)(4) of this section is subject to exemption as described in § 711.6. Persons that elect to report eligible chemical substances in categories must report as described in § 711.15(b)(3)(i).

(1) *A certification statement signed and dated by an authorized official of the submitter company.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person's name, official title, and email address.

(2) *Company and site information.* The following currently correct company and site information must be reported for each site at which a reportable chemical substance is manufactured (including imported) above the applicable production volume threshold, as described in this section (see § 711.3 for the ''site'' for importers and special situations).

(i) The legal name, address, and Dun and Bradstreet D–U–N–S® (D&B) number for the highest-level parent company located in the United States and, if one exists, the highest-level foreign-based parent company. A submitter under this part must obtain a D&B number for the parent company if none exists and must report using the standardized conventions for the naming of a parent company as provided in the CDR Instructions for Reporting identified in § 711.35.

(ii) The name of a person who will serve as technical contact for the submitter company who will be able to answer questions about the information submitted by the company to EPA, and that technical contact person's full mailing address, telephone number, and email address.

(iii) The legal name and full street address of each site. A submitter under this part must include the appropriate D&B number for each site reported, and the county or parish (or other jurisdictional indicator) in which the site is located. A submitter under this part must obtain a D&B number for the site reported if none exists. For a co-manufacturing situation, the contracting company must report both the site controlling the contract and the producing company's site information.

(iv) The six-digit NAICS code for the site. A submitter under this part must include the appropriate six-digit NAICS code for each site reported.

(3) *Chemical-specific information.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in paragraph (b) of this section:

(i) The specific, currently correct CA Index name as used to list the chemical substance on the TSCA Inventory and the correct corresponding CASRN for each reportable chemical substance at each site. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using the corresponding TSCA Accession Number that is listed on the public portion of the Inventory. In addition to reporting the chemical identifying number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 3 of this paragraph.

(A) *Alternative reporting for some inorganic byproduct chemical substances.* Alternately, a submitter under this part may report an inorganic byproduct chemical substance using a designated metal compound category, unless the chemical substance is excluded from reporting in categories. Metal compound categories are listed in Table 4 of this paragraph. For purposes of determining whether any of the thresholds specified in § 711.8 are met for a metal compound category, a submitter must make the threshold determination based on the total amount of all members of the metal compound category manufactured at the site.

Excluded substances. Substances excluded from reporting in categories include barium carbonate (CASRN 513–77–9); chemical substances subject to the rules, orders, or other TSCA actions described in § 711.6; and chemicals undergoing risk evaluation under TSCA section 6, as described on EPA's CDR website at *https://www.epa.gov/cdr.*

TABLE 3—CODES TO SPECIFY TYPE OF CHEMICAL IDENTIFYING NUMBER

Code	Number type
A	TSCA Accession Number.
C	Chemical Abstracts Service Registry Number (CASRN).
M	TSCA Metal Compound Category Code.

TABLE 4—METAL COMPOUND CATEGORIES FOR INORGANIC BYPRODUCT CHEMICAL SUBSTANCES ONLY

Code	Category name
M01	Antimony and Antimony Compounds: Includes any unique chemical substance that contains antimony as part of that chemical's structure.
M02	Arsenic and Arsenic Compounds: Includes any unique chemical substance that contains arsenic as part of that chemical's structure.
M03	Barium and Barium Compounds: Includes any unique chemical substance that contains barium as part of that chemical's structure.
M04	Beryllium and Beryllium Compounds: Includes any unique chemical substance that contains beryllium as part of that chemical's structure.
M05	Cadmium and Cadmium Compounds: Includes any unique chemical substance that contains cadmium as part of that chemical's structure.
M06	Chromium and Chromium Compounds: Includes any unique chemical substance that contains chromium as part of that chemical's structure.
M07	Cobalt and Cobalt Compounds: Includes any unique chemical substance that contains cobalt as part of that chemical's structure.
M08	Copper and Copper Compounds: Includes any unique chemical substance that contains copper as part of that chemical's structure.
M09	Lead and Lead Compounds: Includes any unique chemical substance that contains lead as part of that chemical's structure.
M10	Manganese and Manganese Compounds: Includes any unique chemical substance that contains manganese as part of that chemical's structure.
M11	Mercury and Mercury Compounds: Includes any unique chemical substance that contains mercury as part of that chemical's structure.
M12	Molybdenum and Molybdenum compounds: Includes any unique chemical substance that contains molybdenum as part of that chemical's structure.
M13	Nickel and Nickel Compounds: Includes any unique chemical substance that contains nickel as part of that chemical's structure.

TABLE 4—METAL COMPOUND CATEGORIES FOR INORGANIC BYPRODUCT CHEMICAL SUBSTANCES ONLY—Continued

Code	Category name
M14	Selenium and Selenium Compounds: Includes any unique chemical substance that contains selenium as part of that chemical's structure.
M15	Silver and Silver Compounds: Includes any unique chemical substance that contains silver as part of that chemical's structure.
M16	Thallium and Thallium Compounds: Includes any unique chemical substance that contains thallium as part of that chemical's structure.
M17	Vanadium and Vanadium compounds: Includes any unique chemical substance that contains vanadium as part of that chemical's structure.
M18	Zinc and Zinc Compounds: Includes any unique chemical substance that contains zinc as part of that chemical's structure.

(B) *Joint submissions. (1)* If an importer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must use e-CDRweb to ask the supplier to provide the correct chemical identity and, in the case of a mixture, chemical function information directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically, using e-CDRweb and CDX (see § 711.35), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission.

(*2*) If a manufacturer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because the reportable chemical substance is manufactured using a reactant having a specific chemical identity that is unknown to the manufacturer and claimed as confidential by its supplier, the manufacturer must use e-CDRweb to ask the supplier of the confidential reactant to provide the correct chemical identity of the confidential reactant directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically using e-CDRweb and CDX (see § 711.35), and for clearly referencing the manufacturer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance, and a copy of the request to the supplier must be included with the importer's submission.

(*3*) EPA will only accept joint submissions that are submitted electronically using e-CDRweb and CDX (see § 711.35) and that clearly reference the primary submission to which they refer.

(ii) For the principal reporting year only, a statement indicating, for each reportable chemical substance at each site, whether the chemical substance is manufactured in the United States, imported into the United States, or both manufactured in the United States and imported into the United States.

(iii) For the principal reporting year, the total annual volume (in pounds) of each reportable chemical substance domestically manufactured or imported at each site. The total annual domestically manufactured volume (not including imported volume) and the total annual imported volume must be separately reported. These amounts must be reported to two significant figures of accuracy. In addition, the total annual volume (domestically manufactured plus imported volumes in pounds) of each reportable chemical substance at each site for each complete calendar year since the last principal reporting year.

(iv) For the principal reporting year only, the volume used on site and the volume directly exported of each reportable chemical substance domestically manufactured or imported at each site. These amounts must be reported to two significant figures of accuracy.

(v) For the principal reporting year only, a designation indicating, for each imported reportable chemical substance at each site, whether the imported chemical substance is physically present at the reporting site.

(vi) For the principal reporting year only, the percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance, for each reportable chemical substance at each site, that is manufactured as a byproduct at the site. Where this percentage accounts for less than 5 percent of the total production volume of the reportable chemical substance, submitters instead must report the percentage, rounded off to the closest 1 percent.

(vii) For the principal reporting year only, a designation indicating, for each reportable chemical substance at each site, whether the chemical substance is being recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream.

(viii) For the principal reporting year only, the total number of workers reasonably likely to be exposed to each reportable chemical substance at each site. For each reportable chemical substance at each site, the submitter must select from among the ranges of workers listed in Table 5 of this paragraph and report the corresponding code (*i.e.,* W1 through W8):

TABLE 5—CODES FOR REPORTING NUMBER OF WORKERS REASONABLY LIKELY TO BE EXPOSED

Code	Range
W1	Fewer than 10 workers.
W2	At least 10 but fewer than 25 workers.
W3	At least 25 but fewer than 50 workers.
W4	At least 50 but fewer than 100 workers.
W5	At least 100 but fewer than 500 workers.
W6	At least 500 but fewer than 1,000 workers.
W7	At least 1,000 but fewer than 10,000 workers.
W8	At least 10,000 workers.

(ix) For the principal reporting year only, the maximum concentration, measured by percentage of weight, of each reportable chemical substance at the time it is sent off-site from each site. If the chemical substance is site-limited, you must report the maximum concentration, measured by percentage of weight of the reportable chemical substance at the time it is reacted on-site to produce a different chemical substance. This information must be reported regardless of the physical form(s) in which the chemical substance is sent off-site/reacted on-site. For each chemical substance at each site, select the maximum concentration of the chemical substance from among the ranges listed in Table 6 of this paragraph and report the corresponding code (*i.e.,* M1 through M5):

TABLE 6—CODES FOR REPORTING MAXIMUM CONCENTRATION OF CHEMICAL SUBSTANCE

Code	Concentration range (percent weight)
M1	Less than 1 percent by weight.
M2	At least 1 but less than 30 percent by weight.
M3	At least 30 but less than 60 percent by weight.
M4	At least 60 but less than 90 percent by weight.
M5	At least 90 percent by weight.

(x) For the principal reporting year only, the physical form(s) of the reportable chemical substance as it is sent off-site from each site. If the chemical substance is site-limited, you must report the physical form(s) of the reportable chemical substance at the time it is reacted on-site to produce a

different chemical substance. For each chemical substance at each site, the submitter must report as many physical forms as applicable from among the physical forms listed in this unit:

(A) Dry powder.
(B) Pellets or large crystals.
(C) Water- or solvent-wet solid.
(D) Other solid.
(E) Gas or vapor.
(F) Liquid.

(xi) For the principal reporting year only, submitters must report the percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance, reported in response to paragraph (b)(3)(iv) of this section, that is associated with each physical form reported under paragraph (b)(3)(x) of this section.

(4) *Chemical-specific information related to processing and use.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in this section. Persons subject to paragraph (b)(4) of this section must report the information described in paragraphs (b)(4)(i) and (b)(4)(ii) of this section for each reportable chemical substance at sites under their control and at sites that receive a reportable chemical substance from the submitter directly or indirectly (including through a broker/distributor, from a customer of the submitter, *etc.*). Information reported in response to this paragraph must be reported for the principal reporting year only and only to the extent that it is known to or reasonably ascertainable by the submitter. Information required to be reported under this paragraph is limited to domestic (*i.e.,* within the customs territory of the United States) processing and use activities. If information responsive to a given data requirement under this paragraph, including information in the form of an estimate, is not known or reasonably ascertainable, the submitter is not required to respond to the requirement.

(i) *Industrial processing and use information*—(A) A designation indicating the type of industrial processing or use operation(s) at each site that receives a reportable chemical substance from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not). For each chemical substance, report the letters which correspond to the appropriate processing or use operation(s) listed in Table 7 of this paragraph. A particular designation may need to be reported more than once, to the extent that a submitter reports more than one sector (under paragraph (b)(4)(i)(B) of this section) that applies to a given designation under this paragraph.

TABLE 7—CODES FOR REPORTING TYPE OF INDUSTRIAL PROCESSING OR USE OPERATION

Designation	Operation
PC	Processing as a reactant.
PF	Processing—incorporation into formulation, mixture, or reaction product.
PA	Processing—incorporation into article.
PK	Processing—repackaging.
U	Use—non-incorporative activities.

(B) A code indicating the sector(s) that best describe the industrial activities associated with each industrial processing or use operation reported under paragraph (b)(4)(i)(A) of this section. For each chemical substance, report the code that corresponds to the appropriate sector(s) listed in Table 8 of this paragraph. A particular sector code may need to be reported more than once, to the extent that a submitter reports more than one function code (under paragraph (b)(4)(i)(C) of this section) that applies to a given sector code under this paragraph.

TABLE 8—CODES FOR REPORTING INDUSTRIAL SECTORS

Code	Sector description
IS1	Agriculture, forestry, fishing, and hunting.
IS2	Oil and gas drilling, extraction, and support activities.
IS3	Mining (except oil and gas) and support activities.
IS4	Utilities.
IS5	Construction.
IS6	Food, beverage, and tobacco product manufacturing.
IS7	Textiles, apparel, and leather manufacturing.
IS8	Wood product manufacturing.
IS9	Paper manufacturing.
IS10	Printing and related support activities.
IS11	Petroleum refineries.
IS12	Asphalt paving, roofing, and coating materials manufacturing.
IS13	Petroleum lubricating oil and grease manufacturing.
IS14	All other petroleum and coal products manufacturing.
IS15	Petrochemical manufacturing.
IS16	Industrial gas manufacturing.
IS17	Synthetic dye and pigment manufacturing.
IS18	Carbon black manufacturing.
IS19	All other basic inorganic chemical manufacturing.
IS20	Cyclic crude and intermediate manufacturing.
IS21	All other basic organic chemical manufacturing.
IS22	Plastics material and resin manufacturing.
IS23	Synthetic rubber manufacturing.
IS24	Organic fiber manufacturing.
IS25	Pesticide, fertilizer, and other agricultural chemical manufacturing.
IS26	Pharmaceutical and medicine manufacturing.
IS27	Paint and coating manufacturing.
IS28	Adhesive manufacturing.
IS29	Soap, cleaning compound, and toilet preparation manufacturing.
IS30	Printing ink manufacturing.
IS31	Explosives manufacturing.
IS32	Custom compounding of purchased resins.
IS33	Photographic film, paper, plate, and chemical manufacturing.
IS34	All other chemical product and preparation manufacturing.
IS35	Plastics product manufacturing.
IS36	Rubber product manufacturing.
IS37	Non-metallic mineral product manufacturing (includes cement, clay, concrete, glass, gypsum, lime, and other non-metallic mineral product manufacturing).
IS38	Primary metal manufacturing.
IS39	Fabricated metal product manufacturing.
IS40	Machinery manufacturing.
IS41	Computer and electronic product manufacturing.
IS42	Electrical equipment, appliance, and component manufacturing.
IS43	Transportation equipment manufacturing.
IS44	Furniture and related product manufacturing.
IS45	Miscellaneous manufacturing.
IS46	Wholesale and retail trade.
IS47	Services.
IS48	Other (requires additional information).

(C) For each sector reported under paragraph (b)(4)(i)(B) of this section, function category code(s) as provided in the CDR Instructions for Reporting identified in § 711.35 must be selected to designate the function category(ies) that best represents the specific manner in which the chemical substance is used. A particular function category may need to be reported more than once, to the extent that a submitter reports more than one industrial processing or use operation/sector combination (under paragraphs (b)(4)(i)(A) and (b)(4)(i)(B) of this section) that applies to a given function category under this paragraph. If more than 10 unique combinations of industrial processing or use operations/sector/function categories apply to a chemical substance, submitters need only report the 10 unique combinations for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical substance, measured by weight. If none of the listed function categories accurately describes a use of a chemical substance, the category ''Other'' may be used, and must include a description of the use.

(D) The estimated percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance associated with each combination of industrial processing or use operation, sector, and function category. Where a

particular combination of industrial processing or use operation, sector, and function category accounts for less than 5 percent of the submitter's site's total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent if the production volume attributable to that industrial processing or use operation, sector, and function category combination is 25,000 lb (11,340 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, sector, and function category.

(E) For each combination of industrial processing or use operation, sector, and function category, the submitter must estimate the number of sites at which each reportable chemical substance is processed or used. For each combination associated with each chemical substance, the submitter must select from among the ranges of sites listed in Table 9 of this paragraph and report the corresponding code (*i.e.,* S1 through S7):

TABLE 9—CODES FOR REPORTING NUMBERS OF SITES

Code	Range
S1	Fewer than 10 sites.
S2	At least 10 but fewer than 25 sites.
S3	At least 25 but fewer than 100 sites.
S4	At least 100 but fewer than 250 sites.
S5	At least 250 but fewer than 1,000 sites.
S6	At least 1,000 but fewer than 10,000 sites.
S7	At least 10,000 sites.

(F) For each combination of industrial processing or use operation, sector, and function category, the submitter must estimate the number of workers reasonably likely to be exposed to each reportable chemical substance. For each combination associated with each chemical substance, the submitter must select from among the worker ranges listed in paragraph (b)(3)(viii) of this section and report the corresponding code (*i.e.,* W1 though W8).

(ii) *Consumer and commercial use information*—(A) Using the codes as provided in the CDR Instructions for Reporting identified in § 711.35, submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial products in which each reportable chemical substance is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10 codes apply to a chemical substance, submitters need only report the 10 codes for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight. If none of the listed consumer and commercial product categories accurately describes the consumer and commercial products in which each reportable chemical substance is used, the category ''Other'' may be used, and must include a description of the use.

(B) for each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, code(s) described in paragraph (b)(4)(i)(C) of this section must be selected to designate the function category(ies) that best represents the specific manner in which the chemical substance is used. A particular function category may need to be reported more than once, to the extent that a submitter reports more than one consumer or commercial product category (under paragraphs (b)(4)(ii)(A) of this section) that applies to a given function category under this paragraph. If none of the listed function categories accurately describes a use of a chemical substance, the category ''Other'' may be used, and must include a description of the use.

(C) An indication, within each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, whether the use is a consumer or a commercial use.

(D) Submitters must determine, within each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, whether any amount of each reportable chemical substance manufactured (including imported) by the submitter is present in (for example, a plasticizer chemical substance used to make pacifiers) or on (for example, as a component in the paint on a toy) any consumer products intended for use by children age 14 or younger, regardless of the concentration of the chemical substance remaining in or on the product. Submitters must select from the following options: The chemical substance is used in or on any consumer products intended for use by children, the chemical substance is not used in or on any consumer products intended for use by children, or information as to whether the chemical substance is used in or on any consumer products intended for use by children is not known to or reasonably ascertainable by the submitter.

(E) The estimated percentage, rounded off to the closest 10 percent, of the submitter's site's total production volume of the reportable chemical substance associated with each consumer and commercial product category. Where a particular consumer and commercial product category accounts for less than 5 percent of the total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent if the production volume attributable to that commercial and consumer product category is 25,000 lb (11,340 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular consumer and commercial product category.

(F) Where the reportable chemical substance is used in consumer or commercial products, the estimated typical maximum concentration, measured by weight, of the chemical substance in each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section. For each chemical substance in each commercial and consumer product category reported under paragraph (b)(4)(ii)(A) of this section, submitters must select from among the ranges of concentrations listed in Table 6 in paragraph (b)(3)(ix) of this section and report the corresponding code (*i.e.,* M1 through M5).

(G) Where the reportable chemical substance is used in a commercial product, the submitter must estimate the number of commercial workers reasonably likely to be exposed to each reportable chemical substance. For each combination associated with each substance, the submitter must select from among the worker ranges listed in Table 5 in paragraph (b)(3)(viii) of this section and report the corresponding code (*i.e.,* W1 though W8).

■ 12. Section 711.20 is revised to read as follows:

§ 711.20 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during an applicable submission period, which runs from June 1 to September 30 at 4-year intervals, beginning in 2020. In each submission period, any person described in § 711.8 must report as described in this part.

■ 13. Section 711.22 is amended by revising paragraph (c) to read as follows:

§ 711.22 Duplicative reporting.

* * * * *

(c) *Co-manufactured chemicals.* This part requires that only one report per site be submitted on each chemical substance described in § 711.5. When a company contracts with a producing company to manufacture a chemical substance, and each party meets the definition of ''manufacturer'' as set forth in § 711.3, the contracting company must initiate the required report for that site as the primary submitter. The contracting company must indicate on the report that this is a co-manufacturing situation, notify the producing company, and record the production volume domestically co-manufactured as set forth in § 711.15(b)(3) and processing and use information set forth in § 711.15(b)(4). Upon notification by the contracting company, the producing company must also record the production volume domestically co-manufactured and complete the rest of the report as prompted by e-CDRweb.

* * * * *

■ 14. Section 711.30 is revised to read as follows.

§ 711.30 Confidentiality claims.

(a) Generally. (1) Any person submitting information under this part may assert a confidentiality claim for that information at the time it is submitted, except for information described in paragraph (2).

Any such confidentiality claims must be asserted at the time the information is submitted. These claims will apply only to the information submitted with the claim. Instructions for asserting confidentiality claims are provided in the document identified in § 711.35. Information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2.

(2) *Exceptions.* Confidentiality claims cannot be made:

(i) For public contact information if voluntarily provided;

(ii) For chemical identities listed on the public portion of the TSCA Inventory or for chemical category identification when reporting pursuant to § 711.15(b)(3)(i);

(iii) For processing and use data elements required by § 711.15(b)(4)(i)(A), (B), and (C) and § 711.15(b)(4)(ii)(A), (B), and (C), or

(iv) When a response is left blank or designated as not known or reasonably ascertainable.

(3) All confidentiality claims must be substantiated at time of submission, in accordance with the requirements in subsections (b) through (f) of this section. Confidentiality claims for the following data elements are exempt from this substantiation requirement:

(i) Production volume information required pursuant to § 711.15(b)(3)(iii).

(ii) Joint submission information from the primary submitter including trade name and supplier identification required pursuant to § 711.15(b)(3)(i)(A), (B), and (C).

(iii) Joint submission information from the secondary submitter including the percentage of formulation required pursuant to § 711.15(b)(3)(i)(A), (B), and (C).

(4) All confidentiality claims require certification in accordance with subsection (g) of this section. All asserted confidentiality claims, whether subject to substantiation and review or not, may only be asserted consistent with the representations set forth in the certification described in subsection (h) of this section.

(b) *All confidentiality claims requiring substantiation at time of submission.* For each data element claimed as confidential, you must submit with your report detailed written answers to the following questions signed and dated by an authorized official.

(1) Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, explain the substantial harm.

(2) To the extent your business has disclosed the information to others (both internally and externally), has your business taken precautions to protect the disclosed information? If yes, please explain and identify the specific measures or internal controls your business has taken to protect the information claimed as confidential.

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

(4) Does any of the information you are claiming as confidential constitute a trade secret?

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

(6) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(c) *Additional requirements for specific chemical identity.* The specific chemical identity includes the CA Index name and corresponding CASRN as described in § 711.15(b)(3) of this part, and does not include generic chemical identities or TSCA Accession Number. Generic chemical identities and accession numbers may not be claimed as confidential. A person may assert a claim of confidentiality for the specific chemical identity of a chemical substance only if the identity of that chemical substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that chemical substance. To assert a claim of confidentiality for the identity of a reportable chemical substance, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions signed and dated by an authorized official.

(1) Is this chemical substance publicly known to be in U.S. commerce by a specific chemical identity or name that is consistent with its listing on the confidential portion of the TSCA Inventory? If yes, explain why the chemical identity should still be afforded confidential status (*i.e.,* the chemical is publicly known only as being distributed in commerce for research and development purposes). If no, complete the certification statement:

> I certify that on the date referenced, I searched the internet for the chemical substance identity (*i.e.,* by both chemical substance name and CASRN). I did not find a reference to this chemical substance which would indicate the chemical is being manufactured or imported for a commercial purpose and is available in the United States by anyone. [provide date].

(2) Does this particular chemical substance leave the site of manufacture (including import) in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(3) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

(4) Would disclosure of the specific chemical name release confidential process information? If yes, please explain?

(d) *Company, site, and technical contact identity information.* A

submitter may assert a claim of confidentiality for a site, company, or technical contact identity only if the linkage of that information to a reportable chemical substance is confidential and not publicly available. To assert a claim of confidentiality to protect the link between the company, site, or technical contact identity and the chemical substance information, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions, as applicable, signed and dated by an authorized official.

(1) Has company, site, or technical contact identity information been linked with a reportable chemical substance in any public document or in any other Federal, State, or local reporting scheme? For example, is the chemical identity linked to a facility in a filing under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 311, namely through a Safety Data Sheet (SDS)? If yes, explain why the information should be treated as confidential.

(e) *Additional requirements for processing and use information.* A submitter may assert a claim of confidentiality for each data element required by § 711.15(b)(4)(i)(D), (E) and (F) and § 711.15(b)(4)(ii)(D), (E) and (F) only if the linkage of the information with a reportable chemical substance is confidential and not publicly available. To assert a claim of confidentiality for each data element required by § 711.15(b)(4) which is potentially eligible for protection from disclosure, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions signed and dated by an authorized official:

(1) Is the information claimed as confidential publicly known? For example, is the information available in advertisements or other marketing materials, professional journals or other similar materials, or in non-confidential mandatory or voluntary government filings or publications? Has your company ever publicly released this information? If yes, explain why the information should be treated as confidential.

(2) Has your company ever provided this information on the chemical substance to any person and not asked that it be treated as confidential? If yes, explain why the information should be treated as confidential.

(f) *Joint Submissions.* If a primary submitter asks a secondary submitter to provide information directly to EPA in a joint submission under § 711.15(b)(3)(i)(A) and (B), only the primary submitter may assert a confidentiality claim for the data elements it directly submits to EPA. The primary submitter must substantiate those claims not exempt under subparagraph (a)(3)(ii) of this section. The secondary submitter is responsible for asserting all confidentiality claims for the data elements it submits directly to EPA and substantiating those claims not exempt under subparagraph (a)(3)(iii) of this section.

(g) *Marking substantiations.* If any of the information contained in the answers to the questions listed in subsections (b) though (e) of this section is asserted to contain information that itself is considered to be confidential, you must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(h) *Certification statement for claims.* An authorized official of a person asserting a claim of confidentiality must certify that the submission complies with the requirements of this part by signing and dating the following certification statement:

I certify that all claims for confidentiality asserted with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001. I further certify that: (1) I have taken reasonable measures to protect the confidentiality of the information; (2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and (4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(i) *No claim of confidentiality.* Information not asserted as confidential in accordance with the requirements of this section may be made public without further notice to the submitter.

■ 15. Section 711.35 is amended by revising paragraph (c)(1) to read as follows:

§ 711.35 Electronic filing.

* * * * *

(c) * * *

(1) *By website.* Go to the EPA Chemical Data Reporting internet homepage at *http://www.epa.gov/cdr* and follow the appropriate links.

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PART 712—[AMENDED]

■ 16. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 17. Section 712.25 is amended by revising paragraph (c) to read as follows:

§ 712.25 . Exempt manufacturers and importers.

* * * * *

(c) Persons who qualify as small manufacturers (including importers) in respect to a specific chemical substance listed in § 712.30 are exempt. However, this exemption does not apply with respect to any chemical in § 712.30 designated by an asterisk. A manufacturer is qualified as small and is exempt from submitting a report under this subpart for a chemical substance manufactured at a particular plant site if it meets the definition for small manufacturer in § 704.3.

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