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## **2024** Chemical Data Reporting Questions and Answers

Under Section 8 of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(a)), the Chemical Data Reporting (CDR) rule requires manufacturers (including importers) of certain chemical substances listed on the <u>TSCA Chemical Substance Inventory</u> to report information concerning the manufacturing, processing, and use of those chemicals (40 CFR Part 711).

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- The determination of the need to report is based on production volume during *any* calendar year since the last principal reporting year. For the 2024 submission period, consider the production volumes from years 2020, 2021, 2022, and 2023.
- Information on the reportable chemical substance must be reported during the CDR submission period (40 CFR 711.20).
- All reporting companies must report CDR data electronically, using e-CDRweb, the CDR web-based reporting tool, and EPA's Central Data Exchange (CDX) system. Prior to submitting data, submitters must register with CDX. Ensure that your pop-up blocker is disabled before you begin to use e-CDRweb to complete your Form U.
- Reporting is required for all chemical substances listed on the TSCA Inventory, other than polymers, microorganisms, naturally occurring chemical substances, water, and certain forms of natural gas (40 CFR 711.5 and 711.6) when manufacture (including import) of those chemical substances meets the other reporting requirements. Chemical substances that are the subject of any of certain listed TSCA actions may not be eligible for partial or full exemptions (40 CFR 711.6).
- The reporting threshold is 2,500 lb (1,134 kg) for any person who manufactured a chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4) or 6; an order issued under TSCA sections 5(e) or 5(f); or relief that has been granted under a civil action under TSCA sections 5 or 7. The effects of these TSCA actions on CDR reporting are assessed based on the status of the chemical substance as of the beginning of the submission period (40 CFR 711.8(b) and 40 CFR 711.15).
- Small manufacturers meeting the definition at 40 CFR 704.3 are exempt from CDR requirements unless they manufacture (including import) 2,500 lb or more of a chemical substance that is the subject of a rule proposed or promulgated under sections 4, 5(b)(4), or 6 of TSCA, or is the subject of an order in effect under sections 4 or 5(e) of TSCA, or is the subject of relief that has been granted under a civil action under sections 5 or 7 of TSCA (40 CFR 711.9 and TSCA section 8(a)(3)(A)(ii)).
- Information submitted under CDR may be claimed as confidential; however, such claims must be made at the time of submission and substantiated in accordance with TSCA and the CDR rule. Submitters must provide upfront substantiation of all confidentiality claims except for claims made for domestic manufacture, import, yearly production volume information, and certain joint submission information. Certain processing and use data elements, a blank response, or a response that is designated as "not known or reasonably ascertainable" may not be claimed as confidential (40 CFR 711.30).
- Visit the CDR website (<u>https://www.epa.gov/cdr</u>) for program updates and announcements, guidance materials, and contact information for technical assistance.

## PREFACE

These Frequent Questions (FQs) are intended to provide supplemental information for complying with the requirements for Chemical Data Reporting (CDR) for the 2024 reporting period.

These FQs should be used for information only and are not a substitute for the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) rule. You should carefully review the CDR regulations, located at 40 CFR Part 711, for specific information on how to comply with requirements.

If you need additional assistance, visit EPA's Chemical Data Reporting website at <u>https://www.epa.gov/cdr</u>, contact EPA's TSCA Hotline at <u>tsca-hotline@epa.gov or</u> 202-554-1404, or send an email to <u>eCDRweb@epa.gov</u>.

## **General Chemical Data Reporting Questions**

## 1. Chemical Data Reporting purpose and history, including the Frank R. Lautenberg Chemical Safety for the 21st Century Act

### 1.1. What is the difference between IUR and CDR?

Although there are differences between this information collection when it was called IUR and today's CDR, in effect they are the same program, one which has changed over time. In 2011, EPA changed the name of this TSCA section 8(a) information collection from Inventory Update Reporting (IUR) to Chemical Data Reporting (CDR). The first collection of the IUR occurred in 1986; collections have occurred roughly every four years. The reader should note that wherever IUR is used to refer to the 40 CFR 711 regulations or to future CDR submission periods, IUR and CDR are synonymous.

EPA changed the name from IUR to CDR in recognition that the reporting requirements have changed over time and now include information that was not part of the original TSCA Inventory.

For an overview of reporting requirements and how those requirements have changed over time for the IUR/CDR collections, beginning with the 2006 IUR, view the Summary of CDR Reporting Requirements by Year at <u>https://www.epa.gov/chemical-data-reporting/summary-cdr-reporting-requirements-year</u>.

## **1.2.** Is the purpose of CDR to make additions or deletions to the list of substances included on the TSCA Chemical Substance Inventory?

No. The purpose of CDR is to collect recent information on the manufacture (including importation); processing; and industrial, commercial, and consumer uses of certain chemical substances currently on the TSCA Inventory. Additions to the TSCA Inventory are made through EPA's New Chemicals Program (See 40 CFR Part 720). You can learn more about the New Chemicals Program at <u>https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca</u>.

## **1.3.** What is the difference between the CDR rule and the Toxic Release Inventory (TRI) reporting requirements?

The key distinction is the purpose of the information collected. The CDR was implemented under Section 8 of TSCA. The primary purpose of the CDR is to provide EPA with up-to-date information on the production and use of chemicals in commerce. The TRI was established by the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986. The goal of the TRI is to provide the public, rather than EPA, with information about toxic chemicals. An important use and purpose of the data is captured by the title of the law: Community Right-to-Know. Unlike the scope of chemicals subject to TRI reporting, the scope of chemicals subject to CDR reporting is not limited to chemicals that are toxic. EPA uses CDR information for prioritization purposes and in the assessment of risks posed by these chemicals, among other activities.

Other differences between the CDR Program and the TRI Program are the frequency of data collection and the types of information collected. CDR data are reported to EPA on a four-year collection cycle, whereas TRI data are reported annually to EPA. CDR data primarily pertain to information on processes, uses, and production volumes of chemicals listed on the TSCA Inventory, whereas TRI data pertain to the quantities of chemicals included on the TRI list of

toxic chemicals released to the environment or otherwise managed as waste by industrial and federal sites. While most of the chemicals included on the TRI chemical list of toxic chemicals are also on the TSCA Inventory, toxicity is not a criterion for inclusion of a chemical onto the TSCA Inventory, whereas toxicity is a major criterion for inclusion of a chemical on the TRI list of toxic chemicals (hence the name "Toxics Release Inventory"). As with the CDR and TRI programs themselves, the TSCA Inventory and the TRI list of toxic chemicals serve largely different purposes.

Thus, information collected under the respective TRI and CDR reporting requirements have different purposes and differ based on who reports, the substances reported, and the data elements reported. You may be required to report under both TRI and CDR.

CDR data are comprised of basic exposure-related information on the types, quantities, and uses of chemical substances manufactured domestically or imported into the United States. The CDR rule, promulgated under the authority of Section 8(a) of TSCA, requires chemical substance manufacturers (including importers) to report manufacturing and processing data and industrial, commercial, and consumer use information for certain chemical substances on the TSCA Inventory.

The TRI tracks the waste management practices of certain facilities that manufacture, process or otherwise use chemicals included on the TRI list of chemicals. If the requirements for reporting are met, U.S. facilities (including federal facilities) must report annually the quantities of each TRI chemical it released to air, water, or land; recycled; used for energy recovery; or treated for destruction. (A "release" of a chemical means that it is discharged to air, water, or land.) These requirements are established under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and Section 6607 of the Pollution Prevention Act.

For CDR, manufacturers (including importers) of chemicals listed on the TSCA Inventory are subject to CDR, when they meet other reporting requirements such as production volume. The TSCA Inventory was created in late 1970s and currently lists 86,405 chemical substances with 41,484 of them identified as active in U.S. commerce. In 2020 (the last CDR reporting cycle), about 5,240 sites reported approximately 8,650 chemicals, resulting in close to 43,500 chemical reports.

The TRI dataset consists of information disclosed from approximately 22,000 facilities. Currently more than 820 toxic chemicals and chemical categories are included on the TRI chemical list. Facilities subject to the TRI reporting requirements that manufacture, process, or otherwise use a TRI-listed chemical within a calendar year in an amount above the established threshold level must submit a TRI reporting form for each TRI chemical for which a reporting threshold was exceeded. By making information about industrial management of toxic chemical wastes available to the public, TRI creates a strong incentive for companies to improve environmental performance.

For more information on the TSCA Inventory, visit <u>https://www.epa.gov/tsca-inventory</u>. For more information on TRI, visit <u>https://www.epa.gov/tri</u>.

## **1.4.** How does EPA use the CDR information that is reported?

EPA uses the CDR data to support chemical prioritization, risk evaluation, and risk management activities, among other activities, under TSCA. This information allows EPA to develop an understanding of the types, amount, end uses, and possible exposure to chemicals in commerce.

For example, processing and use information reported in 2012 and 2016 has helped EPA prioritize chemicals for risk evaluation. The data also includes information on the manufacture (including import), industrial processing and use, and consumer and commercial use of certain chemicals currently listed on the TSCA Chemical Substance Inventory (TSCA Inventory), a list of chemicals that are manufactured (including imported) in the United States.

## 2. 2024 Submission Period

### 2.1. When is reporting required for 2024 Chemical Data Reporting?

The 2024 submission period is from June 1, 2024 to September 30, 2024. During this submission period, manufacturers (including importers) are required to report production volume information for the years 2020, 2021, 2022 and 2023, and manufacturing, processing and use information for the year 2023.

### 2.2. What is the reporting frequency for the 2024 submission period and beyond?

The reporting frequency is every four years. The last submission period was in 2020. After the 2024 CDR submission period, the next submission period will be in 2028. In general, the submission period is from June 1 to September 30, or as identified in the regulatory text at 40 CFR 711.20.

#### 2.3. Are there changes to the CDR reporting requirements for 2024?

No, although the changes to the processing and use reporting codes initiated for the 2020 CDR reporting cycle are fully implemented for the 2024 and future reporting cycles; this means that all submitters are required to use the updated processing and use codes. Otherwise, the 2024 CDR reporting cycle has the same requirements as the 2020 CDR reporting cycle. Note that the reporting requirements beginning with the 2020 CDR were revised to better align with new statutory requirements resulting from TSCA amendments by the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act and to address submitters' feedback following the 2016 submission period. For a high-level description of changes to the 2020 CDR reporting requirements, which are also in effect for the 2024 CDR reporting cycle, see <u>Summary of Reporting Requirement Changes</u> on the CDR website.

## 3. Reporting Assistance and Training

#### 3.1. What types of reporting assistance are available?

Reporting assistance is available within the e-CDRweb reporting tool and in various documents on the CDR website. You may also contact the TSCA Hotline at 202-554-1404 or send an e-mail to <u>ecdrweb@epa.gov</u>.

### **3.2.** Is EPA providing training for CDR reporting?

Yes, EPA provides training for CDR reporting. The CDR website includes information on a variety of training opportunities.

Webinars: For each submission period, EPA hosts a series of webinars covering topics such as CDR reporting requirements, using the e-CDRweb reporting tool, and registering with EPA's Central Data Exchange (CDX). Once webinars are scheduled, they are publicly announced by

some or all of these methods: posting on the CDR website, sending a notice out through the TSCA email alerts system, or publishing a notice in the Federal Register. To sign up for TSCA email alerts, go to the <u>CDR homepage</u>. The presentation slides, transcripts, and audio recordings of past webinars are available on the <u>How To Report Under CDR</u> page of the CDR website.

If you need additional reporting assistance, EPA has a variety of information documents available on the *How to Report Under CDR* page of the CDR website, or you may contact the TSCA Hotline at 202-554-1404 or send an e-mail to <u>*eCDRweb@epa.gov*</u>.

## **Determining the Chemical Substances Subject to CDR Reporting**

## 4. General

## 4.1. How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR part 711 to determine your reporting requirements. You should consider the following three steps to determine whether and what information you are required to report for each chemical substance that you manufactured (including imported) in/into the United States or any of its territories since the last principal reporting year:

- Step I: Is your chemical substance subject to the CDR rule?
- Step II: Are you a manufacturer (including importer) who is required to report?
- Step III: What information must you report?

See the <u>CDR Instructions for Reporting</u> for additional guidance regarding reporting requirements.

## **4.2.** Do you have to report for each year during all four years in the reporting period or report for one of the years?

For each potentially reportable chemical substance at your site, consider the production volume for each of the years in the reporting period. For the 2024 CDR reporting period, the years are 2020, 2021, 2022 and 2023.). If the reporting threshold is reached during any one of these four years, you must report the following for each chemical substance at a single site:

- Production volume during each of the four years (2020, 2021, 2022, and 2023)
- Certain manufacturing information for the principal reporting year (2023)
- Processing and use information for the principal reporting year (2023)

## 5. Chemicals Manufactured (Including Imported) for Commercial Purposes

## **5.1.** If a company purchases chemicals and blends them into finished products, with no chemical reactions, is the company required to report these materials?

No. If a company purchases all of its chemicals from domestic sources and does not use them in a manner that manufactures other chemicals (e.g., blending, if no reaction occurs), the company is not required to report the chemicals. Note that if the company purchases chemicals from a foreign company and imports the chemicals, the company may need to report for the chemicals that it imported.

## **5.2.** If a company manufactures a chemical substance on the TSCA Inventory solely for export, is the company subject to CDR requirements?

Yes. Persons who manufacture chemical substances (including byproducts) solely for export are considered manufacturers for purposes of CDR and need to comply with the CDR regulations. Note, however, that the processing and use information required by 40 CFR 711.15(b)(4) is restricted to domestic activities, i.e., within the customs territory of the United States. If the company does not process or use the chemical substance within the customs territory of the United States, the company does not report processing and use information for that chemical.

## **5.3.** Is a company a manufacturer if it buys a chemical substance domestically and resells it or if the company buys a chemical substance domestically and packages it into drums?

In 40 CFR 711.3 "manufacture" is defined in part as "manufacture, produce, or import for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of substances." In both examples included in the question, the company is not manufacturing as long as the company is purchasing from a domestic source and is not extracting, for a commercial purpose, a CDR reportable component chemical substance from the substance it domestically purchased. If the company is importing, then it is considered to be manufacturing for CDR purposes.

#### 5.4. What is an "exporter" under the rule?

The CDR rule does not define or reference a definition for exporter because there are no reporting obligations under CDR for exporters. The definition of manufacture includes importing but not exporting.

### 5.5. Is reporting required if a chemical substance is simply diluted with water?

No. Simply diluting another substance with water does not trigger reporting. However, if your chemical substance reacts with water to create a different chemical substance, you may have manufactured a reportable chemical substance.

## 6. Co-Manufacturing by Contract

#### 6.1. What is the difference between toll manufacturing and co-manufacturing?

As part of the <u>CDR Revisions rule</u>, EPA replaced the term "toll manufacturing" with "comanufacturing" to add clarity for the co-manufacturing situation. In instructions, guidance, and other communication with submitters prior to the CDR Revisions rule, EPA may have referred to co-manufacturing as toll manufacturing, and more specifically to the two parties as the contracting manufacturer and the toll manufacturer. Because EPA does not specifically define the term "toll manufacturer," EPA believes it is clearer to use terms associated with the CDR definition of *manufacturer* in 40 CFR 711.3. Additionally, EPA believes the chemical industry often refers to toll manufacturing in a more general manner, where both of the criteria for comanufacture included in the CDR definition for *manufacture* are not met. These criteria are: (1) The chemical substance is produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process.

## 6.2. What is co-manufacturing by contract?

For CDR purposes, co-manufacturing by contract refers to a particular kind of co-manufacturing situation involving two parties: one company contracts with a second company to domestically produce a chemical substance exclusively for the first company. The first company, or contracting company, determines the specific chemical identity of the substance, and controls the total amount produced and the basic technology for the plant process. The second company, or producing company, generally provides the site, staff, and equipment necessary to manufacture the chemical substance. See 40 CFR 711.3 (definition of "manufacture").

For additional information about co-manufacturing and reporting for CDR purposes, please see: <u>TSCA Chemical Data Reporting Fact Sheet: Co-Manufactured Chemicals</u>.

## **6.3.** Who is primarily or solely responsible for meeting CDR requirements — the contracting manufacturer or the producing company? Does the contracting company have to submit information on behalf of the producing company?

Both the contracting company and producing company are responsible for meeting the CDR requirements. Contracting and producing companies must work together to select between the two following reporting methodologies for preparing their CDR submission. Depending on the reporting methodology selected, the contracting company and producing company will submit distinct information to EPA.

1. First reporting procedure: Under the first reporting methodology, the contracting company (as the primary submitter) has the responsibility to initiate a co-manufacturer report that will prompt the reporting requirements for the producing company (as the secondary submitter). Each party will complete its part of the co-manufacturer joint report as part of its overall CDR submission and will not have access to the information submitted by the other party. Although the contracting company would be submitting the report, both parties are responsible for the report. Therefore, if no report is filed, both the contracting company and the producing company can be held liable.

2. Second reporting procedure: This reporting methodology requires the contracting and producing company, upon written agreement, to work together to complete the report. For this second methodology, the producing company (instead of the contracting company) initiates and completes the report in e-CDR Web. The producing company would then coordinate with the contracting company to obtain the additional information needed to complete the submission. This coordination of information between the two parties must be done outside of e-CDRweb. Although the producing company would be submitting the report, both parties are responsible for the report. Therefore, if no report is filed, both the contracting company and the producing company can be held liable. EPA expects this reporting mechanism would be most appropriate in a scenario in which the producing company has the majority of the information regarding the production of a specific chemical.

Additional information about co-manufacturing and reporting for CDR purposes is found in: *TSCA Chemical Data Reporting Fact Sheet: Co-Manufactured Chemicals*.

## **6.4.** Can the contracting company report all of the information for a co-manufactured chemical?

No, the contracting company is not able to be the sole reporter of the co-manufactured chemical. If the contracting company initiates the co-manufactured chemical report, it must request that the

producing company provide certain manufacturing-related information for the chemical. See frequent question 6.3 for more information.

# 6.5. If the producing company agrees to report the chemical for the given CDR submission period, does that take the burden off of the contracting company? For example, if Company A produces the chemical for Company X and Company A agrees to report the chemical, does that absolve Company X from any reporting?

Not necessarily. If Company A agrees to report the manufacturing, but fails to do so, Company X is still responsible for reporting. The contracting company and the producing company are to decide among themselves how to meet the CDR requirements for a specific co-manufactured chemical substance by selecting between the first reporting procedure or the second reporting procedure for co-manufactured reports. Both parties (i.e., contracting company and producing company) are responsible to ensure that the report is submitted for the chemical substance. Depending on the reporting methodology selected, the contracting company and producing company will submit distinct information to EPA.

Additional information about co-manufacturing and reporting for CDR purposes is found in: <u>TSCA Chemical Data Reporting Fact Sheet: Co-Manufactured Chemicals</u>.

6.6. My company manufactures silica at multiple customer locations. The manufactured silica is solely for the customer's use at their mill. We use our equipment, the equipment is physically located on the customer property, and it is not portable. The amount of silica manufactured is greater than 25,000 pounds per year. Is this considered co-manufacturing under CDR? If we are required to report, would a report be required under our name at that local address? Could it be reported under our U.S. headquarters address where we will have other chemicals reported due to importing through that address?

This does not appear to be a co-manufacturing situation, because your company manufactures the same substance for multiple customers and therefore this activity does not meet the exclusivity portion of the co-manufactured definition. In addition, it is unlikely based on this description that your customer controls the basic technology used to make the chemical, and thus this manufacture would not meet the definition of co-manufacture for this reason as well (see Frequent Question 6.2 for more information).

Because this does not appear to be a co-manufacturing situation, you manufacture the silica, and your equipment is physically located at the customer site, report the silica using your customer's site as the reporting site. Complete separate reports for each customer's site. If the customer is also reporting chemical substances, you should make sure that the site is not identified in exactly the same manner. For example, you could use a different site name (e.g., Site A vs Site A-'Your Company') and/or change the address slightly (e.g., Ave vs Avenue). Because any person who manufactures (including imports) a reportable chemical substance at any single site during any calendar year is subject to reporting requirements under CDR, and CDR requires that one Form U be submitted for all chemicals manufactured (including imported) at a single site, it is necessary to provide a different site identification when there are two operations conducted by more than one person occurring at a single location.

It is not appropriate to report through your U.S. headquarters address or another central location because the equipment is not portable. You are required to report information about each site at which a reportable chemical substance is manufactured. While the definition of site clarifies that "for portable manufacturing units sent out to different locations from a single distribution center,

the distribution center shall be considered the site," this portion of the "site" definition is not applicable to the situation you described. See the definition of site at 40 CFR 711.3, and the reporting requirement applicable to site information at 40 CFR 711.15(b)(2).

## 7. Importers

## 7.1. Are importers of chemical substances required to report under the CDR rule?

Yes, potentially. 40 CFR 711.3 and TSCA Section 3 define "manufacture" to include import. Any person who manufactured (including imported) for commercial purposes a subject chemical substance at any single site during any calendar year since the last principal reporting year and meets a production volume threshold may be subject to reporting requirements (40 CFR 711.8). Certain chemical substances and manufacturers are excepted, exempted, or excluded from reporting (see, e.g., 40 CFR 711.6, 711.8(b), 711.9, 711.10).

For additional information, see: <u>TSCA Chemical Data Reporting Fact Sheet: Importers</u>.

## 7.2. If we are an importer, and reselling to manufacturers, we may not have the life cycle details. Is this correct?

Importers are responsible for reporting under CDR. If you don't know the specific chemical identity of the imported chemicals or mixtures, you may use a joint submission to ask your foreign supplier to send the identity and composition information directly to EPA. You are also responsible for reporting the processing and use information to the extent that it is known or reasonably ascertainable. Please see the *Instructions for Reporting* for a more detailed discussion of "known or reasonably ascertainable," and below for a discussion of "joint submissions."

# 7.3. Although Company S is a non-resident (i.e., non-U.S.) company, Company S is the importer of a chemical substance (shipping directly to Company R, a customer in the United States, and acting as the importer of record for purposes of completing the necessary forms for U.S. Customs, including the payment of duties). Can Company S, an entity that is a non-resident importer, file a CDR Form U?

Yes, but Company S must give its U.S. site address. The definition of "site" at 40 CFR 711.3 states that for an importer, the "site" is "the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance" but also indicates that if there is no such operating unit within the United States, the U.S. address of an agent acting on behalf of the importer may be used. EPA expects that all importers will have a U.S. site meeting the 40 CFR 711.3 definition, because under Customs regulations at 19 CFR 141.18, a non-resident corporation is not permitted to enter merchandise for consumption unless it has a resident agent in the United States.

In addition, CDR requires that one Form U be submitted for all chemicals manufactured (including imported) at a single site. The importer, Company S, would create one Form U, listing the address of its applicable importing agent in the United States as the site of import and listing all the chemical substances it imports. If all the chemical substances are sent directly from the port of entry to customers (without arriving at a U.S. office or facility of Company S or its importing agent), the importer would report that each chemical substance was not physically present at the site of import ("never physically at the reporting site").

For additional information, see: TSCA Chemical Data Reporting Fact Sheet: Importers.

# 7.4. Company XYZ has its corporate office in VA and a manufacturing site in OH. The corporate office is responsible for importing chemicals (importer of record) and the imported chemicals are directly shipped to their manufacturing site in OH. Does it matter if the OH site submits the CDR report instead of the VA site (importer of record)?

For imports, the site for the purpose of reporting under the CDR rule is the site that controls the import. In 40 CFR § 711.3, the regulations state that the "site" for reporting imports is "the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States." In this scenario, Company XYZ's Corporate Office in Virginia meets the definition of "site" with respect to the chemical substances imported by Company XYZ because it controls the import (i.e., is "directly responsible for importing the chemical substance"). In accordance with the regulations, the Ohio manufacturing site should not submit the CDR report because it is not the "site" responsible for the import. If, for some reason not presented in the scenario, the Ohio manufacturing site could meet the definition of "importer" at 40 CFR § 704.3, then it could be considered a responsible party for reporting and could submit the report.

Separate from the question of the appropriate "site" for reporting imports under CDR, in some circumstances, there are multiple entities that could be considered the responsible party (i.e. "importer") for reporting. The CDR regulations at 40 CFR § 711.22(b) states that when two or more persons are involved in a particular import transaction and each person meets the Agency's definition of "importer" at 40 CFR § 704.3, they may determine among themselves which one of them will submit the required report. In this circumstance, it is unlikely that the Ohio manufacturing site would meet the definition of importer in 40 CFR § 704.3. The definition of "importer" is any "person" who imports a chemical substance, including as appropriate the importer of record, and "person" is defined to includes "any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity." The "person" here appears to be Company XYZ, and it does not appear that the Ohio Manufacturing Site (which is owned by Company XYZ) is a separate "person." Thus, the Ohio manufacturing site would not meet the definition of "importer" and is still unable to submit the report to fulfill Company XYZ's obligation to report imports under CDR.

# 7.5. If Company A receives an item from outside the US, but they themselves (i.e., Company A) are not the importer of record for that item, is Company A still considered the importer under CDR and required to file a Form U (assuming applicable reporting thresholds were exceeded)?

The site controlling the import is the site that is responsible for reporting under CDR and the importer must give its U.S. site address. Although the question provides insufficient information to determine whether Company A is the best party in the import to complete the CDR submission, it could be. When two or more persons are involved in a particular import transaction and each person meets the Agency's definition of "importer" at 40 CFR 704.3, they may determine among themselves which one of them will submit the required report. However, if no report is submitted as required under this part, the EPA will hold each such person liable for failure to report. Company A should confer with the other parties to determine who is responsible for reporting.

7.6. A company imports Chemical A and it is shipped directly to a third party warehouse in the U.S. then distributed to customers in the U.S. based on their needs. In some instances, the product is shipped directly from overseas to our customers. The chemical substance is never

## physically located at the company offices. Should we provide our company office information, our third-party warehouse or our customer address information when reporting under CDR?

Report using the site information for the site controlling the import (i.e., the U.S. company office location), which is the site that is responsible for reporting under CDR. It is not unusual for the imported chemical to never be physically located at that site that is responsible for reporting the imported chemicals. Therefore, do not provide site information for your third-party warehouse or end customers' information.

Note that, when reporting in this situation, you will select that the chemical is "never physically at the reporting site."

For additional information, see <u>CDR Fact Sheet: Importers</u>.

# 7.7. When a manufacturer ships a product in a reusable container to a customer located outside of the United States and the customer returns the empty container to the manufacturer, the "empty" container may contain some unconsumed material. In effect, the customer is returning the unconsumed material to the manufacturer. Is the manufacturer subject to reporting the unconsumed material that is returned?

When a substance is exported in a reusable container and the container is returned to the manufacturer with residual material, the need to report depends on what is done with the residual material after it is returned to the US manufacturer.

For purposes of CDR, reporting is not required if the residual matter is disposed of as a waste (e.g., when you clean the returned container). However, if the residual matter is used for a commercial purpose, such as by refilling the container with more of the same material without removing the residual and shipping it back out or emptied out of the container and reclaimed for another commercial use, then reporting is required under CDR.

### 7.8. Is a company operating in a Foreign Trade Zone subject to the CDR rule?

Yes. A company is subject to reporting if it manufactures (including imports) a chemical substance covered under 40 CFR 711.5 in a Foreign Trade Zone. For purposes of CDR, companies operating in a Foreign Trade Zone have the same reporting responsibilities as companies subject to CDR reporting that are not operating in a Foreign Trade Zone.

## **7.9.** A company receives a chemical substance from a foreign source and uses it as a reactant. The reaction completely consumes the chemical substance. Is this chemical substance considered to be site-limited?

No. For purposes of CDR, imported chemical substances are never site-limited (40 CFR 711.3).

## **7.10.** A company transports a chemical substance via pipeline from outside the customs territory of the United States to a plant site in the United States. Is the company subject to the CDR rule for this chemical substance?

Yes. The company is importing the chemical substance into the United States, and, therefore, is potentially subject to CDR regulations. The mode of transporting the chemical substance to a company's site is not relevant when determining CDR obligations.

7.11. If the corporate headquarters is the site of import and the imported substances never come to headquarters but are sent directly to several plants, how is manufacturing, industrial processing and use, and consumer and commercial use data reported? Is the information for the several plants for a particular substance combined?

Report the manufacturing information associated with your site of import as you would for any manufacturing site. For each chemical substance, indicate that the chemical was never physically at the site, and because there would be no potential exposure to the chemical substance at the import site, the code W1 corresponding to fewer than 10 workers would be reported. For production volume, aggregate the volumes for each chemical substance imported by your site, regardless of where the chemical substances are physically shipped.

Also, report the industrial processing and use and consumer and commercial use information for each chemical substance for all the plants that received the chemical substance from your company, whether owned by your company or not. Aggregate the information, such that for the industrial information, you report the top ten combinations of industrial function category, industrial sector, and functional use for each chemical substance across all plants where that particular chemical is processed or used. For the consumer and commercial use information, report the top ten product categories for each chemical substance, aggregating the information from all the plants in which the chemical substances received from your company are used. (40 CFR 711.15(b)(3))

For additional information, see the *Instructions for Reporting* and the *TSCA Chemical Data Reporting Fact Sheet: Importers*.

7.12. I operate a Hazardous Waste Combustor (HWC) MACT (40 CFR 63, Subpart EEE) site that acquires various chemical 'byproducts' as defined under 720.3(d) and either directly burns them as fuel or mixes them to form a waste fuel which is combusted in the cement kiln in production of cement. The site that manufactured the chemical 'byproduct' is paying me to take this hazardous waste, which is subject to stringent disposal requirements. 40 CFR 711.10(c) states reporting is not required for a site manufacturing a chemical substance as described under 720.30(g) or (h). 40 CFR 720.30(g) describes a byproduct who's only commercial purpose is to be burned as a fuel and (h) where the substance is not manufactured for distribution in commerce. This would seem to indicate reporting is not required for waste fuels received from within the United States, but does not necessarily address imports. Because importing is considered manufacture under TSCA, would a site who imports byproducts used as fuels need to consider them against their respective manufactured threshold and thus potentially be subject to CDR? Otherwise, would these imports be exempt from reporting like their counterparts which originate from within the US?

There are two questions here, one associated with byproducts manufactured within the United States and one associated with imports.

For a byproduct that is manufactured within the United States, if its only commercial purpose is to be burned as a fuel, then the manufacture of that byproduct would be exempt from reporting under CDR. Note that, if the manufacturing of the byproduct were reportable, it would be reportable by the entity manufacturing the byproduct, not by the entity receiving the byproduct.

Regarding imported substances: When a chemical is imported into the United States, it does not have a particular identity or reportability status based on intent of the manufacture that occurred

outside of the United States. For purposes of CDR, the act of importing a chemical substance is considered manufacturing, even if the imported substances are considered "wastes." The definition of "byproduct" applicable to CDR reporting is "a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s)." These chemical substances, at the time of their import, do not appear to meet the definition of "byproduct" because they are not "produced without separate commercial intent" during the import process. Further, because these imported substances are not byproducts, they cannot be eligible for the "burned as a fuel" byproduct exemption at (720.30(g)(1) or the other byproduct exemptions at 720.30(g) and (h). In the case described in this question, the imported waste fuels are subject to reporting under CDR.

See the *Byproducts, Impurities, and Recycling Scenarios* for additional guidance.

#### 8. Chemical Substances on the TSCA Inventory — General

#### 8.1. Are all substances on the TSCA Inventory subject to the CDR requirements?

No, some substances are fully exempt or partially exempt from CDR reporting obligations. See 40 CFR 711.6 for information about certain exemptions. The chemical substances that are partially exempt from reporting requirements under CDR are listed in 40 CFR 711.6(b)(1) and 711.6(b)(2). The most recent additions to the partially exempt chemicals list are described on the *CDR Petitions page*.

EPA's Substance Registry Services (SRS) contains searchable information regarding the reporting status of particular chemical substances. Please see the CDR <u>How to Search for</u> <u>Chemicals Subject to Certain TSCA Actions</u> page for additional guidance.

In the event that you are not able to find your chemical substance on the TSCA Inventory, contact the TSCA Hotline at (202) 554-1404 for assistance to determine whether reporting is required.

#### 8.2. Are chemical analyses needed to report CDR information?

No. The CDR regulation does not require submitters to perform chemical analyses. The information required by EPA is limited to information that is "known to or reasonably ascertainable" by the submitter. This standard is applicable to all information reported in accordance with 40 CFR 711.15(b).

### 8.3. How does a person access the TSCA Inventory?

Visit the TSCA Chemical Substance Inventory (*https://www.epa.gov/tsca-inventory*) webpage to access the TSCA Inventory. In addition, the electronic CDR reporting tool, e-CDRweb, has the ability to access the TSCA Inventory using EPA's *Substance Registry Services (SRS)* (*https://cdxapps.epa.gov/oms-substance-registry-services/search*). The public version of the TSCA Inventory lists chemical substances by chemical name and CAS number, except for chemical substances for which specific identities have been claimed as TSCA confidential business information; such confidential chemical substances are identified by generic chemical names and accession numbers.

## **8.4.** What should a company do if it determines that it manufactures a chemical substance that is not included on the TSCA Inventory?

If your chemical substance is not on the TSCA Inventory, you need to evaluate whether it should be listed. Confirm that your substance is identified correctly and is required to be on the TSCA Inventory. For example, substances that do not meet the TSCA Section 3(2)(B) definition of chemical substance\* are not required to be listed on the TSCA Inventory. For additional information about what is required to be listed on the TSCA Inventory, view *https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory*.

As a first step to add a chemical to the TSCA Inventory, you can use the <u>Pre-Manufacture Notice</u> (<u>PMN) Requirement flowchart</u> to determine if a Notice must be submitted to the Agency, prior to manufacture (including import). You can also phone the TSCA Hotline at (202)-554-1404 for assistance. For information about the New Chemicals program and the steps you need to take, please visit <u>EPA's Reviewing New Chemicals page</u>. Also, please see pg 2-18 of the <u>New</u> <u>Chemicals Questions and Answers document</u>.

If a company discovers that it is manufacturing (including importing) a substance which is not on the TSCA Inventory and should have been reported to EPA as a new chemical substance, such manufacture or importation is in violation of Section 5 of TSCA and implementing regulations and could subject the company to enforcement action. If a company finds that it has or may have manufactured or imported a chemical substance in violation of TSCA, it should consider using the automated web site for the Agency's audit policy at the following address: *https://www.epa.gov/compliance/epas-audit-policy.* 

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Even if a company does not meet the conditions for reductions under the Audit Policy, it may still be eligible for penalty relief under other EPA media-specific enforcement policies in recognition of good faith efforts. Note, however, that continued manufacture (including importation) or use of such chemical substances remains a violation per Section 15 of TSCA, even after a company has contacted EPA, until the requirements of TSCA Section 5 and implementing regulations have been met. These reporting requirements are distinct from the CDR.

\*The TSCA Section 3(2)(B) definition of chemical substances excludes: 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.

## **8.5.** What should a company do if it determines that it manufactures a chemical substance that has the commercial activity status "inactive" on the TSCA Inventory?

If your chemical substance has the commercial activity status "inactive" on the TSCA Inventory and you intend to manufacture (including import) it for a nonexempt commercial purpose, you will need to notify EPA to have the substance re-designated as "active." If you need assistance, please contact the TSCA Hotline at (202)-554-1404.

*If the chemical substance is going to be manufactured for a nonexempt commercial purpose:* You will need to file a Notice of Activity (NOA) Form B before manufacturing the chemical substance, but not more than 90 days prior to the date of manufacturing. For more information, visit EPA's TSCA Inventory Notification (Active-Inactive) Requirements Rule (<u>NOA rule</u>) and <u>NOA Form B</u> webpages.

*If the chemical substance is already being manufactured for nonexempt commercial purpose:* If a company discovers that it is manufacturing (including importing) for nonexempt commercial purpose a substance which has the commercial activity status "inactive" on the TSCA Inventory and should have been reported to EPA using an NOA Form A or B, such manufacture (including importation) is in violation of Section 8(b) of TSCA and implementing regulations and could subject the company to enforcement action. In this situation, visit EPA's Audit Policy page to learn how to self-disclose and about the conditions for penalty mitigation. The Audit Policy page is: <u>https://www.epa.gov/compliance/epas-audit-policy</u>.

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Even if a company does not meet the conditions for reductions under the Audit Policy, it may still be eligible for penalty relief under other EPA media-specific enforcement policies in recognition of good faith efforts. Note, however, that continued manufacture (including importation) or use of such chemical substances remains a violation per Section 15 of TSCA, even after a company has contacted EPA, until the requirements of TSCA Section 8(b) and implementing regulations have been met. These reporting requirements are distinct from the CDR.

## **8.6.** How do the TSCA Inventory flags relate to CDR and have they been updated to reflect reporting requirements?

Special flags are used throughout the TSCA Inventory to identify those substances that are the subject of an EPA rule or order promulgated under TSCA, as well as to indicate the types of full exemptions from CDR reporting requirements. A list of flags is available on EPA's website at: https://www.epa.gov/tsca-inventory/how-access-tsca-inventory#flags.

These flags are embedded into the Substance Registry Services (SRS)

(*https://cdxapps.epa.gov/oms-substance-registry-services/search*) chemical lookup used by the e-CDRweb reporting tool. Updated prior to each submission period, the SRS lookup lists reflect the reporting requirements of CDR. If accessing the SRS directly, look for lists appropriate to the submission period of interest (e.g., 2016 TSCA Inventory for the 2016 CDR submission period or 2020 TSCA Active Inventory for the 2024 CDR submission period). If accessing the SRS using the chemical lookup function from within the CDR reporting tool, if the selected chemical has been assigned a special flag the reporting tool will display a notice indicating the TSCA action or exemption status of the chemical.

Please note that you are advised to use the flags only as a guide; you are responsible for verifying whether a chemical substance listed on the TSCA Inventory is exempt from reporting or ineligible for exemption from reporting.

See also <u>Help with Chemical Data Reporting: How to Search for Chemicals Subject to Certain</u> <u>TSCA Actions</u> for additional information.

## 9. Mixtures

## 9.1. Are mixtures listed on the TSCA Inventory?

The TSCA Inventory lists chemical substances, not mixtures. For purposes of the CDR regulation, EPA uses the definition of "mixture" from TSCA Section 3(8): "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined."

#### 9.2. Are mixtures ever reportable?

Mixtures are not themselves reported under the CDR, but the individual component chemical substances of a mixture may be reportable. If you manufacture (including import) the substances as part of a mixture, you would evaluate the CDR requirements for each chemical substance in the mixture. For example, for imported mixtures, you need to identify each component chemical substance to determine if the amount of any individual chemical substance in the mixture when combined with the amount(s) of the same chemical substance otherwise manufactured (including imported) at the same site is sufficient to meet or exceed a CDR reporting threshold.

Note, however, that if you process chemical substances to form a mixture without a chemical reaction by combining domestically manufactured chemical substances you purchase, such that you do not synthesize or produce any of the component chemical substances of the mixture or any different chemical substance, you are not a manufacturer of those chemical substances and are not required to report those chemical substances under the CDR regulation.

### 9.3. How are catalysts reported under CDR?

The CDR requirements for catalysts follow the same rules as for other chemical substances. Note that some catalytic substances supported on an inert substrate are considered under TSCA to be a mixture of the catalyst and substrate. If you manufacture the catalyst and the substrate and process these chemical substances to form a mixture, you would report your manufacture of the catalyst and the substrate separately.

## **9.4.** When metal catalysts supported on fixed, inert substrates are regenerated, the catalyst is subjected to high temperatures which convert the metal to its oxide. This is followed by a reduction step which converts the metal oxide back to the base metal. Is this activity subject to CDR requirements?

The metal catalyst supported on an inert substrate is considered to be a mixture under TSCA. Conversion of the metal catalyst to an oxide and subsequent reduction to the base metal are both manufacturing of different chemical substances for commercial purposes. If the regeneration is all conducted in the same vessel (i.e., the oxide is reduced in the same vessel in which it is made, without storing the oxide or intending to remove it from the vessel for a reason that is not essential to this chemical process), the oxide may satisfy the definition of a non-isolated intermediate for purposes of CDR and be exempt from reporting for that reason. The metal oxide and elemental metal would otherwise both be subject to CDR requirements. Note, however, that only the amounts of the metal oxide and the regenerated base metal must be reported; in many

instances, these amounts will be less than the applicable CDR threshold. Because the inert substrate does not undergo a chemical reaction in this scenario, there is no change in the chemical identity of the inert substrate that triggers CDR reporting requirements.

### 9.5. How does a company report the importation of a solid solution?

Import of solid solutions that are mixtures of chemical substances should be reported in the same manner in which import of liquid solutions or other mixtures are reported, i.e., report the amount imported of each chemical substance in the mixture. Please note, however, that mixed (metal) oxides, for which an oxide contains cations of more than one chemical element or cations of a single element in multiple oxidation states, are not considered to be solid solutions for purposes of CDR and are subject to reporting. Also, intermetallic compounds of well-defined stoichiometry are not considered alloys or solid solutions and are reportable as chemical substances. Although alloys themselves are not reportable as such, manufacture (including import) of the individual metals comprising an alloy must be reported under the CDR.

# **9.6.** A company manufactures many different compounds containing the metal magnesium, for example MgSO4, MgO, and MgCl2. Is each compound a reportable chemical substance or are they mixtures of magnesium? Should the amount of magnesium in each substance be aggregated and reported as the total amount of magnesium?

The three magnesium compounds are unique chemical substances each of which has its own distinct CAS Registry Number and entry on the TSCA Inventory. Therefore, the CDR requirements must be evaluated for each of these different compounds and, if necessary, separate reporting would be required for MgSO<sub>4</sub>, MgO, and MgCl<sub>2</sub>. The compounds would be reported separately because they are separate, unique chemical substances. No reporting would be required of elemental magnesium in this scenario because elemental magnesium is not one of the substances manufactured.

## **9.7.** If a company purchases chemical substances from manufacturers and then mixes it for their own use, do they need to report on the mixture?

A company only reports on the chemical substance that it manufactures. If no other chemical substance is manufactured when the chemical substances are mixed together, then there is no obligation to report.

## 9.8. Must hydrates of chemical substances be reported under the CDR rule?

Yes, if you manufacture (including import) a hydrated chemical substance, report its manufacture using the anhydrous or non-hydrated form and adjust the production volume to exclude water, thereby reporting only the volume associated with the anhydrous or non-hydrated form.

For purposes of CDR, a hydrated form of a chemical substance is considered a mixture of the corresponding anhydrous form and water. See TSCA section 3(2)(B)(i) for the definition of chemical substance.

**9.9.** Our facility manufactures Portland Cement (65997-15-1). In the past, reporting required 4 separate chemicals (Silicate Tricalcium, Silicate Dicalcium, Tricalcium Aluminate, Tetracalcium Aluminoferrite) that together make up a mixture that is Portland Cement to be reported. In the past, all 4 chemicals were reported. Is there an issue with reporting for the manufacture of the single chemical "Portland Cement", rather than reporting for the 4 chemicals listed above that make up Portland Cement?

The use of the listing "Portland Cement" is not appropriate for reporting under CDR because CDR requires reporting of chemical substances, and Portland Cement is a mixture, which is excluded from the definition of "chemical substance" under TSCA section 3. Please continue to report using the four component chemical substances of the mixture (i.e., Silicate Tricalcium, Silicate Dicalcium, Tricalcium Aluminate, Tetracalcium Aluminoferrite). In the past, EPA met with representatives of the Portland Cement industry and reached an agreement that Portland Cement should be reported using certain estimate percentages of the individual chemicals:

- Tricalcium silicate 59%
- Dicalcium silicate 21%
- Tetracalcium aluminoferrite 9%
- Tricalcium aluminate 7%

The TSCA Inventory Reporting Regulations established the TSCA Inventory, as per a requirement in TSCA section 8(b) for EPA to compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Because the TSCA Inventory defines the universe of chemicals reportable under CDR, it is useful to understand the development of the TSCA Inventory. In response to a public comment 33 on the TSCA Inventory Reporting Regulations (42 Federal Register 64585, December 23, 1977) that EPA should exclude from the Inventory reporting requirements such substances as "... alloys including steel, glasses, ceramics, enamels, Portland cement, and similar combinations of chemical substances...", the Agency agreed that these substances are mixtures under TSCA, and manufacturers of these products are not required to report them. However, as stated in a note at section 710.4(c)(2), the exclusion of these products from the TSCA Inventory Reporting Regulations applies only to the mixture and not to the chemical substances of which the mixture is comprised. Thus, the metals in the case of alloys, oxides in the case of glasses and ceramics, or the four components of Portland Cement and any additives or components other than impurities, should be included on the Inventory.

The note in 40 CFR 710.4(c)(2) of the Inventory Reporting Regulations states that "the term 'mixture' includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement." Although such mixtures (sometimes called "statutory mixtures") are excluded from Inventory reporting, several of them, such as CASRN 65997-19-5, are nevertheless listed on the Inventory as special categories to facilitate public understanding of these highly complex products. Each special category includes the various substances formed when a steel, cement, glass, frits, or ceramic is produced. Each category, which constitutes a statutory mixture under TSCA, contains a definition of its components in terms of chemical elements and the chemical substances that may be formed with these elements. The chemical substances that are formed with the listed elements are individually reportable under TSCA section 5 (for chemical substances that are not on the TSCA Inventory) or CDR (for chemical substances that are on the TSCA Inventory).

## **10. Byproducts**

#### **10.1.** What is a byproduct?

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture (40 CFR 711.3, referencing 704.3).

#### 10.2. How is a byproduct chemical substance characterized for identification purposes?

Byproducts are formed by a reaction, and generally, EPA considers each combination of substances resulting from a reaction to be either:

- a. A mixture, composed of two or more fully identified chemical substances to be named and listed separately, or
- b. A reaction product, as a single chemical or a combination of chemicals from a reaction, to be listed as a single chemical substance, using one name that collectively describes the product(s) or, if that is not feasible, describes the reactants used to make the products. This type of byproduct is named as a single chemical substance that is either fully identified or indefinitely described, or as is often the case, of a composition that is uncertain or complex enough to use nomenclature for substances of Unknown or Variable composition, Complex reaction products and Biological materials (a "UVCB" substance) to represent what is often a type of manufacturing process stream.

As described below, it may be appropriate for CDR purposes to treat a complex byproduct as a mixture of well-defined chemical substances or even just a single well-defined chemical substance, even though there are uncharacterized components to the mixture. This would be instead of treating the byproduct as a single UVCB chemical substance. The manufacturing company should determine, based on the specific manufacturing scenario, whether the byproduct is more appropriately represented as a single well-defined chemical substance, a mixture of individual chemical substances, or a UVCB chemical substance.

Where a manufacturer reasonably concludes (after considering all the facts known and reasonably ascertainable) that the uncharacterized components of a complex byproduct will have no subsequent commercial purpose after they are manufactured, for CDR purposes the manufacturer may treat the byproduct as a mixture of the remaining characterized components. The manufacturer would report each component as a separate substance. For each reportable substance, the manufacturer would report the production volume associated only with that substance. The uncharacterized components that have no subsequent commercial purpose would not be reported to CDR.

## **10.3.** How do you characterize a byproduct that is a complex combination of chemical substances?

Byproduct chemical substances are often chemical combinations of variable or complex composition. A complex combination of chemical substances can be identified as a chemical substance of Unknown or Variable composition, a Complex reaction product, or a Biological material (a "UVCB" chemical substance). In this manner, the byproduct can be identified as a single UVCB chemical substance that represents a process stream. Approximately one-third of the more than 86,000 chemical substances listed on the TSCA Inventory are UVCB chemical substances. UVCB substances may have an Inventory definition to further describe the substance.

The following two information documents provide further information about UVCB chemical substances and complex reaction products:

- <u>Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and</u> <u>Biological Materials: UVCB Substances</u> and
- <u>Combinations of Two or More Substances: Complex Reaction Products</u>

## **10.4.** When is a byproduct reportable for CDR purposes? Does the term reportable byproduct in the CDR pertain to a substance with commercial value only?

A byproduct may be reportable when it is manufactured for a commercial purpose. The definition of manufacture for commercial purposes at 40 CFR 704.3 includes: "...substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including...byproducts..."

While byproducts may or may not, in themselves, have commercial value, they are nonetheless produced for the purpose of obtaining a commercial advantage when they are formed as part of the manufacture of a chemical product for a commercial purpose. Thus, chemical substances that are produced as byproducts during the manufacture, processing, use, or disposal of another chemical substance or mixture, like any other manufactured chemical substance, are subject to CDR reporting if they (1) are listed on the TSCA Inventory, (2) are not otherwise excluded from reporting, (3) are manufactured (including imported) in a volume of 25,000 pounds or more at a single site during any calendar year since the last principal reporting year, or 2,5000 pounds for chemical substances subject to certain TSCA actions, and (4) their manufacturers are not specifically exempted or excepted from CDR requirements (see the Instructions for Reporting for a flowchart describing how to determine if your chemical needs to be reported for CDR). If the applicable reporting threshold is met or exceeded during any calendar year since the last principal reporting vear, since the last principal reporting year, reporting threshold is met or exceeded during any calendar year since the last principal reporting year, since the last principal reporting year, reporting threshold is met or exceeded during any calendar year since the last principal reporting year, reporting is required for each calendar year in the CDR submission period. Learn more about the reporting thresholds for CDR on the CDR website (https://www.epa.gov/chemical-data-reporting).

Once you have established that your byproduct was manufactured for a commercial purpose, it becomes potentially reportable when it is used for a non-exempt separate commercial purpose. A byproduct may have a separate commercial purpose even if it is not intentionally commercialized. If a manufacturer sends the byproduct to another person or site where it is used in such a manner that it has a commercial purpose or if the byproduct manufacturer itself uses the byproduct for commercial purposes, then the byproduct manufacturer is potentially required to report the byproduct for purposes of CDR.

In most cases, a byproduct that is used for a commercial purpose is reportable by the manufacturer; however, under 40 CFR 711.10(c), byproducts are not subject to reporting when they meet the requirements of 40 CFR 720.30(g) or when they are not used for commercial purposes (40 CFR 720.30(h)).

**10.5.** Sulfur dioxide gas is produced as a byproduct of smelting copper. The sulfur dioxide gas emissions are controlled using pollution prevention equipment in an acid plant. The treatment of sulfur dioxide in the pollution control equipment produces sulfur trioxide. The sulfur trioxide is then used to manufacture sulfuric acid. Are both sulfuric acid and sulfur trioxide considered reportable under CDR?

In order to qualify for the pollution control equipment byproduct exemption, there are a few requirements: (1) the manufactured chemical is a byproduct; (2) the byproduct is solely manufactured in pollution control equipment; and (3) the pollution control equipment is not integral to the chemical manufacturing processes of the site.

Based on the information provided, it appears that the manufacture of sulfur trioxide through this process is exempt from reporting under 40 CFR 711.10(d)(2) because all of the following apply: (1) the sulfur trioxide is manufactured as a byproduct; (2) the sulfur trioxide is manufactured solely in the pollution control equipment; and (3) the pollution control equipment does not appear to be integral to the chemical manufacturing processes at the site. The manufacture of the sulfur trioxide may also be exempt from reporting as a non-isolated intermediate pursuant to 40 CFR 711.10(c) and 40 CFR 720.30(h)(8), depending upon the process used.

The manufacture of sulfuric acid, which is an intended product and not a byproduct, remains a reportable substance under CDR.

#### 10.6. How does the byproduct exemption at 40 CFR 720.30(g) affect reporting for CDR?

Under 40 CFR 711.10(c), CDR reporting is not required for those substances meeting the requirements of 40 CFR 720.30(g). 40 CFR 720.30(g) covers byproducts whose "...only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)"

In other words, when a byproduct is only burned as a fuel, disposed of as a waste material (including disposal in a landfill or for enriching the soil), or used for extracting component chemical substances (or some combination thereof), the manufacture of that byproduct is not required to be reported for CDR purposes. Additional discussion can be found in the *Instructions for Reporting*.

# **10.7.** We operate a coal fired power plant and produce coal ash and FGD Sludge. In their raw form these materials cannot be disposed of at a landfill. We mix the coal ash, FGD and lime to create a stabilized concrete-like substance that is allowed to be disposed of in a landfill. The power plant does not produce enough coal ash to meet the FGD sludge demand, so we purchase coal ash from other companies to facilitate disposal. Is this activity reportable under CDR?

The coal ash byproduct and FGD sludge produced and used for the disposal activity are exempt under 40 CFR 711.10(c) and 40 CFR 720.30(g)(2) because the only commercial purpose is for disposal as a waste in a landfill. The companies that supply the coal ash would also be exempted under 40 CFR 720.30(g)(2) from reporting the manufacture of the volume of coal ash you purchase because its only commercial purpose is for disposal as a waste in a landfill. 10.8. Our coal-fired power plant produces coal ash and FGD synthetic gypsum. The coal ash and FGD gypsum are combined with lime and water to manufacture a new chemical considered to be "Fixated Scrubber Sludge (FSS)" which has been reported in the past as "Slimes and Sludges, flue gas desulfurization, stabilized – CAS Number 71302-93-7. The TSCA definition of this material is "the stabilized waste product obtained by mixing the scrubber waste from the flue gas desulfurization system with fly ash and lime; composed primarily of the scrubber sludge, calcium sulfoaluminates, and comparable sulfite." This fixated material is used as subgrade structural fill during landfill construction and ash pond closure construction activities. Is any part of this process reportable under CDR?

The use of FSS (or *Slimes and Sludges, flue gas desulfurization, stabilized – CASRN 71302-93-7*) as subgrade structural fill during landfill construction and ash pond closure construction activities constitutes commercial purposes separate from disposal. Therefore, FSS would continue to be reportable under CDR and is not eligible for any exemptions.

In this situation, regardless of purpose of the FSS, due to it being an intentionally manufactured chemical substance (and hence not a byproduct), it is a reportable substance.

Regarding the coal ash and FGD synthetic gypsum that are used to make the FSS, although these substances are typically byproducts from coal-fired power plants, in this case they are being used to manufacture FSS for a commercial purpose, and therefore would be reportable.

If the FGD gypsum is a byproduct manufactured solely in non-integral pollution control equipment, it would be exempt under 40 CFR 711.10(d)(2) (see CDR's Fact Sheet: Reporting for Electricity Generating Sites and the additional information/resources below).

## **10.9.** Is there any circumstance where a byproduct that is sent to a wastewater treatment plant and is converted into methane for use in energy generation could be considered a reportable chemical substance? Would the methane generated by the treatment plant be considered a byproduct or is it considered a reportable chemical substance?

For CDR purposes, a "byproduct" is defined as "a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s)." If the manufacturer of a byproduct adjusts its manufacturing process in some way to make that substance better suited to methane production, then that substance would no longer be considered a byproduct because it would not be manufactured "without separate commercial intent" and would be subject to reporting requirements. Similarly, if the digester or other parts of the wastewater treatment process are adjusted to maximize the production or quality of methane, inconsistent with optimal treatment of the waste, then the methane is considered an intended commercial product manufactured in the digester and not a byproduct. The methane would be manufactured for a separate commercial purpose (i.e., separate from waste treatment) and it would be a reportable chemical substance.

## **10.10.** Byproducts whose only commercial purpose is as a source from which component chemical substances are extracted are not subject to reporting for CDR, because they are exempt under 40 CFR 720.30(g)(3). What is meant by "extract a component chemical substance"?

A component chemical substance is a chemical substance that is present in the byproduct prior to extraction. Heat or chemical reactions can only be used to extract a component chemical substance if the component substance being extracted is being left chemically unchanged by the extraction process. Thus, for example, a chemical reaction could be employed on a byproduct to

convert component Chemical Substance X into Chemical Substance Y, so as to facilitate the extraction of a desired component Chemical Substance Z (which undergoes no chemical transformation) from the byproduct. However, if component Chemical Substance Z from the byproduct were first transformed into another chemical substance, and then that different and desired chemical substance were extracted, the overall process would not qualify as extraction of a "component chemical substance."

Note that the exemption at 40 CFR 720.30(g)(3) only applies to the manufacture of the byproduct itself and does not apply to the manufacture of another chemical substance by extraction from a UVCB byproduct. Thus, regardless of whether the manufacturer of a UVCB byproduct receives the benefit of this exemption (determined in part by whether or not the byproduct is subsequently used to extract component chemical substances), the manufacture of a different chemical substance by extraction from the UVCB byproduct is substance by extraction from the UVCB byproduct is substance.

Note also that the component chemical substance must be a chemical substance having a particular molecular identity. For instance, elemental Nickel (Ni<sup>0</sup>) and nickel hydroxide Ni(OH)<sub>2</sub> have different molecular identities and are not the same chemical substance. Additionally, because the Ni<sup>+2</sup> ion cannot exist on its own and is therefore not considered a chemical substance, the Ni<sup>+2</sup> ion is not considered a component chemical substance of the byproduct. Consider the following scenarios:

- Scenario 1: Ni<sup>0</sup> is recovered from a UVCB byproduct containing Ni(OH)<sub>2</sub>. Ni<sup>0</sup> is not a component chemical substance of Ni(OH)<sub>2</sub>, because Ni<sup>0</sup> does not exist in Ni(OH)<sub>2</sub>. A chemical reaction of Ni(OH)<sub>2</sub> is required to produce Ni<sup>0</sup>. Therefore, an extraction of a component chemical substance has NOT occurred. Rather, the byproduct has been used as a chemical feedstock to manufacture Ni<sup>0</sup>, and both the byproduct and Ni<sup>0</sup> are therefore subject to CDR.
- Scenario 2: Ni(OH)<sub>2</sub> is recovered from a UVCB byproduct containing Ni(OH)<sub>2</sub> as a component chemical substance. The Ni(OH)<sub>2</sub> was recovered without reacting the Ni(OH)<sub>2</sub>, although a chemical reaction of other components of the UVCB may have occurred in order to recover the Ni(OH)<sub>2</sub>. In this case, an extraction of a component chemical substance has occurred. Assuming the byproduct was not put to any other commercial purpose, the manufacture of the byproduct is exempt from reporting under CDR. The manufacture of the Ni(OH)<sub>2</sub> is subject to CDR, as the extracted chemical itself does not qualify for the exemption at 40 CFR 720.30(g)(3) (the provision applies to the byproduct, not to the chemical substance extracted from the byproduct).

For TSCA purposes, chemical substances are specifically and uniquely identified when listed on the TSCA Inventory (<u>https://www.epa.gov/tsca-inventory</u>).

# **10.11.** Are chemical substances produced when controlling emissions, such as when a chemical is introduced into a stack emission control device for the purpose of reacting with another substance, considered reportable chemical substances? If the chemical substance produced is sold to a second company and they extract chemicals from that product, do they also need to report?

When a new chemical substance is formed as the result of the injection of another chemical substance for emission controls, the byproduct that is formed is typically not reportable under CDR when the stack emission control device is not integral to the chemical manufacturing processes of the site (as per 40 CFR 711.10(d)(2)). This is true regardless of whether the resulting byproduct is sold to another company. However, if the manufacturing company modifies the

byproduct or tweaks the production to make the byproduct better able to meet the requirements of the customer, then the resulting chemical substance is a product and not a byproduct and may be reportable under CDR (depending upon meeting other requirements, such as production volume).

Note that, if the emission control device *is* integral to the chemical manufacturing processes of the site, the exemption at 40 CFR 711.10(d)(2) no longer applies and the byproduct could be reportable under CDR when it is used for a commercial purpose. If that byproduct is sent off-site to a second company for reclamation of the byproduct, then it is reportable unless the second company is only extracting components of the byproduct for a commercial purpose (as per 40 CFR 711.10(c) and 720.30(g)(3)).

## 10.12. How do the exemptions at 40 CFR 720.30(h) affect byproduct reporting for CDR?

Under 40 CFR 711.10(c), reporting is not required for those substances meeting the requirements of 40 CFR 720.30(h). That provision lists "chemical substances," manufactured under certain circumstances, including "any impurity" (720.30(h)(1)), "any byproduct which is not used for commercial purposes" (720.30(h)(2)), and "any non-isolated intermediate" (720.30(h)(8)), and notes that "Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part."

In interpreting 40 CFR 720.30(h)(1), (h)(2), and (h)(8), one needs to consider the following important points.

- Regarding 40 CFR 720.30(h)(1), note that the term impurity has a specific definition when determining reporting obligations under TSCA. Under 40 CFR 704.3 (cross-referenced in 40 CFR 711.3), impurity means a chemical substance which is unintentionally present with another chemical substance. When considering how to characterize a separate byproduct stream, it is not proper to consider as an impurity a component of the byproduct stream that was created as part of the process that created the intended product and byproduct stream. It may be proper, however, to consider as an impurity a substance that was introduced as an impurity as part of one of the raw materials used as an input to the process. If such an impurity reacts during the process, however, the result is a manufactured substance that does not meet the impurity definition when separated from the intended product into a byproduct stream.
- Regarding 40 CFR 720.30(h)(2), note that "commercial purpose" refers to the broad definition in 40 CFR 704.3 ("the purpose of obtaining an immediate or eventual commercial advantage"). It is not synonymous with the narrower definition of "commercial use" at 40 CFR 711.3, which is only intended for further subcategorizing reportable uses (in Part II Section D reporting) between industrial, commercial, and consumer settings.
- Regarding 40 CFR 720.30(h)(8), note that non-isolated 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 substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers 'isolates' the substance by removing it from process equipment in which it is manufactured." (40 CFR 704.3). Refer to the *Fact Sheet: Non-isolated Intermediates* for more information.

Although 720.30(h) has descriptions of eight different types of chemical substances, the three listed above are generally the most relevant when considering reporting of byproducts under CDR.

There are, however, other conditions under which byproducts are not required to be reported. See 40 CFR 711.10 (d). As a general rule, if, after it is manufactured, your byproduct chemical substance is not put to use for a separate commercial purpose (see 40 CFR 711.10(c)), you do not need to report it.

### 10.13. How do the exemptions at 40 CFR 711.10(d) affect byproduct reporting for CDR?

There are conditions under which byproducts are not required to be reported (40 CFR 711.10(d)).

• If a byproduct substance listed in 40 CFR 711.10(d)(1)(i) (see below) is produced as part of the listed manufacturing processes and: (1) the byproduct substance is recycled or otherwise used within a site-limited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was produced, and (2) the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or manufactured in the same overall manufacturing process, that byproduct is not required to be reported (40 CFR 711.10(d)(1)).

As of June 1, 2024, the processes and related byproduct substances listed are:

- Portland Cement Manufacturing:
  - CASRN 68475-76-3, Flue dust, Portland cement (commonly referred to as cement kiln dust or CKD)
- Kraft Pulping Process:
  - CASRN 66071-92-9, Sulfite liquors and cooking liquors, spent (often comprised of what is referred to as black liquor)
  - CASRN 68514-09-0, Sulfite liquors and Cooking liquors, spent, oxidized (often comprised of what is referred to as oxidized black liquor)
  - CASRN 471-34-1, Carbonic acid calcium salt (1:1) (commonly referred to as calcium carbonate)

For submission periods after the 2024 CDR, check the listing at 40 CFR 711.10(d)(1) for any updates.

Note that this exclusion only applies to the amount of the byproduct that is recycled in physically enclosed equipment; it does not apply to amounts that are not recycled or that are recycled, but not in physically enclosed equipment.

- If a byproduct substance is manufactured solely in specifically listed equipment when it is not integral to the chemical manufacturing processes of the site, that byproduct is not required to be reported (40 CFR 711.10(d)(2)). The specifically listed equipment are:
  - Pollution control equipment, and
  - Boilers used to generate heat or electricity for that site.

## 10.14. Is a reaction product formed upon end use of a catalyst always exempt under 40 CFR 720.30(h)(5)?

Not always. 40 CFR 720.30(h)(5) states: "Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate."

A chemical substance may qualify for the 40 CFR 720.30(h)(5) exemption if it is not manufactured or imported for distribution in commerce (including for use as an intermediate). If it is to qualify for the 720.30(h)(5) exemption, a chemical substance cannot have a commercial purpose separate from the substance, mixture, or article of which it is a part. (See the introductory language of 40 CFR 720.30(h)). Therefore, where a used or spent catalyst is both a reaction product of the end use of a catalyst for commercial purposes and an intermediate in the manufacturing of fresh catalyst for commercial purposes, it would not qualify for the 720.30(h)(5) exemption.

## **10.15.** It is unclear to me whether I am burning my byproduct for energy recovery or destruction. Is this an issue I need to resolve to determine whether I have a reporting obligation under CDR?

Probably not. The distinction between whether a byproduct is burned for energy recovery or incinerated solely for destruction is generally not relevant under the CDR. This is because the CDR exempts both byproducts whose "only commercial purpose" is for burning as a fuel (40 CFR 720.30(g)(1)), and byproducts that are "not used for commercial purposes" (40 CFR 720.30(h)(2)). This latter category would include incineration, solely for destruction. Note, though, that where a byproduct is burned for energy recovery, but that is not the only commercial purpose for the byproduct (e.g., if the combustion residue is used as a process input), then the exemption under 40 CFR 720.30(g)(1) would not apply. This exemption also does not apply if you have manufactured a coproduct and not a byproduct. For example, if a substance you manufacture is normally intended to be used as a fuel product, it would be considered a coproduct instead of a byproduct.

## **10.16.** If used oil that contains gasoline and diesel when received by a recycler is being used for energy recovery (burned as a fuel) is that used oil subject to CDR reporting?

Under 40 CFR 711.10(c) and 40 CFR 720.30(g), a chemical substance manufactured as a byproduct is exempted from reporting if "...its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel..." In general, used oil is likely to be considered a byproduct of use. The presence of incidental gasoline or diesel in the used oil as an artefact of the collection process is not considered sufficient to warrant CDR reporting. However, if the used oil producer purposefully mixes diesel or gasoline with fuel oil for the purposes of changing the properties of the substance (e.g., making it easier to burn), then the byproduct has been turned into a product.

#### 10.17. How could a byproduct be manufactured while manufacturing an article?

If the use or processing of a chemical substance (Chemical A) to manufacture an article coincidentally produces a different substance (Chemical B), apart from the article, then a byproduct chemical substance has been manufactured. This situation may occur, for example,

when a substance is being stripped off of a part of the article, and the stripping process results in the formation of a different substance (possibly resulting in a "used" stripping solution).

Note that if the byproduct chemical substance (Chemical B, in the above scenario) has been intentionally manufactured for a commercial purpose separate from that of the article, then a coproduct and not a byproduct has been manufactured.

## **10.18.** I have a company that imports aluminum and steel piston castings. My question is with regards to the metals chips that are machined off the piston. They are recycled either on site or off site. Would the metals present within the chips be subject to TSCA CDR reporting?

The metal chips to be generated from the imported aluminum and steel piston castings are not considered to be part of the article and therefore are reportable at the time of import if they are used for a separate commercial purpose, such as being used to recover metals. Therefore, these metal chips are reportable under CDR, assuming the applicable reporting threshold has been met.

Note that, under TSCA, alloys are considered mixtures; therefore, you would report for each component metal of the alloy, determining whether you have met the threshold for each component chemical substance in the alloy. It is possible to exceed the threshold for one component chemical but not for other components; you should only report for chemical components whose volumes exceed the threshold.

## **10.19.** What is the difference between manufacturing a byproduct and manufacturing a coproduct?

The simultaneous manufacture of multiple chemical substances can occur for a variety of reasons. In the case of byproduct manufacture, the byproduct is manufactured without any separate commercial intent — that is, without any commercial intent other than the commercial intent to manufacture, process, use, or dispose of some other chemical substance or mixture. See 40 CFR 704.3 (definition of "byproduct"). The CDR requirements are based on the disposition of the byproduct, as explained above.

In the case of coproduct manufacture, there is commercial intent to produce the coproduct, separate from whatever commercial intent may concurrently exist to manufacture some other chemical substance or mixture. If both coproducts are chemical substances under TSCA, unless exempted from CDR, both are subject to the CDR requirements if listed on the Inventory.

## **10.20.** How does a submitter report under the data element "Is the chemical substance being recycled?" and how does the 2020 CDR Revisions rule affect this data element?

For purposes of CDR, a manufactured chemical substance is being recycled when all or a portion of that substance, which otherwise would be disposed of as a waste, and is being used for commercial purpose. EPA generally expects that byproduct manufacturers often may report that some or all of their byproduct substances may be recycled or otherwise used rather than being disposed of as a waste (as many still have value, e.g., as a feedstock or for other material recovery). Product finishing, on the other hand, does not involve removing a chemical substance from a waste stream and would not qualify as recycling for purposes of this data element.

During the 2020 TSCA CDR Revisions rule under TSCA Section 8(a), EPA modified the data element "recycled, manufactured, reprocessed, or reused" by removing the terms "remanufactured, reprocessed, reused" from the data element description and changing the term

to "recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream." A chemical substance that is manufactured from a recycled chemical substance may previously have reported "Yes" under this data element, but would now report "no" because the term "remanufactured" is no longer a part of the data element.

## **10.21.** EPA has a lot of programs encouraging recycling. If I am recycling my byproduct, do I need to be concerned about the CDR?

EPA encourages recycling and has many programs to educate people about recycling and the reuse of materials. Many recycling activities involve bringing materials (that were manufactured for a commercial purpose) into commerce that otherwise would be disposed of as a waste. If your substances that you manufactured are being recycled and are listed on the TSCA Inventory, those substances may be subject to the CDR.

# **10.22.** Are substances that are given to recyclers at no cost to the company to be recycled, such as lead batteries and electronics, subject to reporting under the CDR rule? If the waste material to be recycled is sold to the recycler instead of being given to the recycler at no cost, does this affect the CDR requirement?

In general, whether a substance is given or sold to recyclers, or whether the recycler is paid to take the substance, is immaterial to the determination of the need to report under CDR. If the substance is manufactured for commercial purposes (which includes byproducts) and not otherwise exempted, then the substance may be subject to reporting under CDR even when it is given to another entity for use.

Regarding waste articles such as lead batteries and electronics, whether the waste articles were generated in the United States (i.e., used as articles within the United States before being recycled) or imported as waste articles for the purpose of recycling impacts whether they trigger the need to be reported under CDR. For the U.S.-generated waste articles, reporting under CDR is not required. For the imported waste articles, the act of importing triggers the need to consider reporting the component substances under CDR.

Note that the act of recovering materials from a waste article may result in the need to report a substance if a chemical process was used to extract the chemical substance of interest. However, when a waste article is disassembled and there are no reactions occuring, no reporting of the chemical substance of interest is triggered. For more information, please see scenarios 16, 17, and 18 in *CDR Byproducts, Impurities, and Recycling Scenarios*.

## **10.23.** Is sludge from a plant operation that is given to another facility for cover on a landfill subject to chemical data reporting? The sludge is 61% calcium carbonate (CaC03), 33% magnesium hydroxide.

Waste sludge from a plant operation is considered a byproduct chemical substance manufactured for a commercial purpose and is only reportable if it subsequently used for a non-exempt commercial purpose. Under 40 CFR 720.30(g), a byproduct chemical substance is exempted from reporting if "...its only commercial purpose is for use by public or private organizations that...(2) dispose of it as a waste, including in a landfill..." The use of a byproduct chemical substance as daily cover in a landfill is considered disposing as a waste and therefore the byproduct chemical substance is exempted from reporting under CDR.

Note that if the substances were reportable, Magnesium hydroxide would be reported as its anhydrous version. For purposes of CDR, a hydrated form of a chemical substance is considered a mixture of the corresponding anhydrous form and water. See TSCA section 3(2)(B)(i) for the definition of chemical substance.

## **10.24.** If my waste material is exempted from reporting by the RCRA program, do I need to be concerned with reporting under CDR? Likewise, if I report under CDR, do I need to be concerned with reporting for RCRA purposes?

The determinations of the need to report for CDR and for RCRA are independent determinations.

# **10.25.** Is the purification of a substance subject to CDR reporting? For example, if a manufacturing location acquires a material at 96% purity and processes it to 99% purity and no new substance is generated during the process is the location subject to CDR reporting?

Purification is not considered manufacture for purposes of CDR and does not trigger the need to report. See the Frequent Questions 10.26 through 10.29 below.

## 10.26. How do I determine if I am manufacturing or purifying a chemical substance?

Start by making sure you have properly chemically identified for TSCA purposes the precursor or impure chemical substance(s). Then compare the specific chemical identities of the precursor or impure chemical substance(s) and the finished chemical substance(s). Purification does not involve a change in chemical identity between the precursor/impure chemical substance and the purified chemical substance. By contrast, removing a chemical substance from a precursor chemical substance having a different chemical identity (for example, the extraction of a discrete chemical substance from a UVCB precursor) is manufacturing. See 40 CFR 711.3 ("[m]anufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances."). Purification is not considered manufacture for purposes of CDR and does not trigger the need to report.

#### **10.27.** Please provide an example of when a substance is purified.

In general, when 80% pure Chemical A (correctly identified, for TSCA purposes, as that discrete substance and not as a UVCB substance) is purified to make 98% pure Chemical A, the activity does not constitute manufacturing of Chemical A, but it is considered to be processing of Chemical A for purposes of CDR reporting. The two batches of Chemical A differ only in their purity. For purposes of TSCA, they are considered to be the same chemical substance.

Note that it is the original manufacturing of the 80% pure Chemical A that triggers reporting of Chemical A under CDR. Note also that the need to report any substance produced during the purification process may need to be addressed (e.g., the substance(s) removed from Chemical A may trigger reporting itself, depending upon the specific situation and the use of the removed substance(s)).

#### **10.28.** Please provide examples of when a substance is extracted and not purified.

For recycling or reclaiming, it is important to determine whether the resulting chemical substance has the same or different specific chemical identity as the starting material. If the starting and

resulting substances are the same (e.g., a newly manufactured substance that one intends to make, such as salicylic acid, which is initially impure but then is purified), then the activity is considered to be processing and no manufacturing has occurred. If the resulting substance is different, for example, the extraction of cresol from "Phenols (petroleum)" [CASRN 64743-03-9], then the activity is considered to be manufacturing.

## **10.29.** My manufacturing process uses Solvent A, resulting in Spent Solvent A. I recover Solvent A from the Spent Solvent A. Under CDR, what are my reporting obligations for the recovered Solvent A?

Depending on your specific manufacturing scenario, Spent Solvent A may be appropriately characterized as a mixture or may be properly characterized as a UVCB substance. The difference between a mixture and a UVCB is that a mixture is when all components are known and UVCBs can be identified as chemical substances of Unknown or Variable composition, Complex reaction products and Biological materials ("UVCB" substances). In this manner, the byproduct can be identified as a single UVCB chemical substance that represents the process stream. There are many thousands of UVCB substances listed on the TSCA Inventory. Reporting obligations associated with the reclaimed Solvent A are dependent upon your characterization of Spent Solvent A.

1. Spent Solvent A is characterized as a mixture of individual chemical substances: In this case, separating Solvent A from the mixture is not considered manufacturing, and the manufacturer does not report for CDR purposes the reclaimed Solvent A. Note that, depending upon what is done with the remaining portion of the mixture, any components of the mixture that were manufactured may need to be individually reported.

2. Spent Solvent A is characterized as a manufactured UVCB chemical substance: In this case, the Solvent A extracted from the Spent Solvent A is also considered to be manufactured, and therefore is reportable for purposes of CDR.

For a more detailed discussion of UVCBs, spent solvents and mixtures, please refer to the fact sheet "2020 Chemical Data Reporting Byproduct and Recycling Scenarios."

**10.30.** At a site, an ore (e.g., bauxite) is refined to create a product (e.g., alumina). The ore contains another metal compound or salt, which is reduced to the elemental metal, removed from the product during processing, and disposed of as waste. Should the elemental form of this metal be reported under the CDR rule? If the elemental metal byproduct is sold for commercial use, is it subject to CDR reporting requirements?

Reporting is not required if the metal byproduct from the refining is only disposed of as a waste. See 40 CFR 711.10(c) which references 40 CFR 720.30(g).

Reporting is required if the elemental metal byproduct is used for commercial purposes, because neither the exemption provision at 40 CFR 720.30(g) nor the exemption provision at 40 CFR 720.30(h)(2) would apply to the manufacture of this byproduct metal. Because the byproduct metal is being used for a commercial purpose (other than the commercial purposes listed in 40 CFR 720.30(g)), you would evaluate the CDR reporting requirements for this substance (e.g., was the amount of the byproduct metal produced at a single site during any calendar year since the last principal reporting year 25,000 pounds or more (or 2,500 pounds or more if subject to certain TSCA actions)?).

## **10.31.** My metal smelting process generates a large amount of dust, which is collected in a baghouse. Since this dust has a high metal content, we recycle the baghouse dust rather than disposing of it. Do I have any reporting obligations for this material?

This depends on what chemicals comprise the baghouse dust and how it is used. The baghouse dust is a byproduct of your manufacturing process that is captured by pollution control equipment. If the baghouse only captures unreacted starting material, see question 10.32. Otherwise, if you use it for a non-exempt commercial purpose, you would evaluate the CDR reporting requirements for the baghouse dust (e.g., was the amount of the baghouse dust produced at a single site during any calendar year since the last principal reporting year 25,000 pounds or more (or 2,500 pounds or more if subject to certain TSCA actions)?). If it meets those requirements, you would report it.

An example of using the baghouse dust for a non-exempt commercial purpose is to smelt the baghouse dust to produce a metal. The smelting process uses chemical reduction, a form of extractive metallurgy. A common mistake is to think that at high temperature the metal melts out of the ore or baghouse dust. However, if you heat up the ore without the proper reducing agent, you will just obtain molten ore. A metal obtained from baghouse dust by chemical reduction or smelting is manufactured using a chemical reaction and cannot be considered to be a component chemical substance of the baghouse dust (so that the 40 CFR 720.30(g) exclusion from reporting would not apply). Both the baghouse dust and the metal produced by the smelting process are subject to reporting under CDR.

Beginning with the 2020 CDR, an exemption for byproducts manufactured by pollution control equipment that is not integral to the chemical manufacturing process is in place. Although the baghouse dust is captured by pollution control equipment, it was not manufactured by the pollution control equipment and therefore the new exemption would not apply (without the need to consider whether the pollution control equipment is integral or not). See 40 CFR 711.10(d)(2). The simple separation of a mixture is not considered to be manufacture under TSCA.

# **10.32.** My process uses a baghouse, but it only captures unreacted starting material. I reintroduce the contents of the baghouse into my processing stream in order to use those materials. Do I have any reporting obligations for the collection of the unreacted starting materials into the baghouse?

EPA does not consider the mere recapture of unreacted starting materials to constitute manufacturing. Therefore, in this situation, reporting under CDR would not be required on the capture of unreacted starting material in the baghouse. Note, though, that if the baghouse dust were to include other components, such as partially reacted intermediates or other substances from a chemical reaction, the baghouse dust may be a byproduct that you are manufacturing. If you use baghouse dust byproduct for a non-exempt commercial purpose after manufacturing it, you would need to evaluate your CDR requirements as a manufacture of the baghouse dust.

# **10.33.** Chemical X is formed unintentionally, without any separate commercial purpose, during the manufacture of another chemical, Chemical Y. Furthermore, Chemical X is not separated from Chemical Y. Would it be accurate to describe substance Chemical X as an impurity with no reporting obligation?

Chemical X could be described as an impurity because it is unintentionally present with Chemical Y, but it would be more accurate to describe it as a byproduct because it is manufactured without

a separate commercial purpose. The manufacture of this byproduct/impurity is not reportable for CDR purposes. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(2).

However, 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.

# **10.34.** The paper pulping process involves a recycling loop for the pulping chemicals. The spent pulping liquors (also called black liquor) is a byproduct of the pulping process. The black liquor is burned to produce power, and the resulting smelt is turned into green liquor and ultimately white liquor. Since the black liquor is used as a fuel, do I need to report it under the CDR?

Prior to the 2020 CDR Revisions rule, the black liquor byproduct was reportable under CDR. This changed with the addition of 40 CFR 711.10(d), added as part of the 2020 CDR Revisions rule.

Under 40 CFR 711.10(d), certain pulping cycle byproduct chemical substances are exempted if the manufacturing process and site meet the requirements of the exemption. The specifically listed substances for the Kraft pulping process are:

- Black liquor: CASRN 66071-92-9, Sulfite liquors and cooking liquors, spent
- Oxidized black liquor: CASRN 68514-09-0, Sulfite liquors and Cooking liquors, spent, oxidized
- Calcium carbonate: CASRN 471-34-1, Carbonic acid calcium salt (1:1)

If the listed kraft pulping process byproduct substances are recycled or otherwise used within a site-limited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was produced, and the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or manufactured in the same overall manufacturing process, that byproduct is not required to be reported (40 CFR 711.10(d)(1)(i)).

In addition, 40 CFR 720.30(g) exempts the manufacture of a byproduct from CDR reporting if: "...its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)" See also 40 CFR 711.10(c), which refers to 40 CFR 720.30(g) for activities for which CDR reporting is not required.

While the black liquor is burned, the volume is burned both for its fuel value and for its value as a feedstock to the production of smelt. The example indicates that the manufactured smelt is then put to non-exempt commercial purposes (to make white liquor, a pulping chemical). Therefore, it is not the case that the only commercial purpose of the black liquor is to "burn it as a fuel." 40 CFR 720.30(g) therefore does not provide an exemption for the manufacture of the black liquor byproduct.

For more information on this topic, please refer to: <u>CDR Fact Sheet on Kraft Pulp and Paper</u>.

**10.35.** Our company purchases a cation resin (H<sup>+-</sup>Resin) for our ion exchange system from a domestic supplier. The ion-exchange resin is used to remove dissolved Metal G from a liquid process stream, which contains metal G in the form of a metal cation. Following removal of the G+ metal ions, the remainder of the liquid process stream is disposed as a waste. The metal ion is subsequently displaced from the ion-exchange resin by the addition of an acid solution and further processed on-site to recover Metal G. Which reaction products should our company report under CDR?

EPA assumes that the liquid process stream is the company's own byproduct. Also, based on the information provided, EPA assumes that the following reactions occur within the ion exchange system:

Ion Exchange:

 $[G^+][anions-] + [H^+][Resin] \rightleftharpoons [G^+][Resin] + [H^+][anions-]$ 

where the particular anions balancing  $G^+$  in the liquid process stream are assumed to be unknown or of variable composition) and

Regeneration:

$$[G^+][Resin] + [H^+][Y^-] \rightleftharpoons [G^+][Y^-] + [H^+][Resin]$$

where Y- is a known anion.

As the liquid process stream passes through a cation resin, H+ cations on the resin are exchanged for G+ cations via chemical absorption (forming a [G<sup>+</sup>][Resin] complex). As the performance of the resin declines, an acid solution ([H<sup>+</sup>][Y<sup>-</sup>]) is typically used to regenerate the cation resin. A subsequent drying step results in the metal salt [G<sup>+</sup>][Y<sup>-</sup>]. The metal salt is subsequently chemically reduced to form elemental metal G.

From this set of reactions, EPA has determined (assuming that all pertinent production volumes thresholds are exceeded) that CDR reporting requirements apply to the company as follows:

Liquid Process Stream: Since the stream contains unknown or variable salts of G+, and there is not a basis to conclude that these various salts would necessarily be exempt from CDR if they were treated as mixture components, it is appropriate to treat the entire liquid process stream as a single UVCB chemical substance. The process stream has a non-exempt commercial purpose (the production of  $[G^+][Resin]$ ) and is subject to CDR. The manufacture of the liquid process stream does not receive the reporting exemption at 40 CFR 720.30(g)(3) because the component chemical substances at issue ( $[G^+][anions^-]$ ) are not extracted from the stream. Rather, they are chemically reacted with  $[H^+][Resin]$  to produce  $[G^+][Resin]$ .

Metal-Depleted Liquid Process Stream: This liquid, which remains after formation of the  $[G^+]$ [Resin], is a byproduct of the chemical processing of the original liquid process stream. The metal-depleted liquid process stream (including  $[H^+]$ [anions<sup>-</sup>] and other constituents) has no commercial purpose except to be disposed as a waste and it is exempt from reporting under 40 CFR 720.30(g)(2).

Metal-Resin Complex: Reporting requirements for the metal-resin complex should be evaluated by each manufacturer. If the process is one of continuous formation of the  $[G^+]$ [Resin] complex and regeneration of the  $[H^+]$ [Resin], the metal-resin complex satisfies the definition of a nonisolated intermediate and is exempt from CDR reporting requirements (see 40 CFR 711.10(c) which references 720.30(h)(8)). However, if the  $[G^+]$ [Resin] complex is stored in the ion-exchange column, such as during periods when the ion exchange system is not in use, the metal-resin complex would not be a non-isolated intermediate. Alternatively, if the  $[G^+]$ [Resin] complex is described as a polymer on the TSCA Inventory and meets the criteria of the CDR polymer definition, it is exempted from reporting (see 40 CFR 711.6(a)(1)).

Regenerated Cation Resin: The regenerated ion-exchange resin ( $[H^+]$ [Resin]) is an insoluble matrix fabricated from an organic polymer substrate, often polystyrene. Many polymers on the TSCA Inventory are exempt from CDR because they meet the criteria of 40 CFR 711.6(a)(1).

Metal Salt: The regeneration process forms a metal salt,  $[G^+][Y^-]$ . This salt is manufactured for a non-exempt commercial purpose and is subject to CDR reporting requirements.

Metal G: The recovery of Metal G from the metal salt requires a chemical reduction process. This involves the chemical conversion of one chemical substance (the metal salt  $[G^+][Y^-]$ ) into a different chemical substance: elemental G. The manufacture of elemental G from  $[G^+][Y^-]$  is subject to reporting.

## **10.36.** Our company manufactures 280,000 tons of urea fertilizer with a time release coating. The coating is a polymer made using several different precursor chemicals. Do I need to report under CDR?

Based on the information provided, you may need to report chemical substances that are manufactured (including imported) for or during the process to produce the product. Reporting is required if you manufacture (including import) a chemical substance that meets the production volume threshold of 25,000 lb or more (or 2,500 lb if the chemical is subject to certain TSCA actions) at a single site during a calendar year. However, if a company purchases all of its chemicals from domestic sources and does not use them in a manner that manufactures other chemicals, the company is not required to report.

- If you domestically procure these precursor substances and mix them together without reaction, then you have not manufactured a reportable substance. Additionally, if in mixing them together they react to form a polymer as defined under TSCA (see the definition of polymer under <u>40 CFR 711.6 (a)(1)</u>), the resulting polymer would be exempt from reporting under CDR (unless it is the subject of certain TSCA actions).
- If you import these precursor substances, you would be required to report them as imported chemical substances (assuming the production volume threshold is met).
- Likewise, if you import or domestically manufacture urea fertilizer, you would need to report urea and potentially other components that comprise the "urea fertilizer" as well.

# **10.37.** If a company mixes chemical X with chemical Y in a furnace at high temperatures to make chemical Z. Chemical Z comes out of the furnace already formed in a design and shape that meets the definition of an article. The article is formed at the same time as the chemical reaction. Is chemical Z reportable under CDR? Alternatively, if Chemical Z comes out of the furnace and is then formed into an article in a mold is it reportable under CDR?

If the chemical reaction to form Chemical Z takes place coincidentally with the formation of the article the chemical reaction product would be exempted by 40 CFR 720.30(h)(6). In the second scenario, Chemical Z would need to be reported because Chemical Z is formed and then shaped into an article, and 40 CFR 720.30(h)(6) would not apply.

### **10.38.** My company creates mixtures and part of the process is neutralization. Is a neutralization product CDR reportable? If so, which component is reportable? Here are two examples:

- Example 1: React borax with sodium hydroxide. Mixed salts formed, making sodium metaborate up to 13% of final product.
- Example 2: Neutralized boric acid with monoethanolamine; monoethanolamine borate will make up to 37.6% of final product.

If the neutralized products/components of your mixtures are intentionally made (reacted to form new substances) they are CDR reportable (if on the TSCA Inventory and meeting the applicable threshold). The exemption at 40 CFR 720.30(h)(7) would not apply because, based on the examples, adjusting pH is not the sole purpose of the neutralization. Rather, new compounds that have a commercial purpose are being formed. Report any salts that are formed and have a commercial purpose. Do not report unreacted chemical substances (unless you manufactured (including imported) the raw materials).

Example 1: Report sodium metaborate and the other salts that are formed and have a commercial purpose. Do not report unreacted borax or sodium hydroxide (unless you manufactured (including imported) the raw materials).

Example 2: Report monoethanolamine borate and the other substances that are formed and have a commercial purpose. Do not report unreacted boric acid or monoethanolamine (unless you manufactured (including imported) the raw materials).

In order for the resulting substance to be exempted from CDR pursuant to 40 CFR 720.30(h)(7), it must fully satisfy all of the following criteria:

1. The substance is formed from a chemical reaction that involves the use of a pH neutralizer that functions as intended;

2. The substance does not function to provide one or more primary properties that would determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and

3. The substance is not itself the one intended for distribution in commerce as a chemical substance per se. Although it may be a component of the product, product mixture, or formulation actually distributed in commerce, it has no commercial purpose separate from the product, product mixture, or formulation of which it is a component. (40 CFR 720.30(h)(7))

# **10.39.** My company buys a cathode (99.99%) pure copper and melts it in a furnace. The liquid copper is extruded into solid copper rod, which is chopped into small pieces to make elbows, adapters, or Tee fittings. A byproduct of the melting furnace operation is a copper oxide (slag) that contains impurities (iron, etc.). This copper oxide (slag) byproduct material is sent out to a copper refiner to reclaim any copper in the impurity material. Is this reportable on our Form U?

If a chemical reaction occurs when the copper is melted and fabricated into the article, any new substance formed would be reportable under CDR (if meeting the threshold and not otherwise exempt, e.g., manufactured as part of an article). Regarding the copper oxide (slag) byproduct, the

slag is reportable as it is a byproduct that is then used for the commercial purpose of reclaiming copper.

**10.40.** Our company uses a process that involves the use of contact cooling water to cool and solidify aluminum ingots during casting operations. This water is then pumped back to a water treatment system after use to remove contaminants picked up during the casting operation so that the water may be reused. We produce chlorine dioxide and introduce it into the water at the water treatment system to inhibit biological growth within our water systems. This treated water is then reused for further contact cooling operations. Is the chlorine dioxide reportable or can the exemption for reporting byproducts manufactured in pollution control equipment (40 CFR 711.10(d)(2)) be applied?

The chlorine dioxide is not reportable because it is being used as a pesticide to inhibit biological growth and therefore doesn't have a use covered by TSCA.

#### 11. Non-TSCA Uses

### **11.1.** If a company manufactures a chemical substance for a non-TSCA use, is the company required to submit CDR information for this chemical substance?

Substances that do not meet the definition of "chemical substance" in TSCA Section 3(2)(B) need not be reported. Those substances 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.

# **11.2.** If a company manufactures a food grade additive, and it is used by our customers in food as well as personal care products like body scrubs, shampoos, and cosmetics, how can we determine if the chemical substance must be reported?

If uncertain whether the substance is used for TSCA or non-TSCA purposes, report the uncertain volume under CDR.

Substances excluded from the definition of "chemical substance" under TSCA Section 3(2)(B) (and therefore not subject to CDR) include 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. The Federal Food, Drug & Cosmetic Act (FFD&C Act) defines cosmetic as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." Therefore, the manufacture of a chemical substance for use as soap is not considered a non-TSCA use, and the chemical substances used to formulate the soap are subject to reporting under CDR. Therefore, any associated volume of chemical substance that is used in soap should be included in calculations to determine if the CDR threshold for reporting has been met. The volume of that chemical substance manufactured, processed, or distributed in commerce for use as food, cosmetics, or

other articles identified in TSCA section 3(2)(B)(vi) should not be included in the total volume calculated to establish reporting thresholds.

# **11.3.** If a company manufactures a chemical substance which may be used for purposes regulated by TSCA and also for uses which are excluded from regulation under TSCA Section 3(2)(B), should the entire quantity that the company manufactures be reported on the CDR submission?

No. Report the manufactured quantity intended for the TSCA use and do not report the quantity that is excluded from TSCA regulation pursuant to Section 3(2)(B).

# **11.4.** A company manufactures Chemical C. Its customers use Chemical C for a variety of uses including the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Does the company need to report industrial processing and use data for this chemical substance?

Where persons manufacture chemical substances for a variety of uses, the CDR rule does not require the reporting of processing and use information on the non-TSCA uses of the TSCA chemical substances they manufacture. Therefore, a person manufacturing a chemical substance which is an active ingredient in a pesticide formulation should report the amount of the chemical substance manufactured but need not report processing and use information for activities occurring after it is incorporated into the pesticide formulation.

### **11.5.** If a chemical is both an Active Pharmaceutical Ingredient (API) and a commercial chemical, do we report the total volume or just that part that does not fall under API?

If your chemical is used as both as an Active Pharmaceutical Ingredient (API) and commercially, you would only report the volume that is used commercially (not used as an API) (See FQs 11.1 and 11.2 for more information). That portion of the volume should also be used for making the threshold determination. For example: if a site imports 50,000 lb of the chemical and uses 40,000 lb in the manufacture of a substance subject to CDR and the remaining 10,000 lb to manufacture a pharmaceutical, the site would be required to report under the CDR. If the TSCA-use portion of the chemical was imported under the standard 25,000 lb threshold, you would then confirm that the chemical is not subject to the certain TSCA actions that trigger the lower reporting threshold of 2,500 lb.

### **12. Exemptions from Reporting**

### **12.1.** Which chemical substances on the TSCA Inventory are generally exempt from CDR requirements and do not need to be reported?

40 CFR 711.6 lists the substances that are exempt from CDR requirements, although most of the listed categories are not exempt if the chemical substance is the subject of any of certain TSCA actions (a final or proposed rule under TSCA Section 4, 5(a)(2), 5(b)(4), or 6; a consent agreement developed under the procedures of 40 CFR Part 790; an order issued under TSCA Sections 4, 5(e), or 5(f); or relief under TSCA Section 5 or 7).

However, naturally occurring substances, including naturally occurring water, are exempt from CDR requirements notwithstanding when they are the subject of the listed TSCA actions. Polymers, microorganisms, water (both naturally and non-naturally occurring), and certain forms

of natural gas are generally exempt from CDR requirements, unless they are the subject of the listed TSCA actions.

Naturally occurring chemical substances are defined as any chemical substance which is naturally occurring and:

(1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) Which is extracted from air by any means, will automatically be included in the inventory under the category "Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals. (40 CFR 710.4(b), referenced by 40 CFR 711.6(a)(3))

A polymer is defined as

(i) Any chemical substance described with the word fragments "\*polym," "\*alkyd," or "\*oxylated" in the Chemical Abstracts (CA) Index Name in the Master Inventory File, where the asterisk (\*) in the listed word fragments indicates that any sets of characters may precede, or follow, the character string defined.

(ii) Any chemical substance that is identified in the Master Inventory File as an enzyme, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane.

(iii) This exclusion does not apply to a polymeric substance that has been depolymerized, hydrolyzed, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure. (40 CFR 711.6 (a)(1))

### **12.2.** Is the resulting product of a naturally occurring substances fermented by yeast subject to reporting under the CDR rule?

The resulting product of a naturally occurring substance fermented by yeast would generally be subject to reporting under CDR (if the resulting substance is listed on the TSCA Inventory and meets the applicable production volume threshold). Fermentation entails chemically changing the structure of a substance, which for the purposes of TSCA, would generally be identified differently on the Inventory and be considered a different/new substance (losing its naturally occurring status).

### **12.3.** We produce a product in volumes over 25,000 lb but it consists of 40% water. Do we still need to report this in CDR?

Whether reporting would be required depends upon certain factors, explained in the following scenarios:

Scenario 1: If your chemical is simply diluted with water, the increased percentage of water itself would not trigger reporting. If the percentage of a chemical substance by itself does not meet the 25,000 lb threshold (or the lower 2,500 lb threshold if that chemical is subject to certain TSCA actions) it would not require reporting.

Scenario 2: If you manufacture (including import) a hydrated chemical substance, report its manufacture using the anhydrous or non-hydrated form and adjust the production volume to exclude water, thereby reporting only the volume associated with the anhydrous or non-hydrated form. For the purposes of CDR, a hydrated form of a chemical substance is considered a mixture of the corresponding anhydrous form and water. See TSCA section 3(2)(B)(i) for the definition of chemical substance.

Scenario 3: If your chemical substance is named such that water is a part of its identity, then you would continue to include the water. For example, this may be the case for substances identified by UVCB names that are intended to identify a somewhat variable combination of substances by a single name. UVCB names are often used for byproduct chemicals.

Scenario 4: Mixtures are not themselves reported under the CDR, but the individual component chemical substances of a mixture may be reportable. If you manufacture (including import) the substances as part of a mixture, you would evaluate the CDR requirements for each chemical substance in the mixture. For example, for imported mixtures, you need to identify each component chemical substance to determine if the amount of any individual chemical substance in the mixture when combined with the amount(s) of the same chemical substance otherwise manufactured (including imported) at the same site is sufficient to meet or exceed a CDR reporting threshold.

Note, however, that if you process chemical substances to form a mixture without a chemical reaction by combining domestically manufactured chemical substances you purchase, such that you do not synthesize or produce any of the component chemical substances of the mixture or any different chemical substance, you are not a manufacturer of those chemical substances and are not required to report those chemical substances under the CDR regulation.

Note that water is fully exempted from reporting under CDR.

# **12.4.** Is pipeline quality natural gas used to produce power that is imported from Canada subject to CDR reporting? It appears on the list of substances subject to reporting and on the list of chemicals that have full exemption from reporting?

If your pipeline quality natural gas is one of the forms listed in 40 CFR 711.6(a)(4), then it is fully exempted from reporting. As of October 2023, the natural gas substances are not the subject of the TSCA actions that can impact the substances' reporting status, and therefore do not appear on the other CDR lists that indicate, for example, if the chemical is the subject of a Section 6 action. See FQ 12.1 for additional information.

Within the <u>Substance Registry Services</u> (SRS), EPA provides lists for each CDR submission period that relate to the chemical status as of June 1 of the submission year. All the lists must be reviewed to determine the actual reporting status. EPA provides information about <u>how to search</u> <u>SRS</u> on the CDR webpage (<u>https://www.epa.gov/chemical-data-reporting</u>).

#### 12.5. A fertilizer produced outside the US is interested in importing their product into the US. Their liquid fertilizer product is made from animal/livestock blood and potassium sulfate. They intend to import several million lb per year. Is the livestock blood considered naturally occurring and therefore exempt from reporting requirements?

Pursuant to 40 CFR 711.6(a)(3) and 40 CFR 710.4(b), any chemical substance which is naturally occurring, and which is (i) unprocessed or (ii) processed only by manual, mechanical, or

gravitational means; by dissolution in water; by flotation; or by heating solely to remove water, is considered exempt from reporting. If the fertilizer producer is processing the animal blood by a method not identified in 40 CFR 710(b)(1-2), and the animal blood is not on the Inventory, it would be considered a "new" chemical subject to the requirements of TSCA section 5, unless it meets some exemption from such requirements. Potassium sulfate is on the Inventory (and reportable under CDR) if the volumes exceed the reporting threshold of 25,000 lb.

**12.6.** Are chemical substances that are normally imported for food use reportable under CDR when they are used in a manner covered by TSCA ? E.g. If we import a vegetable oil to further process (bleach, refine and then blend with other edible vegetable oils) into edible oil, and then a portion of the finished oil is sold (to make candles as an example) for a non-food use, do we have to claim that we imported a chemical substance that would otherwise be exempt (the vegetable oil)?

Yes, you would report the volume that was imported for a non-food use. Many substances have uses covered by FFDCA as well as uses covered by TSCA. The volume of a substance manufactured (including imported) for non-FFDCA uses, unless otherwise exempted, are to be reported under CDR. Note that the fact that the import meets the requirements for FFDCA use is immaterial to the determination to report – the important factor is whether or not the substance was manufactured (included imported) solely for the FFDCA use.

You should also consider whether you are making a different oil. If "refining" only means purification, then you are not making a different, reportable substance. Note that if you are narrowing the range of carbon chain numbers in an alkyl range contained in a substance (e.g., from a C8-18 alkyl range to one that is C10-16, for example), then you likely may be making a different substance. Additionally, if your refining of the oil results in the production of a new substance, such production may be reportable.

### **12.7.** Many polymers are exempt from CDR regulations. How is "polymer" defined under the CDR rule?

The CDR definition of polymer is found in 40 CFR 711.6 (a)(1), which identifies polymers that are fully exempted from reporting under CDR. The regulatory text states:

(1) Polymers—(i) Any chemical substance described with the word fragments "\*polym," "\*alkyd," or "\*oxylated" in the Chemical Abstracts (CA) Index Name in the Master Inventory File, where the asterisk (\*) in the listed word fragments indicates that any sets of characters may precede, or follow, the character string defined.(ii) Any chemical substance that is identified in the Master Inventory File as an enzyme, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane.(iii) This exclusion does not apply to a polymeric substance that has been depolymerized, hydrolyzed, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure.

Note that this definition differs from the definition of polymer used in the Polymer Exemption at 40 CFR 723.250 to determine reportability of new polymers under Section 5 of TSCA.

#### 12.8. Are there any types of polymers that are ineligible for the exemption?

Substances that are not considered to be polymers result from hydrolysis, depolymerization, or chemical modification of polymers, regardless of the extent of these processes, so that as long as the final products are no longer polymeric at all (e.g., a mixture of amino acids that is the result of hydrolysis of a polypeptide); such substances, must be reported to CDR if they are not otherwise excluded.

In addition, a particular polymer is no longer covered under this exemption if the chemical substance becomes the subject of any of certain TSCA actions (a final or proposed rule under TSCA Section 4, 5(a)(2), 5(b)(4), or 6; a consent agreement developed under the procedures of 40 CFR Part 790; an order issued under TSCA Sections 4, 5(e), or 5(f); or relief under TSCA Section 5 or 7).

# **12.9.** My company produces latex mixtures which include natural rubber and chemical X. Is this mixture exempted from CDR reporting because the rubber component is naturally occurring?

Based on the information provided, it is not clear if the rubber component is naturally occurring. Chemical substances that are described in 40 CFR 710.4(b) of the TSCA Inventory Reporting Regulations are considered "naturally occurring." Such chemical substances are not reportable under CDR if the chemical substance is produced solely by means described in section 710.4(b). Examples of chemical substances that are typically naturally occurring materials are raw agricultural commodities, water, air, crude oil, rocks, ores, and minerals. However, because the section 710.4(b) exemption is process-specific rather than chemical-specific, if you manufacture any chemical substance in a manner other than just as described in section 710.4(b), you are required to report it unless it is otherwise exempted (40 CFR 711.6(a)(3)). For this reason, minerals and certain agricultural products are sometimes considered not to be naturally occurring because of the means by which they are produced or isolated. Whether a chemical substance is considered "naturally occurring" for the purposes of the CDR exemption depends on the manner in which it is produced and isolated.

In order to determine if your product is exempt from reporting due to it being considered a natural substance you will need to determine if all the components are exempt from reporting. A mixture with partially naturally occurring components will require reporting of the component that is not naturally occurring unless it is exempted. For example, if the other component of the mixture is a polymer, it may be exempt from CDR.

The regulatory text states:

(1) Polymers—

(i) Any chemical substance described with the word fragments "\*polym," "\*alkyd," or "\*oxylated" in the Chemical Abstracts (CA) Index Name in the Master Inventory File, where the asterisk (\*) in the listed word fragments indicates that any sets of characters may precede, or follow, the character string defined.

(ii) Any chemical substance that is identified in the Master Inventory File as an enzyme, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane.

(iii) This exclusion does not apply to a polymeric substance that has been depolymerized, hydrolyzed, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure.

Note that part (iii) of the definition means that the polymer exemption can continue to apply only if the intended product of a reaction is totally polymeric in structure.

In addition, a particular polymer is no longer covered under this exemption if the chemical substance is or becomes the subject of any of certain TSCA actions (a final or proposed rule under TSCA Section 4, 5(a)(2), 5(b)(4), or 6; a consent agreement developed under the procedures of 40 CFR Part 790; an order issued under TSCA Sections 4, 5(e), or 5(f); or relief under TSCA Section 5 or 7).

**12.10.** A company has facilities to recycle used plastic cartridges. These existing plastic cartridges have been previously manufactured and sold to consumers. The cartridges get returned for recycling. On return, the cartridges are crushed and processed (grinding, fusing and blending, etc.) to form a mixture of pellets. No new materials are added and it is not believed that a chemical reaction is taking place that would chemically change the material into different polymers, etc. It is intended that the original plastic materials are being recycled into pellets and thereafter available for reuse. Are the recycled plastic products subject to CDR requirements?

The plastic cartridges are a combination of polymers, and polymers are generally exempt from reporting under the CDR. The actions listed in this question do not appear to depolymerize the material or otherwise manufacture a chemical substance. Therefore, there is no reporting required for the recycling of the plastic cartridges.

### **12.11.** Microorganisms are usually exempt from CDR requirements. How does the CDR regulation define microorganism?

A microorganism is any combination of chemical substances that is a living organism and that meets the definition of "microorganism" at 40 CFR 725.3. Note that any chemical substance produced from a living microorganism is reportable unless otherwise excluded (40 CFR 711.6(a)(2)).

#### **12.12.** What exemptions exist for substances that are typically not active ingredients of a drug? For example biocides may be used for disinfectant or cleaning or a substance may be used as a process chemical instead of a raw material make-up of the drug.

For purposes of Chemical Data Reporting (CDR), you need to consider reporting for any chemical substance as defined under TSCA, see below. A substance may be both a chemical substance and a substance that is in one of the categories of substances excluded from the definition of chemical substance under TSCA. In that situation, you need to consider reporting for the portion that is considered to be a chemical substance.

In the case of a biocide, the volume of a substance that is a pesticide as defined under FIFRA and is manufactured, processed, or distributed in commerce for use as a pesticide is excluded from reporting under CDR based on the definition of a chemical substance. However, if the same substance is also used for other purposes, such as cleaning or as a process chemical, then the volume associated with those other purposes may be reportable under CDR.

Under TSCA, a "Chemical substance" does not include:

(1) Any mixture;

(2) Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;

(3) Tobacco or any tobacco product;

(4) Any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and the regulations issued under such Act);

(5) Any article the sale of which is the subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges); and

(6) Any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of 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. (See TSCA 3(2))

### **Determining if You Are a Manufacturer or Importer Required to Report**

### **13. Production Volume Thresholds**

#### 13.1. How does a company determine whether it has reporting obligations for the CDR?

A person who manufactured (including imported) for commercial purposes 25,000 pounds or more of a reportable chemical substance at any single site during any calendar year since the last principal reporting year is generally subject to reporting (see 40 CFR 711.8(b)), unless the person is eligible for certain exemptions, such as the small manufacturer exemption (see 40 CFR 711.9) or exemptions for certain activities (see 40 CFR 711.10). A person who manufactured (including imported) for commercial purposes 2,500 pounds or more of a chemical substance subject to certain TSCA actions at any single site during any calendar year since the last principal reporting year is generally subject to reporting.

You should consider the following three steps to determine whether you are required to report for each chemical substance that you manufactured (including import) in/into the United States since the last principal reporting year:

- Step I: Is your chemical substance subject to the CDR rule?
- Step II: Are you a manufacturer (including importer) who is required to report?
- Step III: What information must you report?

See the <u>Instructions for Reporting</u> on the CDR website (<u>https://www.epa.gov/cdr</u>) for help with each of these steps.

### **13.2.** Will EPA provide a consolidated list of substances and thresholds that are relevant for this reporting cycle?

A downloadable spreadsheet is available on the EPA website. It consolidates the 2020 CDR chemical status information available through EPA's Substance Registry Services (SRS) into one spreadsheet, identifying the TSCA Inventory status of each chemical substance, whether the chemical is the subject of the relevant TSCA actions, and whether the chemical is subject to a reduced reporting threshold or ineligible for exemptions. See **EPA 2020 CDR Chemical Status Spreadsheet** on the "Search for chemicals subject to certain TSCA actions" page at: *https://www.epa.gov/chemical-data-reporting/help-chemical-data-reporting-how-search-chemicals-subject-certain-tsca*.

### **13.3.** Does a company that sells more than 25,000 lb of fertilizer in a year need to report this to EPA?

For purposes of Chemical Data Reporting (CDR), the component chemicals in your fertilizer are reportable if (1) you are manufacturing (including importing) the chemicals used in your fertilizer, (2) the chemicals are listed in the TSCA inventory, and (3) the amount of the reportable chemicals in that fertilizer that you manufactured (including imported) at a single site exceed the 25,000 lb threshold. If your company domestically purchased the fertilizer, you are not required to report the fertilizer under CDR. Please see the <u>Who Must Report? section on the Basic</u> <u>Information about CDR Reporting webpage</u> for more information.

# **13.4.** How do manufacturers avoid double counting of chemical substances in intermediates and final products? If a chemical substance is an isolated intermediate during production, that's to be counted. However, if that same chemical substance is present in the final product, should it be added to the amount of isolated intermediate or should the amount in the final product be reported, assuming that amount is greater than what's present in the intermediates?

A substance is reported when it is manufactured. If it is manufactured as an intermediate, then the substance is reportable at that time. If the intermediate that is present in the final product is unreacted material, then it does not need to be reported as part of the final product.

# **13.5.** Are domestically bought substances that are used in processes and are reacted to manufacture a product reportable? The final product is not a mixture containing this substance. The substance either is reacted completely, or whatever remains unreacted is sent to waste.

Only the manufacturer or importer of a chemical substance is required to report under CDR. A domestically purchased chemical substance does not have to be reported for CDR. However, any chemical substance that is manufactured from the purchased chemical substance is reportable. For example, if Company X domestically purchased Chemical A and Chemical B and reacts them to create Chemical C, Company X would only report Chemical C.

### **13.6.** If a company began producing a chemical substance in January 2024, does the company need to send EPA a CDR report for 2023 with all zeros?

No. Reporting for chemical substances is determined based on the volumes produced during any calendar year since the last principal reporting year. Because the company did not manufacture

the chemical during 2020-2023, the company has no reporting obligations for that chemical for the 2024 CDR submission period.

# **13.7.** If a company manufactured 31,000 pounds of a reportable chemical substance at one site and 20,000 pounds at another site, does the production volume meet or exceed the threshold for reporting?

In general, the company only needs to report for those sites at which it manufactured (including imported) 25,000 pounds or more of a reportable chemical substance in any calendar year since the last principal reporting year. If the chemical does not trigger a reduced reporting threshold, the company would report the 31,000 pounds manufactured at the first site but is not required to report the 20,000 pounds manufactured at the second site. If the chemical is subject to a reduced threshold of 2,500 pounds because it is the subject of certain TSCA actions, the company would report for each of the sites.

#### 13.8. What if a company both manufactures and imports a chemical substance at a plant site?

The company should aggregate the total amount of the chemical substance manufactured and imported at the site to determine if a reporting threshold has been met.

# **13.9.** An importer with one site in the U.S. imports the same chemical from two different companies (located in two different countries). Does the importer add the amounts from each source together or are they kept separate?

The importer adds the imported volumes of the same chemical imported by the same site, regardless of the source. Note that this also applies to mixtures — when a mixture is imported, the component chemicals of that mixture are subject to CDR. The determination of whether the production volume threshold is met is based upon the total imports for the chemical substance.

# **13.10.** If a company imports 1 million pounds of a mixture containing 90 percent Chemical A, 9 percent Chemical B, and 1 percent Chemical C, how is this reported? Chemicals A, B, and C are all potentially subject to CDR.

The company should evaluate the reporting requirements for each constituent of the mixture.

- Chemical A: 900,000 pounds (1,000,000 pounds x 90 percent) imported.
- Chemical B: 90,000 pounds imported.
- Chemical C: 10,000 pounds imported; no reporting because the 25,000 pound threshold was not met. (However, if Chemical C is the subject of certain TSCA actions, reporting is required because the 2,500 pound threshold is exceeded.)

# **13.11.** A company imports 200,000 pounds of Alloy 123 and knows the percentage of each component in the alloy (see table below). How does the company report for Alloy 123 under the CDR regulation?

Component	Percent (%) in Alloy 123	PV (Pounds)
Nickel	52%	104,000
Iron	35%	70,000
Cadmium	5%	10,000

Component	Percent (%) in Alloy 123	PV (Pounds)
Molybdenum	3%	6,000
Chromium	2%	4,000
Titanium	0.9%	1,800
Copper	0.9%	1,800
Carbon	0.6%	1,200
Aluminum	0.4%	800
Silicon	0.2%	400

The company must consider each component of Alloy 123 independently and determine if it meets the CDR criteria. The calculations in pounds for each constituent are shown above in the third column. Only Nickel and Iron would be reportable because they are the only two components with production volumes above 25,000 pounds. If any of these substances are the subject of certain TSCA actions the reporting threshold to consider would be 2,500 pounds.

#### 14. Small Manufacturers

#### 14.1. Are small manufacturers exempt from CDR reporting requirements?

Usually, yes. A submitter meeting either of the following standards (40 CFR 704.3) would be considered a small manufacturer and generally exempt from CDR reporting if:

- Total sales during the principal reporting year, combined with those of the parent company, domestic or foreign (if any), are less than \$12 million regardless of annual production volume.
- Total sales during the principal reporting year, combined with those of the parent company, domestic or foreign (if any), are less than \$120 million and your annual production volume of that chemical substance does not exceed 100,000 pounds at any individual plant site. If the annual production volume of the chemical substance at any particular site is more than 100,000 pounds, the submitter is required to report for that particular site, unless the submitter meets the first standard.

Note that under the second standard, it is possible to qualify as a small manufacturer with respect to some chemical substances and not others or with respect to some sites and not others.

For purposes of the definition of a small manufacturer, total annual sales include all sales of the company, not just the total sales of a given chemical substance (40 CFR 704.3).

### **14.2.** There have been changes to the definition for Small Manufacturers. Will the 100,000 pounds threshold still apply to the small business entities?

Yes. The 100,000 pounds threshold is applied as follows (40 CFR 704.3):

- You are exempt from reporting as a small manufacturer if:
- Total sales during the principal reporting year, combined with those of the parent company, domestic or foreign (if any), are less than \$120 million and your annual production volume of that chemical substance does not exceed 100,000 pounds at any individual plant site. If the annual production volume of the chemical substance at any particular site is more than

100,000 pounds, the submitter is required to report for that particular site, unless the submitter meets the first standard.

• Total sales during the principal reporting year, combined with those of the parent company, domestic or foreign (if any), are less than \$12 million regardless of annual production volume.

#### 14.3. Are small governments also exempt from reporting under CDR?

Yes, small governments are also exempt from reporting under CDR. In May 2020, EPA finalized the Small Manufacturer Definition Update for TSCA Section 8(a) rule, which added a small government definition. For purposes of CDR, a manufacturing site that is owned by a small government is not required to report manufactured (including imported) chemical substances. *Small government* means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. (40 CFR 704.3)

### **14.4.** Are there any situations where small manufacturers are not exempt and may be subject to CDR reporting?

Yes. The exemption for small businesses does not apply to persons who manufacture (including import) a chemical substance that is the subject of a rule proposed or promulgated under Section 4, 5(b)(4), or 6 of TSCA; or is the subject of an order in effect under Section 4 or 5(e) of TSCA; or is the subject of relief that has been granted under a civil action under Section 5 or 7 of TSCA (40 CFR 711.9). In such circumstances, the volume thresholds for reporting found in §711.8 apply.

# 14.5. When evaluating my small business exemption status with respect to production volume being less than 100,000 pounds, do I consider each chemical substance separately or all of my chemicals together?

You determine your status as a small manufacturer on a chemical-by-chemical basis, taking into account the total sales of the company. Therefore, if your company has total sales of \$12 million or over but under \$120 million and manufactured 35,000 pounds of Chemical A, 140,000 pounds of Chemical B, and 95,000 pounds of Chemical C, your company qualifies for small manufacturer status with respect to Chemicals A and C, but not Chemical B. Note that, if Chemical A or C is subject to any of certain TSCA actions, your company would be required to report for that chemical, notwithstanding its small manufacturer status. If you have trigger the need to report for a particular chemical substance at a particular site based on your production volume in any calendar year during the reporting period, you are required to report all of the information for that substance at that site regardless of the production volumes from the other years.

#### 14.6. If a company qualifies as a small manufacturer, should that information be sent to EPA?

No. A company does not need to send the information regarding qualifying as a small manufacturer to EPA.

## **14.7.** To determine if we qualify as a small manufacturer, when calculating total annual sales of a parent company, should we only add sales of the domestic parent company or are sales of the foreign parent company included too?

To determine whether you meet the small manufacturer definition, calculate total sales for the entire company, including the sales of a foreign parent company. In the definition of a small manufacturer, in 40 CFR 704.3, a parent company is defined more broadly geographically than the definition of U.S. parent company.

#### **15. Certain Regulated Chemical Substances**

# **15.1.** One of the chemicals that Company B manufactures is the subject of a TSCA Section 4(a) test rule proposed in 1999. Is this still active and does it affect the CDR status of the chemical substance? Does it matter that Company B didn't start to manufacture the chemical substance until 2023?

Unless EPA has withdrawn or finalized the rule in the Federal Register, the proposal is still pending and the chemical substance is thus still the subject of a proposed TSCA Section 4(a) test rule. Company B cannot claim a reporting exemption for the chemical under 40 CFR 711.6 or, if Company B meets the requirement of a small manufacturer, under 40 CFR 711.9. The fact that Company B did not start to manufacture the chemical substance until 2023 does not change this conclusion.

# **15.2.** A chemical substance that Company C manufactures is the subject of a TSCA Section 4(a) test rule which is listed as having a sunset date before the current CDR reporting year. Does this test rule still affect the CDR status of the chemical substance?

Final TSCA Section 4 test rules, test orders and/or enforceable consent agreements will have a sunset date which is the termination of the TSCA Section 4 requirements. After the sunset date has passed, the chemical substance is no longer subject to TSCA Section 4. Therefore, in this case, Company C would not need to be concerned about a test rule which terminated before the current CDR reporting period. Consider the TSCA regulatory status of the chemical substance at the beginning of the reporting period (e.g., June 1, 2024 for the 2024 reporting period).

#### 16. Small Quantities for Research and Development

### **16.1.** If a company manufactures a small quantity of a chemical substance solely for research and development, is CDR reporting required?

No. A chemical substance manufactured solely in small quantities for research and development need not be reported under the CDR regulation (40 CFR 711.10(a)). However, the company must be sure that it can verify that this chemical substance is used solely for research and development.

# 16.2. A company manufactures 26,000 pounds of a chemical substance, uses 2,000 pounds for research and development, and sells the remaining chemical substance for industrial uses. Is CDR reporting required? The chemical substance is not otherwise exempted from CDR requirements.

Yes, CDR reporting is required. A person is exempt from CDR requirements for a chemical substance manufactured for research and development only if they do not also manufacture the chemical substance for other non-exempt uses (40 CFR 711.10(a)). The total amount of the

chemical substance manufactured, 26,000 pounds, exceeds the reporting threshold and therefore all 26,000 pounds of the chemical must be reported.

### **17. Imported Articles**

### **17.1.** If a chemical substance is part of an article when it is imported, is the chemical substance reportable under the CDR regulation?

Maybe. If the chemical substance is imported solely as part of an article and is not intended to come out of the article during use, the chemical substance is exempt from CDR reporting. 40 CFR 711.10(b). For example, a pen is considered an article and any chemicals that comprise the pen body are not subject to reporting; the ink in the pen is not considered to be part of the article because it is intended to come out of the pen in order for it to be used and any chemicals in the ink are subject to reporting.

An article is defined in 40 CFR 704.3 as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

See <u>TSCA Chemical Data Reporting Fact Sheet: Imported Articles</u> for additional information.

# **17.2.** If a company imports metal ingots that are melted and reshaped into finished products in the United States, is the company required to submit a CDR report for the ingots that are imported?

Probably, yes. Although chemical substances imported as part of an article are exempt from CDR reporting (40 CFR 711.10(b)), ingots typically do not qualify for this exemption. If an item is manufactured or imported in a particular shape for convenience during shipping and the shape of the item has no function in the end use, it would not be considered an article. A metal ingot is typically intended to be melted and extruded; the shape or design of the end use application is independent of the shape of the ingot. Consequently, the importation of chemical substances that are present in ingots generally must be reported for CDR.

# **17.3.** If a company purchases metal ingots from a domestic supplier that are subsequently melted and reshaped into finished products, is the company required to submit a CDR report for the ingots that are purchased from a domestic supplier?

No. The company is not manufacturing (or importing) the metal ingots but is only processing them. The CDR rule applies only to manufacturers (including importers) of chemical substances.

**17.4.** A metal alloy disk containing iron, nickel, cobalt, and other metals is imported and subsequently machined to design specifications and assembled into the final product. The shape of the imported disk is commonly referred to as "near-final-shape," in that its overall

### shape and dimensions are largely preserved following the machining process. Does EPA consider the metal alloy disk an article for CDR purposes?

Yes. The disk comports with the definition of an article and the chemical substances comprising the disk would not need to be reported under CDR. An article is an item manufactured in a specific shape or design that has end use function dependent upon its shape or design. In addition, an article has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of the article (40 CFR 704.3). In this fact pattern, the disk is imported in near-final-shape which is maintained as the part is machined from the disk, the use of the disk depends on the near-net shape of the disk, and the chemical composition of the article does not change during machining or use except for any unintended corrosion. Therefore, the disk satisfies all three parts of the article definition and is eligible for the exemption for imported articles at 40 CFR 711.10(b).

#### 17.5. Can imported metal powders ever be considered "articles" regardless of their end use?

No. Powders cannot be considered articles. The definition of article includes the statement that "fluids and particles are not considered articles regardless of shape or design" (40 CFR 704.3).

### **18. Impurities**

#### 18.1. Must impurities be reported under the CDR regulation?

No. Impurities are exempted from CDR requirements. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(1). An impurity is defined as a chemical substance which is unintentionally present with another chemical substance (40 CFR 704.3). Impurities are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.

# **18.2.** A company purchases Chemical X which contains impurities, and then uses Chemical X as a reactant to manufacture Chemical Y. The impurities that were present in Chemical X may then be present in Chemical Y and there may be other impurities in Chemical Y. Must the company now report the impurities in Chemical Y because they are present in a chemical substance that the company has manufactured?

If the impurities retain their status as impurities (i.e., they remain unintentionally present with Chemical Y) then they are not reportable. However, it should be noted that the company may possibly also have manufactured one or more reportable byproducts as part of making Chemical Y.

# **18.3.** Our company manufactures a product (flux-calcined diatomaceous earth) shipped to another company to be acid-washed to produce a high purity grade; however, the composition doesn't change. Are we responsible for CDR reporting? Or is this considered co-manufacture product? Also, where the calcination only results in the removal of water/impurities or just a phase transition (natural – calcined), is the calcined product exempted?

Your company would report its product, the flux calcined diatomaceous earth. If the other company is acid-washing the product solely to remove impurities, then it is not manufacturing a different substance and is not incurring the need to report the purified flux-calcined diatomaceous earth.

If the calcination of a naturally occurring chemical substance occurs only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water to result in the removal of water/impurities or create a phase transition (natural – calcined), the calcined product would retain the naturally occurring chemical substance exemption. Calcined diatomaceous earth would only be exempted if it continued to meet the definition of a naturally occurring chemical substance even after processing/calcination.

### **19. Non-Isolated Intermediates**

#### **19.1.** What is a "non-isolated intermediate"?

*Intermediate* means any chemical substance that is consumed, in whole or part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions. (40 CFR 704.3)

*Non-isolated 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 substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured. (40 CFR 704.3, referenced by § 711.3)

In the definition for Intermediate, "intentional manufacture" can be equated with "Manufacture for commercial purposes."

# **19.2.** Reactants C and D are charged to a vessel where they react to form Chemical P. Chemical E is then added to the reaction vessel and Chemical P is completely consumed in the formation of Chemical Q, which is then drummed for shipment. Is the manufacture of Chemical P subject to CDR requirements?

No. In this example, EPA considers Chemical P to be a "non-isolated intermediate" because it is not stored in or intentionally removed from the reaction vessel in which it is manufactured and it is reacted in that vessel to form another chemical substance. Persons who manufacture chemical substances solely as non-isolated intermediates are exempt from CDR requirements for those chemical substances (40 CFR 711.10(c) which references 40 CFR 720.30(h)). Note, however, that the manufacturer should determine whether Chemical Q meets the criteria for being reportable under CDR requirements.

**19.3.** Our company operates SNCR (selective non-catalytic reduction) units on our power plants for pollution control of NOx. All of our SNCR units use liquid urea which we purchase and inject directly into the boiler where it converts to ammonia due to the heat and reacts with the NO and NOx to form N, CO2, and H2O. The only ammonia that leaves through the emission stack is a very small amount of ammonia slip. Is it correct that since the conversion of urea to ammonia takes place in the boiler and the ammonia is fully consumed

### (except for slip), the ammonia is therefore non-isolated and we would be exempt from reporting ammonia.

No, the ammonia is reportable (assuming it is manufactured in volumes exceeding the threshold and is not otherwise exempt). In the process described, the manufactured ammonia is used as a reagent to react with NO and NOx within the pollution control equipment with the intention to remove the NOx, not with the intention to produce CO2, H2O, and N. Although the manufactured ammonia may be non-isolated, it is a reagent and not an intermediate; therefore the non-isolated intermediate exemption cannot be applied.

### **19.4.** Is it possible that I need to report more volume than the raw materials I used to make a product?

If a raw material is processed to make an intermediate and that intermediate is then processed to create a finished product, and both the intermediate and the finished product are reportable chemical substances and your total reportable quantities would in fact exceed the volume of raw materials used. This is because EPA is concerned not only with the final product, but also the intermediate substance that is manufactured. However, if the intermediate is considered non-isolated, as defined in the example above, you would not need to report both the intermediate and the final product volumes.

### **19.5.** Does sampling for quality control purposes negate the non-isolated intermediate status of a chemical substance?

No. Sampling for quality control does not negate the non-isolated intermediate status of a chemical substance.

### **Determining the Information You Must Report**

#### 20. Processing and Use Reporting

#### 20.1. Is there a separate threshold that triggers the need for processing and use reporting?

There is no separate threshold that triggers the need to report processing and use information. If you are reporting a chemical under CDR, you must also report its processing and use information unless the chemical substance is exempted from processing and use reporting by 40 CFR 711.6(b). Processing and use information is only reported for the principal reporting year (i.e., 2023 for the 2024 reporting period).

### **20.2.** If a company does not manufacture or import a chemical substance, does the company have to report processing and use information for TSCA chemicals purchased from a manufacturer for use in making a product?

Only companies that manufacture or import chemical substances (as defined under TSCA) are required to report. If you purchase a chemical substance from a manufacturer (including importer) you are not required to report information under CDR for that purchased chemical substance.

# **20.3.** If a company in the United States is 50% owned by a foreign entity does that facility only need to report 50% of the product that is produced? Which entity in the joint venture is responsible for the reporting in CDX?

CDR data is collected at the site level. If production at a facility is 100% in the United States (and not abroad), 100% of manufacturing will need to be reported to CDR (if other threshold requirements are triggered). Participants in a joint venture may determine among themselves who will report. If no report is submitted when required, EPA may hold each party in the joint venture liable for the failure to report.

# **20.4.** Company A manufactures over 25,000 pounds of a chemical substance and exports 90 percent of it. Since the remaining 10 percent is less than 25,000 pounds, does Company A need to report processing and use information in Part II of the form?

Yes. The need to complete the processing and use information is based on the overall production volume, which would include the amount exported. Once a chemical substance is exported, further reporting is not needed on the exported volume. However, if the chemical substance goes to a distributor prior to being exported, Company A may need to report on any processing activities that might occur prior to export, such as the repackaging of the material. If it is directly exported, Company A would not need to report processing and use information on that volume that is directly exported.

# **20.5.** When a site manufactures a reportable chemical substance, mixes it with other substances to form a product, and prepares the product for further distribution by transferring it from an onsite tank to a tanker truck or railcar, how would the site report the industrial processing and use operations?

In the situation described, the processing portion of the effort includes two steps – processing to incorporation into a mixture (code PF) and processing to repackage (code PK). The processing and use portion of the CDR Form U would include two lines of data for this operation, based on a combination of the first three processing/use elements – type of processing or use, sector, and function, which together comprise a unique exposure scenario. For each unique scenario, report the additional information, including the %PV and the number of potentially exposed workers. Because workers could potentially be exposed on-site when adding the chemical substance to a product or repackaging, include the workers involved with transferring the product from an on-site tank or stockpile to a tanker truck or railcar in the worker count for processing to repackage (PK).

Similar to the TRI program, for TSCA purposes, EPA considers the transfer of a reportable chemical from an on-site tank or stockpile to a tanker truck or railcar (repackaging) prior to further distribution of the product to be processing. See the definition for Process for commercial purposes at 40 CFR 704.3 and below:

*Process for commercial purposes* means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

### 21. Full Reporting for Chemical Substances

#### 21.1. What is full reporting under CDR?

Full reporting means that all Parts of Form U must be completed.

#### **21.2.** Which chemical substances are subject to full reporting?

Reportable chemical substances manufactured (including imported) in amounts of 25,000 pounds or more at a single site during any calendar year since the last principal reporting year (e.g., for the 2024 reporting period the last principal reporting year is 2019; therefore the years considered are 2020-2023) are subject to full reporting for the current principal reporting year (e.g., 2023 for the 2024 reporting period). Full reporting means that all Parts of Form U must be completed. Additionally, chemical substances that are the subject of certain TSCA actions are reportable when manufactured (including imported) in quantities of 2,500 pounds or more at a single site during any calendar year since the last principal reporting year.

If you manufacture a chemical substance that is partially exempt from full reporting, reporting of data elements in Part II – Section D of Form U (industrial processing and use and consumer and commercial use data elements) is not required. The list of partially exempted chemical substances is found in 40 CFR 711.6(b), and is replicated on the CDR website and in EPA's Substances Registry Services (SRS). The eCDRweb reporting tool will search SRS and report back to you if your chemical substance is partially exempted.

See <u>TSCA Chemical Data Reporting Fact Sheet: Chemical Substances which are the Subject of</u> <u>Certain TSCA Actions</u> for information on how to identify chemical substances that are the subject of a TSCA action that affects the reporting threshold or the partial exemption status, including how to search EPA's Substance Registry Services to identify the status of a chemical.

#### 22. Partial Reporting Exemptions

### **22.1.** What substances are exempt from Processing and Use Information reporting because they qualify for a partial reporting exemption?

If a chemical substance is subject to reporting but qualifies for a partial exemption, a company must report the information required by 40 CFR 711.15(b)(1)-(3) (which corresponds to Part I and Part II – Section A - C of Form U); however, a company is not required to report the information described in 40 CFR 711.15(b)(4) (which corresponds to Part II – Section D of Form U). Chemical substances in the following two groups qualify for a partial exemption from reporting requirements:

- a. Petroleum process streams listed in 40 CFR 711.6(b)(1) and
- b. Specific chemical substances listed in 40 CFR 711.6(b)(2)(iv)

Note that these partial exemptions are negated if the chemical substance is the subject of any of certain TSCA actions.

The most recent additions to partially exempt chemicals list can be found on the <u>CDR Petition</u> <u>page</u>.

## 22.2. If a company manufactures more than 25,000 pounds of a chemical substance listed as a petroleum process stream at 40 CFR 711.6(b)(1) and is not the subject of any TSCA actions that would negate its partial exemption, which sections of Form U must be completed?

Based on these facts, the company only needs to complete Part I (site identification) and Part II – Sections A - C (chemical substance and technical contact identification and manufacturing information) of Form U. Part II – Section D (processing and use information) of Form U is not applicable.

### **22.3.** How do the "specific chemical substances" get listed for partial exemptions from CDR reporting?

EPA created a partial exemption for certain chemical substances for which EPA has identified a low current interest in their processing and use information. The specific chemical substances are listed at 40 CFR 711.6(b)(2)(iv). If your chemical substance is partially exempt, you are required to complete only Part I and Part II – Sections A-C of the Form U.

EPA may add additional chemical substances to the partially exempt list on its own initiative or in response to a petition from a member of the public. In 40 CFR 711.6(b)(2)(iii), EPA provides a process whereby any person may request EPA to amend the chemical substance list. Such a request must be submitted to EPA no later than 12 months prior to the start of the next principal reporting year.

### **Completing Form U**

### 23. General

#### 23.1. Can a secondary authorized official access a primary Form U?

If you are registered within CDX only as a secondary authorized official, you will only have access to the secondary form. To access the primary form, you would need to register as a primary authorized official. Note that you can be registered as both a primary and a secondary authorized official. Please see the <u>CSPP CDX Registration Guide</u> for help in creating user roles and access to the Form U.

#### 23.2. Does a whole new Form U need to be completed for each chemical substance?

No. Only one Form U is submitted for a site; all reportable chemicals for a site are reported on a single Form U. The certification statement and Part I are completed once for a Form U, regardless of the number of chemical substances reported. Parts II and III are completed for each chemical substance, and Part IV is only completed in the special case of a joint submission.

#### 23.3. Can one Form U be submitted for the same chemical substance used at two different sites?

No. You must submit a separate Form U for each site for which you are required to report. Therefore, in cases where you have two separate sites manufacturing the same chemical substance, you must prepare separate Form Us for each site.

#### 23.4. Should I report known values and estimated values differently on Form U?

No. Report all information requested in Form U to the extent it is known to or reasonably ascertainable by you and your company.

# **23.5.** The person previously responsible for this reporting is no longer working here and we cannot locate the user ID and password to gain access to our previous chemical reporting information on e-CDRweb. How do I gain access to earlier reported data? Can you reset the passphrase to grant me access?

To access previous chemical reporting information for a company, you must be registered in EPA's Central Data Exchange (CDX) with your own username and password and know the eCDRweb passphrase. If in CDX you register for the exact same organizations (same Organization ID) and exact same facilities (same facility ID) as your predecessor, you will be able to see what forms were previously created and submitted.

In the event the original passphrase has been lost, the information on the Form U itself will not be electronically accessible. However, you can request a paper copy of the previously submitted information.

To request a copy of your site's CDR Form U from a prior reporting year (e.g., 2016 and 2020), please submit a request to EPA via the TSCA Communication module in CDX. The request must include the name and address of the site of the desired Form U and a statement certifying you are authorized to receive this potentially confidential information.

To access the TSCA Communications module, log into CDX and click on the CSPP Primary Authorized Official link on the MyCDX tab. This will take you to the Chemical Information Submission System screen. In the drop-down, select 'TSCA - Communications' and click OK.

🖓 CSPP	👗 Logged in a	as: William Brigman, Primary Authorized Official Log Out
Welcome to the EPA's Chemical drop-down menu.	CHEMICAL INFORMATION SUBMISSION SYST Endocrine Disruptor Screening Program (EDSP) Mercury Electronic Reporting - MER TSCA - Communications	
	TSCA - Enforcement and Compliance TSCA Chemical Data Reporting (CDR) 2020 TSCA Chemical Data Reporting (CDR) 2012 and 2016 TSCA FYI Submission TSCA Risk Evaluation Rule TSCA Section 12(b) TSCA Section 4 TSCA Section 5 Notices and Supports - ePMN	•

In the TSCA Communications application, click on the 'Start New Communication' and provide the required information to create the communication. Then submit.

					د	William Brigman, NEW	TEST ORG (Prin	nary Authorized Officia
TSCA General Communications								
TSCA General Communications is used for attachments for ea	isting submissions. Note: this should not b	e used for amend submissio	ns if you are lock	ed out of your form.	For issues related to that co	ntact CDX Help.		
<ul> <li>To submit an attachment and/or comment about a submit To see details about the communication click the O icon To create an additional submission under an existing Cas</li> <li>To delete a communication submission click to it is in a To delete a communication submission click to it is in a submission submissible submission submission submissin submission submission s</li></ul>	o expand e Number click 🔽 icon ions column.	utton.						
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Communication Number	Communication Alias	Case Number	Office	Subject	Date Opened	Created By	Status	Actions

### **23.6.** May I amend a submission from the current or most recent reporting period if I realize I made a mistake?

If you make a reporting mistake, you must amend your Form U. To amend a Form U, the Authorized Official or the Agent will need to unlock the submission to make the changes. See the <u>CSPP CDX Registration Guide</u> for more information. There will be an opportunity to explain why the change is being made - please be sure to complete that section.

Under CDR, you should report to the extent that is known to or reasonably ascertainable by you (40 CFR 711.15). Under the "known to or reasonably ascertainable by" reporting standard, a submitter would therefore prepare its report about the processing and use of a chemical substance it manufactures (including imports), without confining its inquiry solely to what is known to managerial and supervisory employees, but would also be expected to review information which the manufacturer (including importer) may have in their possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

If you are amending your Form U based on newly available information and believe that you reported to the extent that was known to or reasonably ascertainable to you at the time of the original submission, please indicate so when you explain why the change is being made.

If you believe your facility is or may have been in violation of reporting requirements under CDR, please refer to EPA's Policy entitled, "Incentives for Self-Policing: Discovery, Disclosure, Correction, and Prevention of Violations" (*Audit Policy, April 11, 2000 (65 FR 19618)*). You may qualify for having all gravity-based penalties waived if your facility meets all nine (9) conditions of the Audit Policy. For more information on EPA's Audit Policy, see the Agency's website at <u>https://www.epa.gov/compliance/epas-audit-policy</u>.

Note that if you did not claim (and substantiate if required) a particular data element as confidential at the time you submitted the data element to EPA, you cannot later add a claim of confidentiality.

# **23.7.** When completing a bulk upload, is the Excel file designed to be directly imported into the Form U? If so, can I truncate some of the entries (columns) unrelated to my company/chemical? Or do I have to use the template as is?

Use the template as is. This Excel file is designed to be directly imported into the Form U. Truncating some of the entries/columns may cause issues; it would be best to upload the template unaltered (without removing columns).

### 24. "Known to or Reasonably Ascertainable by" Reporting Standard

24.1. Please provide further clarification on the scope of what would be required under the "known to or reasonably ascertainable by" reporting standard. How would this reporting standard apply to processing and use information? How does this standard differ from the "not readily obtainable" standard, previously applicable to such reporting? Does the change of standard indicate that "extensive file searches and customer surveys" are now expected of submitters in order to assemble data for the purposes of chemical data reporting?

The term "known to or reasonably ascertainable by" is defined at 40 CFR 704.3. It means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." By contrast, "readily obtainable" information did not even cover all the information in a submitter's possession or control. As defined for the 2006 submission period, it was limited to what was known by certain "management and supervisory employees of the submitter." See 68 FR 879 (2003).

Under the "known to" portion of the standard, a submitter must ascertain what it knows about the processing and use of a chemical substance it manufactures (including imports), without confining its inquiry to what is known to managerial and supervisory employees. A submitter would also be expected to review other information which the manufacturer (including importer) may have in its possession. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

Inquiry under the "reasonably ascertainable" portion of standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Note, however, that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable" to the submitter. Thus, there is not a need to conduct new customer surveys for purposes of the CDR. As described above, however, existing customer survey data may nevertheless be "known to" the organization.

# 24.2. What are some examples of types of information that are considered to be in a person's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know?

Information could be possessed by employees or other agents of the company reporting under the CDR rule, including persons involved in the research, development, manufacturing, or marketing

of a chemical substance. This information includes knowledge gained through discussions, symposia, and technical publications. Other examples include:

- Files maintained by the submitter or employees in the submitter's company, such as marketing studies, sales reports, or customer surveys;
- Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
- Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

### 25. Part I – Company and Site Identification Information

#### **Section A. Parent Company Information**

#### 25.1. What information must I provide about my parent company?

For purposes of CDR, a parent company is the highest-level company of your site's ownership hierarchy as of the start of the submission period, according to the definitions of *highest-level parent company* at 40 CFR 711.3. Submitters must report the highest-level parent company located in the United States (the domestic parent company) and, if one exists, the highest-level foreign-based parent company (40 CFR 711.15(b)(2)(i)). For each parent company, provide the company name, address, and the D&B number.

See the *Instructions for Reporting* for examples of how to identify the parent company(ies) in different situations.

# 25.2. When filling in forms to report CDR information what should I indicate for "domestic parent company" if there is no separate company? The form will not allow this input to be left blank. Also, the headquarters of the company is at a different location than the factory. What address should I use?

If a site is entirely owned by a single U.S. company, and is not owned by another company, that single company is the U.S. parent company. If the company headquarters is at a different location from the manufacturing site, please use the address of the company headquarters when reporting parent company information. Site information must still be provided in this event.

See the *Instructions for Reporting* for examples of how to identify the parent company(ies) in different situations.

**25.3.** Can EPA clarify how the responsibility will be assigned for reporting chemical substance manufacture and import activities for entities that were acquired or divested since the last submission period? For example, the current owner of a newly acquired facility may not have access to manufacture/import volume information for years before they acquired the facility. Would exemptions be provided for any company engaged in an acquisition or divestiture during the years since the last reporting cycle?

Reporting should be based on ownership of the manufacturing entity, as of the date that the report is submitted. EPA acknowledges that there will be submitters who have been involved in an acquisition or divestiture since the last submission period and for whom certain information is not known or reasonably ascertainable. If information is not known or reasonably ascertainable, it need not be reported under the CDR. See the <u>*Reporting After Changes to Company Ownership or Legal Identity*</u> fact sheet for further information.

25.4. During the first six months of the current CDR reporting year (e.g., 2023 for the 2024 reporting period), Company X manufactured 30,000 pounds of a chemical substance included on the TSCA Inventory and not otherwise excluded from the CDR at a particular site. In the middle of the same year, Company Y purchased Company X, acquiring all the assets of Company X and assuming all of the liabilities of Company X. During the last six months of the same year, Company Y manufactured 40,000 pounds of the same chemical substance at the site. Who should report the amounts of the chemical substance manufactured?

Because all of the assets and liabilities of Company X were merged into Company Y, and Company Y continued as a going concern, Company Y is required to report the entire 70,000 pounds of the chemical substance manufactured at the site during the reporting year (e.g., 2023 for the 2024 reporting period), as well as the production volume of the chemical substance during any year since the last principal reporting year. More information about the effect of company mergers on CDR reporting can be found in the <u>Reporting After Changes to Company Ownership or Legal Identity</u> fact sheet.

25.5. On January 1, 2024, Company A will sell the portion of its business that conducted manufacturing in 2023. Company B will purchase this portion of the business, acquiring all of its assets and assuming all of its liabilities. Whose company identification should be reported for the "U.S. parent company"? Company A's because Company A was the owner when the manufacturing occurred? Or Company B's because Company B was the owner of the submission?

By the time of the CDR submission in 2024, Company B owns the entity that conducted the manufacturing in 2023. Company B should report its own identity, not the identity of a previous owner. More information about the effect of the sale of a company on reporting requirements can be found in the <u>Reporting After Changes to Company Ownership or Legal Identity</u> fact sheet on the CDR website.

# **25.6.** A company has 3 small facilities (1 chemical substance to report) that closed during the CDR submission period and the company cannot reasonably obtain the manufacturing data for the facilities. How should the company complete the form for these facilities?

Assuming each of the facilities met or exceeded the production volume threshold for the subject chemical substance during any calendar year since the last reporting period, the company should submit a Form U for each of the closed facilities and report the CDR information to the extent that it is known to or reasonably ascertainable by the company. Additional information about the effect of ceasing manufacturing operations at a site on CDR reporting can be found in the *Reporting After Changes to Company Ownership or Legal Identity* fact sheet on the CDR website.

### **25.7.** Which company should report if a chemical substance is being manufactured by a joint venture?

Participants in the joint venture may determine among themselves who will report. If no report is submitted when required, EPA may hold each party in the joint venture liable for the failure to report.

25.8. Company CDE owns CDE Texas. CDE Texas has a site which is also its headquarters. This site is partly owned as a joint venture between CDE Texas and Company CDE and is partly owned solely by Company CDE. The joint venture part makes certain chemicals, and the solely owned part makes different chemicals. Company CDE has a D&B number for its headquarters at another location but not for the solely owned part of the Texas site. Does Company CDE need to get a site-specific D&B number for the part of the Texas site that it solely owns? Do the two entities need to do separate reporting for the site, one for the jointly owned part and one for the solely owned part?

In this description, Company CDE and CDE Texas are separate corporate entities. Therefore, the land on which these companies manufacture chemical substances is composed of two distinct sites, one owned solely by Company CDE and a second jointly owned by Company CDE and CDE Texas. Company CDE may use its corporate D&B number to report the chemical substances on the part of the site that it owns alone. Because CDE Texas is a distinct corporate entity, it seems appropriate that this entity should have a distinct D&B. For chemical substances manufactured by the joint venture on the jointly owned part of the site, it would seem appropriate to use the D&B number for CDE Texas, as the site is also its headquarters.

### **25.9.** On January 1, 2024, Company ABC will change its name to Company XYZ. What name should be used for CDR reporting, the new name, or the name of the company in 2023?

By the time of the CDR submission in 2024, Company XYZ is the current name of the business entity that conducted the manufacturing in 2023. Company XYZ should report its current name, not a prior name that it used when manufacturing in 2023.

#### **Section B. Site Information**

## **25.10.** A company's headquarters is responsible for ordering and importing several chemical substances that are sent to warehouses in two other states once they have cleared U.S. Customs. The company does not know which site to report on Form U.

The company should list the site that controls the import transaction, which may or may not be the site that receives the material. The site where a chemical substance is imported is the site of the operating unit within the organization that is directly responsible for importing the substance and controls the import transaction. In some cases, the import site may be the organization's headquarters in the United States. (See the definition of site in 40 CFR 711.3). If for a given substance that a company imports at a given site, more than one person meets the definition of importer at 40 CFR 704.3, only one person should report. See 40 CFR 711.22(b).

## **25.11.** Form U requests the Dun & Bradstreet D-U-N-S® number for the Site. If a site is comprised of two facilities, each with its own D&B number, should one or both numbers be used?

A company should use the D&B number that most closely relates to the manufacture of the chemical substance listed on Form U.

## **25.12.** If a company will be using the corporate D&B number for a site-specific CDR submission, should the corporate D&B number be placed in both the company Dun & Bradstreet block and the site Dun & Bradstreet block on Form U?

The D&B number of the corporation that owns the site should be reported as the site D&B number. If the corporation owning a site is controlled by another entity, the D&B number of that entity should be entered as the company D&B number. If the owner of the site where the chemical substance reported in the CDR submission is manufactured is not owned or controlled by another firm, the D&B number of the site owner may be reported as both the company and the site D&B number. Neither the block for the company nor the site D&B number should be left blank.

# **25.13.** A company that has a D&B number for its company headquarters is not in the practice of obtaining D&B numbers for its various facilities. The company does not want to engage in such a practice for commercial reasons (e.g., this would create listings and ratings the company would prefer to be published by D&B solely on the basis of its headquarters entries). Must the company obtain separate site D&B numbers to comply with CDR?

The CDR regulation requires that the submitter include the appropriate D&B number for each site reported. A corporation may use its corporate D&B number for all sites owned by that firm.

### **25.14.** Does the definition of site force different companies that are at the same site to report together?

No. The definition does not require different companies located at the same site to report together. However, if a single company operates multiple plants at a single site, those plants should report together for the site. See the definition of site at 40 CFR 711.3.

## **25.15.** A company transferred 30,000 pounds of a chemical substance from Site B to Site A within the company during the CDR principal reporting year. This chemical substance was initially imported by Site B. Does Site A report it as an imported chemical substance?

No. Site A was not the site directly responsible for the import of this chemical substance. The import of the chemical should be reported by Site B.

**25.16.** A company has portable tanks for slurrying lime at construction sites for customers. These sites include building construction sites and road and highway projects. The dry powder quick lime (CaO) is sent to the job site and mixed with water in the tank where it reacts to form a slurry of "hydrate" (calcium hydroxide, Ca(OH)2), along with water), so the calcium hydroxide is reportable under CDR. The company wants to report these sales in CDR as calcium hydroxide produced in the terminals from which the portable tanks are run. Sales of the slurry are claimed by the terminals and the terminal is responsible for the operation of the portable tanks, as well as the maintenance and movement of the tanks. Is this approach, to account for the sale of calcium hydroxide as if the portable tank were located at the terminal producing the slurry, appropriate for CDR reporting?

Yes. The definition of site states that "for portable manufacturing units sent out to different locations from a single distribution center, the distribution center shall be considered the site." See the definition of site at 40 CFR 711.3.

#### 25.17. How do I identify the appropriate NAICS code for a reporting site?

EPA requires submitters to report the 6-digit North American Industry Classification System (NAICS) code that best describes the activities conducted at the reporting site. The NAICS code is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. Information about NAICS codes can be obtained from the U.S. Census website at <u>www.census.gov/eos/www/naics/</u>.

In some circumstances it may be challenging to identify a single NAICS code for the site. In those circumstances, you may report up to three NAICS codes to more appropriately describe your site. Entering more than one NAICS code is expected to be an unusual situation. For example, headquarter sites that import for other sites may have difficulty identifying a single NAICS code.

### 26. Part II – Section A. Chemical Substance Identification

### **26.1.** How does a submitter determine the Chemical Abstracts Service Registry Number (CASRN) for a chemical substance and what if the submitter can't find it?

Submitters must use the <u>Agency's Substance Registry Services (SRS)</u> to report the chemical substance identification information consisting of the currently correct Chemical Abstracts (CA) Index Name and the correct corresponding Chemical Abstracts Service (CAS) Registry Number (CASRN). The SRS is EPA's central system for information about chemical substances that are tracked or regulated by EPA or other sources. It is the authoritative resource for basic information about chemicals, biological organisms, and other chemical substances of interest to EPA and its state and tribal partners. However, submitters of Inventory-listed substances should generally know already what CASRNs have been assigned to their substances.

Note that EPA itself does not assign CAS Registry Numbers (CASRNs). CASRNs are developed by the Chemical Abstracts Service (CAS). If you are uncertain as to the correct identification for your chemical substance, many people use the services of the CAS Inventory Expert Service to assist them in identifying their chemical substances for TSCA reporting, record-keeping, or compliance purposes, etc. You can ask for the Inventory Expert Service through the main switchboard number of CAS, 1-800-848-6538.

Submitters will be able to connect directly to the SRS database from the e-CDRweb reporting tool to report the correct CA Index Names and CASRNs for all non-confidential chemical substances on the TSCA Inventory. TSCA Accession Numbers and generic chemical names will be listed in the SRS for chemical substances on the confidential portion of the TSCA Inventory. The use of the SRS to obtain the identities for all CDR reportable chemical substances is a convenient way to meet the chemical nomenclature requirement and will help to prevent errors in the reporting of chemical identification information for the CDR.

Every non-confidential chemical substance reported in accordance with CDR must be accompanied by its correct CASRN, corresponding to the chemical substance's correct, specific chemical name. (40 CFR 711.15(b)(3)(i)). Submitters may enter either a CASRN or the specific name of the chemical substance to select the appropriate CASRN/Chemical Abstracts (CA) Index Name combination from the SRS database. To report a substance on the confidential Inventory, the TSCA Accession Number must be submitted as the chemical identifying number.

### **26.2.** If the substance is confidential, can the Accession Number or the PMN case number be used instead?

In the case of confidential chemical substances, EPA is requiring that submitters report only the TSCA Accession Number as a chemical identifying number. If the PMN case number of a confidential substance was used for reporting in the past, submitters can use the PMN case number to search the SRS to populate the pertinent chemical identification information for the confidential chemical substance listed on the TSCA Inventory.

The SRS contains a cross-reference list that displays the Accession Number, generic chemical name, and the PMN case number (or for an initial TSCA Inventory substance, the TSCA Inventory reporting form number) for any confidential chemical substance listed on the TSCA Inventory. Submitters can use the SRS to select the correct Accession Number corresponding to the confidential chemical substance intended to be reported (the generic name corresponding to the Accession Number will automatically be incorporated into the report).

EPA recognizes that there are certain circumstances where a submitter occasionally may not be sure of the particular PMN case number and Accession Number that EPA has assigned to one of its confidential chemical substances so that they do not have enough information to search the SRS. This could happen, for example, if the chemical substance were originally reported as part of a consolidated PMN and a submitter did not learn from EPA which particular case number in the consolidated PMN number sequence corresponds to which of the several reported confidential chemical substances. This could also happen if a certain PMN represented a mixture of two or more confidential chemical substances, such that multiple Accession Numbers were assigned to the different chemical substances reported in that single PMN, and a submitter didn't already request the particular Accession Numbers from EPA for the individual chemical substances comprising that multi-component type of PMN.

Submitters who are not able to identify the Accession Number by searching the SRS should read "*How do I find out if a substance is on the Inventory?*" Individuals are urged to submit a complete and accurate TSCA Inventory Correspondence at least one month before the submission deadline. Note that incomplete and/or inaccurate requests may be rejected. The Agency will respond to such inquiries in as timely a manner as possible. It is the responsibility of the submitter to contact the Agency for such information in sufficient time to allow for the Agency to respond.

#### 26.3. Does EPA provide a cross-reference list of PMN Numbers and Accession Numbers?

EPA's <u>Substance Registry Services (SRS)</u> contains a cross-reference list that displays the Accession Number, generic chemical substance name, and the PMN case number (or for an initial TSCA Inventory chemical substance, the TSCA Inventory reporting form number) for any confidential chemical substance listed on the TSCA Inventory. The e-CDRweb reporting tool allows you to search SRS using the PMN number in order to populate your CDR report with the pertinent chemical identification information for confidential chemical substances listed on the TSCA Inventory. In addition, you may obtain the accession number by contacting EPA's Hotline by phone at 202-554-1404 or by e-mail at <u>tsca-hotline@epa.gov</u>.

# **26.4.** A company is importing a mixture under a trade name, and the foreign manufacturer refuses to reveal the specific chemical identity of a confidential component of the mixture. How does the company report?

If an importer submitting a report cannot provide the information specified in 40 CFR 711.15(b)(3)(i) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must ask the supplier to use e-CDRweb to provide the complete, currently correct chemical identity information directly to the EPA in a joint submission. Contact information for the supplier, a trade name or other designation for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission for the chemical substance.

26.5. A company notices that there are CASRNs for several gas streams listed in the Partially Exempt Petroleum Process Streams listed in §711.6(b)(1) that appear to be molecularly similar to its fractionated products propane, butane and ethane. However, the CASRNs that the company previously used to report these products are not listed as partially exempt. The table below shows the CASRNs previously used in reporting by the company as compared to the CASRNS of molecularly similar partially exempt petroleum process streams.

CASRNs used by Company	CASRNs of Partially Exempt Streams
74-98-6, Propane, C <sub>3</sub> H <sub>8</sub>	68476-49-3 Hydrocarbons, C2-4, C-3
106-97-8, Butane, C <sub>4</sub> C <sub>10</sub>	68476-42-6 Hydrocarbons, C4-5
74-84-0, Ethane, C <sub>2</sub> H <sub>6</sub>	68606-25-7 Hydrocarbons, C2-4

The company wants to know whether these CASRNs would be considered synonyms and if they can use the CASRNs for the partially exempt process streams for their CDR submission.

The CASRNs listed above for the partially exempt petroleum process streams are for Class 2 substances, which are combinations of possible hydrocarbons with the chain lengths in the ranges indicated. Such Class 2 substances are not intended to encompass Class 1 substances, which can be more precisely described with a specific chemical structure and molecular formula. For example, the substance identified above as butane is not considered the same substance as "Hydrocarbons, C4-5," even though it falls within the C4 to C5 range, because butane is a more precise description of the substance as it was actually manufactured, and "Hydrocarbons, C4-5" is considered to be a combination of possible hydrocarbons (not limited to alkanes) in the C4 to C5 carbon number range. A company should use the CAS number that is the best fit for the chemical substance being manufactured or imported and is consistent with how the substance is accurately described in commerce and was reported by the company for TSCA Inventory purposes. In this case, the correct CAS number for butane is 106-97-8. This substance is not partially exempt from CDR.

EPA expects that use of SRS to identify chemical substances and their correct CASRNs will help improve the accuracy of identification. In the example above, a search of "butane" or "106-97-8" gives two results: one for 106-97-8 and another for 68476-85-7. The systematic name for CASRN 68476-85-7 is "petroleum gases, liquefied" which also is listed in the table at 40 CFR 711.6(b)(1) as partially exempt from CDR reporting. However, in the SRS section titled "Associated Identifiers", CASRN 106-97-8 is listed as an incorrectly used CAS number. None of the CASRNs that the company previously used list the partially exempt CASRNs as synonyms and vice versa.

#### 26.6. What purpose does the "chemical alias" serve?

The "chemical alias" serves different functions depending on the type of submission that you are completing. In section A of the primary report, the chemical alias is not a required data element. Rather, it is provided to enable you to use your own name for the chemical if desired, other than the name that is used to list the chemical on the TSCA Inventory. The chemical alias cannot be claimed as CBI, only the connection between the chemical identity (which does include the alias) and the company, site, or technical contact information.

When reporting as the contracting company for a co-manufactured chemical (section C-2 of the primary report), the chemical alias is provided to help your producing company know what substance is the topic of the report. This needs to be non-CBI because the information is transmitted via email and confidentiality cannot be assured.

### 27. Part II – Section B. Technical Contact Information

#### 27.1. What role does the technical contact play?

The technical contact is the person whom EPA may contact for clarification of the information in a CDR submission. The technical contact should be a person who can answer questions about the reported chemical substance(s). Typically, a person located at the manufacturing site is best able to answer such questions. However, companies may use their discretion in selecting a technical contact or multiple technical contacts, as provided by the e-CDRweb reporting tool. Submitters should consider, in selecting the technical contact, that EPA may have follow-up questions about a CDR submission one or more years after the submission date. The technical contact need not be the person who signs the certification statement. The technical contact can be selected from the drop-down list of registered support registrants.

# **27.2.** Are companies allowed to use their discretion in identifying the most appropriate technical contact to list on the Form U? Do technical contacts need to be physically located at the reporting site?

While companies are allowed to use their discretion in selecting a technical contact or multiple technical contacts, as permitted by the e-CDRweb reporting tool, EPA expects a technical contact to be someone who can answer detailed follow-up questions that EPA may have regarding the Form U. EPA has found that technical contacts not at the reporting site generally are less knowledgeable about the chemical substance or the types of information needed for the Form U and therefore may not be able to discuss follow-up questions. Also, it has been EPA's general experience that short-term contractors have not been suitable technical contacts because they may no longer be under contract with the submitting company a year or more after the Form U is submitted when EPA may want to contact them.

### **27.3.** Can two different plant sites within the same company that are both reporting under CDR have different technical contacts?

Yes. A different technical contact may be reported for each site. A Form U would be completed for each plant site, and each Form U would list the technical contact able to answer questions about the information in the report. In fact, a different technical contact may be provided for each chemical substance reported on the Form U.

#### 27.4. Can companies have more than one technical contact for a site?

Yes. The e-CDRweb reporting tool allows the identification of a different technical contact for each chemical substance.

#### 28. Part II – Section C. Manufacturing Information

#### 28.1. How precisely must the manufactured (including imported) volume be reported?

The production volume must be reported to at least two significant figures of accuracy. See 40 CFR 711.15(b)(3)(iv). EPA will accept more accurate reporting.

#### 28.2. How should the percent of production volume figures be rounded for purposes of CDR?

When rounding a number to the closest ten percent for CDR, round a number ending in 5 percent or greater up to the next higher 10 percent. For example, 5 percent is rounded up to 10 percent, 15 percent is rounded up to 20, and 25 percent is rounded up to 30 percent. Round a number ending in less than 5 percent down to the next lower 10 percent. For example, 14 percent is rounded down to 10 percent, 24 percent is rounded down to 20 percent, and so forth.

An exception to this rule applies where a particular combination of industrial processing or use operation, Industrial sector code, and function category accounts for 5 percent or less of the submitter's site's total production volume of a reportable chemical substance; in this case, the percentage must not be rounded off to zero percent if the production volume attributable to that industrial processing or use operation, industrial sector code and function category combination exceeds the applicable reporting threshold during the reporting year. Instead, in such an instance, submitters must report the percentage, rounded to the closest 1 percent of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, industrial sector code, and function category (40 CFR 711.15(b)(4)(i)(D)). A similar exception pertains to commercial and consumer use information (40 CFR 711.15(b)(4)(i)(D)).

### **28.3.** If a company manufactures a site-limited chemical substance that is on the TSCA Inventory, does the company need to report that substance under the CDR rule?

Yes, possibly. There are no exemptions for site-limited chemicals.

In some cases, a chemical that is site-limited may also be a non-isolated intermediate and be exempt from CDR reporting. For information on non-isolated intermediates, see the <u>TSCA</u> <u>Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates.</u>

Additionally, a byproduct chemical that is recycled in a site-limited enclosed system may be exempt from CDR reporting. For information on this byproduct-specific exemption, see the *Instructions for Reporting*.

#### 28.4. Can imported chemical substances be reported as used on-site?

Yes. The data element Production Volume Used On-Site represents the volume of the chemical substance that does not leave the manufacturing site. If the imported chemical substance is used to manufacture another chemical substance on-site, report that volume as used on site. If the imported chemical substance is used to form a mixture without a chemical reaction, and that

mixture is used on-site, report the volume as used on-site. If the imported chemical substance is used to form a mixture without a chemical reaction, and that mixture is then sent off-site, do not report the volume as used on site.

### **28.5.** If both domestically manufactured and imported chemical substances are used at a reporting site, how is that reported?

Report the total volume of each domestically manufactured and imported chemical substance used at the reporting site, in pounds. The number represents the volume of the chemical substance that does not leave the manufacturing site and should not exceed the sum of the domestically manufactured and imported volumes minus any volume exported.

# **28.6.** A company produces over 25,000 pounds of a reportable chemical substance. Most of this production is for on-site use but a small amount is sent to another site. How should this be reported?

Report the full amount manufactured as the production volume, and report only the amount used on-site in the designated field in Part II – Section C. (Manufacturing Information) of the CDR Form U for this chemical substance.

### **28.7.** A company imports 30,000 pounds of a chemical substance and sends the entire volume directly to various warehouses owned by its customers. How is this reported on Form U?

Report 30,000 pounds for volume imported and indicate that the imported chemical substance is never physically at the reporting site.

#### 28.8. How is volume "used on-site" calculated if the substance is stored after its manufacture?

The volume "used on-site" represents the volume of the chemical substance domestically manufactured or imported that does not leave the manufacturing site. If after manufacture (including import), you use a portion or the entirety of the chemical substance on-site (e.g., to produce other chemical substances), then that portion is considered to be "used on-site." If you have been accumulating your chemical substance and storing it on-site, only report as "used on site" the volume that is from the amount that you've actually manufactured that year. In other words, only account for the volume used on-site that came from the volume manufactured in the principal reporting year (e.g., 2023 for the 2024 submission period).

# **28.9.** I manufacture a product for sale within the United States as well as for export. Does the Production Volume Exported apply to exports out of the United States or does it apply to the production volume that is not used on site?

For Production Volume Exported, report the production volume of the chemical substance directly exported outside of the United States, and not domestically processed or used.

Note that direct exporting includes sending a chemical substance to a distributor who then exports to the foreign customer without repackaging it, even if it is relabeled. However, direct exporting does not include sending a chemical substance to a distributor who repackages and relabels it. The latter case would be considered a processing and use activity potentially reportable under Part II – Section D of Form U.

#### **Physical Form**

#### 28.10. How is the physical form of slurry or a solid/liquid suspension identified?

For purposes of CDR, slurries, colloidal suspensions, and other solids-liquid mixtures should be reported as a "water- or solvent-wet solid."

#### 28.11. What is the difference between water- or solvent-wet solid and liquid?

For purposes of CDR, water- or solvent-wet solids include mixtures of liquids and solids, such as slurries and colloidal suspensions. Liquids include liquid-liquid mixtures and liquid solutions containing dissolved solids.

# **28.12.** We need help determining the physical form for a chemical that is a mixture of a solid and water. For example, we react anhydrous ammonia with phosphoric acid to produce a melt product. Then water is added to produce an aqueous solution. The solution is: 55.5% polyphosphoric acids, ammonium salts (CAS 68333-79-9) and 45.5% water.

Report all physical forms of a chemical substance at the time it is reacted or as it leaves the site. For each chemical substance, the submitter must report as many physical forms as applicable from the following six physical forms: dry powder; pellets or large crystals; water or solvent-wet solid; other solid; gas or vapor; or liquid. See the 2024 Instructions for Reporting for more guidance. Water is a fully exempted substance and does not need to be reported under CDR.

For the specific example, based on the information provided, you manufacture the chemical substance CAS 68333-79-9 (polyphosphoric acids, ammonium salts) that is then mixed with water to produce a solution. CAS 68333-79-9 is likely produced as a dry powder. When mixed with water, it likely becomes a waterwet solid.

Reporting the physical form under CDR depends on the physical form of the substance that is sent off-site. If the chemical substance is sent off-site in more than one physical form, report all the physical forms in which it is sent off. For instance:

If CAS 68333-79-9 is only sent off-site in the aqueous solution form, then you would report that the physical form water-wet solid is 100% of the total production volume:

• Water-wet solid – 100%

If CAS 68333-79-9 is sent off-site in both dry powder form and aqueous solution form (or other physical forms), then round the percentage of the total production volume for each physical form to the closest 10 percent. As an example, if the company produces 100,000 lb of CAS 68333-79-9, 60,000 lb is mixed with water to produce the aqueous solution and the other 40,000 lb is sent offsite in dry powder form, the company should report:

- Dry powder 40%
- Water-wet solid 60%

#### 28.13. Does EPA differentiate between pellets and granules when reporting the physical form?

No. For purposes of CDR, pellets and granules should be reported as "pellets or large crystals."

## **28.14.** What physical form does a submitter use for a chemical substance when the chemical substance is manufactured at elevated temperatures as a liquid but then a portion is cooled and pelletized? The chemical substance may leave the site in either form.

Report the physical form of the chemical substance when it leaves the site. In this case, the submitter should report both "liquid" and "pellets or large crystals" because the chemical substance may leave the site in either form.

#### 28.15. How does one identify physical form for a compressed gas, as a liquid or a gas/vapor?

Submitters are asked to report the physical form(s) of the reportable chemical substance as it is sent off- site from each site. When reporting for a chemical substance which is a compressed gas, the best response would be to report both the liquid and the gas or vapor as physical forms. The percentages, rounded to the closest 10 percent, of the production volume, by weight, reported for each physical form would most likely be 100 percent for the liquid and 0 percent for the gas or vapor.

# 28.16. A company buys hydrochloric acid 37 percent solution, CAS Registry Number 7647-01-1, in a diluted liquid form instead of a gaseous form. It is then diluted further to approximately 31.4 percent, re-packaged in 1-gallon bottles for sale to the swimming pool industry for pH control of swimming pools. The company believed that only the gaseous form of hydrochloric acid was covered. Is this dissolving, dilution, and re-packaging covered under the CDR regulations?

Manufacturers, including importers, of subject chemical substances are required to report under the CDR regardless of the physical form or state of the chemical substance. However, it does not sound as though this company is manufacturing a chemical substance — unless the company is importing the 37 percent solution of hydrochloric acid. If 25,000 pounds or more of hydrochloric acid is imported, based on the "dry" weight of gaseous hydrochloric acid actually dissolved in the solution, and if all is in solution, then it is reportable and also it is likely that the company should be reporting 100 percent.

#### **Other: Maximum Concentration, Recycling**

## **28.17.** A company manufactures a chemical substance that is sent off-site in products containing from 3 percent to 33 percent by weight of the chemical substance. What code should be used to report the maximum concentration?

The maximum concentration leaving the site is 33 percent. Therefore, report code M3, which represents a concentration of 31 to 60 percent by weight.

## **28.18.** How does a company report the maximum concentration if a chemical substance never leaves the site where it is produced?

For site-limited chemical substances, report the maximum concentration at the time the chemical substance is reacted on-site to produce a different chemical substance.

**28.19.** A company produces a chemical substance at 98 percent concentration and then reacts the chemical substance to form other chemical products. When the products are packaged and distributed to customers, small amounts of the original chemical substance may be

## unintentionally present in these products. How should the maximum concentration be reported in Form U?

Based on the facts given (the first chemical substance is only "unintentionally present" in the product sent off-site) it is appropriate to treat the first chemical substance as site-limited—it only leaves the site as an impurity in the other products. Thus, the maximum concentration is the concentration at the time that it was reacted on-site to produce the other products: 98 percent. 40 CFR 711.15(b)(3)(viii). Therefore, report M5 for the maximum concentration code, corresponding to 98 percent.

## **28.20.** If samples are sent off-site for analysis, should these samples be included when reporting the maximum concentration of the chemical substance leaving the site?

Analytical samples for purposes of certification and quality control are presumed not to be distributed for a separate commercial purpose and do not impact the reporting status of a chemical substance. Therefore, analytical samples do not need to be considered when reporting the maximum concentration. Note, however, that if the chemical substance was sent off-site for research and development purposes, the maximum concentration of the chemical substance leaving the site for these purposes would be reported.

# **28.21.** A company manufactures a chemical substance at 100 percent concentration. It is then blended with other chemical substances, resulting in a final product at 60 percent concentration. This product is drummed and distributed to customers. How should the maximum concentration be reported?

The maximum concentration of the chemical substance as it leaves the site would be reported. For this example, the code is M3 which corresponds to the 60 percent concentration leaving the manufacturing site.

#### **Past Production Volume**

## **28.22.** Is there a requirement to report production volumes for years other than the principal reporting year?

Yes. If a chemical substance was manufactured (including imported) for commercial purposes in volumes of 25,000 pounds or more (2,500 pounds for a chemical subject to certain TSCA actions) at any single site during <u>any</u> calendar year since the last principal reporting year, report the total volume of the chemical substance domestically manufactured and imported at a site during each calendar year since the last CDR principal reporting year. For example, during the 2024 CDR submission period, report production volumes for 2020, 2021, 2022, and 2023. More detailed manufacturing, processing, and use information is required for the principal reporting year only (2023, for the 2024 CDR submission period). This more detailed information for the principal reporting year is required if <u>any</u> calendar year triggers reporting.

#### 29. Part II – Section D – Industrial Processing and Use Data

#### 29.1. Who must report on processing and use information?

Processing and use information is required for manufacturers with production volumes of 25,000 lb or more, at a site, unless subject to a reduced threshold of 2,500 lb more at a site, unless

otherwise exempted. For a more detailed discussion of processing and use reporting exemptions, please see question 21.2: "Which chemical substances are subject to full reporting?"

#### 29.2. What sorts of processing and use information am I required to report?

For industrial processing and use information, reporters are required to provide unique combinations of the industrial function category, industrial sector, and functional use. If more than 10 unique combinations apply to a chemical substance, submitters need only report the 10 unique combinations for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical substance, measured by weight. For each unique combination, the reporter provides: the associated percent production volume, number of workers and number of sites.

For commercial and consumer use data, the reporter are required to provide unique product categories (as with the industrial processing and use information, submitters can stop at 10 unique product categories). For each unique product category, the reporter indicates whether the use is consumer, commercial or both, the functional use and use in products intended for children and the associated percent production volume, maximum concentration, and number of commercial workers.

#### **29.3.** How does EPA interpret the processing and use data?

EPA views the CDR processing and use data as potential exposure scenarios that may be used to inform actions on specific conditions of use during chemical prioritization, risk evaluation, risk management, or other activities under TSCA. For industrial processing and use data, EPA considers a combination of the first three elements - the industrial type, sector and function - to be a unique exposure scenario. The same is true for a combination of the first four consumer/ commercial use elements; a combination of product category, consumer or commercial use, fundtional use, and use in products intended for children amounts to a unique exposure scenario.

## **29.4.** A company manufactures chemical substances but often does not know how these chemical substances are used by downstream customers. Does EPA intend for submitters to send questions to customers requesting information about downstream uses?

It depends on what is meant by sending "questions to customers." Submitters need not send out a comprehensive set of identical questions to multiple customers in order to fulfill the CDR's reporting standard. That is, they need not conduct a new survey of their customers. However, fulfilling the reporting standard may entail inquiries outside the organization (e.g., contacting a major customer or examining that customer's public website) to fill in gaps in the submitter's knowledge, where the submitter's current knowledge is less than what a "reasonable person similarly situated might be expected to possess, control, or know." See 40 CFR 704.3.

# **29.5.** All of a company's products are used to make commercial products through various process steps by different manufacturers. For Part II – Section D, should the company provide information about consumer and children's uses even if its chemical substance is not the end use product?

Yes. If the chemical substance is used in a consumer product, the company would still report the information, even if the company does not manufacture the end use item. The information provided in Part II – Section D is associated with the processing and use of chemical substances and typically relates to processing or use that is outside of the manufacturing or importing site,

unless, of course, the manufacturer or importer also processes or uses the chemical substance. The codes that a company selects for Part II – Section D generally relate to what subsequent users and processors are doing with the product.

To the extent the information is known to or reasonably ascertainable by the manufacturer or importer of the subject chemical substance, information on subsequent industrial uses and processing would be reported on Part II, Section D.1, and commercial and consumer uses of the chemical substance would be reported on Part II, Section D.2 of CDR Form U. A company which is a manufacturer or importer should report information about the distribution, processing, and use of the chemical substance known to or reasonably ascertainable by the company. To the extent the information is not known or reasonably ascertainable, the company may report NKRA (i.e., "not known or reasonably ascertainable").

## **29.6.** How should industrial, commercial, and consumer uses of fungible commodities be reported when they are distributed via a delivery mechanism shared with other manufacturers?

Manufacturers of such fungible commodities should report based on intended distribution for use or processing. For example, if a submitter produces 100,000 tons of ammonia that is transported via a pipeline in common with ammonia produced by other manufacturers to various distribution points along the pipeline, that submitter should, for CDR purposes, consider their site's 100,000 tons to have only been extracted from the pipeline by its customer. Thus, this individual submitter does not have to account for all potential downstream processing and use scenarios for all persons drawing ammonia from the common pipeline. Instead, this submitter should provide processing and use information based on the premise that the 100,000 tons of ammonia that it injected into the pipeline is the same 100,000 tons of ammonia withdrawn from the pipeline by its intended customer.

**29.7.** Company A manufactures greater than 25,000 pounds of an additive for polymer resins and sells it to Formulator F. Formulator F formulates a can coating and sells its product, which contains the additive, to Can Coater C. Can Coater C applies the coating to steel and aluminum cans. The additive is completely reacted when the coating is cured. Can Coater C sells the cans to Paint Formulator P, who fills the coated cans with paint and sells its formulated paint product to the public (consumers). Which company is responsible for reporting for the additive for polymer resins?

As the manufacturer of the additive, Company A is responsible for meeting all reporting obligations for this chemical substance. Company A would report information on Part II – Section D of Form U reflecting the formulation activities of Formulator F and the coating activities of Can Coater C. Reporting downstream uses for the additive ceases when the coating is cured (i.e., the additive is reacted to form another chemical substance).

Note that a different chemical substance is created when the additive is cured, but this newly created chemical substance (cured can coating) is exempt from CDR (40 CFR 711.10(c) which references 40 CFR 720.30(h)(6)).

**29.8.** A company manufactures more than 25,000 pounds of an organic chemical substance, which is used as an intermediate to manufacture other chemical substances. A small amount of the organic chemical substance may be unintentionally present in the reaction product, but it does not have a separate commercial purpose. The reaction product is sold

### for commercial and/or consumer use. How should Part II – Section D of Form U be completed for the original chemical substance?

The company would complete Part II, Section D.1 of Form U to reflect the use of the originally manufactured organic chemical substance as a chemical intermediate. The reporting of further downstream uses for the intermediate ceases when it is fully reacted to form a different chemical substance. Because the remaining organic chemical substance is unintentional, it is likely to meet the definition of an impurity in the other chemical substances. Impurities, as defined in 40 CFR 704.3, are exempt from CDR (see 40 CFR 711.10(c)).

# **29.9.** A company manufactures Chemical P and distributes it to several customers who consume Chemical P in the production of Chemicals Q and R. Chemicals Q and R are then used in the metal plating industry. Under the CDR regulation, if the company must report Chemical P, must the company also report the uses for Chemicals Q and R on Part II – Section D of Form U?

The company is only required to report the uses for Chemical P. Once Chemical P is converted into other chemical substances, in this case Chemicals Q and R, it no longer exists, so there are no further reportable uses of Chemical P.

Note that customers who use Chemical P to produce Chemicals Q and R may be subject to CDR for their manufacture of Chemicals Q and R and may be required to report the use of their chemical substance in the metal plating industry.

#### 29.10. How is the use of an organic fertilizer reported in Part II – Section D of CDR Form U?

The industrial, commercial, and /or consumer uses of organic fertilizers should be reported up to the point at which they are applied as fertilizers. Therefore, the final use that a fertilizer manufacturer would need to report would be the application of the fertilizer. See 40 CFR 711.15(b)(4) for reporting processing and use information.

# **29.11.** Company A manufactures a chemical substance that is used as a component in a larger mixture which is then further processed, bottled and sold to consumers. Should Company A report on uses by its customers in addition to reporting on Company A's facility that further processes the mixture to complete the end product before it's sold to consumers?

Yes. For the Part II – Section D information, each line of data represents an exposure scenario, and a new line should be used for each different exposure scenario. For the processing of the substance, Company A would report in Section D.1. of Part II on the uses associated with the industrial processing that is conducted by its facility. Because the chemical substance is further processed and sold, Company A should also complete the commercial and consumer use information in Section D.2. of Part II to the extent that it is known or reasonably ascertainable.

## **29.12.** Company D's chemical substances are used in oilfields. Company D is not sure whether use of its chemical substances by oilfield service companies would make it commercial or consumer use, and thus subject to Part II – Section D.2 reporting.

Company D should report the processing and use information to the extent that it is known to or reasonably ascertainable by Company D, such as by using its own knowledge of the function of its chemical when used in oilfields, which may indicate whether the chemical will be used in downstream applications, such as for consumer or commercial uses. In addition, the type of

company that constitutes Company D's customers could serve as an indication of where and how the chemical is used. For example, if the function of the chemical is such that it would reasonably be expected to be used at an oilfield production facility to maintain equipment, then it is used at an industrial setting. For another example, if the customer is by an oilfield service company means that the product will be used in an oilfield or a related production facility; such a use, would constitute an industrial use operation. Both of these examples would be reported in Section D.1. of Part II. However, if the substance is used by a company to fill home fuel tanks, for instance, it would be considered a consumer or commercial use and would be reported in Section D.2. of Part II. If Company D is not sure of the consumer or commercial use, then it should report "NKRA" for not known or reasonably ascertainable in Section D.2.

## **29.13.** How will the revised lists of codes for Type of Processing and Use (TPU), Industrial Sectors (IS), and Function Categories (FCs) be used?

Each combination of the three codes describes a potential industrial exposure scenario for EPA to consider during prioritization, risk evaluation, and other risk management activities.

## **29.14.** Is there a crosswalk between the North American Industrial Classification System (NAICS) codes used in 2006 and the current Industrial Sector (IS) codes?

Yes. This information can be located on the <u>*Replacement of 5-digit NAICS Codes with Industrial</u></u> <u>Sector Codes</u> page of the CDR website. Submitters who do not know a specific NAICS code may be able to identify a more general category.</u>* 

## **29.15.** Which Industrial Sector (IS) codes should be reported for processing and use of chemical substances which a company also manufactures?

For Part II – Section D of Form U, A company should report the IS code(s) that correspond to the processing and use activities for its chemical substance. The company reports its manufacturing information in Part II – Sections C of Form U. The IS codes are included in the e-CDRweb reporting tool.

## **29.16.** How does a company determine the top 10 combinations of TPU, IS, and FC codes if the company does not know the amount of chemical substances dedicated to each use? Should the company report "other" when it does not know the uses?

Use known or reasonably ascertainable information to select the 10 combinations of codes for the three data elements, TPU, IS and FC, for the chemical substance that cumulatively represent the largest percentage of production volume, measured by weight. If the company knows of some uses but does not know the amount of chemical substance for each use, the company should list the uses that it knows and identify any remaining information that is not known or reasonably ascertainable as "NKRA." Codes for "Other" should only be used when it is known that the listed codes do not apply, and the required written description of the "other" use can be provided. Provide any volume information according to this standard as well.

## **29.17.** How is Part II – Section D of Form U completed for Chemical A when it is used as an intermediate to manufacture Chemical B? The site manufactured Chemical A, which is stored until needed to manufacture Chemical B.

When Chemical A is used as a chemical intermediate to manufacture Chemical B, in the Industrial processing and use section report "processing as a reactant" for the Type of Processing or Use (TPU). Also report the associated Industrial Sector (IS) and Function Category (FC) (indicating the function of Chemical A). For that combination of TPU, IS, and FC, report the Percent Production Volume, Number of Sites, and Number of Workers. Because Chemical A is consumed and further processing and use information for Chemical A will not exist, there is no further downstream processing and use information to be reported for that particular type of processing or use operation under 40 CFR 711.15(b)(4). For Part II – Section D.2. (Consumer and Commercial Use), when Chemical A is used as an intermediate in an industrial setting, then there is no consumer/commercial use and the "N/A" box should be checked. If Chemical A is also used for other industrial applications, then evaluate the reporting requirements for that alternate scenario.

Note that there are some intermediates that are non-isolated. To determine if your intermediate is non-isolated, see the <u>CDR Fact Sheet: Non-Isolated Intermediates</u>.

The manufacturer should also evaluate the need to report Chemical B, which would be reported on the same Form U site report but in its own chemical-specific report.

# **29.18.** A company knows the volume of a chemical substance that it supplies to a customer and the TPU and NAICS codes as well as two FC codes but doesn't know what percentages of the volumes go to the customer's various FC codes or how many FC codes apply. Should the company report the TPU and NAICS codes and leave the FC code blank or put in "U999" for "Other"?

The company should fill out the portion of the Part II – Section D information that it knows (that is, the TPU, IS, and FC codes) and any other information that is known or reasonably ascertainable. The company can select the appropriate IS codes by using the document which identifies the correspondence between the NAICS codes and the IS codes. If any information is not known or reasonably ascertainable, the company can enter or select "NKRA" for "not known or reasonably ascertainable" in the box corresponding to that data element. The "U999 — Other" code should not be selected unless the company can provide a written description.

# **29.19.** My company would like to use code U999 in the function category. However, we are unsure what to put in the written description of the function of the chemical substance? If there is no specific function code, how would you advise that we come up with the written description for U999?

In cases where there is not a code that applies and the reporter is required to use U999 or F999 – Other (specify), you should "provide a description at a comparable level of specificity as found with the current codes." Note also that the reporting standard under CDR is to report to the extent the information is known to or reasonably ascertainable by the submitter. See the Section 4.2 of the Instructions for a discussion of this reporting standard. The submitter should follow the suggestions in the Instructions for ideas of how to provide information that they do not definitely know. However, if it is information that is not known or reasonably ascertainable, complete "NKRA" in the fields that you cannot provide.

## **29.20.** Both the Industrial Sector Code and Function Code allow a submitter to report "other" in place of one of the listed codes. When should "other" be used, and how much information should be provided?

Codes for "Other" should rarely be used and should only be used when it is known that the listed codes do not apply. When "other' is used, include a written description that provides a description

of the use at a comparable level of specificity as found with the current codes. Do not chose "other" or use the written description to provide additional, more specific detail than is provided by simply choosing the existing codes.

## **29.21.** How does harmonizing CDR function and product codes with OECD-based codes impact reporting codes for industrial function categories?

The 2020 CDR Revisions rule updated industrial function codes based on OECD functional use categories. Under this rule, the previous 35 function codes were replaced by 117 updated, OECD-based function codes, which are fully implemented in the 2024 reporting cycle. The OECD-based codes for function categories are listed in Table 8 in 40 CFR 711.15.

Reporting using the new OECD-based codes will be phased in during the 2020 and 2024 CDR submission periods. Manufacturers (including importers) of the chemicals listed in Table 7 at 40 CFR 711.15 are required to use the updated codes in 2020 CDR submissions. All manufacturers (including importers) are required to use the updated codes in 2024 submissions and beyond.

Additional details about the function categories and how they are related to the OECD functional use categories can be found in the <u>Technical Support Document: Harmonizing CDR Functional</u> and <u>Product codes with OECD Functional</u>, <u>Product, and Article Codes</u> located in the CDR Revisions rulemaking docket at <u>www.regulations.gov</u>, docket number EPA-HQ-OPPT-2018-0321. A crosswalk table can be found in the <u>Instructions for Reporting</u>.

# **29.22.** As a manufacturer, I directly sell to both industrial and consumer customers. How do I report the % production volume in sections D1 (industrial processing & use information) and D2 (consumer/commercial information). Must the end commercial/consumer direct sales be included in the volume used to calculate the % production volume for section D1?

The volume basis to determine the percent production volume (%PV) is the total volume reported as manufactured (including imported) for the principal reporting year. For example, if your total volume manufactured is 100,000 lb and 60,000 lb is sold direct to an industrial use and 40,000 lb is sold direct to a consumer/commercial use, then report:

- Industrial processing and use % PV = 60%
- Consumer/commercial use %PV = 40%.

As a second example, in the event that your situation is different such that 80,000 lb goes to an industrial use and, of that 50,000 is sent on to a consumer/commercial use and you sell the remaining 20,000 lb directly to a consumer/commercial use, then report:

- Industrial processing and use %PV = 80% (80,000 lb of the 100,000 lb manufactured volume)
- Consumer/commercial use %PV = 70%. (50,000 lb from the processing site plus 20,000 lb directly from the manufacturing site)

As demonstrated by the second example, the %PVs may not add up to 100% and can be either under or over 100%.

## **29.23.** If the direct commercial/consumer sales are less than 0.5% of production volume but more than 25,000 pounds, do we report 0%?

Reporters may submit 0 for the percentage of production volume to indicate when a percentage is less than 0.5%.

#### 30. Part II - Section D - Consumer and Commercial Use Data

## **30.1.** The Consumer and Commercial Category code allows a submitter to report "other" in place of one of the listed codes. When should "other" be used, and how much information should be provided?

Codes for "Other" should rarely be used and only when you know that the listed codes do not apply. When "other" is used, include a description at a comparable level of specificity as found with the current codes. Do not chose "other" or use the written description to provide additional, more specific detail than is provided by simply choosing the existing codes.

## **30.2.** Why do submitters have to designate whether the indicated product category is consumer use, commercial use, or both, when submitters may not always know who ultimately uses their products?

The intent of the consumer and commercial use data element is to identify the exposed populations. These two populations (i.e., consumers and commercial workers) are very different from each other, and the ability to distinguish uses between the two enables better exposure-based screening of chemical substances. Submitters may not always have detailed information about how the chemical substance(s) they make are used and to what extent they are used. However, EPA believes that industry possesses a greater knowledge than EPA about its own operations and the downstream uses of chemical substances it manufactures and sells, even if they do not control their customers' sites.

## **30.3.** How do submitters report CDR information for chemical substances they manufacture and sell directly to consumers?

If submitters manufacture (including import) 25,000 pounds or more (2,500 pounds for a *chemical subject to certain TSCA actions*) of a chemical substance and sell it for direct consumer use, mark the "Not Applicable" box under Part II – Section D.1 of Form U to denote that there is no industrial processing of the chemical substance. Complete Part II – Section D.2 to reflect the manner in which consumers use the chemical substance.

#### **30.4.** How is "intended for use by children" defined for purposes of CDR?

For purposes of reporting in accordance with the CDR regulation, under 40 CDR 711.3, "intended for use by children" means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least one of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:

- 1. Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?;
- 2. Does the manufacturer of the product state through product labeling or other written materials that the product is intended or will be used by children age 14 or younger?; or
- 3. Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

Certain products, such as household cleaning products, automotive supplies, and lubricants, typically are not intended to be used by children age 14 or younger. As such, if a submitter determines that the chemical substance or mixture is used only in automotive care products and lubricants, for example, he would typically report "No" for children's use for Product Categories C401 and C402.

## **30.5.** How does harmonizing CDR function and product codes with OECD-based codes impact reporting codes for consumer/commercial product categories?

The 2020 CDR Revisions rule updated consumer/commercial product codes based on OECD product categories. Under this rule, the previous 33 consumer/commercial product categories are being replaced by 96 updated, OECD-based product codes. The updated codes will be fully implemented by the next reporting cycle in 2024. The updated codes for reporting consumer and commercial product categories are listed in Table 11 and the function codes are in Table 8 in 40 CFR 711.15.

Reporting using the new OECD-based codes will be phased in during the 2020 and 2024 CDR submission periods. Manufacturers (including importers) of the chemicals listed in Table 7 at 40 CFR 711.15 are required to use the updated codes in 2020 CDR submissions. All manufacturers (including importers) are required to use the updated codes in 2024 submissions and beyond.

Additional details about the function and product categories and how they are related to the OECD categories can be found in the <u>Technical Support Document: Harmonizing CDR</u> <u>Functional and Product codes with OECD Functional, Product, and Article Codes</u> located in the CDR Revisions rulemaking docket at <u>www.regulations.gov</u>, docket number EPA-HQ-OPPT-2018-0321. Crosswalk tables can be found in the Instructions for Reporting on the CDR website at <u>www.epa.gov/cdr</u>.

## **30.6.** What is the distinction between consumer, commercial, and industrial chemical use categories?

"Consumer use" encompasses the use of a chemical or mixture containing a chemical that is sold to or made available to consumers for their use (including as part of a manufactured product or article, e.g. laundry and dishwashing products, furniture, clothing). See 40 CFR 711.3.

"Commercial use" is the use of a chemical or mixture containing a chemical in a commercial enterprise providing a saleable good or service (e.g. dry cleaning, carpet cleaning, or oil change services). See 40 CFR 711.3

"Industrial use" is the use at a site in which one or more chemicals or mixtures are manufactured (including imported) or processed. See 40 CFR 711.3.

In short, a company that is processing or otherwise using the chemical at a manufacturing site would report the processing or use under the industrial processing and use section of the CDR report. Additionally, these uses are not necessarily mutually exclusive – a use may be industrial, consumer, and commercial (e.g., a lubricating oil could be used in all three categories).

## **30.7.** If Company A's chemical substance is being sold to a Manufacturer B who then uses the chemical to manufacture an article, ultimately selling the article to consumer/commercial users, does Company A need to report the consumer/commercial use for the chemical?

In general, a company that manufactures (including imports) a chemical substance and is completing a CDR submission is responsible for reporting all uses of the chemical, regardless of whether they directly sell to the user, to the extent such information is known to or reasonably ascertainable to the company completing the submission. In some situations, the chemical substance is processed as part of a reaction to form another substance, a mixture, or an article. When the chemical is fully reacted, it would no longer exist in the ultimate product. In such situations, the chemical manufacturer would not need to report the uses after the chemical is fully reacted.

## **31.** Part II – Estimating Number of Workers Reasonably Likely to be Exposed to a Chemical Substance

#### 31.1. What does "reasonably likely to be exposed" to a chemical substance mean?

EPA defines "reasonably likely to be exposed" as exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use, is more likely to occur than not occur. Such exposures would normally include but are not limited to activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures. See 40 CFR. 711.3.

# **31.2.** Does EPA provide information on how the frequency and duration of exposure should be considered when estimating the number of workers reasonably likely to be exposed to a chemical substance? Is there a minimum duration of exposure that does not need to be reported (e.g., one minute)?

Under the CDR rule, there is no minimum duration or frequency of exposure for determining the number of workers reasonably likely to be exposed to a chemical substance. If it is determined that a worker is reasonably likely to be exposed at any time during the year for any length of time, this worker should be included in the estimate.

## **31.3.** Should contractors and temporary employees be included in the number of workers likely to be exposed?

Yes, include temporary, seasonal, or contract workers in the number of workers estimate if they are reasonably likely to be exposed.

## **31.4.** Should the number of workers reasonably likely to be exposed to a chemical substance be reported as full-time equivalents or the actual number of workers?

Do not report full-time equivalents. EPA requires that the total number of individuals reasonably likely to be exposed to each reportable chemical substance be reported (40 CFR 711.15(b)(3)(vii) and 40 CFR 711.15(b)(4)(i)(F)). When a site employs temporary, seasonal, or contract workers in the manufacture of a reportable chemical substance, those workers should be included in the number of workers reasonably likely to be exposed if they work in areas where the chemical substance is manufactured. Those employees whose jobs are not associated with potential exposures to a chemical substance or mixture (e.g., administrative staff who never enter areas where the chemical substance is manufactured and persons working elsewhere on site who are not reasonably anticipated to be exposed to the chemical substance for even a brief period of time) should not be included in the reported number of workers reasonably likely to be exposed to a chemical substance. The same considerations would be applied if you are estimating the number of workers related to the processing or use of the chemical substance.

#### 31.5. Should administrative staff be included in the estimate for number of workers?

There may be instances in which administrative staff working at the site are reasonably likely to be exposed to the chemical substance and thus should be included in the number of workers reported. However, if the administrative workers do not enter areas where the chemical substances are manufactured (or in the processing and use) and are not reasonably likely to be exposed to a chemical substance for even a brief period of time, they should not be counted among the number of workers.

#### **31.6.** A company knows that a chemical substance that it manufactures and processes is present in the air in non-manufacturing areas of the plant site at measurable concentrations. How should the company estimate the number of workers reasonably likely to be exposed to the chemical substance? Are all workers employed at the site reasonably likely to be exposed?

The CDR regulation requires the reporting of the number of workers reasonably likely to be exposed to a reportable chemical substance (40 CFR 711.15(b) (3)(vi) and 40 CFR 711.15(b)(4)(i)(F)). There is no minimum level of exposure to a chemical substance for CDR below which a worker need not be counted among the number reasonably likely to be exposed to a chemical substance. Therefore, if a company knows that a chemical substance manufactured at the site is present in the air throughout the site, all workers at the site must be included in the number of workers reasonably likely to be exposed to the chemical substance.

## **31.7.** Why are engineering controls and personal protective equipment (PPE) not considered when estimating the number of workers reasonably likely to be exposed?

Engineering controls and personal protective equipment (PPE) may reduce but do not preclude exposure to a chemical substance. Examples of engineering controls include ventilation systems, nitrogen blankets, and dust collectors. Examples of PPE include chemical gloves, respirators, goggles, and protective clothing. Based on EPA's experience, the definition and use of engineering controls and PPE varies from site to site. In addition, the effectiveness of engineering controls and PPE is limited by possible equipment malfunction and improper use. When reporting the number of workers reasonably likely to be exposed to a chemical substance, no allowance should be made for the possible protection provided by engineering controls and PPE.

## **31.8.** Should workers that may be exposed to a chemical substance during accidental releases be included in the estimate of number of workers reasonably likely to be exposed?

No. Workers that may be exposed during accidental releases should not be included in the number of workers reasonably likely to be exposed to a chemical substance. Only workers reasonably likely to be exposed to a chemical substance during normal manufacturing, processing, and use of a chemical substance, as well as ancillary activities such as equipment cleaning and maintenance, must be included for CDR.

#### **31.9.** Is the number of workers estimated for the facility or the customers?

It depends on which section of Form U is being completed. Form U requires separate estimates for three different types of workers. For Part II – Section C information, a company only reports the number of workers associated with the site of manufacture and/or import identified in Part I. Part II – Section C covers activities at the site of manufacture or import and so the number of workers reasonably expected to be exposed at that site would be reported.

For Part II – Section D information, a company reports the number of workers associated with industrial processing and use as well as commercial use, whether it is the reporting company's site or someone else's. Part II – Section D covers not only processing and use activities that may occur at the site of manufacture and import, but also those activities that occur downstream at customers' sites after the product leaves the site of manufacture or import. Therefore, the number of workers that are reasonably likely to be exposed to the chemical substance would be reported for each combination of type of process or use operation, industrial sector and function category identified in Section D.1. This would include workers at sites controlled by the manufacturer or importer as well as workers at sites not under the control of the manufacturer or importer. Likewise, the number of commercial workers reasonably likely to be exposed while using the chemical substance would be reported for each product category identified in Section D.2.

## **31.10.** A company imports reportable chemical substances that are not actually received at the reporting site. How does this company fill in Part II – Section C for the range of workers likely to be exposed to the chemical substance?

For an imported chemical substance, the site reported in CDR is the site of the operating unit within the organization of the person reporting which is directly responsible for importing the substance and which controls the import transaction; however, this may not be where the chemical substance is received. If the imported chemical substance is never physically received at the reported site, then no workers at that site are exposed to the chemical substance and the code, W1, would be reported in Part II – Section C for less than 10 workers reasonably likely to be exposed to the chemical substance.

## **31.11.** Does the number of workers reasonably likely to be exposed include foreign workers (i.e. non-U.S.) workers? If 100% exported should the quantity by NKRA or less than 10?

The number of workers reasonably likely to be exposed does not include workers outside of the United States. This would be the case, for instance, when a chemical substance is imported in sealed containers and resold without repackaging or is shipped from a foreign source directly to a customer. If 100% exported *and* there is no potential exposure to a chemical substance, the code W1 corresponding to fewer than 10 workers would be reported.

However, make sure to consider in your estimate the workers employed during the transportation of your chemical(s) within the United States, before and during preparation for exportation; refer to the section below (copied from the CDR Instructions for Reporting):

Persons reasonably likely to be exposed to a chemical substance include workers whose employment requires them to pass through areas where chemical substances are manufactured, processed, or used (e.g., production workers and foremen, process engineers, and plant managers). Workers employed to drive vehicles which transport the chemical substance should be included in the number of workers reasonably likely to be exposed to the chemical substance if they come into contact with the chemical substance during loading or unloading. For example, workers engaged in the connection or disengagement of hoses used to load or unload the chemical substance should be included. However, workers involved solely with transporting chemical substances in sealed containers that are totally enclosed with no potential for exposure should not be included.

In addition, when a site employs temporary, seasonal, or contract workers in the manufacture of a reportable chemical substance, these workers should be included in the number of workers reasonably likely to be exposed to a chemical substance if they work in areas where the chemical substance is manufactured. The term does not include those employees whose jobs are not associated with potential exposures to a chemical substance or mixture (e.g., administrative staff who never enter areas where the chemical substance is manufactured) and who are unlikely to be exposed to a chemical substance for even a brief period of time. No allowance is made for personal protective equipment or for engineering controls that reduce but do not preclude exposure to a chemical substance; however, if contact between a worker and a chemical substance is highly improbable, the worker should not be included among those persons reasonably likely to be exposed to the chemical substance.

# **31.12.** Company A imports a chemical substance and hires a trucking company to do all the chemical distribution, so that no employees of Company A are exposed to the chemical substance. How does this company fill in Part II – Section C for the range of workers likely to be exposed to the chemical substance?

If the imported chemical substance is physically received at the reporting site, then workers at that site may be reasonably likely to be exposed to a chemical substance, regardless of their employer. Workers engaged in the loading of chemicals into transportation vessels, including trucks, may be reasonably likely to be exposed to a chemical substance during loading. If workers, including persons working for other companies, are reasonably likely to be exposed to the reported chemical substance at the site of manufacture (or import), then they should be included among those reported by Company A in Part II – Section C on Form U.

# **31.13.** Company B employs 12 workers to operate manufacturing lines for three different chemical substances, X, Y, and Z. The workers rotate among the different manufacturing lines. Only four workers work on the manufacturing line for Chemical X at any given time. However, any of the 12 workers may be assigned to Chemical X production. How should Company B report the number of workers reasonably likely to be exposed during the manufacturing of Chemical X?

Because any of the 12 workers may have worked on the Chemical X production line during the reporting year, Company B should report code W2 in Part II – Section C to reflect at least 10 but fewer than 25 workers.

## **31.14.** How does a company make judgments about the number of workers at processing and use sites that it does not control?

A submitter should report the number of workers reasonably likely to be exposed to a chemical substance at processing and use sites, to the extent the information is known or reasonably ascertainable. If a company manufactures multiple chemical substances that have similar use operations and knows the number of workers reasonably likely to be exposed to the chemical substance at one of the downstream sites, the company can reasonably assume that the same number of workers are likely to be exposed at the other downstream sites. See the *Instructions for Reporting* for discussion of the "known to or reasonably ascertainable by" reporting standard.

#### 32. Joint Submissions (Primary Form)

#### 32.1. When are joint submissions allowed?

A joint submission is most typically used when a substance or a mixture is imported and the supplier does not provide to the importer the specific chemical identity of the substance or substances that comprise the mixture. Joint submissions are allowed only where a supplier will not disclose to the manufacturer (including importer) the specific chemical name of the imported chemical substance or of a reactant used to manufacture the chemical substance, because the supplier claims the specific chemical name is confidential. This may happen, for instance, when a company is importing a mixture under a trade name, and the foreign manufacturer refuses to reveal the chemical identity of a component of the mixture that the foreign manufacturer considers confidential or trade secret. In this case, the importer and the supplier can jointly report the information through a joint submission. The importer must ask the supplier of the confidential chemical substance to directly provide EPA with the correct chemical identity in a Secondary Form U (see 40 CFR 711.15(b)(3)(i)(A)). In the event that the supplier also does not know the identity, the supplier can, in turn, use the secondary Form U to request that another entity submit the required information. The other entity is considered the tertiary submitter and would follow the reporting instructions using the Secondary Form U.

This may also happen in the event a manufacturer cannot provide the entire chemical identity of a chemical substance it manufactures because the chemical substance is manufactured using a reactant having a specific chemical identity that the reactant supplier claims as confidential and will not reveal to the manufacturer. In this case, the manufacturer and the supplier of the reactant can jointly report the information through a joint submission. The manufacturer must submit a report directly to EPA containing all information he or she knows or can reasonably ascertain about the chemical identity. Furthermore, the manufacturer must also ask the reactant supplier to directly provide to EPA the correct chemical identity of the confidential reactant in a Secondary Form U (see 40 CFR 711.15(b)(3)(i)(B)).

Because signatures are required by each party of a joint submission, secondary submitters who wish to report must each register with CDX and complete a Secondary Form U report. The reporting tool will match both submissions based upon the unique ID number sent by the manufacturer (including importer) to notify the supplier of the partial CDR submission. Suppliers do not have access to any of the information submitted to EPA by the manufacturers (including importers), unless the manufacturers provide it directly to the suppliers. Likewise, the manufacturers (including importers) cannot see the information that the suppliers report to EPA. This way, the confidentiality of information for all submitters is protected. The information provided by both submitters will be combined and processed as one joint submission once they are received by EPA.

#### 32.2. I'm an importer. Am I required to initiate a joint submission?

No. If you know the specific chemical identity for the imported substance you are reporting, you can provide the full information on your primary form. A joint submission is only necessary when an importer cannot provide the specific chemical identity of the imported chemical substance.

# **32.3.** As a company generally has no contractual means to require foreign suppliers of already purchased materials to either register with CDX or file a joint submission electronically, what can the company do to ensure that a foreign supplier prepares a secondary submission?

The joint submission requirement is to properly ask that suppliers provide secondary submissions to EPA. Therefore, it is the responsibility of the domestic company, the primary submitter, to ask the foreign company, the secondary submitter, to complete a Secondary Form U and send the information to EPA by the end of the submission period. The secondary submitter is expected to provide the chemical composition of an imported product or mixture, the chemical-specific function of each constituent substance, and information on chemical composition of the imported product or mixture. It is also the responsibility of the primary submitter to include a copy of the request to the secondary submitter with the Primary Form U that the primary submitter sends to EPA. (See 40 CFR 711.15(b)(3)(i)(B)). This is done when reporting using the eCDRweb electronic reporting tool.

## **32.4.** How will the manufacturer's information be matched with the foreign supplier's information if they are filing separately?

After the manufacturer (including importer), acting as a Primary Submitter, fills in the trade name or other proprietary identifier in the "Chemical Identification" section of the "Joint Submission Report", the primary submitter will use instructions in a box labeled "Unique Identifier for Joint Submission" to send an e-mail with a unique ID number and language to notify the supplier, acting as secondary submitter for the partial CDR submission containing information for the trade name product. The ID number will be used to link the joint reports in an internal database after the secondary submitter reports the correct chemical identity information to EPA by completing a Secondary Form U.

# **32.5.** A company plans, as a primary submitter, to submit a joint submission with the supplier of a mixture the company imports. Although the company knows the chemical identity of the chemical substances used in the mixture, the supplier has asked that the identity be kept confidential. In this case, does the company submit a joint submission using the trade name instead of using the chemical name?

No. Joint submissions are used only in cases when a supplier will not disclose to the submitter the specific chemical identity of the imported TSCA Inventory chemical substance or a reactant used to manufacture the TSCA Inventory chemical substance because the name is claimed confidential. If a manufacturer (including importer) actually knows or can reasonably ascertain the chemical identity (e.g., the CASRN or Accession Number) of a chemical substance subject to CDR, the manufacturer (including importer) must provide that information irrespective of a supplier's confidentiality claims.

If, on the other hand, the manufacturer (including importer) as primary submitter wishes to claim the chemical identity as confidential, the chemical substance must be listed on the confidential portion of the TSCA Inventory, in which case the submitter must check the confidential business

information (CBI) box and provide the appropriate upfront substantiation. The substantiation question at 40 CFR 711.30(b)(1) accommodates consideration of harm to the submitter's competitive position, which could include consideration of the competitive positions of business partners or others with which the supplier has contractual or similar relations.

## Asserting Confidential Business Information (CBI) Claims and Certification Statements

#### 33. CBI - General

#### **33.1.** What are the restrictions on submitting confidential information under CDR?

Most information submitted under CDR may be claimed as confidential at the time the Form U is submitted, although there are exceptions. Specifically:

- Confidentiality claims for data elements identified as "not known or reasonably ascertainable" are not allowed (40 CFR 711.30(a)(iii)).
- Many "use" information data elements are not eligible for CBI status. (40 CFR 711.30(a)(2)(ii)).
- Chemical identities listed on the public portion of the TSCA Inventory are ineligible for CBI status, (40 CFR 711.30(a)(2)(i)).

## **33.2.** Do the Frank R. Lautenberg Chemical Safety for the 21st Century Act and the 2020 CDR Revisions rule change the requirements for substantiation of CBI claims asserted with submission of CDR forms?

EPA made changes to requirements related to claiming CDR information as confidential to be consistent with new statutory requirements from amendments to TSCA enacted in 2016 under the Lautenberg Act. Changes to confidentiality claims included the addition of upfront substantiation requirements and exemptions consistent with the Lautenberg Act, changes to the substantiation questions, specification of data elements that are not eligible for confidentiality claims, and the development of joint submitter confidentiality considerations. For example, certain chemical specific "use" information data elements are not eligible for CBI status.

Additional information on how the 2020 CDR Revisions rule changed requirements for substantiation of CBI claims and CBI claims in general can be found on the CDR website at <u>www.epa.gov/cdr</u>.

Submitters with CBI claims should be aware of Final TSCA Confidential Business Information Procedures Rule (88 FR 37155, June 7, 2023), which made a variety of changes to existing EPA regulations regarding assertion and treatment of confidential business information (CBI) under TSCA and is codified in 40 CFR 703. The CDR-specific requirements are consistent with the new CBI requirements in 40 CFR 703, but remain in 40 CFR 711.30. General information about CBI under TSCA can be found at <u>https://www.epa.gov/tsca-cbi</u>.

**33.3.** TSCA section 14(c)(2) now provides that certain information claimed as confidential will not be subject to substantiation requirements, including "[s]pecific information describing the processes used in the manufacturing or processing of a chemical substance, mixture, or article," and "[s]pecific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture or article." Do these provisions conflict

## with the prohibition on certain claims or the substantiation requirements of 40 CFR 711.30?

No. The information for which confidentiality claims are barred or for which upfront substantiation is required under 40 CFR 711.30 (e.g., general use and process information collected under 40 CFR 711.15(b)(4) of CDR) is not the type of specific information within the scope of TSCA section 14(c)(2).

#### 33.4. What must generally be considered in making a claim of confidentiality under TSCA?

Procedures for the assertion, substantiation, and review of confidentiality claims are set forth at TSCA section 14; 40 CFR part 2, subpart B; 40 CFR part 703; and 40 CFR 711.30. When claiming information as confidential, an authorized official for the submitting company must certify that for all information claimed as confidential, the claimant has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the company; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. See TSCA section 14(c), 15 U.S.C. 2613(c).

Additional requirements apply when information reported under CDR is claimed to be confidential (See 40 CFR 711.30).

## **33.5.** How does a submitter make CBI claims and provide the required substantiation in e-CDRweb?

CBI claims are made for CDR submissions by checking a box next to the data element in the e-CDRweb reporting tool. For those data elements that require upfront substantiation, and most data elements require upfront substantiation, checking the CBI box automatically triggers the substantiation questions when reporters review the CBI claims for accuracy in e-CDRweb. The answers must be complete and specific to the chemical substance in question.

#### **33.6.** What should be included in a substantiation?

The CDR reporting tool includes questions to be answered to substantiate each data element claimed as confidential, consistent with the requirements at 40 CFR 711.30. These questions include, but are not limited to, whether the information claimed confidential includes a trade secret, or whether any of the information claimed to be confidential is required to be publicly disclosed under another law, and address issues related to the substantial harm that might result from the disclosure of the information. See, in general, 40 CFR 711.30(b). CBI claims for specific chemical identity must address additional substantiation questions at 40 CFR 711.30(c) related to reverse engineering. In response to these questions, submitters may provide to EPA any information they believe supports the validity of their CBI claims. Submitters must ensure that the responses to these questions provide a sufficient factual basis for the assertion that the particular data element is CBI.

The substantiation questions will appear when reporters review the CBI claims for accuracy in the e-CDRweb reporting tool.

## **33.7.** Can information that is "not known or reasonably ascertainable" be claimed as confidential?

No. Information entries designated as "not known or reasonably ascertainable" (i.e., "NKRA") may not be claimed as confidential (40 CFR 711.30(a)).

## **33.8.** If EPA determines that information claimed as CBI is not entitled to confidential treatment, does the Agency contact the submitter before releasing the information to the public?

Yes, if the information was properly claimed as CBI in the CDR submission.

CBI claims made under the CDR rule must comply with certain procedural provisions in order to be considered properly asserted, and if the procedures for asserting a claim are not followed the information may be disclosed without further notification to the submitter.

Information properly claimed as confidential may only be disclosed to the public pursuant to specific statutory and regulatory provisions. EPA has long established procedures for the protection of properly asserted CBI claims and the review of these claims. Where EPA concludes, upon review, that the information is not entitled to confidential treatment, the Agency follows the procedures in 40 CFR part 703, which include notification to the submitter prior to disclosure, consistent with TSCA section 14(g)(2).

Note that TSCA section 14(g)(1)(A) provides that EPA must make a CBI determination on 100% of specific chemical identity CBI claims and at least 25% of all other CBI claims. This means that a CBI claim asserted in June, could be subject to a determination in September.

#### **33.9.** How will the confidentiality of CDR data submitted electronically to EPA be maintained?

EPA maintains data security according to the Federal Information Processing Standards (FIPS) standards. The Central Data Exchange environment maintains 'In Progress' and 'Submitted' Form U's in an encrypted state within a firewalled environment. Submissions can only be accessed by passphrase as a secondary security mechanism to prevent unauthorized access to company submissions. The submissions remain encrypted through the transmission process from CDX into EPA's firewalled Confidential Business Information (CBI) LAN. Only once inside EPA backend systems is the data decrypted for EPA use. In summary, all data is encrypted during preparation, during transmission to EPA, and while it is maintained post submission within CDX. The information only becomes available for use once securely inside EPA systems.

#### **33.10.** How do I assert a confidentiality claim for information included in a substantiation in the e-CDRweb reporting tool?

In order to claim your response to a required CBI substantiation question as CBI in the e-CDRweb reporting tool, you must check the CBI box associated with the response you are claiming as confidential.

#### 34. CBI - Part I – Company, Site, and Technical Contact Identification

## **34.1.** Can the identity and contact information for the person listed as the technical contact for a site be claimed as confidential?

Reporters are able to assert a confidentiality claim for the link between the technical contact identity and the chemical substance, for each chemical substance reported. In the e-CDRweb reporting tool, check the box associated with "technical contact" when asked to "check any claim(s) below to mark the corresponding information as confidential" in Part II of Form U. Note that this CBI claim must be made separately for each reported chemical substance for which the technical contact information is being claimed as confidential.

## **34.2.** How does a submitter claim the link between the identity of the company and the chemical information submitted under CDR to be confidential?

Reporters are able to assert a confidentiality claim for the link between company identity for each chemical substance reported. To claim this link as confidential, check the box next to "company information" when asked to "check any claim(s) below to mark the corresponding information as confidential" in Part II of Form U. Note that this CBI claim must be made separately for each reported chemical substance for which the company identity information is being claimed as confidential. Also, if you separately send correspondence to EPA that may link the company name or site to the reported chemical substance, you would need to mark that information as confidential in order to maintain the confidentiality claim.

#### 34.3. How does a submitter claim site information as CBI?

Under CDR, a CBI claim for site identity is appropriate if the chemical link between the information reported in the CDR report and the site is confidential. A submitter may assert a confidentiality claim for the site identity for each chemical substance reported. Claiming site information confidential protects the release of the site name, address, city, county, state, zip code, and Dun & Bradstreet number. Confidentiality claims should be limited to circumstances in which they are absolutely necessary and legally justified (see TSCA section 14(c)(1)(B) and 40 CFR 2.208). Note that claiming site identity confidential does not alone protect the link between the specific chemical identity and the company's identity. It does protect the identity of the site where the chemical substance was manufactured (including imported). To claim the site address as confidential on the e-CDRweb reporting tool, check the box next to "site information" when asked to "check any claim(s) below to mark the corresponding information as confidential" in Part II of Form U. Note that written substantiation is required to claim site information as CBI. Note that this CBI claim must be made separately for each reported chemical substance for which the site identity information is being claimed as confidential.

## **34.4.** What is the difference between claiming Company Information as confidential and claiming Site Information as confidential? Should they both be claimed confidential?

Confidentiality claims for both site and company information are to be made in conjunction with a specific chemical substance and cannot be made generically for a whole submission. A claim of confidentiality for the identity of the site may be made if the linkage of the site with a reportable chemical substance and the fact that the substance is manufactured there is confidential and not publicly available. Selecting the CBI box in Part II for site information protects the link between a specific chemical substance and the information reported in Part I of Form U. Claiming site identity as confidential does not protect the link between the chemical identity and the company

name. Selecting the CBI box for company information protects the link between a specific chemical substance and the information reported in Part I Form U. Both of these confidentiality claims require upfront substantiation.

Where several chemical substances are being reported, a submitter may claim the company name and/or site identity as confidential for some of the chemical substances being reported, while not making those claims for others. EPA also has observed that submitters sometimes claim only their company identity, but not their site identity, as confidential. EPA will not impute the existence of a CBI claim for site identity from a CBI claim for company identity, even if the company name appears within the site identity information. Neither will EPA impute the existence of a CBI claim for company name or site identity from a CBI claim associated with a different chemical substance.

#### 35. CBI - Part II – Sections A - C – Chemical Substance and Manufacturing Information

## **35.1.** When is written substantiation required for claiming confidentiality under Part II of Form U?

Checking the CBI box for any data element requiring upfront substantiation will automatically trigger the appropriate substantiation questions in the "CBI Substantiation" section of the e-CDRweb reporting tool. In addition to signing the Certification on page one of CDR Form U, an Authorized Official must also electronically sign and date the responses to the substantiation questions. CBI claims will not be accepted if they are not asserted as required at the time information is submitted to EPA. If these instructions for making CBI claims are not followed, EPA may release the information to the public without further notice to the submitter. Written substantiation at the time of submission is not required for confidentiality claims for the five production volume data elements. See the *Instructions for Reporting* for additional information.

**35.2.** A company plans to report a chemical substance on a CDR submission using the TSCA Accession Number and associated generic name listed on the public portion of the Inventory, which represent the chemical substance as listed on the confidential portion of the TSCA Inventory. To maintain the listing of the specific chemical identity for this substance on the confidential portion of the Inventory, does the chemical identity information need to be claimed CBI on the CDR form and must written responses be provided to the substantiation questions up front with the CDR report?

Yes, to both questions. In order to maintain the specific chemical identity for the chemical substance on the confidential portion of the Inventory, the company must claim chemical substance identity as confidential and provide written answers to the provided substantiation questions when submitting the CDR report.

# **35.3.** If a company has previously reported production volume, plant site, or other information for the original TSCA Inventory (1977 data) or for subsequent IUR or CDR reporting periods, and did not claim the information as confidential at the time, can the company now make confidentiality claims for any of that information?

Yes, with a new information collection, a company may assert new CBI claims under certain circumstances, even ones which are different than previous data collection submissions. However, any assertion of a confidentiality claim must include a statement certifying, among other things, that the company has taken reasonable measures to protect the confidentiality of the information, that disclosure of the information is likely to cause substantial harm to the

competitive position of the company, and that the information is not readily discoverable through reverse engineering. In addition, no person may assert a new confidentiality claim for a specific chemical identity that already appears on the public portion of the Inventory.. CBI claims for information in a CDR submission must be <u>made</u> at the time the information is submitted. 40 CFR 711.30(a).

## **35.4.** Do submitters need to provide written upfront substantiation when production volumes are claimed confidential?

No. Confidentiality claims for production volumes have the option to be marked as confidential without further justification or upfront substantiation at the time of CDR Form U submission. 40 CFR 711.30(a)(3). The reporting tool will not ask for substantiation of the five production volume data elements: for 2024 reporting, these are the total volume for 2020, 2021, and 2022 and, for 2023, the domestically manufactured volume and the import volume.

However, any confidentiality claim for production volume that is exempt from upfront substantiation under this rule may later be subject to review as authorized under TSCA section 14(f). If the claim is subject to review, the company will be notified and required to substantiate the claim(s) at that time if they wish to maintain the claim.

## **35.5.** A company makes a chemical substance which is listed on the public version of the TSCA Inventory. How can the company keep the manner in which it uses the chemical substances confidential?

The company may keep the manner in which it uses the chemical substances confidential by claiming as confidential the connections between the chemical substance (including its uses) and the company name, site, and/or technical contact by checking the appropriate CBI boxes in Part II of Form U.

## **35.6.** If I am reporting a chemical on the confidential portion of the TSCA Inventory and claim the chemical identity as CBI, is the CBI claim subject to review?

Yes. Under TSCA section 14(g)(1)(C)(i), all CBI claims for chemical identities reported under CDR must be reviewed and either approved or denied.

Note that, from time to time, EPA determines a chemical on the confidential portion of the TSCA Inventory (and identified by an accession number and generic chemical name on the public portion of the Inventory) is ineligible for confidential treatment. This can happen, for example, when EPA, after the review of a CBI claim for the chemical identity, denies that claim. EPA will post updates: <u>Updates to Confidential Status of Chemicals</u> on the TSCA Inventory.

Information specific to the 2020 CDR submission period: <u>CBI Information for the 2020 Chemical</u> <u>Data Reporting Submission Period</u>.

## **35.7.** Do I have to re-substantiate CBI claims for chemical identity that I asserted in the 2020 CDR collection or other more recent TSCA collections?

A report submitted for one CDR reporting cycle is a separate submission from a report for a different CDR reporting cycle. Because it is a separate submission, it requires its own substantiation for any confidentiality claims requiring up-front substantiations. Note the CDR regulations at 40 CFR 711.30(b)(6) provide that a submitter should address in their substantiation

whether EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance. This is your opportunity to identify that the claim was previously made and approved.

#### 36. CBI - Part II - Section D - Processing and Use Information

## **36.1.** Can processing and use data reported in Part II – Section D of Form U be claimed as confidential?

Some of the processing and use data elements cannot be claimed as confidential. In total, there are six industrial processing and use data elements, three of which cannot be claimed as confidential, and seven consumer and commercial data elements, four of which cannot be claimed as confidential.

The following data elements, which provide general processing and use information within the meaning of TSCA section 14(b)(3)(B), cannot be claimed as confidential:

- Certain Industrial processing and use data elements:
  - type of process or use (40 CFR 711.15(b)(4)(i)(A));
  - $\circ$  industrial sector (40 CFR 711.15(b)(4)(i)(B)); and
  - function code (40 CFR 711.15(b)(4)(i)(C)).
- Certain Consumer and Commercial use data elements:
  - $\circ$  product category (40 CFR 711.15(b)(4)(ii)(A));
  - function of the chemical in the consumer or commercial product (40 CFR 711.15(b)(4)(ii)(B));
  - whether the chemical is used in commercial or consumer products (40 CFR 711.15(b)(4)(ii)(C)); and
  - whether the chemical predictably is used in children's products (40 CFR 711.15(b)(4)(ii)(D)).

A claim of confidentiality may be asserted for other data associated with the processing and use information, if a submitter has reason to believe that release of the information would reveal confidential commercial or financial information, as provided by section 14 of TSCA, , and 40 CFR part 703. The electronic reporting tool will enable a submitter to check a CBI box next to each data element and complete the required upfront substantiation for such claims. Checking a CBI box for a specific data element automatically triggers the required substantiation questions in the "CBI Substantiation" section of the e-CDRweb reporting tool. The written answers must be complete and specific as to the chemical substance and each data element in question. If any information is not known or reasonably ascertainable, "NKRA" for "not known or reasonably ascertainable," may be selected for the box corresponding to that data element. However, submitters cannot claim an "NKRA" designation as confidential. See the *Instructions for Reporting* for more information.

#### 37. CBI - The Secondary Form U – Joint Submissions

## **37.1.** Are confidentiality claims for chemical identity treated differently for submissions made directly by suppliers in a joint submission?

A joint submission is necessary when a manufacturer (including importer) cannot provide the specific chemical identity of a chemical substance it manufactures, either because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture,

or because the chemical substance is manufactured using a reactant having a specific chemical identity that is unknown to the manufacturer and claimed as confidential by the reactant supplier.

In a joint submission, the primary submitter should identify whether the supplier information, including the supplier identity and the chemical substance or mixture trade name (or other designation), is confidential. Substantiation of the confidentiality claims for this information will not be required at the time of submission. The secondary submitter of the joint submission will provide its company name and location, a technical contact, trade name, chemical identity(ies), function, percentage, and function of each chemical substance in the composition of the substance or mixture represented by the trade name.

The secondary submitter is responsible for asserting all confidentiality claims for the data elements that it submits directly to EPA and for substantiating those claims not exempt under 40 CFR 711.30(a)(3)(iii). Chemical substance identity can be claimed as confidential by the secondary submitter following the provisions in 40 CFR 711.30. Except for the percentage composition information, which is generally exempt from substantiation pursuant to TSCA section 14(c)(2)(D), all other reported data elements are subject to substantiation at the time the information is submitted.

## **37.2.** What assumptions about CBI claims does EPA make with respect to information submitted in a Secondary Form U and the participants in joint submissions?

For 2020 and future CDR submissions, EPA has enabled the joint submitters to identify if data related to their submissions is confidential. See the *Instructions for Reporting* for additional information.

#### **Other Issues**

#### 38. Recordkeeping Requirements

#### **38.1.** Are companies required to keep records related to CDR reporting?

Companies must maintain records that document any CDR information reported to EPA for a period of 5 years beginning on the last day of the submission period (40 CFR 711.25). For example, if a CDR report was submitted for a submission period ending September 30, 2016, the records on which the report is based must be retained until September 30, 2021. Persons submitting CDR information are encouraged to retain their records longer than 5 years to refer to when new Form Us are being prepared.

#### 38.2. What must records maintained to document CDR reporting include?

As long as the records are maintained in a manner consistent with normal business practices, submitters may determine their exact format. Retained records should include all the information used to complete the Form U, such as those that show the production volume, plant site, and site-limited status of each chemical substance reported.

## **38.3.** If a company's annual production is less than the reporting threshold for a chemical substance, must records still be kept?

The CDR regulation does not itself require any company to maintain information upon which a decision not to report is based. Consistent with their own business practices, companies may elect to retain documentation of their conclusion that they were not subject to reporting requirements.

#### 38.4. If a company qualifies for a small business exemption, does it need to keep CDR records?

The CDR regulation does not itself require any company to maintain information upon which a decision not to report is based. Consistent with their own business practices, companies may elect to retain documentation of their conclusion that they were not subject to reporting requirements.

#### **39.** Penalties for Not Submitting a Report

## **39.1.** What are the consequences for failure to report when required to do so or failure to report on time?

Manufacturers or importers subject to the CDR rule would be in violation of TSCA if they fail to comply or are late in complying with the CDR rule and may be subject to enforcement action. If you are required to report, failure to do so is a violation of TSCA Section 15 and may subject you to penalties (40 CFR 711.1(c)).

For additional information, see <u>EPA's Audit Policy</u> and <u>Enforcement Response Policy for</u> <u>Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13.</u>

### **39.2.** What are the consequences if a company reports incomplete or incorrect information on the CDR report?

If EPA detects an error or omission on Form U, the Agency may send a letter requiring the company to correct the error within a specified time. If a timely correction is not received, the company may be subject to an enforcement action.

#### 40. Additional Regulatory Information for CDR Chemical Substances

### **40.1.** Where can I find more information about TSCA Section 4 proposed or final rules or orders?

For chemical substances subject to a final test rule, you can learn more about the requirements by viewing <u>test rule requirements (Subparts B and D</u>), as well as EPA's <u>sunset table</u> to determine the sunset date of the rule and the applicable Federal Register citation. If your chemical substance is in an active final test rule, then you may be required to submit a letter of intent to conduct testing or submit an exemption application. For more information, see <u>EPA's website</u> or contact the TSCA Hotline at (202)-554-1404.

To determine whether your chemical substance is in an active proposed or final test rule or order for CDR submission purposes, visit <u>Substance Registry Services</u> and view the submission period-specific lists (e.g., for 2024 CDR, see "2024 CDR TSCA 4 TR" and "2024 CDR TSCA 4 order" lists). The lists for a specific submission period will be made available prior to June 1 of the submission year.

## **40.2.** Where can I find more information about a TSCA Section 4 Enforceable Consent Agreement (ECA)?

You can learn more about the specific ECA, its requirements, and verify whether your company is subject to the ECA by viewing <u>40 CFR 799,5000 and 5025</u>, as well as EPA's <u>sunset table</u> to determine the sunset date of the ECA and its applicable Federal Register citation. In addition, even if your company is not a signatory to the ECA, your company may be subject to export notification requirements. For more information, contact the TSCA Hotline at (202)-554-1404.

To determine whether your chemical substance is in an active ECA for CDR submission purposes, visit <u>Substance Registry Services</u> and view the submission period-specific lists (e.g., for 2024 CDR, see "2024 CDR TSCA 4 ECA" list). The lists for a specific submission period will be made available prior to June 1 of the submission year.

## **40.3.** Where can I find more information about a TSCA Section 5(a) Significant New Use Rule (SNUR)?

To find out the requirements for a chemical substance that is the subject of a SNUR, visit <u>*ChemView*</u>. To determine whether your chemical substance is in a proposed or final SNUR for CDR submission purposes, visit <u>*Substance Registry Services*</u> and view the submission period-specific list (e.g., for 2024 CDR, see "2024 CDR TSCA 5(a) SNUR." The lists for a specific submission period will be made available prior to June 1 of the submission year.

If you have questions on the applicability of an existing use, need a copy of the existing SNUR, or have other questions related to SNURs, please contact the *appropriate individual* on EPA's New Chemicals Management Branch webpage.

#### 40.4. Where can I find more information about a TSCA Section 5(e) Consent Order?

You can review the 5(e) consent order restrictions for the chemical substance(s) that you manufacture (including import). You should have the full version of the order, including confidential business information, on-site. If you need a copy or have other questions, then please contact the *appropriate individual* in EPA's New Chemicals Management Branch for more information.

To determine whether your chemical is in a 5(e) consent order for CDR submission purposes, visit <u>Substance Registry Services</u> and view the submission period-specific list (e.g., for 2024 CDR, see "2024 CDR TSCA 5(e) Consent Orders" list). The list for a specific submission period will be made available prior to June 1 of the submission year.

#### 40.5. Where can I find more information about a TSCA Section 5(f) rule?

Orders issued pursuant to TSCA section 5(f) may limit the amount of such substances that may be manufactured (including imported), processed, or distributed in commerce. For additional information, you can view applicable Federal Register notices for the chemical substances that you manufacture (including import) and verify that you are in compliance with any applicable restrictions. For more information, contact the TSCA Hotline at (202)-554-1404.

To determine whether your chemical is in a 5(f) rule for CDR submission purposes, visit <u>Substance Registry Services</u> and view the submission period-specific list (e.g., for 2024 CDR, see "2024 CDR TSCA 5(f) Specific Labeling" list). The list for a specific submission period will be made available prior to June 1 of the submission year.

#### 40.6. Where can I find more information about a TSCA Section 6 rule?

You can review the TSCA section 6 restrictions (and proposed restrictions) in applicable Federal Register notices for the chemical substances that you manufacture (including import) and verify that you are in compliance with any applicable restrictions. For more information, contact the TSCA Hotline at (202)-554-1404.

To determine whether your chemical is in a section 6 rule for CDR submission purposes, visit <u>Substance Registry Services</u> and view the submission period-specific list (e.g., for 2024 CDR, see "2024 CDR TSCA 6 Unreasonable Risk" list). Note that this list includes all chemicals that are the subject of all TSCA section 6 rules. The list for a specific submission period will be made available prior to June 1 of the submission year.