# Response to Public Comments

# TSCA Chemical Data Reporting Revisions for Reporting and Recordkeeping Requirements under TSCA Section 8(a) RIN 2070-AK33

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Office of Pollution Prevention and Toxics

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

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Note: Each comment summary is followed by the end portion of one or more Federal Docket Management System ID numbers. The numbers identify the public comments used to compile the comment summary. The comments were submitted to the rulemaking docket during the comment period for the proposed rule (Docket # EPA-HQ-OPPT-2018-0321).

## List of Abbreviations

CASRN – Chemical Abstracts Service Registry Number

CBI – Confidential business information

CCR – Coal combustion residual

CDR – Chemical Data Reporting

CDX – Central Data Exchange

CFR – Code of Federal Regulations

CKD – Cement kiln dust

eCDR – electronic Chemical Data Reporting tool

ESD – Emission Scenario Documents

EPA – Environmental Protection Agency

EPCRA – Emergency Planning and Community Right-to-Know Act

FOIA – Freedom of Information Act

FRS – Facility Registry Service

NAICS – North American Industrial Classification System

OCSPP – Office of Chemical Safety and Pollution Prevention

OECD – Organisation for Economic Co-operation and Development

OPPT – Office of Pollution Prevention and Toxics

PMN – Premanufacture Notice

RCRA – Resource Conservation and Recovery Act

TRI – Toxics Release Inventory

TSCA – Toxic Substances Control Act

# Response to Comments: TSCA Chemical Data Reporting Revisions for Reporting and Recordkeeping Requirements under TSCA Section 8(a) RIN 2070-AK33

## Introduction

This document is an addendum to Unit III of the final rule under the Toxic Substances Control Act (TSCA) section 8(a) Chemical Data Reporting (CDR) rule, identified by docket identification number EPA-HQ-OPPT-2018-0321.

Public comment was taken on the proposed rule published on April 25, 2019. During the 60-day comment period, 24 unique comments were received from different groups, 23 of which addressed the CDR revisions. Comments were from government entities (including Tribal) (two comments), industry trade associations (18 comments representing 23 organizations) and non-governmental organizations (three comments). Commenters provided feedback on many provisions of the rule. The proposed rule also contained updates to the TSCA section 8(a) small manufacturer definition, which are being finalized in a separate action.

EPA is finalizing as proposed or with minor modifications data elements for which there were either no comments, only positive comments, comments that will be addressed through improved guidance, or comments to clarify the burden in a qualitative manner. The following data elements are being finalized as proposed: the function of the chemical in consumer and commercial uses; the chemical-specific function in a joint submission; NAICS codes and parent company information for the manufacturing site; and whether the chemical is recycled. For reports of the chemical substances designated in 2019 as a high priority for risk evaluation under TSCA section 6(b) (84 FR 71924, December 30, 2019), EPA is finalizing the requirement to report processing and use codes based on OECD codes. For reports of all other chemicals, these codes are not required in 2020, but may be used voluntarily if reporters choose. These codes will be required for all reporters of processing and use information in 2024. The percentage of chemical that is a byproduct is being finalized with minor modifications. EPA is not finalizing the proposed voluntary public contact data element. For the proposed co-manufacturing reporting mechanism, comments were generally supportive of the proposal but requested additional flexibility. EPA is finalizing the co-manufacturing reporting mechanism with the requested increase in flexibility.

For the two proposed exemptions from reporting for byproducts, EPA received multiple comments, most of which were supportive; EPA is finalizing both exemptions for: (1) listed site-limited, enclosed byproducts that are recycled in a site-limited, enclosed system (including the petition process to make changes to the list) and (2) byproducts from non-integral equipment. Based on comments received, EPA is not finalizing the alternate reporting in specified categories for inorganic byproducts.

EPA also received several comments requesting changes to current exemptions and other potential future changes, some of which were not in the scope of this action. EPA is not finalizing the proposal to consolidate the existing byproduct exemptions in order to take the time to better consider the variety of comments about these exemptions and determine if future changes are warranted.

EPA received multiple comments about changes to requirements for claiming confidentiality. Some commenters addressed the prohibition of confidentiality claims for general processing and use data, suggesting alternative applications for the prohibition; two commenters requested automatic confidentiality protection without upfront substantiation for all data elements containing specific volumes; and one commenter specifically stated that burden was underestimated. A commenter requested changes to the substantiation questions. EPA is finalizing the confidentiality-related changes, with certain modifications to address some commenter requests.

## A. General comments on the proposed CDR revisions

***1. Summary:*** EPA received nine comments offering general support of the CDR rule and the proposed revisions to support EPA's implementation of TSCA. One commenter supported a single Federal authority under TSCA, rather than numerous "state-by-state regulatory actions," citing that these changes provide predictability in the regulatory process for industry. This commenter also expressed support for EPA's use of the CDR rule as an efficient, predictable means to collect robust data on chemical substances to inform EPA activities. Another commenter supported using CDR to inform EPA activities but noted that TSCA section 8(a) was not intended to fill every information gap regarding chemical substances in commerce. A different commenter stated "that EPA needs to stay within the bounds of its TSCA mandate for requiring information, consider the practical utility of the information it requires, and minimize the reporting burden on respondents to the extent possible." Several of the commenters expressed interest in continuing to work with EPA to further improve the data while minimizing industry's reporting burden.

Two commenters stated that CDR is an important information collection tool and they agree with EPA that the information collected via CDR supports the EPA's health, safety, and environmental protection activities related to chemical manufacturing and use, especially in support of the implementation of TSCA section 6, including prioritization and risk management. The data collection periods are scheduled and predictable, which the commenter explains is better than ad hoc data collection under TSCA sections 4, 8 and 11. The commenters explain that the data is also useful for other parts of the Agency, governments (including tribes), and public communities as well. One commenter explained "apart from TSCA implementation, CDR reports are uniquely valuable to communities and vulnerable populations seeking to better understand potential risks and exposures they may face."

***Sources:*** 0321-0089, 0321-0093, 0321-0096, 0321-0098, 0321-0100,0321-0102, 0321-0103, 0321-0105, 0321-0106, 0321-0108

***Response:*** EPA appreciates the supporting comments; the final rule is consistent with the commenters' requests: make regulatory updates to align with new statutory requirements of TSCA, improve the CDR data as necessary to support the implementation of TSCA, and reduce burden for certain CDR reporters. These goals are consistent with the TSCA mandate for information collection. 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)).

***2. Summary:*** A commenter expressed that the information collected through CDR will enable the implementation of TSCA, but that the data collected from printed circuit board manufacturers is not necessary for TSCA implementation, as the industry's reportable chemicals are not listed on the TSCA Work Plan for Chemicals Assessments and are managed

in pipes, tanks, and containers. The commenter requested information as to how CDR information on its reportable chemicals is used to help protect human health and the environment.

***Source:*** 0321-0103

***Response:*** CDR provides a unique database of information about chemicals in commerce in the United States. The CDR data are essential for the implementation of TSCA, including, but not limited to, the newly amended TSCA section 6. TSCA implementation is not restricted to chemicals on the TSCA Work Plan. Data gathered through CDR not only support ongoing risk evaluations but also provide exposure-related information on chemicals in commerce, which EPA uses to support risk screening and prioritization processes and other actions carried out as part of TSCA implementation. Additionally, EPA and other federal, state, local, and tribal entities use the data reported pursuant to the CDR rule to support health, safety, and environmental protection activities related to chemical manufacturing, processing, and use.

***3. Summary:*** A commenter identified ways that EPA could combine the CDR data with the updated TSCA Inventory data to better educate the public, including to identify the extent to which the Agency has already gathered information on or evaluated active chemical substances in commerce. Combining the TSCA Inventory, CDR, and other ChemView data elements, this commenter found that EPA and others have already contributed greatly to a better understanding of the highest production chemical hazards and exposures through EPA's implementation of TSCA to this point.

***Source:*** 0321-0106

***Response:*** EPA appreciates the suggestions for how to better use CDR data, combining it with other publicly available data, to improve public understanding of chemicals and the strides that EPA has made in improving chemical manufacturing and use knowledge and related risk concerns. CDR data is available publicly and will continue to be made available in ChemView at https://chemview.epa.gov/chemview/. The proposed changes to CDR will better enable the Agency to implement TSCA sections 4, 5, and 6, to make scientific decisions consistent with best available science, to effectively provide public access to information, and to obtain new and updated information regarding potential exposures to a major subset of chemical substances listed on the TSCA Inventory.

***4. Summary:*** A commenter stated that EPA should also make any new reporting requirement forward-looking for the 2024 reporting period and not retrospective for the 2020 reporting period. Any new requirement for the 2020 reporting period could necessitate reworking materials that might not be available to analyze or collecting information that may no longer exist. Even if those information and data are available, it would be a significant burden on reporters to recreate and/or capture that additional data.

***Source:*** 0321-0102

***Response:*** While EPA recognizes the challenges that may be associated with identifying which information from 2016 to 2020 would now be needed for reporting under the new requirements, the reporting standard for CDR continues to be information that is *known or reasonably ascertainable*. EPA intends to provide an improved, user-friendly reporting tool; enhanced instructions; and outreach such as webinars to help the regulated community with the new requirements.

***5. Summary:*** Two commenters identified that improvements to the electronic reporting tool will provide significant value in reducing reporting burden. However, one of these commenters claimed that the only true burden reduction will occur with reduced data requirements and broader exemptions. A third commenter expressed that the increase of data collection for the 2020 cycle could crash the CDR submission system, identifying that the increase in information is significant and far more information than was collected in 2016. The commenter stated that the task of entering and submitting data in 2020 will be labor- and time- intensive. The commenter stated a concern that this increase in information would cause it to "time out" or crash the submission system.

***Sources:*** 0321-0096, 0321-0106, 0321-0109

***Response:*** EPA is balancing the interest in reduced reporting burden with maintaining EPA's ability to receive the information it needs to understand potential chemical exposures in its implementation of TSCA's new requirements. Certain data elements, such as information about byproducts, help EPA to better understand the manufacturing of chemical substances and the impact of current or potential future exemptions to reporting. EPA acknowledges the comment that reporting to the CDR will inherently cause burden for reporters (Ref. 1), but the data are necessary to perform EPA's obligations under TSCA.

EPA disagrees that the changes to the CDR requirements result in a significant increase in data input over that collected in 2016. Requirements to report processing and use information remain at the same amount of information. Submitters will continue to be required to report up to 10 distinct combinations of both industrial and consumer/commercial entries. Therefore, even though the number of choices for function and consumer/commercial products has increased, the number to be reported has not. EPA agrees that reporting the function for uses in consumer and commercial products is new and has added estimates of the burden to the Economic Analysis. EPA estimates that different companies will experience different burden impacts. Generally, EPA estimates that, with the electronic reporting tool improvements, the change to replace certain CDR Part III codes with selected OECD function, product and article use category codes would reduce burden by about thirty minutes for reports on a single chemical in Part III.

***6. Summary:*** One commenter stated that reporters, especially new submitters, may be overwhelmed by reporting due to the new regulatory changes and recommended that EPA take a few preparatory steps before the next reporting period to familiarize reporters with the electronic reporting system, including webinars with the option for feedback, and a public listserv to answer technical questions about the reporting requirements and CDX functionality (similar to the e-Manifest listserv used by EPA for hazardous waste shipment reporting). The commenter suggested that EPA improve public communication and guidance, especially issuing guidance on completing and submitting CDR reports using the electronic reporting tool and presenting the submitted date in context with the updated TSCA Inventory. Several commenters supported the non-regulatory changes that the EPA is making to the electronic reporting tool, but encouraged the Agency to expand the pilot testing of the tool before the submission period from 25 users to a larger group of users. Two commenters encouraged EPA to consider updating CDR to allow submitters to copy and modify a prior report for the next submission period to reduce burden on manufacturers.

***Sources:*** 0321-0093, 0321-0096, 0321-0098, 0321-0106

***Response:*** EPA agrees that improving communication, outreach, and information to the regulated community will improve the reporting experience. EPA is working on multiple improvements, including a new reporting tool that is more intuitive for the user. As noted in the proposed rule, EPA plans to beta-test the improved reporting tool to ensure that it works as expected, and that the issues experienced during the 2016 submission period are prevented. EPA understands the desire to open the beta testing to all whom are interested but is unable to due to resource constraints. As was done prior to the 2016 submission period, EPA will host webinars to explain the reporting requirements, including introducing changes from 2016 reporting, and to demonstrate the new reporting tool. EPA is exploring ways to enable the upload of information from previous submissions into the current year submission. EPA will also update existing instructions and other materials to support reporters.

## B. Changes to Reportable Data Elements

### B.1. Processing and use codes

***7. Summary:*** In general, commenters supported EPA's proposal to harmonize the processing and use codes with codes based on the OECD functional use and product and article use codes, noting the considerable utility of CDR for EPA, other federal programs, states, tribes, and other stakeholders and to better fulfill EPA's mandate of implementing TSCA. A commenter "believes this revision will improve the accuracy of EPA's prioritization and risk evaluation activities. OECD codes more accurately represent exposure pathways for chemicals by better linking the substance with the type of product(s) that they are used in." Another commenter wrote that the harmonization of OECD codes will be particularly important for reporters whose operations span beyond the United States.

Commenters also noted that replacing the current CDR codes with a higher number of OECD-harmonized codes will increase burden for reporters; one commenter noted that EPA was "replacing the broad and limited CDR function and use codes … [with] an expanded and more detailed coding system…" Commenters identified the need to update company systems designed to capture information using the old codes, noting that for the 2020 CDR companies will have only a few months to update their internal tools in order to capture and submit information under these new requirements and suggesting that using the new codes will "likely double or triple the amount of pre-work needed to accurately classify substances." Commenters claimed the burden increase would especially be true for companies with a lot of chemicals or companies importing mixtures, such as multi-ingredient consumer products. A commenter recommended "that EPA consider how to address a substance which may have different functions in products (e.g. citric acid) in the updated eCDR software." One commenter noted that "beyond the 2020 reporting cycle, it is unclear whether the specificity of the OECD codes will reduce or increase industry's reporting burden."

***Sources:*** 0321-0088, 0321-0093, 0321-0094, 0321-0096, 0321-0098, 0321-0099, 0321-0106, 0321-0107, 0321-0108

***Response:*** EPA agrees that there are substantial benefits in harmonizing the processing and use codes with OECD. Because there are a greater number of choices for both function and product codes, EPA is making use of information technology features such as a smart search function within the eCDRweb reporting tool to assist the submitter by narrowing and better targeting the choices the submitter needs to consider. EPA estimates a small burden increase for this finalized provision, and as a result is only finalizing the required use of the new OECD harmonized codes for manufacturers (including importers) of the chemical substances designated in 2019 as a high priority for risk evaluation under TSCA section 6(b) (84 FR 71924, December 30, 2019). Reporters of all other chemical substances will have the option to report the existing CDR processing and use codes that were used in 2016 and prior cycles, but can instead choose to voluntarily report using the OECD harmonized codes if applicable and if their own tracking systems have been updated accordingly. Reporting using the OECD codes will be required for all reporters of processing and use information in 2024.

Harmonizing CDR use codes with the OECD codes expands 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. For example, EPA will have better information to improve the exposure scenarios and other tools used to evaluate both new and existing chemicals. Additionally, this harmonization provides industry with international uniformity in use and exposure information reporting, enabling industry to better streamline their different country-specific reporting requirements.

EPA also recognizes that any time the reporting requirements change, there may be a need for a submitter to adjust its internal systems used to collect such information. This burden is captured in the higher reporting burden estimated for new reporters of the 20 chemical substances designated in 2019 as a high priority for risk evaluation. It is also captured for existing reporters of these 20 high priority chemical substances following a change in requirements. Specifically, reporting burden associated with new and changed form completion activities are

applied to all reporters (new and experienced) in the first cycle. The same unit burdens are also applied to new reporters only in future cycles.

Regarding a chemical substance with multiple functions in the same product, EPA has included the language similar to the following in the Instructions for Reporting:

> If the chemical substance has multiple functions within the same product, you can report that in one of two ways: 1) If one function is predominant, you can simply report the primary function; or 2) If all functions represent a substantial portion of the product, you can report each on a separate line and bifurcate the percent production volume equally across the functions (so as not to double or triple-count the percent production volume for the one product) or estimate the portions individually.
>
> For example, Citric acid (CASRN 77-92-9) may be reported by one site as:

| Product Category | Functional Use | Percent Production Volume |
|---|---|---|
| CC116-Dishwashing detergent (liquid/gel) | F073-Cleaning agent | 25% |
| | F043-Fragrance | 15% |
| | F065-Processing aids not otherwise specified | 15% |
| | F079-Viscosity modifiers | 10% |
| CC109-All-purpose liquid cleaner/polish | F073-Cleaning agent | 12% |
| | F064-pH regulating agent | 10% |
| | F065-Processing aids not otherwise specified | 8% |
| | F043-Fragrance | 5% |

***8. Summary:*** One commenter strongly recommended training webinars and guidance for manufacturers and formulators about the new OECD codes, suggesting case studies similar to the CDR byproducts and recycling guidance EPA has issued in the past. The commenter explained that "This is particularly important now that companies will have many more options to choose from among the OECD codes."

***Source:*** 0321-0098

***Response:*** EPA appreciates the comment and recognizes that the regulatory community would benefit from training webinars and guidance on the changes made for the 2020 CDR and CDR rule more generally. EPA intends to host a series of webinars before reporting begins. EPA will begin hosting webinars prior to the 2020 reporting period, in which EPA will provide an

overview of requirements for the next reporting, as well as topic-specific webinars for importers and co-manufacturers. EPA intends to begin hosting webinars beginning February 2020 on a monthly basis though the beginning of the reporting period to provide ample opportunity for reporters to engage. Additionally, EPA will provide new guidance and update existing guidance documents ahead of the 2020 reporting period. Dates for training webinars and updated guidance material will be posted online at www.epa.gov/cdr.

***9. Summary:*** One commenter did not support EPA's proposal to use the CDR instructions "as the vehicle for converting to the use of the OECD's 2017 product use, function, and article codes," citing the length of the instructions and identifying that the Instructions document contains a qualifier that it is not a substitute for the CDR rule in 40 Part 711. The commenter stated that including the CDR codes in the Code of Federal Regulations would promote transparency, require a rulemaking process to update the codes, and could facilitate the Agency's responsiveness to suggestions for "the need to eliminate or consolidate codes now and in the future, since it is important to limit the codes to only those relevant for CDR reporting."

***Source:*** 0321-0108

***Response:*** EPA agrees with the commenter's suggestion and will codify the codes in the Code of Federal Regulations, such that the new codes are treated in a similar fashion to the codes for other CDR data elements.

***10. Summary:*** One commenter suggested an update to the function code U040A, to enable its use for the base metal in an alloy. Currently code U040A is defined as Alloying Element – Chemical substances that are added to materials/metals to modify properties such as strength, hardness, or to facilitate treatment. The commenter stated that aluminum, when used in an aluminum alloy, is not "added to materials/metals" but rather is the material/metal. As proposed, a submitter reporting for an imported alloy will need to continue to use U999A (other) and include a comment like "Structural component of an alloy." The commenter suggested addressing this by updating the U040A code description to be "Alloys – Chemical substances that are a combination of materials/metals formulated for specific properties such as strength, hardness, or to facilitate treatment."

***Source:*** 0321-0101

***Response:*** EPA agrees with this comment and is updating the definition for code U040A (revised to code F100) to read: Alloys – Chemical substances that are a combination of materials/metals formulated for specific properties such as strength, hardness, or to facilitate treatment.

***11. Summary:*** One commenter suggested EPA will get stronger data by allowing chemical distributors to voluntarily report the processing and use codes. The commenter stated that the proposed codes may be too specific to be reported effectively by chemical distributers, and that mandatory reporting would result in "best guess" since the exact final use is determined by the end-user or customer. The commenter further suggested that the requirement to designate from current 35 codes is more feasible than designating from 117 codes. In addition, another commenter explained that, "We think that function and use are important additions but [have] concerns that upstream manufacturers will not have robust understanding of function and that this could possibly impact the quality of information provided."

***Sources:*** 0321-0097, 0321-0098

***Response:*** EPA recognizes that some manufacturers may have less knowledge than other manufacturers about the downstream processing and use of their reported chemical substances. The reporting standard for CDR is to report to the extent the information is "*known to or reasonable ascertainable by*" the submitter, including 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. As described in the Instructions for Reporting, submitters are to exercise certain levels of due diligence in gathering the information required by the CDR rule and, if the knowledge is *not known or reasonably ascertainable*, to indicate so on the reporting form by selecting "NKRA." See the Instructions for Reporting for examples (Ref. 2).

EPA recognizes that downstream processors and users may have better knowledge of the functions and uses than the chemical manufactures, but the Agency is balancing the need to minimize reporting burden with maintaining the ability to receive the information needed to understand potential chemical exposures. The CDR database provides a high-level picture into the chemical industry, helping the EPA identify trends with certain chemicals and trends in the chemical industry. The Agency relies on this information as a starting point for prioritizing and evaluating chemical substances under section 6 and conducts supplemental research and data collection to further understand the processing and use of a chemical substance.

***12. Summary:*** Three commenters provided statements discussing how certain processing and use information should or should not be combined for reporting under CDR. Two of the commenters stated that EPA should revise the Form U to separate consumer and commercial uses. One of the commenters suggested requiring the separate identification of consumer or commercial by subdividing question b in Part III.B. of Form U into two boxes – one for commercial uses and the second for consumer uses. The other commenter suggested splitting the consumer and commercial product list into separate lists of consumer products and commercial products. This commenter stated that such separation would further simplify the task of reporting. Both commenters stated this would improve the Agency's ability to assess exposure, one noting that "EPA has acknowledged that it lacks the ability to determine whether the downstream uses of chemicals reported by manufacturers include consumer applications, commercial applications, or both when assessing the Work Plan chemicals." One of the commenters noted that the consumer and commercial uses "are not necessarily fungible uses in

terms of use or exposure potential" and stated that not all of the product and article use categories EPA proposed are likely to result in exposures, referencing the OECD 2017 guideline at p. 28. Both commenters agreed with combining the OECD separate lists of product and article codes, while a third commenter stated the product and article codes should remain separate, to retain consistency with the OECD lists.

***Sources:*** 0321-0100, 0321-0107, 0321-0108

***Response:*** The current requirement is to indicate whether the chemical substance is used, for a particular product category, in consumer uses, commercial uses, or both consumer and commercial uses. EPA believes this achieves the majority of the separation sought by the commenters. In addition, EPA also believes that there is a large overlap such that many products can be both consumer and commercial. For example, many products used by a day care operation (commercial use) would also be used by a household (consumer use). For this reason, EPA also does not believe separate lists for consumer and commercial products is necessary.

***13. Summary:*** One commenter suggested changes to the reporting of information relevant to children's exposures under the CDR to (1) expand reporting to include identification of chemical substances *known or reasonably ascertainable* to be used in products that children may use, that children may be exposed to as bystanders, and that pregnant women may be exposed to and (2) expand reporting to include processors of any such chemical substance. The commenter stated that this information was needed to address TSCA requirements to identify, evaluate and mitigate risks to "potentially exposed or susceptible subpopulations," a term that is defined as including "infants, children [and] pregnant women." 15 U.S.C. § 2602(12).

***Source:*** 0321-0107

***Response:*** This comment is out of scope for this rulemaking. The definition of the children's use data element was carefully considered when it was added as part of the IUR Amendments rule (68 FR 848, January 7, 2003). EPA is working on a variety of data collection efforts outside of CDR to obtain information that is reasonably available for future activities under TSCA, including information useful to address potentially exposed or susceptible subpopulations.

***14. Summary:*** Two commenters supported including all of the OECD harmonized codes, even if those uses are not considered TSCA uses. One of the commenters discouraged EPA from including non-TSCA uses and encouraged EPA to be precise about which codes to list without being over-inclusive or under-inclusive. This commenter supported the use of the catch-all "non-TSCA" code for the OECD codes that do not correspond with TSCA, specifically requesting "to exclude the use of the OECD code for articles intended for food contact." The other commenter supported EPA requiring the use of all OECD codes, including those for non-

TSCA uses, explaining that "exposures from non-TSCA uses add to the baseline exposures that help to determine the extent of risk presented by exposures from the TSCA uses EPA is required to assess and mitigate" and noting that "EPA has said that it may consider these non-TSCA uses in its section 6 risk evaluations as background exposures. *See, e.g.*, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,735 (Jul. 20, 2017)."

***Sources:*** 0321-0107, 0321-0108

***Response:*** As described in the Risk Evaluation Rule cited by the commenter, knowledge of the potential risks of non-TSCA uses may help inform the Agency's risk evaluation for the exposures from uses that are covered under TSCA (e.g., as background exposures that would be accounted for, should EPA decide to evaluate aggregate exposures). EPA will retain the general non-TSCA code (CC990) and will not list separately the specific OECD codes designed for non-TSCA uses. Substances exempted in TSCA section 3(2)(B) are considered non-TSCA uses and do not need to be reported; these include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide; any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code.

Regarding the two codes associated with food contact, EPA agrees with the commenter and is consolidating both C206A (Articles for food contact, including metal articles) and C301A (Articles intended for food contact including paper articles; plastic articles (soft); plastic articles (hard); rubber articles; metal articles; fabrics, textiles, and apparel) with CC990, (Non-TSCA use). Although articles that fit within these two food contact associated codes may be used for purposes other than for food contact, EPA believes CC980 (Other (specify)), the code for all other uses not described by the 94 specific consumer and commercial product categories, will be sufficient to capture those articles that may be used for both TSCA and non-TSCA uses.

As explained in the proposal, chemical substances may be manufactured that are used for both TSCA and non-TSCA uses. In such instances, the manufacturer should report the manufactured quantity intended for the TSCA use and not report the quantity that is exempt from TSCA in section 3(2)(B). For past reporting cycles, several manufacturers have chosen to report downstream processing and use information for non-TSCA uses. If a company chooses to provide information on such non-TSCA uses, they may use the general non-TSCA code.

**B.1.1. Adding function code**

***15. Summary:*** EPA received three comments supporting adding a function code to consumer/commercial products. One commenter stated that collecting this information through CDR is "consistent with the heightened focus in TSCA on conditions of use and the need to provide EPA with tools to collect information on exposure and use," and further noted that this information may enable program efficiencies later and that…[it]… better informs prioritization and risk evaluation decisions." Another commenter noted that the consumer and commercial information, including the function information, "will be useful when characterizing the composition of consumer products and developing exposure scenarios for consumer products." This commenter noted that there is no comprehensive source of information on the functional use of chemical ingredients used in consumer product and article categories.

***Sources:*** 0321-0088, 0321-0107, 0321-0108

***Response:*** EPA appreciates these comments and is finalizing the requirement to report the functional use categories for both industrial and commercial/consumer products. Reporting by OECD function, product, and article codes will be required for manufacturers (including importers) of the chemical substances designated in 2019 as a high priority for risk evaluation under TSCA section 6(b) (84 FR 71924, December 30, 2019). Reporters of all other chemical substances will have the option to report the existing CDR processing and use codes that were used in 2016 and prior cycles, but can instead choose to voluntarily report using the OECD harmonized codes if applicable and if their own tracking systems have been updated accordingly. Reporting using the OECD codes will be required for all reporters of processing and use information in 2024. Harmonizing CDR use codes with the OECD codes expands 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, such as by enabling improvements to exposure scenarios used in such activities. 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.

***16. Summary:*** EPA received two comments on requiring the secondary submitter to include the function of the chemical as part of its portion of the joint submission. One commenter explained that requiring this information in each CDR joint submission may require significant time to complete. The commenter suggested, "EPA should include the option to report either the function of the imported product (as traditionally done), or the chemical-specific function, without requiring information on the chemical composition of the imported product or mixture." The other commenter supported EPA's proposal to add this reporting requirement.

***Sources:*** 0321-0106, 0321-0107

***Response:*** EPA believes any burden associated with the function of the chemical was already accounted for in the burden assessment, because the rule already required reporting of the function of the chemical substance. The change EPA is finalizing enables the secondary submitter of the joint report to provide the function, because the secondary submitter is the

person who knows what chemicals are in the imported product. EPA notes that the secondary submitter already provides the chemical identity(ies) and percentage of each chemical substance in the composition of the substance or mixture that is imported. Without the percentage of the chemical within the product, EPA would not be able to determine the portion of the imported volume to assign to each chemical. 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.). To enhance a submitter's understanding of the regulation, EPA improved the regulatory text to clarify the requirement to report the percentage of formulation for a chemical substance in an imported product to EPA in the regulatory text at 40 CFR 711.15(b)(3)(i)(A).

## B.2. General comments on adding NAICS codes for manufacturing site

**17.** ***Summary:*** EPA received five comments on adding NAICS codes for manufacturing sites. One commenter supported adding NAICS codes for manufacturing sites stating that they understood that the use of NAICS codes would enable EPA to create industry-specific analyses and to use the data in conjunction with TRI to support the implementation of TSCA, identifying that sites that already report through TRI should have no additional burden associated with reporting NAICS codes. Another commenter stated that it supported adding NAICS codes if the information has practical utility in prioritization of chemicals for risk assessment. Three other commenters stated that the inclusion of NAICS codes would increase burden and complexity for reporters. One commenter said that for some reporters, choosing one NAICS code may be challenging, especially with the added complication of replacing existing processing and use codes with OECD codes. The commenter explained that this would be especially complicated for companies with a large number of substances. Another commenter explained that for companies with a diverse product portfolio, choosing a single NAICS code may be challenging. Two commenters highlighted the challenges of reporting imports, particularly those who consolidate imports at the company headquarters.

***Sources:*** 0321-0093, 0321-0098, 0321-0099, 0321-0103, 0321-0106

***Response:*** EPA believes the NAICS code for the manufacturing site will be a valuable data element for future use of CDR data. EPA will use the NAICS code information in its analysis of the reported manufacturing-related information to better analyze the data by industry sector as part of activities to support TSCA implementation. EPA's insight into particular industry sectors has been limited without this particular data element. EPA acknowledges the challenges for some industries in selecting a single NAICS code and will provide guidance on how to do so. For example, an importer of a diverse set of chemical substances may report 325199 (all other basic organic chemical manufacturing).

However, in consideration of the comments received, EPA is providing additional flexibility in the CDR reporting tool that will allow a site to report multiple NAICS codes on a chemical-

specific basis, similar to reporting the technical contact, if the submitter believes there is not a single NAICS that adequately represents the chemicals. The EPA reporting tool will allow a site to report up to three NAICS codes to address the issues of some reporters with selecting one NAICS. Ultimately, EPA believes that the overall burden is a minimal increase compared to the improved quality of industry-specific analyses that EPA can complete.

## B.3. Percent recycled

***18. Summary:*** Three commenters responded to EPA's request for comment on whether submitters should be required to identify the percentage of total production volume of a chemical substance that is recycled instead of only designating whether the recycling occurred. One commenter was concerned that it would be overly burdensome and impractical for the manufacturer to identify this percentage because much of the recycling may be done by downstream customers and users and, because manufacturers would not have such information themselves, the submitter would have to poll its customers. Another commenter questioned whether companies that both manufacture and recycle the reported chemical, such as for substances that are manufactured as both a primary chemical and as a byproduct, might face additional reporting challenges. A third commenter stated that such information would be highly useful to EPA, providing a more robust and granular understanding of a chemical's conditions of use or related potential exposures. This commenter identified a concern with EPA's suggestion that such information would aid the identification of reporting exemptions, stating that there are substantial impacts of chemical exposures from recycling activities.

***Sources:*** 0321-0094, 0321-0106, 0321-0107

***Response:*** After considering the comments and weighing the burden of reporting the data versus the Agency's need for the data for TSCA implementation, EPA determined that the need for information about the percent recycled was insufficient to justify the burden. EPA finalized only the modification to remove "remanufactured, reprocessed, or reused" from the existing data element, retaining the yes/no checkbox. For example, a site that manufactures metals from a variety of sources may have difficulty determining how much is recycled. EPA will consider the issues raised by commenters to improve the Instructions for Reporting to add clarity to what to consider when responding to the yes/no response version of this data element. Although EPA is not finalizing the percent recycle, EPA notes that the concern about the need to poll customers is unwarranted. As with all data reported under CDR, information is to be reported to the extent that it is *known or reasonably ascertainable*. This reporting standard does not require extensive polling of customers, as described in the Instructions for Reporting (Ref. 2).

## B.4. Percent byproduct

***19. Summary:*** Four commenters expressed support for requiring the reporting of the percent production volume that is a byproduct. One commenter expressed support for this data element

to the extent it helps EPA "better understand a larger spectrum of exposure scenarios, by improving understanding of the connection between manufacturing and downstream activities for the purposes of substance life cycle assessments and risk evaluation." Another commenter stated that this information will enable the EPA to identify manufacturers, such as the printed circuit board fabricators, who only report to CDR due to their byproduct production. Two commenters stated that they believed this data element was not necessary. One of those commenters stated that, while they "recognize that the Agency wishes to utilize this information in section 6 prioritization and risk evaluation activities, incorporating the OECD use codes for CDR reporting will provide significant processing and use information for the Agency to fulfill its obligations under TSCA. Congress did not intend that section 8(a) be used to fill every information gap regarding chemical substances in commerce." Another commenter stated that requiring the manufacturer to determine whether that substance qualifies as a *byproduct* as defined by EPA and what portion of product is a byproduct (in the scenario in which the chemical is the primary substance manufactured in some portion of production, but a byproduct in another portion) would be burdensome, without commensurate benefit.

***Sources:*** 0321-0089, 0321-0099, 0321-0100, 0321-0103, 0321-0106, 0321-0107

***Response:*** EPA finalized this data element as voluntary and not required reporting. EPA is adding this data element to become more aware of which industries primarily manufacture byproducts and to be better able to understand a larger spectrum of potential exposure scenarios, for the purposes of chemical substance life cycle assessments and risk evaluation. EPA will use information about the percent byproduct to better understand the manufacturing of byproduct chemical substances and the impact of current or potential future exemptions to reporting. Further information collection on byproduct manufacture may provide additional distinguishing considerations for the assessment of byproduct chemicals versus primary product chemicals. For example, this may inform any potential exposure differentiation between primary chemical products and byproducts. Although having such data would make it easier for the Agency to inform future agency actions, in particular about potential future deregulatory actions for byproduct manufacturers, EPA finalized this as a voluntary data element because of comments received from industry regarding the burden associated with collecting this information.

***20. Summary:*** Two commenters stated that the addition of the percent byproduct data element runs counter to Congress's mandate to the Agency to explore regulatory relief through negotiated rulemaking for manufacturers of byproduct substances that are recycled. One of the commenters also stated that the percent byproduct "is not one of the byproduct exemption considerations, thus violating the [TSCA] section 8(a)(5)(A) prohibition on unnecessary requirements under the CDR. Generating data for the sake of generating data – without having a specific, tangible purpose – is not permissible under the law."

***Sources:*** 0321-0102, 0321-0109

***Response:*** Information about byproduct reporting has been of particular interest recently due to the TSCA section 8(a)(6)(A) requirements to conduct a negotiated rulemaking about inorganic byproducts with the objective of developing a proposed rule providing for limiting the reporting requirements for manufacturers of any inorganic byproducts. During the deliberations of the negotiated rulemaking committee, EPA was unable to specifically identify, from the CDR data, either (1) chemical substances manufactured as byproducts, or (2) byproduct manufacturers who would be impacted by potential changes to the reporting requirements. However, EPA recognizes that collecting this information can be burdensome to reporters. Based on comments received from stakeholders concerned about reporting burden, EPA finalized this as a voluntary data element.

***21. Summary:*** Several commenters stated that reporting the percent byproduct would create complexity and significantly increase burden. One commenter explained: "Reporting the percentages of unintentional byproducts with no commercial purpose in the intended products would be a significant increase in burden. All compositions would have to be reviewed and updated; databases performing the calculations would also need to be updated to ensure the minute volumes of those byproducts are included. Since unintentional byproducts with no commercial purpose are not subject to PMN reporting, these byproducts would have no CAS number assignments and therefore, would be problematic to report." Other commenters expressed similar concerns. One commenter asked that if EPA finalizes this data element, "to bifurcate the exemption from the production volume reporting, and delay production volume reporting until the next CDR cycle to provide companies time to identify how best to comply."

***Sources:*** 0321-0093, 0321-0102, 0321-0109

***Response:*** Based on concerns regarding burden and other tools available to the Agency, EPA has finalized this reporting as voluntary. Additionally, EPA is not requiring the reporting of the byproducts within the intended product, which frequently are referred to by industry as contaminants, but rather the byproducts that are manufactured and then separated from the intended product; these byproducts are required to be reported separately unless the production volume is under the reporting threshold or another exemption identified in applies (e.g., see 40 CFR 711.10). Likewise, EPA is not requiring the speciation of waste streams. The definition and interpretation of byproduct under the amended CDR rule continues to be consistent with the requirements under TSCA section 5 (PMN program); that is, a byproduct with a separate commercial purpose that is not exempted by 720.30(g) is subject to regulatory requirements.

***22. Summary:*** One commenter stated that reporting the percent byproduct could force companies to provide confidential business information about the manufacturing process, placing additional burdens on the manufacturer not just to determine this percent and report it, but also to ensure that the information properly receives CBI protection.

***Source:*** 0321-0102

***Response:*** As with any data element, the Agency does recognize that there is burden associated with the need to claim and substantiate the data element as confidential. EPA does not consider the potential need to claim and substantiate a data element as confidential to be a reason not to collect it.

***23. Summary:*** One commenter expressed concerns that EPA is making unstated assumptions that exposure and risk potential for byproducts is inherently lower than chemical products and requested EPA to provide compelling factual basis for byproduct exemptions. Another commenter stated that "it is well-known that byproducts (organic and inorganic) can be important sources of exposure and risk; they therefore should be captured under the CDR rule so EPA can assess their health and environmental impact."

***Sources:*** 0321-0100, 0321-0107

***Response*:** The voluntary collection of percent byproduct is intended to increase EPA's understanding of the chemical industry and does not indicate a predisposition of less or more exposure or risk. EPA is stating that there may be certain conditions in which a byproduct chemical is manufactured, processed, or used (including recycled) that may result in lower exposure or risk potential or may be of lower interest to the agency (i.e., in scenarios that meet the criteria for the new exemption for byproducts recycled in site-limited, enclosed systems). EPA agrees that any proposed changes in exemptions for byproducts or other chemicals based on the information collected from this new voluntary data element will need a compelling factual basis and, as with the current rulemaking, will allow for public comment on any future byproduct or other exemption to ensure EPA makes a well-informed decision.

## B.5. Report using a naming convention for providing the parent company name(s)

***24. Summary:*** Two commenters expressed concern about the use of the parent company naming convention. Both commenters expressed that they would like EPA to inform industry of how this proposed change would impact the historic records and record amendments. Both commenters discouraged the requirement to add new instances of existing sites in CDX under the new naming convention. One commenter expressed that it was unclear how mergers and acquisitions would be handled with the new naming convention. The commenter expressed concern over the issue of legacy records, and how for legacy records with multiple instances in CDR, there does not currently seem to be a way to update or consolidate these records.

***Sources:*** 0321-0093, 0321-0098

***Response:*** EPA is establishing a naming convention to prospectively reduce the number of inconsistencies in the CDR database in order to increase the reliability and usability of the data going forward. EPA is not asking submitters to clean up past records; rather, this requirement

begins with the 2020 CDR submission period and will be enforced by the electronic reporting tool (eCDRweb). EPA's practice has been to work extensively with companies after the submission period is completed to make changes similar to those that are now standardized. That effort was burdensome for both submitters and EPA, and resulted in delayed usability of the data for both EPA and the public.

Within CDX, EPA's Central Data Exchange, companies register sites and not parent companies. A site's address is stored in EPA's Facility Registry Service (FRS) and when the site initiates a site report, its address is downloaded into the reporting tool from the FRS database. Site names cannot be changed within the reporting tool, but they can be adjusted, if necessary, within CDX. Although it would be useful to have site names follow similar conventions, EPA did not propose to mandate the use of these conventions for site names. EPA does encourage submitters, if entering a new site into CDX, to make use of the naming conventions.

Regarding mergers and acquisitions, EPA recognizes that the reported parent company for a particular site may change from one reporting period to another. If a company or site name changes as a result of new ownership, instead of simply updating the company and/or site name, a new facility should be created within CDX.

## B.6. Would PV in ranges reduce burden for submitters?

***25. Summary:*** In response to EPA's general request for comment regarding reporting any of the production volumes in ranges, two commenters supported reporting production volumes in ranges instead of to two significant figures. Both commenters stated that allowing for the reporting of the production volume in ranges would reduce the burden on reporters while still providing the information that EPA needs to implement TSCA. One reporter emphasized that this would be helpful for the reporters of coal combustion residual (CCR) inorganic byproducts that are recycled.

***Sources:*** 0321-0104, 0321-0109

***Response:*** EPA appreciates the feedback on whether it would reduce burden for reporters if the option were available to report in ranges instead of two significant figures. Both commenters provided a general statement of support but did not indicate what types of ranges would reduce burden while providing EPA with a sufficient level of detail. Upon review, EPA has concluded that reporting to two significant figures in effect is comparable to reporting in ranges. EPA is concerned that reporting in ranges broader than those represented by the current two significant figure approach may be too broad, especially for high production volume substances. When the ranges are too broad, EPA will not be able to complete the analyses needed to effectively implement TSCA.

EPA also asked for comment on how to implement reporting production volume in ranges, for example 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. These implementation concerns were not addressed by the commenters.

EPA did not finalize the option of reporting in ranges instead of reporting to two significant figures.

## B.7. Need for public contact

***26. Summary:*** One commenter stated that a new field for public contact is "not necessary and could be misleading." The commenter explained that the reporter already provides technical contact for each submission, and the purpose of CDR is not a "right-to-know" for the public which would necessitate a direct line of communication between individual companies and the public.

***Source:*** 0321-0089

***Response:*** EPA agrees that CDR is not explicitly a "right to know" rule and notes that the primary purpose of CDR data is for the Agency's use in implementing TSCA. However, EPA was concerned that the CDR information provided for public use could be incorrectly interpreted by the public. The intent of the public contact was to provide an additional venue for the public to ask questions about the data, when the technical contact information is not available. Because EPA did not receive any supportive comments on this voluntary data element, EPA reconsidered the balance of burden to report the data and anticipated benefit and did not finalize its addition.

## B.8. Co-manufacturing Reporting Methodology Comments

***27. Summary:*** Four commenters supported EPA's proposal to develop a joint submission mechanism for the reporting of co-manufactured chemicals, stating that it would standardize and simplify the CDR reporting process for such situations and would help facilitate protection of confidential information between the contracting and producing companies. Three of the commenters also requested that EPA adopt a flexible approach to allow reporting by the producing company on behalf of both parties, as long as both parties agree with this approach. One commenter stated that this agreement should be by contract in writing and include the accuracy of the report to be submitted.

***Sources:*** 0321-0093, 0321-0096, 0321-0098, 0321-0106

***Response:*** EPA agrees with the suggestion to enable greater flexibility in reporting for co-manufactured chemicals, including allowing reporting by the producing company on behalf of both parties. EPA recognizes that there are many different relationships among the parties participating as co-manufacturers and has established reporting responsibilities to give a large

amount of flexibility. Manufacturers can report their co-manufactured chemicals following either one of two approaches: (1) by separately reporting the respective information known by the contracting and the producing manufacture or (2) by working together, with a written agreement and the producing company submitting the report. EPA believes allowing this flexibility provides submitters with the ability to provide EPA with improved information. However, in either case, both the contracting company and producing company are liable if no report is made.

EPA agrees with the comment that, if the second approach is used where the producing company submits the report, the agreement between the contracting company and the producing company should be by contract in writing; however, EPA would not be a party to any such contractual agreement. The commenter also suggested that the written agreement specify the accuracy of the report to be submitted. EPA notes that the CDR reporting standard is that information is to be reported to the extent that it is *known or reasonably ascertainable*. Because both the producing and contracting companies are involved in the single report to be submitted by the producing company, the reporting standard encompasses the knowledge of both parties.

***28. Summary:*** One commenter was concerned that joint submissions could be inadvertently edited by both submitters, which included creating/deleting sites for the other company outside of the joint submission. The commenter encouraged EPA to limit the functionalities to protect the security of both companies' information.

***Source:*** 0321-0098

***Response:*** EPA has taken steps to address the issue that occurred with co-manufacturing joint submissions during the 2016 CDR submission period. At that time, either entity, whether the producing company or the contracting company, could initiate the joint submission using the producing company's site address. The CDR Revisions final rule addresses this issue by having each entity separately initiate its own portion of the report, using its own site address. The contracting company now has a place in its report to indicate the producing company's site. EPA is also allowing the producing company to report all of the information for the co-manufactured chemical by working with the contracting company to gather the information the contacting company would have reported using the new joint submission process.

Note, however, that a submission could still be edited by multiple parties if the users were both registered for the same organization and site, one of the users was an Agent or assigned Support for a primary Authorized Official, and if the users had the passphrase. Although the CDR Revisions final rule has addressed this issue for co-manufactured chemicals, it may still be a concern for sites that were sold if there is confusion about which company is responsible to report under CDR. EPA encourages Authorized Officials to carefully manage the users that are registered within CDX for access to their site.

## C. Confidentiality Related Comments

### C.1. TSCA 14(b)(3)(B) not CBI

***29. Summary:*** Several commenters disagreed with EPA's assertion that TSCA section 14(b)(3)(B) bars confidentiality claims for selected processing and use data in CDR submissions. The commenters observed that Congress used the phrase, "does not prohibit disclosure," in TSCA section 14(b)(3) instead of affirmative language, such as "the following information is not protected from disclosure" or "EPA shall make public, upon request, the following information." One commenter stated that the plain meaning of the phrase "does not prohibit" in this context is that the Agency has the discretion to disclose the general information described in TSCA section 14(b)(3)(B), but it is not mandated to do so by the express language of the statute. Two commenters stated that EPA should read TSCA section 14(b)(3)(B) to create a rebuttable presumption that the information discussed in this subsection should be made public. Companies should then be allowed to make a claim for CBI protection and substantiate it. If EPA agrees that this information should be protected after reviewing the substantiations, then the general provisions governing CBI should apply.

***Sources:*** 0321-0102, 0321-0106, 0321-0108

***Response:*** The language "does not prohibit disclosure" in section 14(b)(3)(B) makes information described by that provision ineligible for confidential protection. Section 14 of TSCA defines what is eligible for confidential protection, providing that EPA "shall not disclose information" falling within the confidentiality exemption to the Freedom of Information Act that is reported to or otherwise obtained by the Administrator under TSCA, and for which the requirements of TSCA section 14(c) are met. TSCA section 14(b), entitled "Information not protected from disclosure," including subsection (b)(3), entitled "Other information not protected from disclosure," describes categories of information that are not entitled to the protections from disclosure afforded to CBI under TSCA section 14. TSCA section 14(b)(3)(B) plainly bars confidentiality for information within that category.

Because the statute precludes confidentiality for this information, EPA chose in the final rule to bar submitters from asserting CBI claims for this information. Barring the assertion of CBI claims for specific CDR data elements that categorically cannot be protected as CBI under the statute provides certainty to CDR submitters regarding the information's non-confidential status and creates administrative efficiencies by avoiding the unnecessary expenditure of EPA resources to review and deny CBI claims for information that is clearly not entitled to protection from disclosure under the statute.

EPA disagrees with the commenters who interpret TSCA section 14(b)(3)(B) as allowing EPA to protect such information from disclosure as CBI in the exercise of the Agency's discretion and/or on a case-by-case basis.

EPA agrees with one of the commenters that TSCA section 14(b)(3) does not itself require the Agency to proactively make public information within that category. However, where EPA has determined that information falls within TSCA section 14(b)(3), other authorities may require

that the information be made available to the public. See, e.g., TSCA section 14(b)(5). In any event, EPA may exercise its discretion to make information public (without applying one of the exceptions to protection from disclosure listed in TSCA section 14(d)) where the Agency has determined that the information is not confidential under TSCA section 14.

***30. Summary:*** Two commenters supported barring confidentiality claims for general information on chemicals' processes, functions and uses, and other commenters agreed that such fields would not typically be considered confidential. Nevertheless, some commenters asserted that there were circumstances in which such information could potentially reveal specific information on manufacturing and use that is eligible for confidential treatment. The commenters stated that with expansion to the more specific OECD-based codes there is greater potential for some combinations of codes to reveal specific and unique use information that may be considered confidential, and that submitters should be able to substantiate these as confidential in unique situations. One commenter urged the Agency not to disclose function and use codes without first considering whether, in any given single case (such as a market with a small number of participants), disclosure would turn out to reveal specific information on manufacturing and use that is entitled to CBI protection without substantiation, because it would provide a competitive advantage to others through public release. Another commenter stated that chemical function, especially in consumer and commercial products, is more likely to be used in a unique way.

***Sources:*** 0321-0093, 0321-0098, 0321-0100, 0321-0102, 0321-0106, 0321-0107, 0321-0108

***Response:*** EPA believes that certain processing and use information collected under CDR is the type of general information covered by TSCA section 14(b)(3)(B) and is therefore ineligible for CBI protection. This bar would cover all responses to 40 CFR 711.15(b)(4)(i)(A), (B) and (C) and (ii)(A), (B), (C) and (D). All of these data elements are reported through the use of generic category codes or other multiple-choice responses that provide "a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance" within the meaning of TSCA section 14(b)(3)(B). Concerning the assertion that the processing and use codes in combination might identify a specific and unique use or function, the commenters did not provide an example illustrating how combinations of generic category codes could reveal specific information about a use, function, or application, as opposed to a general description; nor was EPA able to identify any examples. EPA notes that submitters retain the ability to protect confidential business information by asserting a CBI claim for a site, company, or technical contact identity where the linkage of that information to a reportable chemical substance is confidential and not publicly available.

***31. Summary:*** Two commenters agreed with EPA 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)." These processing and use data elements include percent production

volume, number of sites, number of workers, and maximum concentration. A third commenter stated that other data elements – such as the physical form of the reported chemical and whether the reported chemical is site-limited or produced as a byproduct – qualify as "general" processing information under TSCA section 14(b)(3)(B) that cannot be withheld from disclosure. A fourth commenter stated that the number of workers potentially exposed data element qualifies as a general description under TSCA section 14(b)(3)(B) because the data element is reported in ranges. This commenter also noted that while EPA's proposed rule preamble discussed barring CBI claims for the data element indicating presence in or on products intended for use by children (children's use) pursuant to TSCA section 14(b)(3)(B), this data element was not barred from CBI claims in the proposed regulatory text. The commenter requested that EPA correct this apparent error and bar CBI claims for that data element because it constitutes a general description of use under TSCA section 14(b)(3)(B).

***Sources:*** 0321-0100, 0321-0102, 0321-0107, 0321-0108

***Response:*** EPA agrees with the two commenters that processing and use-related data elements, such as percent production volume, number of sites, and maximum concentration, are not "a general description of a process used in the…processing [or] industrial, commercial, or consumer functions and uses of a chemical substance" that always should be barred from CBI protection under TSCA section 14(b)(3)(B). Although at least some of these data elements might be considered "general" information, they do not constitute a general description of a process. Regarding the fourth commenter's assertion that the data elements pertaining to number of workers are ineligible for CBI status, EPA believes that these data elements do not constitute a "general description of a *process* (emphasis added) used in the manufacture or processing" of a chemical substance, or of "industrial, commercial, or consumer functions and uses of a chemical substance." The commenter provided no support for why they might be considered *process* information. The fact that the information would be provided via a range might support the notion that it is a general description, but it does not support the notion that it would be a "general description of a process."

Regarding the comment that CBI claims should be barred under TSCA section 14(b)(3) for data elements such as physical form and reporting percent byproduct, EPA also does not believe that this information would qualify as a "general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance or mixture or article."

Regarding the children's use data element, as EPA discussed in the preamble to the proposed rule (84 FR at 17699), the Agency agrees that whether a chemical substance is present in or on products intended for use by children constitutes a general description under TSCA section 14(b)(3)(B). EPA inadvertently excluded this data element from the proposed codified list of barred data elements in the proposed regulatory text at 40 CFR 711.30(a)(2)(iii) and has corrected the cross-references in the final regulatory text to bar CBI claims for information indicating whether a reportable chemical substance is present in or on products intended for use by children.

Regarding the comment that CBI claims should be barred under TSCA section 14(b)(3) for a data element indicating whether a chemical substance is site-limited, the comment is unclear regarding which data element(s) the commenter intended to reference. In the past, EPA replaced the site-limited data element with a different data element, one which asks for the volume of the manufactured chemical that is used on site. EPA does not believe that a data element that requests specific volume information could be considered general.

***32. Summary:*** A commenter asserted that confidentiality claims should be barred under TSCA section 14(b)(2) for the children's use and number of workers data elements on the grounds that they meet the definition of a "health and safety study." The commenter quoted the definition of "health and safety study" at 40 CFR 720.3(k), which includes: "(iii) Assessments of human and environmental exposure, including workplace exposure" and "(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." The commenter asserted that the children's use and number of workers data elements meet this definition of a "health and safety study" because they are key elements of any assessment of human or workplace exposures and are a measure of the exposure of humans or the environment to a chemical substance or mixture.

***Sources:*** 0321-0107

***Response:*** As explained in the previous comment response, EPA notes that the children's use data element is already barred from CBI claims in the CDR data collection based on TSCA section 14(b)(3)(B).

TSCA section 14(b)(2) limits the circumstances in which information from a health and safety study submitted under TSCA can be protected as CBI. TSCA section 3(8) defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter." As noted by the commenter, EPA regulations applicable to premanufacture notification list as examples of health and safety data, "[a]ssessments of human and environmental exposure," and "[m]onitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." 40 CFR 720.3(k). Neither a CDR submitter's estimate of the number of workers reasonably likely to be exposed to a substance, nor a CDR submitter's indication of whether a substance is used in or on consumer products intended for use by children, would constitute "[a]ssessments of human . . . exposure" within the meaning of 40 CFR 720.3(k), because this information does not include measurements of a chemical's concentration that have been analyzed to draw conclusions about human exposure. Compare, e.g., 47 FR 38780, 38782 (September 2, 1982) ("When measurements of a chemical's concentration have been analyzed to draw conclusions about occupational or environmental exposure, a 'health and safety study' has been done."). Nor has this information been "aggregated and analyzed to measure the exposure of humans . . . to a chemical substance" in any CDR submission, even if any of the

information submitted were originally derived from some form of monitoring data. Indeed, EPA has explained in a prior Federal Register publication that "daily or routine monitoring records" "are not by themselves treated as studies." 47 FR at 38786. While information from a CDR submission might theoretically be used one day as a piece of underlying data for some future health and safety study, the information is neither a "health and safety study" itself nor "underlying information" from a health and safety study when submitted to EPA under the CDR rule.

***33. Summary:*** A commenter requested that EPA treat function and use codes as voluntary submissions if received directly from processors and users as part of a joint submission. The commenter stated that because this information would be voluntarily submitted and TSCA section 8(a) does not require the disclosure of the function and use information, it could be eligible for confidential treatment under 40 CFR 2.208 if the other criteria for confidentiality are met.

***Source:*** 0321-0108

***Response:*** EPA uses CDR data to support initial risk screening, assessment, priority setting, and risk management activities under TSCA. Only manufacturers (including importers) are subject to the rule. EPA is not accepting CDR submissions directly from processors or users (either independently or as part of a joint submission). Processing and use information reported under CDR is reported to the extent that it is *known to or reasonably ascertainable by* the manufacturer, with instructions that specifically state that surveys or similar communications with customers is not necessary (Ref. 2). In the future, EPA could consider obtaining information directly from processors for more targeted efforts than the full CDR collection; at this time, however, EPA considers enabling the submission of such data unnecessary for the full CDR collection, particularly in light of the associated burden increase.

***34. Summary:*** Two commenters requested that EPA give companies the opportunity (1) to correct any potential issues or (2) respond to any potential concerns about the substantiation before the Agency makes an adverse confidentiality determination. The companies stated that EPA should not create a framework where the only recourse would be to file a complaint in federal district court within thirty days of an adverse determination and requested that EPA work with companies to develop a better system.

***Sources:*** 0321-0102, 0321-0108

***Response:*** EPA disagrees with this comment. TSCA section 14(g)(1) requires that EPA complete its review of certain confidentiality claims not later than 90 days after receipt of the claim. A regulatory provision giving claimants an opportunity to submit additional or revised substantiations after EPA's initial claim review could significantly impede the Agency's ability to meet its statutory 90-day deadline for completion of such reviews. It is the submitter's

responsibility under TSCA section 14 to provide sufficient information upon submission to allow EPA to make a determination on the validity of the CBI claims. The regulations and the e-filing software have been updated to ease submitter burden while also eliciting sufficient facts from the submitter to allow for an Agency determination. Moreover, EPA believes that the statutory process outlined in TSCA section 14(g)(2) for appealing the Agency's denial of a CBI claim is sufficient to ensure that information which should be protected from disclosure under TSCA section 14 is not inappropriately disclosed.

***35. Summary:*** One commenter asserted that EPA should use greater care in the language it uses to describe what the statute requires and what EPA requires as an interpretation of the statute. The commenter specifically objected to one statement in the proposed rule preamble that described up-front substantiation of CBI claims as a requirement under TSCA section 14(c)(3), rather than as a requirement imposed by EPA.

A second commenter stated that the proposal to explicitly require upfront substantiation was in accordance with section 14(c)(3) requirements and was a positive if overdue step toward implementing the 2016 CBI reforms.

***Sources:*** 0321-0100, 0321-0106

***Response****:* EPA noted in the proposed rule preamble, 84 FR at 17698, that "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," and referred the public to the Agency's formal announcement of this interpretation in the January 19, 2017 publication of the Federal Register (82 FR 6522). The final rule codifies EPA's 2017 interpretation of TSCA section 14(c)(3) as requiring up-front substantiation of all CBI claims that are not exempt from substantiation under TSCA section 14(c)(2).

***36. Summary****:* One commenter supported the EPA's proposal to exclude from upfront substantiation requirements only specific production volume and certain supplier information associated with joint submissions. Three commenters asserted that all volumes provided to EPA (e.g., manufactured volume, imported volume and volume used on site and exported volumes) contain specific production volume information that is highly sensitive in nature and therefore the Agency should exempt these data elements from substantiation requirements and afford submitters automatic confidentiality protection. These commenters stated that release of production volume information for any of these elements could result in reverse engineering of volume information and substantially harm businesses in a competitive global economy.

***Sources:*** 0321-0093, 0321-0098, 0321-0106, 0321-0107

***Response:*** EPA disagrees with the comment that any data element referencing a volume is exempted from substantiation requirements by TSCA section 14(c)(2)(G), which exempts from

substantiation requirements "[s]pecific production or import volumes of the manufacturer or processor." The provision does not discuss the uses of portions of the production volume, e.g., volume used on site or volume exported. EPA believes the statutory language is clear and declines to read in additional exemptions for data elements that describe where portions of the total production and/or import volumes are used, as opposed to the "[s]pecific production or import volumes" themselves. Companies may still claim such information as confidential, but the information is not categorically exempt from substantiation under TSCA section 14(c)(2)(G).

***37. Summary:*** A commenter supported EPA's proposal to exempt certain supplier information associated with joint submissions from upfront substantiation pursuant to TSCA section 14(c)(2) but disagreed that a chemical's trade name is part of the supplier information. The commenter stated that trade names are not mentioned among the eligible chemical identifiers denoted in TSCA section 14(c)(2)(G); they are not included in EPA's online guidance for what elements qualify as exempt in either CDR Form U's or PMNs; and by their very nature trade names are shared in commerce. The commenter asserted that EPA should strike references to trade names from the provision proposed to be codified at 40 CFR 711.30(a)(3).

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. Trade names are directly linked to a particular entity and in this instance a supplier. Although a trade name typically may be expected to be public, its use in CDR reporting will help identify a relationship between two parts of a joint submission (either the importer and its foreign supplier or the contracting company and its producing company). Therefore, in the specific context of a joint CDR submission, EPA believes that the trade name is exempt from upfront substantiation as "[i]nformation identifying a supplier" under TSCA section 14(c)(2)(C). EPA also notes that the statutory provision referenced by the commenter, TSCA section 14(c)(2)(G), is specifically associated with TSCA section 5 and the period of time prior to the date on which a chemical substance is first offered for commercial distribution, and is therefore immaterial to reporting under CDR.

***38. Summary:*** One commenter asserted that public access to CDR Form Us has been limited because of the large amount of reported data redacted based on CBI claims and this information is vital for public understanding of chemical manufacturing. The commenter's experience is that the claims are unwarranted.

***Source:*** 0321-0100

***Response:*** One of the goals of the CDR revisions rule is to codify new TSCA section 14 requirements pertaining to the assertion, substantiation, and certification of CBI claims. The Agency expects that the revisions will help ensure that claims are well considered and consistent with the parameters of the law, help to discourage submitters from asserting

frivolous claims, and facilitate EPA's timely review of CBI claims pursuant to the new TSCA section 14 provisions. To address the CBI review requirements of TSCA section 14(g), the Agency has been refining the CBI review processes to include better crafted substantiation questions and timely Agency determinations on CBI claims.

***39. Summary:*** One commenter stated that EPA has not codified the correct substantive criteria for review of CBI claims by its reference to 40 CFR part 2 in the regulations at 40 CFR 711.30(a)(1), because confidentiality claims must meet both the substantive criteria codified in 40 CFR 2.208 and the additional requirements of TSCA section 14(c). The commenter asserted that the Agency had failed to codify the requirements of TSCA section 14(c), noting that TSCA section 14(c)(1)(B) requires that confidentiality claims be accompanied by certain factual assertions that EPA must ensure have been adequately substantiated when reviewing CBI claims.

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. EPA has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule. Moreover, the CDR revisions rule properly codifies requirements of TSCA section 14(c) by requiring CBI claimants to assert any claims at the time of submission, to include the statement required under TSCA section 14(c)(1)(B), to substantiate all CBI claims that do not fall within an exemption described in TSCA section 14(c)(2), and to certify that the required statement and any information submitted to substantiate a claim are true and correct.

***39a. Summary:*** The commenter asserted that TSCA section 14(c)(1)(B)(ii) (requiring claimants to state that they have "determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law") is more demanding than the standard under 40 CFR 2.208(d) (requiring that "[n]o statute specifically requires disclosure of the information") because Federal law encompasses federal regulations and rules as well as statutes, and because the statutory phrase "or otherwise made available to the public" sweeps more broadly than disclosure standing alone.

***Source:*** 0321-0107

***Response:*** EPA has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule.

***39b. Summary:*** The commenter asserted that EPA's substantive standard at 40 CFR 2.208 fails to capture the TSCA section 14(c)(1)(B)(iv) requirement that a person have "a reasonable basis to believe that the information is not readily discoverable through reverse engineering."

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. EPA has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule.

***39c. Summary:*** The commenter asserted that EPA should not rely on a cross-reference to 40 CFR part 2 to codify the TSCA section 14(c)(1)(B)(iii) requirement that a person have "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person," because the cross-reference to EPA's general FOIA regulations in 40 CFR part 2 may become inaccurate in the near future. The commenter noted that on June 24, 2019, the U.S. Supreme Court held in *Food Marketing Institute v. Argus Leader*, 139 S. Ct. 2356 (2019), that a showing of substantial harm to a person's competitive position is not required for confidentiality under FOIA Exemption 4. The commenter noted that this decision likely has significant implications for EPA's general FOIA regulations in 40 CFR part 2, but has no effect on the TSCA section 14(c)(1)(B)(iii) competitive harm requirement.

***Source:*** 0321-0107

***Response:*** In light of the recent Supreme Court decision in *Argus*, EPA is considering whether revisions are warranted to EPA's substantive review criteria for CBI claims not submitted under TSCA. However, EPA is not removing the "substantial competitive harm" substantiation question for the TSCA CBI claims addressed in this rulemaking, because Congress amended TSCA section 14 in 2016 to, among other things, specifically require any person asserting a CBI claim under TSCA to include a certified statement that the person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." TSCA section 14(c)(1)(B)(iii), (c)(5); see also TSCA section 14(c)(1)(C)(ii)(II) (referencing substantial competitive harm).

EPA disagrees with the commenter that the cross-reference to 40 CFR part 2 would become inaccurate if EPA were to later revise the substantive review criterion at 40 CFR 2.208(e) for CBI claims not submitted under TSCA. Any future amendment to 40 CFR 2.208 in light of *Argus* would be accompanied by a conforming amendment to the TSCA-specific standard at 40 CFR 2.306(g) to ensure that the TSCA-specific standard still requires a substantiation that the submitter has a reasonable basis to conclude that disclosure of the information would result in substantial harm to their competitive position. Thus, the reference to 40 CFR part 2 that EPA is finalizing in the regulation at 40 CFR 711.30(a)(1) is not expected to become inaccurate.

***39d. Summary:*** The commenter further objected to EPA's cross-reference to 40 CFR part 2 because the current regulation at 40 CFR 2.208 does not always require a person to meet the TSCA section 14(c)(1)(B)(iii) requirement that a person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." Specifically, 40 CFR 2.208(e) provides that a person "*either"* must show "that disclosure of the information is likely to cause substantial harm to the business's competitive position or [that] [t]he information is voluntarily submitted information (see § 2.201(i)), and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future." 40 CFR 2.208(e) (emphases added).

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. Information collected through CDR is never "voluntarily submitted information." Moreover, EPA has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule.

***40. Summary:*** One commenter supported some of the proposed questions that all CDR submitters asserting CBI claims would be required to answer to substantiate their CBI claims, noting particular support for the question that asks claimants to indicate whether their CBI claim is intended to last less than 10 years. However, the commenter urged EPA to make some additions and changes to this set of questions to fully address all the criteria EPA must consider when reviewing CBI claims under TSCA section 14.

***Source:*** 0321-0107

***Response:*** EPA appreciates the commenter's support for some of the substantiation questions. The question asking whether a CBI claim is intended to last less than 10 years has been finalized as proposed. EPA has clarified some other substantiation questions in response to the commenter's concerns. The specific changes sought by the commenter and EPA's responses are discussed individually below in comments 40a -40d.

***40a. Summary:*** The commenter objected to EPA's proposal to remove a question from the existing CDR regulation at 40 CFR 711.30(b)(1)(iii) that addressed whether a chemical substance had been patented and therefore disclosed through the patent. The commenter urged EPA to either add specific reference to patents and patent applications to the proposed question at 40 CFR 711.30(b)(3), or to maintain the question about patents from the existing regulation and expand it to include patent applications. The commenter asserted that this information is directly relevant to determining whether information about a chemical substance is reasonably attainable by the public.

***Source:*** 0321-0107

***Response:*** Though EPA considers patents and patent applications to be included within the scope of the proposed substantiation question asking whether "any of the information claimed as confidential appear[s] in any public documents," EPA has clarified the substantiation questions in the final rule to add a more specific inquiry about both patents and patent applications. The final rule asks all CBI claimants the following question: "Does any of the information claimed as confidential appear in a patent or patent application? If yes, please provide the associated patent number and explain why the patent or patent application does not reveal the information."

***40b. Summary:*** The commenter urged EPA to add a specific reference to "state, local, or Federal agency files" to the list of examples of "public documents" in the proposed substantiation question asking whether "any of the information claimed as confidential appear[s] in any public documents." The commenter noted that the existing CDR regulation had included a reference to those documents.

***Source:*** 0321-0107

***Response:*** In the final rule, EPA has clarified this substantiation question to add a specific reference to "state, local, or Federal agency files" in the non-exclusive list of public documents. The finalized version of this substantiation question appears at 40 CFR 711.30(b)(3)(B).

***40c. Summary:*** The commenter asserted that the Agency must add a substantiation question to determine, consistent with TSCA section 14(c)(1)(B)(ii), whether the "information is required to be disclosed or otherwise made available to the public under any other Federal law."

***Source:*** 0321-0107

***Response:*** The Agency has clarified the substantiation questions to ask more specifically whether any of the information claimed as confidential is required to be disclosed under any other Federal law. This question appears in the final regulation at 40 CFR 711.30(b)(3)(A).

***40d. Summary:*** The commenter suggested that EPA should ask further questions about the likelihood of substantial harm to competitive position, as it does in its current CDR Rule. In particular, the commenter urged EPA to ask specific questions about how a competitor could use such information and the causal relationship between the disclosure and the harmful effects. The commenter asserted that without answers to these questions, a company's explanation of why and how disclosure would likely result in substantial harm will likely lack the detail necessary for EPA to sufficiently evaluate the company's claim.

***Source:*** 0321-0107

***Response:*** In the proposed rule, EPA had proposed a substantiation question that asked CBI claimants to "explain the substantial harm" to their business's competitive position that would likely be caused by disclosure of the information claimed as confidential. In the final rule, EPA has added language to clarify EPA's expectation that this explanation should include a description of "how a competitor could use such information and the causal relationship between the disclosure and the harmful effects." The finalized substantiation question appears at 40 CFR 711.30(b)(1).

***41. Summary:*** One commenter supported the proposed substantiation questions applicable only to CBI claims for company, site, and technical contact identity and processing and use information. The commenter noted that asking whether the information claimed as confidential is present in "any public document" will provide useful information to EPA when evaluating the substantiations. The commenter also supported the proposed text in 40 CFR 711.30(d) stating that "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."

***Source:*** 0321-0107

***Response:*** EPA is finalizing the proposed regulatory text at 40 CFR 711.30(a)(6) that explains that a CBI claim for a site, company, or technical contact may only be asserted if the linkage of that information to a reportable chemical substance is confidential and not publicly available. As EPA had noted in the preamble to the proposed rule, "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." 84 FR at 17699. EPA is not finalizing the proposed substantiation questions applicable only to CBI claims for company, site, and technical contact identity and processing and use information. Upon further review of these proposed questions, EPA determined that they solicited the same information that claimants would already be required to provide in their responses to the substantiation questions applicable to all CBI claims. In particular, EPA determined that the questions that appeared in the proposed rule at 40 CFR 711.30(d)(1) and (e)(1) would merely duplicate the questions that the Agency is finalizing at 40 CFR 711.30(b)(3), and the question that appeared in the proposed rule at 40 CFR 711.30(e)(2) would duplicate the question that the Agency is finalizing at 40 CFR 711.30(b)(2). Because EPA does not believe that the questions proposed to appear at 40 CFR 711.30(d)(1)-(2) and (e)(1) would provide additional information that is uniquely necessary for adjudicating CBI claims for company, site, technical contact identity, or processing and use information, EPA is not finalizing those proposed questions. However, EPA intends to include in the CDR reporting instructions the specific example listed in the proposed question at 711.30(d)(1) of a Federal public file that may contain information linking company, site, or technical contact information to a reportable chemical substance, i.e., "a filing under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 311, namely through a Safety Data Sheet (SDS)."

***42. Summary:*** A commenter asserted that the Agency should incorporate into its regulation the authority in TSCA section 14(b)(3)(A) allowing EPA to disclose general volume information "expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges."

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. The Agency does not believe it is necessary to codify TSCA section 14(b)(3)(A)'s general volume information provision in this rule. The commenter did not explain why it would be necessary or desirable to incorporate this statutory provision into the rule (other than for duplication's sake), or how it should be incorporated into the rule. EPA also notes that the Agency has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule.

***43. Summary:*** A commenter asserted that the Agency should incorporate into its regulation TSCA section 14(e)(1)(B)'s various limits on the duration of protection from disclosure for confidential information. The commenter observed that EPA would need to implement these limits when processing CDR submissions, so it would make sense for EPA to codify them into the CDR regulations. The commenter noted that EPA had proposed to codify the TSCA section 14(e)(1)(B) limits in a different proposed rule, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (84 FR 16826, 16833; April 23, 2019) (to be codified at 40 CFR 710.55(b)), and believed that EPA should strive to make these two rules consistent.

***Source:*** 0321-0107

***Response:*** EPA has added an explicit reference to TSCA section 14 in 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14 will be applied to information claimed as CBI under the rule. This would include the limits on duration of protection from disclosure described in TSCA section 14(e)(1). EPA does not believe it is necessary to duplicate the full text of TSCA section 14(e)(1) in this rule. EPA notes that the other proposed rule referenced by the commenter, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (84 FR 16826, 16833; April 23, 2019), is different in scope and focus from the CDR rule, because its scope is prescribed by the statutory mandates of TSCA section 8(b)(4)(C)-(D). Moreover, the provision in that rule that is proposed to be codified at 40 CFR 710.55(b) would implement TSCA section 8(b)(4)(D)(ii)(III), not TSCA section 14(e)(1)(B).

***44. Summary:*** A commenter pointed out that EPA's cross references in subparagraphs 711.30(a)(3)(ii) and (iii) of the proposed regulatory text were incorrect, and that it appeared EPA meant for the cross reference to be to section 711.15(b)(3)(i)(B)(1), (2), and (3).

***Source:*** 0321-0107

***Response:*** EPA appreciates the comment and has corrected the cross reference in the final rule. Because the final regulatory text is different than the proposal, the correct cross reference is to section 711.15(b)(3)(i)(A) and (B).

## C.2. Chemical identity confidentiality

***45. Summary:*** A commenter cautioned the Agency not to disclose information, such as chemical identities, without considering whether they may reveal CBI and provide a competitive advantage through public release. The commenter noted as an example that disclosing chemical identity may inadvertently provide strategic information to companies on what their competitors are working on.

***Source:*** 0321-0102

***Response:*** EPA appreciates the comment and is committed to protecting CBI consistent with TSCA section 14.

***46. Summary:*** One commenter generally supported the questions in the proposed rule that CDR submitters asserting CBI claims for specific chemical identity would be required to answer to substantiate their chemical identity CBI claims, but stated that some additions and modifications were necessary. See summaries 24a to 24c:

***46a. Summary:*** The commenter supported the substantiation questions proposed at 40 CFR 711.30(c)(2) and (3), which asked whether the chemical leaves the site of manufacture in any form, and if so, whether measures have been taken to guard against the discovery of a chemical's identity; and if the chemical leaves the site in a product that is available to the public or competitors, whether it can be identified by analysis of the product. However, the commenter urged EPA to add a follow-up question that directly addresses whether existing technologies (including, but not limited to, Gas Chromatography/Mass Spectroscopy, Liquid Chromatography/ Mass Spectroscopy, Ion Chromatography, and Fourier Transform Infrared Spectroscopy) make it possible for the specific identity of the chemical substance to be readily discoverable. The commenter asserted that without asking a question directly addressing the availability of these technologies, EPA will not be able to adequately determine whether the information is "readily discoverable through reverse engineering" in accordance with TSCA section 14(c)(1)(B)(iv).

***Source:*** 0321-0107

***Response:*** In the final rule, the Agency has revised one of the proposed substantiation questions to clarify EPA's expectation that the response take into account existing

technologies. EPA has also clarified the language of the question to make clear that the inquiry is intended to address whether a chemical identity is "readily" discoverable (i.e., reasonably obtainable, taking into consideration cost or other difficulties in acquiring the information). This question has been finalized at 40 CFR 711.30(c)(3) to read: "If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (e.g., product, effluent, emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not." EPA intends that this inquiry would be answered based on information that is *known to or reasonably ascertainable by* the CBI claimant, about reasonably available analytical capabilities currently in use by the chemical industry. EPA does not intend to require claimants to initiate a special research program to answer the inquiry, or to speculate about hypothetical analytical capabilities.

***46b. Summary:*** The commenter asked EPA to clarify what the Agency meant in the question proposed at 40 CFR 711.30(c)(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?"* (emphasis added). The commenter also noted that the example in the follow-up question proposed at 711.30(c)(1) is introduced in the regulation with "i.e." when it is more appropriate to use "e.g."

***Source:*** 0321-0107

***Response:*** The Agency agrees that the question could have been more clearly drafted and has revised the question to remove the language identified as confusing by the commenter. The question has been finalized at 40 CFR 711.30(c)(1) to read as follows:

> 1) Is this chemical substance publicly known (including by your competitors) to be in U.S. commerce? If yes, please explain why the specific chemical identity should still be afforded confidential status (*e.g.,* the chemical is publicly known only as being distributed in commerce for research and development purposes). If no, please 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 by anyone for a commercial purpose in the United States. [provide date].

***46c. Summary:*** The commenter noted that EPA had proposed to eliminate from CDR a question that appears in the existing regulation at 40 CFR 711.30(b)(1)(iv): "Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?" The commenter urged EPA to retain this question because competitors often have access to numerous pieces of

information that would allow them to determine that a chemical substance is being manufactured or imported, beyond the public's general knowledge. The commenter asserted that if competitors can determine that the substance is being manufactured "by anyone," then it loses its confidentiality even if the general public would not be aware of this information.

***Source:*** 0321-0107

***Response:*** Competitors are included among members of the public. To better reflect that fact, EPA has clarified one of the proposed substantiation questions to add an explicit reference to competitors' knowledge. This question appears in the final rule at 40 CFR 711.30(c)(1) and now reads: "Is this chemical substance publicly known (including by your competitors) to be in U.S. commerce?"

The Agency disagrees with this comment to the extent it implies that a competitor's knowledge of the existence of a chemical substance in commerce would always invalidate a CBI claim for specific chemical identity, under any circumstance. For instance, particularly where non-disclosure agreements are in place, information may be held as confidential by more than one manufacturer (including importer) without being readily discoverable by other competitors or the public at large, and disclosure of such information to the other competitors could cause substantial competitive harm to the current manufacturers. That said, EPA agrees with the commenter that where a chemical substance is generally known to be in commerce, the specific chemical identity would not merit protection from disclosure, but a company could assert a CBI claim for the linkage of the company name to that chemical substance by claiming company name as CBI in the CDR submission.

***47. Summary:*** One commenter asserted that to the extent persons are asserting confidentiality claims for specific chemical identities, each claim must include a structurally descriptive generic name that meets the requirements of TSCA section 14(c)(1)(C), as well as EPA guidance. The commenter asserted that many current generic names on the Inventory do not meet those requirements. The commenter proposed that the Agency should require each CBI claimant to submit a generic name, a certification that the generic name meets the TSCA section 14(c)(1)(C) requirements, and a statement explaining how the generic name meets the TSCA section 14(c)(1)(C) requirements. The commenter further suggested that EPA should review generic names for compliance with TSCA section 14(c)(1)(C) as part of the Agency's review of the CBI claim for specific chemical identity, and should address the appropriateness of the generic name in any final determination approving the CBI claim.

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. The chemical substances at issue in CDR submissions have already been assigned generic names on the TSCA Inventory. In instances where a CDR submitter may claim the specific chemical identity of a substance as CBI, such persons report their substances by selecting existing generic names and numeric identifiers from an OPPT pick list generated from the public portion of the TSCA Inventory. These

existing generic names were first reported and reviewed primarily in section 5 notices and the names to be provided were to be consistent with the existing generic name policy and were subject to review. The submission and review of generic names therefore is outside the scope of the CDR rule. In instances where it has come to the Agency's attention that a generic name might not meet the Agency's generic name guidance, the Agency may review these on a case by case basis.

***48. Summary:*** One commenter noted that the Agency was required to assign unique identifiers to substances for which the "Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term." TSCA section 14(g)(4)(A)(i). EPA must then "apply that identifier consistently to all information relevant to the applicable chemical substance." *Id.* section 14(g)(4)(A)(ii). The commenter stated that EPA should incorporate this requirement into the confidentiality provisions of the CDR rule.

***Source:*** 0321-0107

***Response:*** EPA does not believe it is necessary to duplicate the TSCA section 14(g)(4)(A) provisions regarding unique identifiers in the CDR Revisions rule but agrees regarding the Agency's obligations to assign and apply unique identifiers. EPA announced its policy on the assignment of unique identifiers in the Federal Register at 83 FR 30168 (June 27, 2018) and has been following the policy since its publication. Incorporating this TSCA-wide statutory requirement into the CDR regulations is outside the scope of the CDR rulemaking.

***49. Summary:*** One commenter asserted that the Agency must disclose information when no claim of confidentiality or substantiation is submitted with the information, because there would be no statutory basis for withholding such information from the public. The commenter specifically asserted that the term "may" should be replaced with "shall" in the proposed regulatory text stating that "[i]nformation not asserted as confidential in accordance with the requirements of this section *may* be made public without further notice to the submitter" (emphasis added). The commenter further asserted that the CDR rulemaking should address the steps associated with TSCA section 14(g) reviews of CBI claims, as well as the steps EPA will take if a claimant does not challenge EPA's denial of a CBI claim or if the courts reject the claimant's challenge to the denial. In addition, the commenter stated that EPA should clarify in this rulemaking how it intends to implement the TSCA section 26(j) requirement to make CBI determinations and findings available to the public.

***Source:*** 0321-0107

***Response:*** EPA disagrees with the commenter that the CDR rule should provide that information "shall be made public"—as opposed to "may be made public"—if not asserted as confidential in accordance with the rule. As a matter of policy, EPA is committed to

proactively making available to the public non-confidential information gathered under the CDR rule, but EPA is not required by law to proactively publish every piece of non-confidential information contained in every CDR submission. Revising the regulatory text pursuant to the commenter's suggestion would change the meaning and purpose of the text from a statement advising submitters of the potential consequences of not properly asserting CBI claims for information in their submissions, to a new regulatory requirement to publish every piece of data not asserted as confidential. EPA agrees with the commenter that information which has not been "asserted as confidential in accordance with the requirements of" the CDR rule—which would include information that is not accompanied by the substantiation or certification statement required by the rule—would be subject to release if requested under FOIA (assuming the absence of any other applicable FOIA exemption).

EPA also disagrees with the comment that the rulemaking should address the specific steps associated with CBI reviews under TSCA section 14(g) or the publication of determinations under TSCA section 26(j), and believes that these are outside the scope of the CDR rulemaking. EPA has, however, added an explicit reference to TSCA section 14 in the final rule at 40 CFR 711.30(a)(1) to make clear that all relevant provisions of TSCA section 14—including those of TSCA section 14(g)—will be applied to information claimed as CBI in accordance with the rule. EPA notes that TSCA sections 14(g) and 26(j) apply of their own force, and that the Agency is providing information related to confidentiality reviews in other venues, including on EPA's website. Interested persons could look at other materials, largely online, to learn of the specifics of the TSCA CBI review process. See, for example, EPA Review and Determination of CBI Claims under TSCA, found at https://www.epa.gov/tsca-cbi/epa-review-and-determination-cbi-claims-under-tsca.

***50. Summary:*** One commenter suggested that persons making CBI claims with accompanying substantiations should provide sanitized or redacted versions of the substantiations as such materials may be subject to FOIA request. Providing sanitized versions of substantiations would assist EPA with processing any future FOIA requests made for these documents. The commenter also asserted that where the information submitted to substantiate a CBI claim is itself marked as CBI, EPA should require the claimant to separately substantiate the CBI claim for the substantiation and should review a representative subset under TSCA section 14(g) of the CBI claims made within the substantiations.

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment. While EPA agrees that providing sanitized or redacted versions of substantiations is potentially desirable, the technical challenges and costs associated with incorporating this ability into the electronic reporting system prevent EPA from doing so at this time. In addition, the Agency does not agree that TSCA section 14 requires a submitter to concurrently substantiate any CBI claims within a substantiation, or for EPA to review such claims under TSCA section 14(g). Information provided to substantiate a CBI claim may reasonably be anticipated to reference confidential information related to the original CBI claim. EPA does not believe Congress intended to require iteration upon iteration

of upfront substantiation and review when the information submitted to substantiate a CBI claim pursuant to TSCA section 14(c) itself contains information claimed as CBI. Otherwise, there could be a continual loop of new substantiations and Agency review of confidentiality claims that would significantly increase burden to both reporters and the Agency. However, EPA acknowledges that members of the public may potentially request copies of substantiations under FOIA, and at that time any CBI claims would be handled in accordance with TSCA section 14(f)(2)(A).

***51. Summary:*** One commenter asserted that the proposed changes in the CBI substantiation rules will not result in a reduction of reporting burden as claimed in the Agency's Economic Analysis; rather, the burden will not change or will increase for certain substances.

***Source:*** 0321-0099

***Response:*** The economic analysis describes the overall economic impact of the rule changes and presents averages for an individual chemical report or a complete Form U that is comprised of multiple chemical reports. Because the actual reporting on one site's Form U or on an individual chemical report can vary, the burden of the individual can likewise vary. For example, one chemical report may only report past production volumes, resulting in a lower than average burden, while another chemical report may contain twenty lines of processing and use information, resulting in a higher than average burden. Because some aspects of the CBI changes will result in reductions in burden while others will result in increases, the impact on the individual will also vary. For example, because CBI claims are barred for certain data elements, the CBI-related burden associated with those data elements is eliminated. Because under the Lautenberg Act TSCA now requires upfront substantiation for most data elements, the burden increased for reporting those data elements that previously did not require upfront substantiation.

## D. Reporting of Byproducts

***52. Summary:*** A commenter stated that the three byproduct provisions for streamlining reporting of byproducts were framed "carefully to avoid creating reporting loopholes for inorganic byproduct production activities that could be important for an understanding of exposure scenarios of concern," also asserting that it "is essential that the final rule continue to place these limits on the scope of the streamlining provisions."

Another commenter identified that EPA proposed major expansions of exemptions for byproduct reporting, stating that these changes "are overboard and will severely constrain EPA's ability to obtain information it needs to carry out its duties under TSCA." The commenter stated EPA's proposed expansions to byproduct reporting exemptions would hinder EPA's ability to conduct chemical prioritization, risk evaluation, and risk management responsibilities.

***Sources:*** 0321-0100, 0321-0107

***Response:*** EPA agrees that the new byproduct provisions have been framed carefully to avoid creating reporting loopholes for byproduct production activities. The Agency is finalizing as proposed the criteria and limits in scope outlined for these provisions in the proposed rule. For the reasons described in subsequent responses and in the proposed rule, EPA disagrees that the new reporting exemptions hinder EPA's ability to carry out its obligations under TSCA.

***53. Summary:*** Several commenters discussed EPA's obligations under TSCA section 8(a)(6). One commenter stated that the proposed revisions fail to limit, in any meaningful way, reporting requirements for recycled inorganic byproducts as Congress intended. The proposed revisions related to inorganic byproducts sent for recycling are either narrowly targeted or offer little or no actual burden reduction. Other commenters noted that the proposed changes align with Congress's intent, with one commenter stating that the proposed revisions are an important first step to reduce some of those burdens and encouraging EPA to continue to seek additional ways to reduce reporting burden.

***Sources:*** 0321-0089, 0321-0094, 0321-0095, 0321-0104

***Response:*** The purpose of the negotiated rulemaking committee was to conduct a negotiated rulemaking in a good faith attempt to reach consensus on proposed regulatory language that would limit chemical data reporting requirements under section 8(a) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, for manufacturers of inorganic byproduct chemical substances, when such byproducts are subsequently recycled, reused, or reprocessed. The CDR negotiated rulemaking conducted these discussions, and, while unable to reach consensus, nevertheless accomplished its purpose of attempting in good faith to reach consensus. Through its formation of the CDR negotiated rulemaking committee and good faith participation in the Committee's discussions, EPA fulfilled its mandate to enter into the negotiated rulemaking. Nonetheless, portions of the proposed and final rule, including the byproduct exemptions, were informed from feedback received during the negotiated rulemaking, and as explained above (see the response to comment summary 20), EPA is finalizing two new exemptions, a petition process that provides a way to expand one of the exemptions, and a new voluntary data element that may allow for further analysis to be conducted on reporting for those byproducts that are used for a non-exempt commercial purpose. EPA appreciates the comments that recognize that the changes align with Congress's intent.

***54. Summary:*** A commenter noted that there would be limited time (i.e., less than a year) for familiarization with the changes before the next reporting cycle. Reporters will bear an increased burden in the near future. This commenter also noted that there have been changes to CDR requirements for each of the past five reporting cycles.

***Source:*** 0321-0094

***Response:*** EPA also agrees that sufficient clarification will be needed before the reporting period begins and, in light of the limited timeframe for familiarization with changes before the next reporting cycle, will provide enhanced guidance and webinars to clarify aspects and scenarios of each newly finalized exemption for certain byproducts.

***55. Summary:*** One commenter stated that they have not received a clear explanation about the value to the EPA of CDR reporting on byproducts sent for recycling. This commenter noted that they provided clear evidence of reporting burden and regulatory risk (see EPA-HQ-OPPT-2016-0597, Negotiated Regulation for Recycled Inorganic Byproduct Chemical Substances) and would like to see the scope of their concerns better addressed. This commenter also expressed interest in working with EPA to improve industry-specific guidance.

***Source:*** 0321-0103

***Response:*** EPA developed a supporting document (Chemical Data Reporting (CDR): Importance of Data and Need for Data on Inorganic Byproducts. August 3, 2017; EPA-HQ-OPPT-2016-0597-0057) during the 2017 negotiated rulemaking that provided substantial explanation regarding the reason for collecting CDR information on byproducts, including byproducts that are recycled. As described therein, EPA does not see an inherent difference with regard to exposure concerns for byproducts vs. non-byproduct chemical substances: "A byproduct that is used for a commercial purpose is a chemical substance which is manufactured, processed, and/or used in some manner that may involve exposure to persons or the environment. As with all manufactured chemical substances, CDR information on byproducts is of interest to the EPA because such exposure-related information is not otherwise available, and it is necessary for the Agency to manage risks associated with these chemical substances, to fulfill its mandate of protecting human health and the environment. EPA does not believe chemicals manufactured in a way that characterizes them as byproducts inherently pose lower exposures or risks than chemicals manufactured in other processes." Although EPA recognizes the importance of recycling activities to conserve natural resources and reduce waste, the fact that a chemical, including a byproduct chemical, is recycled does not negate the potential for exposures and risks associated with that chemical.

Regarding regulatory risk and other concerns expressed during the negotiated rulemaking, EPA continues to work with the industry to improve reporting guidance. Meetings with industry groups, such as the June 13, 2019, meeting with IPC and the follow-up tour of a printed circuit board facility provided the Agency with information useful for future updates. EPA will provide an update to the current "TSCA Chemical Data Reporting Fact Sheet: Byproducts Reporting for the Printed Circuit Board Industry" and other information documents in advance of the 2020 reporting cycle to incorporate changes from the CDR Revisions based on knowledge gained from industry interactions. These stakeholders will also be given the opportunity to review and provide input on this fact sheet.

***56. Summary:*** One commenter requested EPA provide additional clarifications about product reporting, providing additional explanation and examples illustrating the differences between "coproduct" and "byproduct" and between "commercial purpose" and "commercial intent."

***Source:*** 0321-0102

***Response:*** EPA provides definitions for "coproduct" and "byproduct" in the CFR (40 CFR 704.3) and these are further explained in the 2016 CDR Frequent Questions (Q/A 10.11 and 10.22). A coproduct means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance or mixture, whereas a byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. For another example differentiating a coproduct and byproduct (Q/A 10.22), if a manufactured chemical substance that remained with the primary product did have a separate commercial purpose – for instance, if it improved the performance of the primary product or provided a primary property to the commercial product – it would be a coproduct, not an impurity or a byproduct, and its manufacture would be reportable for CDR purposes. Commercial purpose applies to "obtaining an immediate or eventual commercial advantage" whereas commercial intent typically "applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture (40 CFR 704.3 – *Manufacture for commercial purposes*)."

## D.1. Comments on alternative reporting in metal compound categories for inorganic byproducts

***57. Summary:*** Comments were mixed on the proposed alternative method of reporting in metal compound categories for inorganic byproducts. A few commenters supported the proposal. One commenter agreed that aligning TRI and CDR in this way would be beneficial to companies reporting under both programs. Another commenter supported the proposal as long as certain substances would be ineligible. Other commenters expressed doubt that category reporting would be used. These commenters stated that some industry participants on the 2017 CDR negotiated rulemaking committee identified that they were unlikely to choose category reporting because they had already identified the makeup of the substances in previous submissions and because precise nomenclature was needed to comply with other sections of TSCA. Another commenter stated that additional stipulations in the category reporting, such as reporting in weight versus volume and exclusions from category listing, may reduce reporters' interest in using the exemption. One supporting commenter stated that category reporting may provide substantial reporting relief to companies that have not already done the costly chemical analyses needed for recycling of inorganic byproducts. Commenters stated that this proposal would add complexity, referring to the discussion in the proposed rule preamble. A commenter asked how the proposed data element percent byproduct would be reported when the byproduct

is being reported as part of a category and noted that because some qualifying compounds will contain multiple metals, the need to be reported under multiple categories would result will be duplicative reporting that does not provide an accurate estimate of actual production either of individual compounds or categories.

***Sources:*** 0321-0089, 0321-0094, 0321-0095, 0321-0098 ,0321-0099, 0321-0101, 0321-0103, 0321-0104, 0321-0107

***Response:*** EPA is not finalizing the proposed category reporting. EPA agrees that the issues related to complexity and the stated unlikeliness that companies would choose to report in categories for inorganic metal byproducts outweigh the potential benefits. EPA proposed category reporting as an alternate method of reporting to reduce burden for those who would have chosen it as a way to report. However, the complexities in understanding the methodology and issues such as how to report for other data elements, such as the percent byproduct or maximum concentration, seem to add unnecessary confusion to the CDR requirements.

**58.** ***Summary:*** One commenter stated that category reporting provided companies with a means to avoid reporting the identities of compounds they make – by hiding them within a category – even if those substances are already public on the TSCA Inventory and hence not eligible to be withheld from the public.

***Source:*** 0321-0107

***Response:*** EPA is aware that category reporting could result in companies reporting within a category of chemicals that are publicly available on the TSCA Inventory. TSCA section 8(a), which authority the CDR rule is promulgated under, provides EPA with the authority to have manufacturers report certain information about the chemicals they manufacture but does not dictate the specifics of the information that is reported. TSCA does not require EPA to collect the chemical identity as it is listed on the TSCA Inventory, and in fact states that the Administrator "may" require reporting of information including the "common or trade name, the chemical identity, and the molecular structure of each chemical substance." In fact, TSCA provides authority for the Administrator to collect information in many ways, including by the "common or trade name, the chemical identity, and the molecular structure of each chemical substance." See 15 U.S.C. § 2607(a)(2)(A). Although this commenter is correct that the company reporting in categories would not have provided the specific chemical identity, EPA disagrees that EPA is required to have the company report as it is listed on the TSCA inventory. Nonetheless, EPA has not finalized the proposed category reporting scheme for separate reasons as noted above.

***59. Summary:*** One commenter stated that information reported in categories would be less useful for EPA if seeking to initiate activities leading to prioritization or risk evaluation of one or more of the compounds that fall within a category. Both EPA and the public would not be

able to use past CDR information to analyze trends in production, processing and use of a specific chemical over time. The commenter also stated that the lumping together of production, processing and use information on a group of compounds that may have significantly different individual uses, exposures and hazards, will greatly hamper EPA's ability to make high-quality decisions about TSCA's prioritization, risk evaluation and risk management processes. For example, EPA would have difficulty providing meaningful national aggregated volumes for substances that were sometimes reported as individual chemicals and other times reported within a category, without identification of the specific substances in the category.

***Source:*** 0321-0107

***Response:*** EPA agrees that the Agency and the public's abilities to analyze trends over time, provide accurate national aggregate volumes for individual chemicals, and differentiate individual uses, exposures and hazards, would be made more difficult for specific inorganic chemicals if reported under metal categories. Considering this and other factors regarding potential added complexity and reporting burden, EPA is not finalizing the proposed optional category reporting.

***60. Summary:*** A commenter supported the proposal to use the weight of metal manufactured of the parent metal portion in the metal compound category for CDR reporting since this approach aligns with TRI's reporting of metal compound categories. The commenter stated that the weights of associated metal compounds are more difficult to determine than the parent metal weight. Another commenter indicated concern that reporting in weights versus volumes may affect stakeholders' interest in using the voluntary category reporting option. A third commenter asserted that EPA has not demonstrated why it is significantly more burdensome to continue the current requirement to report metal compounds individually.

***Sources:*** 0321-0094, 0321-0103, 0321-0107

***Response:*** EPA agrees that it may have been appropriate to align the category reporting methodology with TRI's reporting under certain circumstances. However, upon further consideration, it could create a complicated outcome to allow the use of a metal compound category in certain circumstances yet not in other circumstances. Similarly, inconsistent use of this optional reporting method could complicate the use of reported data. On balance, EPA believes it simplest to have sites report on metal compounds as listed on the TSCA Inventory. TRI reporting of metal compound categories, except for the handful of instances where a metal compound is listed separate from a metal compound category, is more uniform in its implementation and thus better lends itself to the use of combined metal compound reporting.

## D.2. Comments on exemption for specific site-limited recycled byproducts for specific industries

***61. Summary:*** Some commenters strongly supported the exemption. A commenter expressed concern about losing information but did not oppose the exemption. This commenter stressed that the enclosed system condition of the "exemption is critical to avoid compromising CDR requirements and must be carried forward into the final rule without change."

***Sources:*** 0321-0100, 0321-0109, 0321-0110

***Response:*** Based on commenter feedback, EPA is finalizing this exemption as proposed, including the associated conditions put forth in the proposal (e.g., that the byproduct be recycled in an enclosed system, and what constitutes an enclosed system). While a major consideration in proposing these revisions was to reduce reporting burden on the regulated community, one of EPA's primary goals for byproduct reporting exemptions was to balance reduced reporting burden with maintaining EPA's ability to receive the information it needs to understand potential chemical exposures to byproducts (84 FR 17694, April 25, 2019).

***62. Summary:*** Two commenters supported the exemption but expressed concern that the inclusion of specific site-limited recycled byproducts exempt from CDR reporting was narrow in scope and would "only affect very few submitters." One of the commenters indicated that other manufacturing industries subject to CDR reporting may produce byproducts incidentally and are not currently covered by the scope of site-limited recycled byproduct exemptions in the proposed rule.

***Source:*** 0321-0089, 0321-0099

***Response:*** While EPA recognizes that the new byproduct reporting exemptions may be perceived as limited in scope, EPA relied specifically on the extensive information gathered during the recent 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) in determining the scope of expanded exemptions included for the 2020 reporting cycle. EPA developed these proposals with the intent of addressing reporting burden for manufacturers of these byproducts that EPA had information on, while also ensuring that information collected through 2020 CDR reporting maintains the full scope of information required to be collected by EPA under TSCA.

With the addition of the petition process, reporters are able to petition EPA to expand the list of exemptions applicable to site-limited recycled byproducts through the procedures under 40 CFR 711.10(d)(1)(ii) (proposed under 40 CFR 711.10(c)(2)(ii)). Though not available for use for expanding this list of exempt inorganic byproducts for the 2020 reporting cycle, EPA's intent in providing this process is to provide a mechanism for expansion of this reporting exemption based upon information provided by industry and specifically analyzed by the Agency, as appropriate.

**63.** ***Summary:*** One commenter suggested that, instead of listing substances, the exemption should be self-executing, where the site documents in its own records that it meets the exemption conditions (similar to the TSCA section 5 PMN polymer exemption).

***Source:*** 0321-0089

***Response:*** EPA disagrees that it is appropriate for this exemption to be self-executing. EPA believes this is a nuanced exemption with requirements that may not be correctly or uniformly applied by individual reporters. Therefore, EPA believes it is important to have an opportunity for agency review to ensure that there is a thorough understanding of the engineering processes and controls of the operations and, if the petition is granted, for the public to have an opportunity to provide comment. In addition, the specific listing procedure enables EPA to ensure that chemicals for which EPA may have current interest are not inadvertently excluded from reporting by a site which elects a "self-executing" avenue for exemption. As discussed in the preamble to this proposed rulemaking action, there are several different sections under TSCA for which EPA may have a current interest in a chemical byproduct. Conversely, EPA may have a current interest for other reasons, including activities under other statutes, such as the Resource Conservation and Recovery Act (RCRA). Should a situation arise in which a facility (or grouping of facilities) that manufacture a similar byproduct determine that byproduct is exempt from CDR reporting through a self-executing avenue, EPA would be limited in its ability to implement its duties under TSCA in the absence of relevant and necessary data that would otherwise have been reported to EPA through the CDR.

Additionally, EPA has already established precedent under 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. As such, EPA has a well-established framework in place for efficiently reviewing and effectively responding to requests for new exemptions from the CDR reporting process that can be readily applied to this new section of the CDR provisions.

### D.2.1. Kraft pulping cycle byproducts

***64. Summary:*** One commenter stated that past CDR reporting provides an inaccurate representation of production and exposure for the pulping cycle because the reporting requirements result in artificially inflated manufacturing figures for chemicals that are confined in closed recycling systems.

***Source:*** 0321-0109

***Response:*** EPA disagrees that CDR reporting for the pulp and paper industry resulted in an inaccurate representation of the chemical production resulting from the pulping cycle. The pulping cycle requires the manufacture of a series of chemicals to take a byproduct resulting from the pulping process and ultimately transform it into a chemical needed for the pulping process. This cyclical process greatly reduces the amount of material that needs to be purchased and is an excellent example of a manufacturing system that is recycling a substance that

otherwise would be treated as a waste. The pulping cycle generates and uses a large volume of chemicals. Potential exposures to these chemicals are to the full volume of chemicals, not to the volume for an individual cycle. Under CDR each manufactured chemical is required to be reported unless it is exempted.

***65. Summary:*** One commenter requested that EPA provide a non-isolated intermediate exemption determination for five chemicals that they manufacture: black liquor, oxidized; furnace smelt; green liquor; lime (calcium oxide); and white liquor. The commenter also thanked EPA for including Sulfite liquors and Cooking liquors, spent (CASRN 66071-92-9) (a.k.a., black liquor) and Carbonic acid calcium salt (1:1) (CASRN 471-34-1) (a.k.a., calcium carbonate) in the newly proposed exemption for byproducts recycled in site-limited, enclosed systems.

***Source:*** 0321-0109

***Response:*** Because EPA did not propose changes to the non-isolated intermediate exemption, this comment is largely out of scope for this rulemaking. However, EPA is taking this opportunity to address this comment because of its connection with the new byproduct exemption in an effort to help the commenter apply the updated CDR reporting requirements in its 2020 reporting. EPA will also develop a CDR Fact Sheet for the Kraft pulping cycle.

In the proposed rule, EPA included two pulping cycle chemicals as part of the new byproduct exemption, commonly referred to as black liquor and lime mud.

EPA has examined each of the five pulping cycle chemicals identified in the comment that were not included in the new byproduct exemption as proposed (Black liquor, oxidized; Energy recovery furnace smelt; Green liquor; Lime; and White liquor) as to whether each substance is likely to be a byproduct. Of these five pulping chemicals, EPA identified:

- Black liquor, oxidized (CASRN 68514-09-0, *Sulfite liquors and Cooking liquors, spent, oxidized*) as a byproduct that was added to the byproduct exemption for listed pulping cycle chemicals and
- Energy recovery furnace smelt as a byproduct currently not reportable under CDR because it does not seem to have a CAS number and is not listed on the TSCA Inventory.
    - EPA notes that, based on the information provided by the commenter, if this substance were on the TSCA Inventory it would be eligible for the byproduct exemption.

Regarding the other three pulping streams, if an intermediate, the manufacturer would examine whether the non-isolated intermediate exemption could be applied. The non-isolated intermediate exemption is a self-executing exemption from reporting under CDR (see 40 CFR 720.30(h)(8), referred to by 40 CFR 711.10(c)). As a self-executing exemption, determinations by EPA are not required to enable manufacturers to make use of the exemption and not report

under CDR. In addition, because manufacturing can vary from site to site and may change over time, EPA also cannot make blanket determinations that apply to an entire industry or to a particular substance. There are multiple guidance documents on EPA's website that provide information to help a site make its own determination. The most relevant to CDR is the TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates (Ref. 3). If an individual manufacturing site were to find that their substance(s) functions as an intermediate and is non-isolated throughout the entire process sequence from manufacture to use of the intermediate, the exemption would apply and be self-executing. Companies may obtain help with reporting questions, including about how to determine if their production meets the non-isolated intermediate exemption or any other exemption by emailing EPA's CDR team at eCDRweb@epa.gov.

EPA is aware of a letter from the New Chemicals Program for January 24, 2000 that states that a flow-through in-line vessel that holds sufficient volume to keep a subsequent part of the operation going for six days could still be considered non-isolated. EPA considered and rejected this previous conclusion a number of years ago and incorporated the corrected interpretation into CDR guidance, such as the TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates (see, in particular, Case Studies A and D) (Ref. 3). Accumulating a chemical in any vessel, regardless of whether it is a flow-through in-line vessel, for reasons that are not necessary to the process's technical/chemical success but rather to keep the operation moving in the case of an unexpected interruption in the supply as a matter of plant convenience, is considered by EPA to be storage and isolation.

In considering whether a chemical substance is an intermediate, EPA generally thinks of an intermediate as a kind of "building block" precursor chemical used to make what is, at least to some degree, a structurally-related product. A reaction sequence containing an intermediate could be represented as A → B → C, where A is an initial feedstock that is transformed into B which is then transformed into C, the product. The product C is built upon the chemical structure/composition of B, which is built upon the chemical structure/composition of A. Substance B therefore can be considered an intermediate for making C. There may be reagents or other reactants involved in transforming A to B or B to C, but such reagents or other reactants are not typically viewed as intermediates.

The definitions of byproduct, intermediate, and non-isolated intermediate are found in 40 CFR 704.3 and read:

> *Byproduct* means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.
>
> *Intermediate* means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

*Nonisolated intermediate* means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

For the purposes of this response, a *product* is a chemical substance that is intentionally manufactured (*i.e.*, for distribution into commerce or as a process input) for commercial purposes (*i.e.*, with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer). As a process input, a product would serve a specific function.

In the preamble for the proposed rule, EPA described the pulping cycle as beginning with the production of pulp and black liquor as a byproduct of the pulping process after which the black liquor is 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. In its comments on the rule, the commenter further discussed two additional chemicals: black liquor, oxidized and energy recovery furnace smelt. EPA examined the information provided by the commenter and offers the following additional information about the pulping cycle chemicals:

1. Black liquor (CASRN 66071-92-9, *Sulfite liquors and Cooking liquors, spent*)

   This is listed in the byproduct exemption finalized as part of the CDR Revisions final rule.

2. Black liquor, oxidized (CASRN 68514-09-0, *Sulfite liquors and Cooking liquors, spent, oxidized*)

   As presented by the commenter, this substance results from the oxidation of the byproduct: S*ulfite liquors and Cooking liquors, spent* (CASRN 66071-92-9, referred to by industry as *black liquor, oxidized*). The oxidation is done at some sites to facilitate odor reduction during combustion in the recovery furnace. Other than odor reduction at the manufacturing site, the oxidation of the byproduct serves no commercial purpose separate from that of the *black liquor*. The site treats both *black liquor* and *black liquor, oxidized* for the same purpose, which is to burn it in the energy recovery furnace. EPA believes that, for purposes of CDR, both substances are byproducts.

   As part of the development of the proposed exemption, EPA reviewed the information provided by the industry concerning the use of the *black liquor* and recognizes that the same information, which included the consideration of the oxidization process, also applies to the *black liquor, oxidized*. Because EPA already considered *black liquor* in the pulping cycle process as part of its development of this new exemption, and based on the information contained in the comment, the Agency is including *black liquor, oxidized* as part of the list of certain pulping cycle byproduct chemicals that are eligible for the exemption at 40 CFR 711.10(d)(1)(i)(B).

3. Green liquor (CASRN 68131-30-6, S*ulfite liquors and Cooking liquors, green*)

As presented by the commenter, *black liquor* or *black liquor, oxidized*, is burned for energy recovery in the Kraft cycle and the component chemicals in the alkaline pulping process (also known as energy recovery furnace smelt) are recovered in solution by dissolving them in water to form green liquor. The TSCA Inventory definition associated with the formal chemical name for green liquor, *Sulfite liquors and Cooking liquors, green* (CASRN 68131-30-6), states that it is "[a] solution obtained by dissolving the chemicals recovered in the alkaline pulping process in water." The commenter also identified that this substance is fully consumed to make another substance. As used in the pulping cycle, this substance is an intermediate.

Because the process as presented by the commenter conforms to the reaction that is required to occur to form green liquor and make white liquor in an enclosed process, EPA believes this substance could be exempt under the non-isolated intermediate exemption. However, each manufacturing site needs to make its own determination of whether the non-isolated intermediate exemption applies. For example:

- Clarifiers: EPA has previously described "ancillary" equipment as "auxiliary or supplemental to the reaction vessel" and "used for performing necessary or important parts of the manufacturing process involving the intermediate, such as filtration, distillation, drying, size (volume) reduction, heating or cooling." (Ref. 3) The use of this processing circuit returns the green liquor to the primary process and is therefore "ancillary to the reaction vessel" in the primary pulping process loop.
- Flow-through storage tanks: When the green liquor residence time in the tank is limited to only the time needed for dissolution with water, then the use of the in-line, flow-through tank would allow the non-isolated designation.

4. Lime (CASRN 1305-78-8, *Calcium oxide (CaO)*)

*Calcium oxide* is formed when the calcium carbonate byproduct is heated in the lime kiln to drive off $CO_2$, retaining the calcium in the form of calcium oxide. The calcium oxide is reacted with *green liquor* to form *white liquor*. Thus, this substance is consumed in reaction with *green liquor* and could be exempt under the non-isolated intermediate exemption in this process. However, each manufacturing site needs to make its own determination of whether the non-isolated exemption applies.

5. Lime mud (CASRN 471-34-1, *Carbonic acid calcium salt (1:1)*) (commonly called Calcium carbonate)

This is listed in the byproduct exemption finalized as part of the CDR Revisions final rule.

6. White liquor (CASRN 68131-33-9, S*ulfite liquors and Cooking liquors, white*)

Based on the information currently available to EPA, *white liquor* is the product of a series of reactions from *black liquor* to *green liquor* to *white liquor*. The white liquor is used to break down the pulp to release *lignin* (CASRN 9005-53-2), allowing the resulting cellulose fibers (now lignin-free) to be used for paper production. If, however, in the future new information is provided to EPA to further inform EPA's understanding of the liquors and the Kraft pulping process EPA will assess such specific factual circumstances as appropriate.

***66. Summary:*** A commenter stated that, in the form in which the proposed regulatory language was drafted, the exemption did not account for the fact that the identified streams represent only a portion of the Kraft recovery process, asking that the proposed language be revised to: "(B) Certain Kraft Pulping Process Streams (~~i.e.,~~ CASRN 66071-92-9..."

***Source:*** 0321-0109

***Response:*** The regulatory text (finalized at 40 CFR 711.10(d)(1)(i)) provides a list of the industry processes and the associated byproduct substances that are exempted from reporting under CDR when the site meets the requirements of the exemption. EPA disagrees that the process identity should be written to describe the streams rather than the process itself. The identification of streams focuses on the identity of the chemicals themselves and is duplicative with the chemical listing. Such a description results in an inconsistency within the regulation and may add confusion as other processes and related chemical substances are added to the exemption (through the petition process). For example, another listing is: Portland Cement Manufacturing (*i.e.*, CASRN 68475-76-3, Flue dust, portland cement). The process description is "Portland Cement Manufacturing" and the specific byproduct from that process is listed following the process description. Similar to the Kraft Pulping Process, there are other reportable substances included in Portland Cement Manufacturing. EPA did not include the changes suggested by the commenter.

### D.2.2. Portland cement byproducts

***67. Summary:*** A commenter stated, "CDR is not designed to (and in most cases does not) require manufacturers to report where and how manufactured or processed substances are stored, and requiring reporting of material temporarily stored during the manufacturing process provides little value in achieving the goals of CDR. There is no chemical difference between CKD that is reintroduced immediately and CKD which is held temporarily before reintroduction to the process, and no regulatory or public policy rationale for the distinction given the other regulatory programs already in place to address the safe storage, transport, handling, and disposal of materials. Indeed, the current regulation fundamentally undermines the purpose of the CDR program by misrepresenting the amount of CKD generated during the manufacturing process."

***Source:*** 0321-0110

***Response:*** EPA disagrees that the CDR reporting requirements misrepresent the amount of CKD generated during the manufacturing process. EPA agrees that, at this time, CDR is not designed to collect information on where and how chemicals are stored. Although storage information is not currently collected under CDR and is not being added by this rulemaking, it is information needed for EPA to implement TSCA. For example, to support a proposed priority designation, EPA will screen the chemical substance under its conditions of use against certain criteria specified in TSCA section 6(b)(1)(A) by reviewing the reasonably available information with respect to, among other criteria: storage near significant sources of drinking water. In addition, the nature of chemical manufacture and processing for each specific condition of use is needed to assess potential worker exposure and to inform EPA's ongoing efforts related to chemical prioritization and risk evaluation activities. The fact that there is no chemical difference between a material that is reintroduced immediately and a material that is held for a time and then reintroduced is immaterial because the potential exposures of those two scenarios are different. Even if destined for eventual reuse, chemicals temporarily stored may result in greater susceptibility to unintentional release/exposure.

As stated in the proposed rule preamble, 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. For example, on-site recycling systems that rely on open troughs for moving material have an increased opportunity for exposures due to dusting, splashing, or volatile air releases as compared to the use of an enclosed pipe for moving material from one part of the manufacturing process to another. 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. Any volume 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.

### D.2.3. Comments on petition process to change list of industries/byproducts

***68. Summary:*** Two commenters requested that EPA eliminate the second factor required for application of this byproduct exemption. One of commenters expressed concern that the factors proposed by EPA for evaluation under 40 CFR 711.10(c)(2)(ii)(B) will result in "additional analysis, tracking, and reporting than what is required today." Additionally, the commenter stated that the second consideration proposed by EPA under 40 CFR 711.10(c)(2)(ii)(B)(*2*) is unnecessary because "EPA should not be concerned about potential exposures if the byproduct is part of an enclosed system."

***Sources:*** 0321-0102, 0321-0109

***Response:*** In its proposed revisions to the byproducts reporting provisions for the 2020 CDR reporting cycle, EPA developed a four-factor evaluation approach for evaluating whether a specific site-limited recycled byproduct stream is eligible for an exemption from CDR reporting if said byproduct stream is brought to EPA's attention via the petition process proposed as part of this rulemaking effort. While a major consideration in proposing these revisions was toward reducing reporting burden on the regulated community, one of EPA's primary goals for byproduct reporting exemptions was to balance reduced reporting burden with maintaining EPA's ability to receive the information it needs to understand potential chemical exposures to byproducts, regardless of whether byproducts are contained in enclosed systems or not (84 FR 17694, April 25, 2019). EPA disagrees that the second petition factor would result in more analysis, tracking or reporting than is already required. The second factor is a requirement that the byproduct substance itself (*e.g.*, a portion of the byproduct is used for a different purpose and not recycled in an enclosed system) or another chemical substance from the same overall manufacturing process is being reported. If the site has previously reported under CDR, then the site will have the information needed to address this factor.

Data provided through CDR reporting is used in a wide variety of activities ranging from chemical prioritization and risk evaluation activities to inform response actions. Though chemical byproducts addressed under these petitions will be present within an enclosed system (as discussed by the commenter), EPA is concerned with potential exposure information as it is feasible that *some* type of exposure and/or chemical release may occur. As referenced in the preamble to this rulemaking effort, "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 (84 FR 17708, April 25, 2019)."

Regarding the second consideration specifically, EPA expects to be able to ascertain typical exposure scenarios for an exempted byproduct's manufacturing process based on information for other substances that are reported at the facility in the same manufacturing process. If no other substances are reported, EPA would not otherwise have any exposure-related information associated with the manufacturing site (84 FR 17709, April 25, 2019). As such, EPA is generally finalizing the petition process as proposed, including the second consideration (now clarified as a requirement at 40 CFR 711.10(d)(1)(ii)(B)(*2*), see comment response number 72 below), in order to continue to meet its obligations under TSCA. EPA expects that companies requesting to amend the list of exempted substances/industries will provide information for specific site-limited recycled byproducts using the proposed petition process.

***69. Summary:*** Most commenters supported the proposed petition process for the exemption while also suggesting modifications and guidance. Some argued that the proposed process is too onerous to demonstrate meeting the criteria for the exemption and others requested that EPA clarify how this process will operate, including: the criteria for seeking an amendment,

how potentially sensitive information can be claimed confidential, and additional explanation and examples of what constitutes Agency "interest" in a byproduct substance and if there is a particular timeframe for the interest.

***Sources:*** 0321-0094, 0321-0095, 0321-0102, 0321-0106, 0321-0107

***Response:*** EPA will provide information on the CDR website, similar to the information available for the current CDR petition process (40 CFR 711.6(b)(2)), to assist the petitioner in understanding the types of information that a petition should include to assist EPA in determining if certain types of manufacturing processes and associated byproduct substances meet the criteria of this exemption. Regarding how to claim information in a petition as confidential, the petitioner must clearly mark the confidential information, provide the required substantiation and signed and dated certification statement unless exempted by TSCA section 14(c)(2), and provide a version of the petition with the information claimed as confidential redacted (see in particular 40 CFR 711.30 (a)(3), (b), and (d)(2)). In general, EPA determines current interest based on both current and anticipated future needs. For example, chemicals that are the subject of TSCA rules or activities, such as chemicals for which prioritization was initiated and/or priority designations were proposed, could be expected to be considered of current interest. To inform its determination of current interest, the Agency may utilize its current knowledge and understanding of the individual chemical's structure, properties, indications of hazards and potential exposures (e.g., potential for persistence, bioaccumulation, health effects, or environmental effects). The Agency also considers whether the potential risks of the chemical substance are already adequately managed by EPA or another agency or authority, and takes into account the information needs of EPA, other federal agencies, tribes, states, and local governments, as well as members of the public.

***70. Summary:*** A commenter stated that the timing of the rulemaking and proposed petition process does not allow requests to be submitted and reviewed in time for the 2020 reporting. Furthermore, the proposed process of submission of a detailed request followed by lengthy EPA review is not fit-for-purpose.

***Source:*** 0321-0089

***Response:*** EPA proposed and finalized the exemptions with the information it had available, as described in the response to comment summary 62. EPA's intent in providing the petition process is to provide a mechanism for expansion of this reporting exemption based upon information provided by industry and specifically analyzed by the Agency, as appropriate. Although there will be insufficient time for the petition submission, review, and, if granted, subsequent rulemaking for the 2020 CDR, there is sufficient time for the 2024 CDR submission period. Petitioners must submit their request to EPA no later than 12 months prior to the start of the next principal reporting year. For the 2024 submission period, the principal reporting year is 2023. Therefore, petition requests for the 2024 submission period must be submitted before January 1, 2022.

***71. Summary:*** A commenter emphasized that decisions to make any changes to the list of exempted industries/substances need to be subject to public notice and a public comment opportunity.

***Sources:*** 0321-0107

***Response:*** Because rulemaking is required to change the list of manufacturing processes and chemicals eligible for the exemption, the public will receive notice of the change and have the opportunity to comment. This rulemaking could be a direct final or proposed rule specific to a particular petition or done in combination with another proposed rule (i.e., before the next reporting cycle). In the regulatory text at 40 CFR 711.10(c)(2)(ii)(C) in the proposed rule (now at 40 CFR 711.10(d)(1)(ii)(D)), the term "As needed" was only meant to differentiate the petitions that are granted and not granted; if not granting a petition, rulemaking would not be required. To avoid potential future misinterpretation, "As needed…" has been replaced with "After granting a petition…" in the phrase at 40 CFR 711.10(d)(1)(ii)(D).

***72. Summary:*** A commenter requested that the regulatory text be changed to better reflect the preamble where the description is for the two considerations that must be met for additions to the list of exempted substances and that these considerations be linked with an "and" as they are in the preamble.

***Source:*** 0321-0107

***Response:*** EPA agrees with this comment and has changed the regulatory text to describe that the first two of the four proposed considerations are requirements and not considerations. The final regulatory text includes two requirements at 40 CFR 711.10(d)(1)(ii)(B) which reflect the requirements of the exemption and two considerations at 40 CFR 711.10(d)(1)(ii)(C) which EPA will use to evaluate petitions. EPA is not limited to those four items when petitions are evaluated and may rely on additional information or internal decision criteria.

## D.3. Comments on exempting byproducts from non-integral equipment

***73. Summary:*** Several commenters supported the proposed exemption for byproducts produced from non-integral equipment. A commenter requested that EPA provide examples applying this exemption to wastewater treatment processes and another commenter requested EPA confirm the flue gas desulfurization example provided with the proposal.

***Sources:*** 0321-0089, 0321-0099, 0321-0103, 0321-0104, 0321-0105, 0321-0109

***Response:*** EPA has added to the Instructions for Reporting wastewater treatment, flue gas desulfurization, and catalytic reduction systems as examples of specific scenarios that meet the criteria of this exemption. The Instructions for Reporting are included as an attachment to the ICR addendum and will be finalized prior to the start of the next reporting period (June 2020).

***74. Summary:*** Two commenters requested EPA expand the exemption scope to include beneficially used byproducts (i.e., CCR from utilities). The commenters stated that CCR has been subject to EPA risk assessments under RCRA, resulting in a determination that CCR did not warrant regulation as a hazardous waste or regulations governing the proper disposal of CCR and the identification of its beneficial uses. The commenter expressed belief that, because the beneficial use of CCR is already subject to conditions under RCRA, EPA is unlikely to take action under TSCA and beneficially used CCR also should be exempt from CDR reporting requirements.

***Sources:*** 0321-0104, 0321-0105

***Response:*** EPA disagrees with the comment. The production of CCR from utilities is integral to the generation of electricity (which is a utility's product), and thereby not applicable for the byproducts from non-integral equipment exemption.

EPA disagrees that an exemption from a waste management statute (*i.e.*, RCRA) for beneficial uses automatically means that a similar exemption should apply to CDR, which is a tool to collect exposure-related information on chemicals in commerce. In addition, EPA believes that adding a different exemption for CCRs that are beneficially used is outside the scope of this rulemaking. Regarding the commenter's characterization of the RCRA coal ash rule (40 CFR § 257.53 – definition of "beneficial use of CCR") as finding that CCR did not warrant regulations governing its proper disposal and the identification of its beneficial uses, when promulgating those regulations in 2015, EPA established a definition for beneficial use to distinguish legitimate and responsible beneficial use from disposal. EPA specifically defined beneficial use of CCR as providing a functional benefit, substituting for a virgin material, meeting applicable product specifications, and, in the case of unencapsulated uses involving placement on the land of 12,400 tons or more in non-roadway applications, being able to demonstrate that environmental releases to groundwater, surface water, soil and air are comparable to or lower than those from analogous products made without CCR, or that environmental releases to groundwater, surface water, soil and air will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use. In addition, RCRA regulates waste management, while TSCA is concerned with chemical substances that are in commerce. Therefore, beneficially used substances that are re-entered into commerce remain of interest for purposes of TSCA.

***75. Summary:*** One commenter did not support the proposed byproduct exemption, stating that EPA didn't provide a sufficient basis. Regarding EPA's statement that release from pollution

control equipment can often be obtained through national inventories such as TRI, the commenter noted that TRI covers only about 600 chemicals and for the 2016 CDR manufacturers reported information on about 8,700 chemicals. The commenter noted that in past rulemakings EPA has identified the differences between TRI and CDR. Regarding EPA's discussion about how it uses Emission Scenario Documents (ESDs), the commenter stated that "a deficiency in the ESDs cannot be used as the basis to ignore a known environmental release of a chemical or an exemption from reporting under the CDR."

***Source:*** 0321-0107

***Response:*** EPA disagrees with this comment and believes the reasons for exempting these byproducts are sufficient. The Agency carefully considers its needs for the information collected under CDR and the burden associated with providing such information. As stated in the proposal, EPA considers the information that would be provided through reporting of byproducts generated by this type of non-integral equipment to be generally less critical than similar information that will continue to be obtained for integral equipment (i.e., CCR). Because releases from non-integral equipment are not typically included in EPA's environmental release assessments under TSCA, at this time EPA believes such information does not need to be collected through CDR. EPA may elect to collect such information in the future through other venues or if the Agency's need for CDR information changes.

## D.4. Consolidating byproduct exemptions

***76. Summary:*** Commenters opposed directly integrating without modification the existing 40 CFR 720.30 (g) and (h) regulatory text. Commenters suggested that EPA review the exemptions against the current TSCA and EPA data needs, justify exemptions that will continue, and provide an opportunity for public comment on the justification. Some commenters advocated for the expansion of the exemptions while others for the elimination of the exemptions. One commenter stated that continuation of all of these exemptions is hard to justify in light of the TSCA amendments that greatly expanded EPA's duties to prioritize and evaluate the risks of chemicals under their conditions of use and to identify potentially exposed or susceptible subpopulations. Most or all of the exemptions apply to activities that TSCA now defines to be conditions of use of a chemical substance. If exemptions are retained, commenters suggested both regulatory and guidance changes.

Specific comments, by exemption, are "for any byproduct if its only commercial purpose is for use by public or private organizations that":

- 720.30(g)(1), burn as a fuel: Two commenters stated that this exemption should be eliminated because burning as a fuel fits within the definition of "conditions of use." In addition, a commenter stated that this exemption is inappropriate for inorganic byproducts, because they have no value as a fuel. If the exemption is retained, EPA should improve the CDR guidance to limit the applicability of this exemption for

inorganic byproducts, similar to the TRI guidance that indicates metal and metal compounds cannot be reported as burned for energy recovery.

- 720.30(g)(2), dispose of as a waste, including in a landfill or for enriching soil: Three commenters stated that this exemption should be eliminated, either because disposal is not a "commercial purpose" or because it fits within the definition of "conditions of use." Commenters noted that considering "disposal" as a commercial purpose is confusing because it is internally inconsistent with 720.30(g), which exempts byproducts that are not used for a separate commercial purpose. A commenter suggested that EPA require one-time reporting to identify the chemicals and uses now falling within the exemption. Regarding fitting with the definition of "conditions of use," one commenter provided examples of data gaps that result from not requiring reporting of the disposal of byproducts, citing a recent EPA Inspector General report that details EPA's lack of adequate data, tools, staff, and resources to make sound determinations on the safety of pollutants found in biosolids applied to land and the impacts of this exemption on actions associated with per- and polyfluoroalkyl substances (PFAS). A commenter also noted that the exemption as it applies to "soil enrichment" is vague because it is unclear how the exemption applies to inorganic byproducts used to produce a fertilizer or other product used for alleged soil nutrient purposes and is overly broad because it is a condition of use capable of potentially widespread exposures, through a variety of exposure routes, citing concerns for substances listed on EPA's workplan.
- 720.30(g)(3), extract component chemical substances for commercial purposes: Two commenters stated that this exemption should be removed, stating that it fits within the definition of "conditions of use" and that this exemption prevents EPA from using CDR to identify downstream uses of the byproduct. Another commenter stated that EPA has changed its interpretation of this exemption over time and that it is now too narrow of an interpretation and should be broadened. This commenter advocated for expanding EPA's interpretation of "extracted component chemical substance" (as proposed during the 2017 CDR Negotiated Rulemaking in what was known as "Approach B" detailed in the document "*Potential Approaches for the Chemical Data Reporting (CDR) Inorganic Byproducts Negotiated Rulemaking Committee*") to allow heat or reaction to create the substance to be "extracted."

***Sources:*** 0321-0095, 0321-0100, 0321-0104, 0321-0107

***Response:*** EPA did not propose changes to the current byproduct exemptions, but rather had proposed to replicate language from 40 CFR 720.30(g) and (h) that is currently incorporated by reference into 40 CFR 711.10(c) without change, so that all of the CDR byproduct-related exemptions are in one place. Though these comments were not germane to the change that was proposed, and were thus out of scope for the rulemaking, they reinforce similar concerns associated with the existing exemptions that were raised during the 2017 negotiated rulemaking, and the Agency has taken them into consideration. EPA is not finalizing this change in order to take additional time to better consider the variety of comments about these exemptions and determine if future changes are warranted, and if so, provide additional opportunities for notice and comment on these very technical issues that are of interest to a variety of groups. Obtaining information on percent byproduct in the next reporting cycle will

further EPA's understanding of byproducts in commerce and help to inform any future determination as to whether alteration of the existing exemptions is warranted. To the extent that commenters identified areas of confusion, EPA will be providing enhanced guidance that will incorporate additional examples covering the topics raised by the commenters, including examples shared during the negotiated rulemaking.

In regards specifically to the exemption at 720.30(g)(3), EPA disagrees with the comment that the Agency changed its interpretation of "extracted component chemical substances" over time. The commenter misconstrued the historical language they cited and more recent CDR guidance (e.g., the CDR Frequent Questions and Instructions for Reporting, both available on the CDR website) has directly addressed the misinterpretation of this exemption.

## E. Other Comments

***77. Summary:*** Two commenters stated that EPA needs to address gaps in its use and exposure information. The commenters proposed that EPA consider requesting information that will assist with identifying high-priority substances and performing their subsequent risk evaluations. One commenter stated that, in anticipation of the next round of prioritization, EPA must keep in mind TSCA section 6(b)(2)(D)'s requirement to give preference to chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemicals Assessments as PBT chemicals. The commenter stated that collecting information on these chemicals up front would allow the Agency to prioritize the chemicals with the greatest risk to human health and the environment for risk evaluation. A second commenter stated that reporting rules should be expanded for: "(i) substances designated high-priority, (ii) substances included on the 2014 TSCA Work Plan list, and (iii) substances subject to industry risk evaluation requests," in order to receive expanded information on chemicals now undergoing, or likely to undergo, TSCA risk evaluations. This commenter also stated that EPA should collect information from processors for chemicals listed as high priority. A third commenter stated that if a chemical has undergone the TSCA section 6 prioritization process, EPA should waive the reporting requirements for any chemical determined to be low-priority.

***Sources:*** 0321-0100, 0321-0102, 0321-0108

***Response:*** EPA believes the changes finalized in this rule help to address some of the data gaps and improve the information reasonably available to EPA to make decisions regarding the prioritization of chemicals and for other uses. For example, the CDR processing and use information has been improved by harmonizing with OECD data characterizations (for those reporting using these codes voluntarily and for reporters of chemical substances designated in 2019 as a high priority for risk evaluation under TSCA section 6(b) (84 FR 71924, December 30, 2019)); adding the function for a chemical in consumer and commercial uses; and collecting the function specific to each chemical in a mixture, when the composition considered confidential by the foreign supplier.

EPA agrees that additional data may be needed to address certain requirements under TSCA and is working on a variety of data collection efforts to augment the information available for future activities, including risk evaluations and other efforts under TSCA section 6. EPA will work with stakeholders to collect the most accurate use information regarding chemicals designated as high priority. For example, EPA will conduct outreach meetings and open public dockets. In addition, EPA will consider using TSCA authorities under sections 4 and 8 to collect information when necessary.

***78. Summary:*** One commenter expressed belief that the 2,500 lb reporting threshold for chemicals that are the subject of certain listed TSCA actions should be increased to 25,000 lbs, which is the threshold for other chemicals. The commenter stated that EPA already has a high level of information on these chemicals because they are subject to other TSCA submissions and/or actions. In addition, this and another commenter stated that EPA is now issuing TSCA section 5 consent orders and significant new use rules more frequently, thereby triggering the need for these new chemicals to be reported at the lower threshold when most of them have already been reviewed and restricted by EPA. The commenter expressed belief that EPA has not made a case for why these chemicals warrant a higher degree of information collection and believes this puts an unnecessary burden on the reporting companies. The second commenter suggested alternate thresholds based on risk determinations stemming from TSCA sections 5(a) and 5(e) actions. A third commenter stated that the current lower threshold should apply to chemicals listed as high priority, included in the 2014 Update to the TSCA Work Plan, or subject to industry risk evaluation requests.

***Sources:*** 0321-0089, 0321-0096, 0321-0100

***Response:*** EPA did not propose or ask for comment on changing the reporting thresholds, therefore these comments are out of scope for this rulemaking. However, EPA will consider these comments for future changes to CDR and for improvements to information gathering tools.

***79. Summary:*** One commenter requested an exemption for an imported chemical substance if the same domestic chemical substance under the same circumstances is not reportable or is exempt from reporting. The commenter stated that EPA has been misapplying for CDR purposes the definition of "manufacture" respecting "import," and questions why the term "import" was included in the definition of "manufacture." Citing Congressional discussions from 1971, the commenter stated that "if a TSCA requirement does not apply to a chemical substance produced by a U.S. manufacturer, that same TSCA requirement does not apply to imports of the same chemical substance produced by a non-U.S. manufacturer."

The commenter used imported scrap metal as an example, stating that it makes no sense that importing scrap metal results in reporting under CDR while domestically sourced scrap metal is not reportable, even if the metal container was originally imported [as an article] and reporting

was not required. The commenter stated that "EPA's error in applying CDR automatically to imports alone explains the CDR oddity that imported scrap metal is reportable under CDR but not the recycling of domestically sourced scrap metal."

***Source:*** 0321-0111

***Response:*** This comment is out of scope for this rulemaking, but EPA is taking this opportunity to address it. EPA disagrees that it is wrongly applying the definition of manufacture to scrap metal and other imports that are in a similar situation. While the Agency appreciates the comment's details on one possible reason for why "import" is included in the definition of "manufacture" in TSCA section 3(9), the legislative history cited is from five years prior to the passage of the original statute and thus is not as authoritative as the commenter suggests. Since the passage of original TSCA in 1976, EPA has a long history of applying the definition of manufacture to include import regardless of the status of domestic manufacture of the same chemical substance, in both the TSCA section 5 new chemicals program and the TSCA existing chemicals program, including TSCA section 8. This consistent application of TSCA's definition of "manufacture" to imports was not changed by the 2016 amendments to TSCA.

Scrap materials that are imported into the United States are considered raw materials that are imported for the intention of commercial use. Articles, such as metal cans, that have completed their useful life within the United States are not chemical substances produced by a manufacturer, but rather are end-of-life articles that are pulled from the waste stream and recycled. The act of recycling itself is not considered manufacturing, but rather is a form of processing what otherwise would be a waste material.

***80. Summary:*** One commenter requested exemptions for facilities that process scrap metal, for the metal-oxide byproducts derived from the feedstock metal, and for the feedstock metal that was chemically liberated from the metal-oxide byproduct.

The commenter stated that metal recycling facilities may be required to report byproducts formed during the metal-melting process because the process may generate metal oxides as a manufacturing byproduct. The commenter stated that they believe this situation, in which the "metal-oxide byproduct and the metal derived from the metal-oxide byproduct are reportable under CDR while the 'new' metal (main) product is not reportable," creates a disincentive for facilities to recycle valuable metal-containing byproducts back into their processes and instead "favors disposal of a byproduct over its chemical conversion back to its original state" by imposing an additional recordkeeping and reporting burden. The commenter also noted that the metal-oxide byproduct is effectively an intermediate, consistent with the definition at 40 CFR 720.3(n).

The commenter requested that EPA establish and make effective before the 2020 CDR reporting period exemptions from reporting for both metal-melting byproducts that are converted back to their original metal states and the resulting metal derived from these byproducts.

***Source:*** 0321-0111

***Response:*** EPA did not create exemptions specific to metal-melting byproducts that are converted back to their original metal states or the resulting metal derived from these byproducts. In both situations, the site is manufacturing a chemical substance that is subject to reporting, unless a current exemption applies or other requirements (such as production volume) are not met. Whether the intermediates, byproducts, or final products are reportable under CDR depend upon the individual circumstances at each site. Additionally, establishing such a reporting exemption would be outside the scope of this rulemaking because it is not in response to specific amendments made to CDR by the proposed rule.

In the circumstances where the melting of the scrap feedstock results in a chemical reaction, creating a metal-oxide byproduct as described by the commenter and the metal-oxide byproduct is not separated from the primary product and does not impart a desired attribute to the primary product, the byproduct is not reportable under CDR.

In the circumstances where the melting of the feedstock scrap metal does not result in a chemical reaction, for purposes of CDR there is not a different substance being manufactured and therefore no reporting is required.

Although not mentioned by the commenter, in the past EPA discussed the issue of byproducts resulting from metal recovery operations with industry, such as dross that is skimmed from the scum in the secondary furnace or other byproducts. These discussions resulted in clarifications in the CDR Instructions for Reporting regarding when and how to report such byproducts (see, specifically, pages 2-7 and 2-8 of the 2016 Instructions for Reporting, Ref. 5).

EPA disagrees that reporting under CDR is a disincentive to recycling. During the 2017 negotiated rulemaking, EPA examined CDR and TRI data from metal byproduct manufacturers and recyclers and determined that, based on disposal and recycling data reported to TRI, there was no evidence that requiring CDR reporting for byproduct chemicals reduced byproduct recycling rates (Ref. 6).

## E.1. Statutory and executive order reviews67

***81. Summary:*** EPA received one comment on statutory and executive order reviews. The commenter emphasized that tribal consultation under Order 13175, and EPA's 1984 Indian Policy should have been carried out by this rulemaking.

***Source:*** 0321-0092

***Response:*** EPA disagrees that a tribal consultation was necessary for this rule. EPA stated in Unit VII.G of the proposed rule that this rule 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). EPA concluded that the impacts of the rule would not significantly nor uniquely affect the communities of tribal governments. Thus, EPA determined that Executive Order 13175 did not apply to this rule.

Even though EPA determined that Executive Order 13175 did not apply, EPA conducted tribal outreach on the TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a) from May 2019 through August 2019 to provide information to tribes on the proposed rule and to obtain feedback. Two nationwide outreach sessions were conducted, and tribal comments were accepted through August 30th. In addition, EPA developed supplemental background information to further explain proposed actions to tribes.

## E.2. Comments unrelated to the proposed revisions

***82. Summary:*** One commenter encouraged EPA to end the partial reporting exemptions for the petroleum process streams due to the potential for soil and water contamination from hydraulic fracturing operations.

***Sources:*** 0321-0092

***Response:*** This comment is related to CDR but is outside the scope of this rulemaking because it is not in response to specific amendments made to CDR by the proposed rule. EPA will consider the comments for potential future changes to CDR.

***83. Summary:*** Two commenters expressed concern that because asbestos is exempt from reporting under CDR, there is a serious gap in EPA and public understanding of exposure to this substance. The commenters claim that EPA has failed to articulate a rationale for why asbestos is not required to be reported. One of the commenters argued that EPA should eliminate the reporting exemption for naturally occuring chemical substances or for such substances that have been designated as high priority chemicals or otherwise nominated for risk evaluation.

***Sources:*** 0321-0090, 0321-0100

***Response:*** These comments are related to CDR but are outside the scope of this rulemaking because they are not in response to specific amendments made to CDR by the proposed rule. EPA will consider the comments for potential future changes to CDR. EPA recently denied petitions seeking changes to the CDR exemptions related specifically to the reporting of asbestos. EPA provided detailed rationale for not changing the CDR exemptions relating to asbestos in response to those petitions. (84 FR 3396 February 12, 2019; 84 FR 20062 May8, 2019). Both petition denials are currently undergoing judicial review."

***84. Summary:*** EPA received one comment that was unrelated to CDR or the TSCA section 8(a) small manufacturing definition. The commenter stated that it is pleased with the vision of the Agency regarding the general proposed fees structure, but is concerned about the "over fee proportionality, timelines surrounding consortia formation, and overestimating costs for certain section 5 activities."

***Source:*** 0321-0098

***Response:*** These comments are outside the scope of this rulemaking because the comment pertains to the fees rule and TSCA section 5 activities. The comment will be transmitted to the appropriate personnel.

***85. Summary:*** One commenter provided suggestions to reduce reporting under CDR. The suggestions were to:

- Limit the information requirements for site-limited intermediates (e.g., site-limited monomers and petrochemical derivatives) by omitting the reporting of processing and use information; and
- Reduce reporting burden of inorganic byproducts resulting from catalytic processes (e.g., metal or acid catalysts) that are recycled on-site or confined to recycling at another site, where recycled material is sent back to the original site of use by requiring only one-time reporting of the name of the byproduct and the average percentage range of byproduct that is recycled for subsequent use.

***Source:*** 0321-0099

***Response:*** The suggestions are out of scope for this rulemaking because the suggestions do not pertain to provisions in the proposed rule. However, the comments will be considered for potential future changes to CDR. In addition, EPA will use some of the information about catalysts to enhance the current guidance.

## 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. *Economic Analysis for the Final Rule on TSCA Chemical Data Reporting (CDR) Revisions - (RIN 2070-AK33)*. Office of Pollution, Prevention, and Toxics. Washington, DC. December 2019.

2. EPA. TSCA CDR Instructions for Reporting (EPA Docket EPA-HQ-OPPT-2018-0321). Office of Pollution Prevention and Toxics. Washington, DC.

3. EPA. TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates. Office of Pollution Prevention and Toxics. Washington, DC. https://www.epa.gov/chemical-data-reporting/tsca-chemical-data-reporting-fact-sheet-non-isolated-intermediates

4. EPA. Kraft Pulp Mill Compliance Assessment Guide (CAA, CWA, RCRA, EPCRA), United States Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Office of Compliance Manufacturing, Energy and Transportation Division. Washington, DC. May 1999.

5. EPA. Instructions for Reporting 2016 TSCA Chemical Data Reporting. Office of Pollution Prevention and Toxics. Washington, DC. June 23, 2016. https://www.epa.gov/sites/production/files/2016-05/documents/instructions_for_reporting_2016_tsca_cdr_13may2016.pdf

6. EPA (2017). Examples: Reporting under CDR, TRI, and RCRA - Chemical Data Reporting (CDR) Inorganic Byproducts Negotiated Rulemaking; Presentation. EPA-HQ-OPPT-2016-0597-0030.