

2016 Chemical Data Reporting Frequent Questions

(Updated July 11, 2016)

These Frequent Questions (FQs) are intended to clarify the reporting requirements for Chemical Data Reporting for the 2016 reporting period.

In EPA's August 16, 2011, Chemical Data Reporting rule, the Agency changed the name of its chemical reporting regulation from the Inventory Update Reporting (IUR) Rule to the Chemical Data Reporting (CDR) Rule, which is codified at 40 CFR 711. However, throughout this document, EPA has retained the use of the term "IUR" to reflect historic terminology and has used the term "CDR" to describe the revised reporting requirements under the new rule. In other words, EPA is using "IUR" to refer to the 2006 and earlier submission periods; it's using "CDR" to refer to the 2012 and later submission periods, to which the new rules apply.

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 CDR requirements.

If you need more help, visit EPA's [Chemical Data Reporting webpage](#), contact EPA's TSCA Hotline at tsc-hotline@epa.gov, call 202-554-1404, or send an email to eCDRweb@epa.gov.

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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?

As part of the 2011 IUR Modifications final rule, EPA changed the name of the regulation from the Inventory Update Reporting (IUR) Rule to Chemical Data Reporting (CDR) Rule. 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.

Some CDR rule changes were effective for the 2012 CDR and some effective with the 2016 CDR submission period. Changes in reporting implemented for the 2012 CDR submission period included lowered processing and use reporting thresholds, upfront substantiation requirements for confidentiality claims, and a revised list of consumer and commercial product categories. During the 2016 CDR submission period, the remaining CDR changes were put into effect including required reporting for chemical substances with production volumes of 25,000 pounds or greater at a single site in any calendar year since the last principal reporting year, a reduced reporting threshold of 2,500 pounds or greater for chemical substances that are the subject of certain TSCA actions, and the removal of the different reporting threshold for processing and use information.

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).

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

The CDR rule, promulgated under the authority of Section 8(a) of TSCA, requires chemical substance manufacturers (including importers) to report manufacturing data and industrial, commercial, and consumer processing and use information for certain chemical substances on the TSCA Inventory. Under the TRI rule, regulated facilities must report information on the releases and other waste management for chemical substances specified under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA).

1.4. How does the Frank R. Lautenberg Chemical Safety for the 21st Century Act affect the 2016 Chemical Data Reporting?

Effective June 22, 2016, the Toxic Substances Control Act (TSCA) was amended, including revisions of TSCA section 14 related to confidential information submitted under TSCA. For 2016 CDR submitters, EPA has changed the wording of the CBI certification statement in the reporting system to be consistent with new requirements. EPA is updating the guidance, instructions, and other information documents to be consistent with the new certification language.

2016 CDR submitters should be aware that the amended section 14(e) limits the duration of many confidentiality claims to 10 years, unless those claims are timely reasserted. EPA will be developing policies, rules, and/or guidance to implement this provision.

Other changes in the law will affect processes that will take place after the 2016 CDR Form Us are received. Most notably, section 14(g) requires that EPA review and make determinations on all CBI claims for chemical identity made in CDR submissions after the date of enactment. Other CBI information submitted under CDR may be reviewed as part of EPA's section 14(g) obligation to review a representative subset of other sorts of CBI claims. The Agency's procedures for CBI reviews are reflected in the regulations at 40 CFR part 2, and the regulations at 40 CFR 711.30 contain the substantiation questions for CDR filings.

1.5. I submitted my 2016 CDR before enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and the change in certification statement. Do I need to resubmit my 2016 Form U?

No. 2016 CDR Form Us submitted before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act do not need to be resubmitted. However, if you revise your submission, your revision will be certified using the new certification statement.

2. 2016 Submission Period

2.1. When is reporting required for 2016 Chemical Data Reporting?

The 2016 submission period, during which 2012-2015 production volume information and 2015 manufacturing, processing and use information are to be reported, is scheduled to occur from June 1, 2016 to September 30, 2016.

2.2. What is the reporting frequency for the 2016 submission period and beyond?

The reporting frequency is every four years. After the 2016 CDR submission period, the next submission period will be in 2020.

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 202-564-1404 or send an e-mail to eCDRweb@epa.gov.

3.2. Is EPA providing training for CDR reporting?

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

Webinars: EPA will host 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). Dates and other information for the webinars will be posted on the [CDR website](#). The presentation slides and audio recordings of the webinars held to date are available on the [How To Report Under Chemical Data Reporting](#) 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 Chemical Data Reporting](#) page of the CDR website, or you may contact the TSCA Hotline at 202-564-1404 or send an e-mail to eCDRweb@epa.gov.

3.3. Will EPA provide a schema for uploading data to the e-CDRweb reporting tool?

Yes, EPA will provide a final XML schema for the 2016 CDR submission period for both primary and joint submissions, allowing companies to verify their internal systems and to upload data to the e-CDRweb reporting tool. The final schema for 2016 CDR reporting is now available on the CDR website.

Determining the Chemical Substances Subject to the CDR Rule

4. General

4.1. How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR 711.5 to determine your reporting requirements. You should consider the following three steps to determine whether you are required to report for each chemical substance that you domestically manufactured (including imported) 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?

5. Manufactured Chemicals (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. The CDR rule requires only manufacturers, including importers, of chemical substances listed on the TSCA Chemical Substance Inventory to report. Therefore, if a company purchases all of its chemicals from domestic sources and does not use them to manufacture other chemicals, the company is not required to report.

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

Yes. Persons who manufacture chemical substances solely for export are considered manufacturers for the 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 all processing and use occurs outside the United States, the company would fill out Parts I and II of Form U and check the box labeled “N/A” in the upper right-hand corner of Sections A and B of Part III on Form U.

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 of the examples included in the question, the company is not manufacturing as long as the company is purchasing from a domestic source. 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.

6. Toll Manufacturers

6.1. What are toll manufacturing and co-manufacturing?

For CDR purposes, toll manufacturing 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 toll manufacturer, 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 toll manufacturing and reporting for CDR purposes, please see: [TSCA Chemical Data Reporting Fact Sheet: Toll Manufacturing](#).

- 6.2. Company B is a “toll” manufacturing facility which has a contract with Company A to make a specific chemical substance using Company A’s technology and raw materials. Company B supplies Company A with the resulting product, charging a “toll” fee for the conversion process, and is not involved with subsequent marketing or sales of the product. Company A has indicated that Company B is responsible for completing the CDR Form U. Company B believes that Company A should be the responsible party since it is their material and Company B has no control over the product, market, applications or uses. What should Company B do?**

Company B should refer Company A to the CDR regulations, specifically to 40 CFR 711.22(c), which states that while the companies can work out among themselves who should report, EPA holds both of the parties (i.e., contracting company and toll manufacturer) responsible for the submission of a report by either one of the parties. Company B and Company A should then decide how to comply with the CDR regulations for the chemical substance.

Additional information about toll manufacturing and reporting for CDR purposes is found in: [TSCA Chemical Data Reporting Fact Sheet: Toll Manufacturing](#).

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

In a co-manufacturing situation, the toll and contracting manufacturers can share information and agree between themselves that one or the other will undertake all or a portion of the work associated with meeting the CDR regulations for a given co-manufactured chemical substance. EPA expects that in most instances, a person that contracts with a toll manufacturer will generally know more about the particular chemical substances, and will usually be in a better position to report about industrial processing and use of a chemical substance, and about commercial and consumer uses of products containing the chemical substance. Similarly, EPA expects that the toll manufacturer will generally be in a better position to report the number of workers and other information associated with the manufacturing site.

Additional information about toll manufacturing and reporting for CDR purposes is found in: [TSCA Chemical Data Reporting Fact Sheet: Toll Manufacturing](#).

- 6.4. If the contracting manufacturer agrees to report the chemical for the given CDR submission period, does that take the burden off of the toll manufacturer? For**

example, if Company A tolls for Company X and Company X agrees to report the chemical, does that absolve Company A from any reporting?

Not necessarily. If Company X agrees to report the manufacturing, but fails to do so, Company A is still responsible to report. The contracting company and the toll manufacturer are to decide among themselves how to meet the CDR requirements for a specific co-manufactured chemical substance. Both parties (i.e., contracting manufacturer and toll manufacturer) are responsible to ensure that one of the parties reports the chemical substance. Care should be taken to avoid duplicative reporting, so that only one Form U for the co-manufactured chemical substance is submitted to EPA.

Additional information about toll manufacturing and reporting for CDR purposes is found in: [TSCA Chemical Data Reporting Fact Sheet: Toll Manufacturing](#).

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(b)).

[For additional information, see: TSCA Chemical Data Reporting Fact Sheet: Importers.](#)

7.2. 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, 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.

[For additional information, see: TSCA Chemical Data Reporting Fact Sheet: Importers.](#)

7.3. 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 not operating in a Foreign Trade Zone.

7.4. 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?

For purposes of CDR, imported chemical substances are never site-limited (40 CFR 711.3).

7.5. 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.

7.6. 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, process 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 all the plants, 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 used. For the consumer and commercial information, report the top ten product categories for each chemical substance, aggregating the information from all the plants in which the chemical substances are used.

8. Chemical Substances on the TSCA Inventory — General

8.1. For what chemical substances must CDR information be submitted?

In general, chemical substances that are listed on the TSCA Inventory and manufactured (including imported) may be subject to CDR. Carefully review the regulations located at 40 CFR 711.5 to determine your reporting requirements. You should consider the following three steps to determine whether you are required to report for each chemical substance that you domestically manufactured (including import) 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 [Instructions for Reporting](#) for help with each of these steps.

Chemical substances that are the subject of certain TSCA actions have different reporting requirements. Please see the [Chemical Substances which are the Subject of Certain TSCA Actions](#) fact sheet for additional information about these specific reporting requirements.

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

No, some substances are fully exempt or partially exempt from the CDR regulation. See 40 CFR 711.6, 711.9, and 711.10 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 partially exempt chemicals list can be found under the Petition Results tab of the [How To Report Under Chemical Data Reporting](#) page of the CDR website.

EPA's Substance Registry Services (SRS) contains searchable information regarding the reporting status of particular chemical substances. [Please see the CDR instructions on how to search SRS.](#)

In contrast to reporting periods prior to the 2012 CDR, inorganic chemical substances are no longer partially exempt from reporting requirements. Therefore, submitters should report complete information on inorganic chemical substances.

8.3. 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." This standard is applicable to all information reported in accordance with 40 CFR 711.15(b).

8.4. How does a person access the TSCA Inventory?

Visit the [TSCA Chemical Substance 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 \(SRS\)](#). The public Inventory

does not contain the chemical name and CAS number of chemical substances for which specific identities have been claimed as TSCA confidential business information; only generic chemical names and accession numbers are included for these substances.

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

In order to manufacture (including import) a chemical substance for a non-exempt commercial purpose, it must be: on the [TSCA Inventory](#), a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.4(b)), or excluded by TSCA Section 3(2)(B)*. You can visit [Substance Registry Services](#) and view its “2016 CDR TSCA Inv” list to determine whether your chemical substance is on the TSCA Inventory for 2016 CDR purposes.

If your chemical substance is not on the TSCA Inventory, please see EPA’s [Pre-Manufacture Notice \(PMN\) Requirement](#) flowchart to determining 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.

A chemical substance that is not on the [TSCA Inventory](#), a naturally occurring chemical substance as defined by TSCA, or exempted in TSCA Section 3(2)(B)) must be submitted with a notice as per 40 CFR 720.22(a)(1), prior to manufacture (including import).

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 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, contact the Agency at the following address: <https://www.epa.gov/compliance/epas-edisclosure>.

[Significant reductions](#) in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a company has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the CDR.

**Substances exempted in TSCA Section 3(2)(B) 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.*

8.6. How do the TSCA Inventory flags relate to CDR and have they been updated for the 2016 CDR submission period?

Special flags are used throughout the TSCA Inventory to identify those substances on the Inventory that are the subject of an EPA rule or order promulgated under TSCA, as well as to indicate the types of full or partial exemptions from TSCA reporting requirements. The following is a list of flags that are used and would be of interest for CDR:

- E — indicates a substance that is the subject of a Section 5(e) Consent Order under TSCA.
- F — indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
- N — indicates a polymeric substance containing no free-radical initiator in its Inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
- P — indicates a commenced PMN substance.
- R — indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
- S — indicates a substance that is identified in a proposed or final Significant New Use Rule.
- T — indicates a substance that is the subject of a Section 4 test rule under TSCA.
- XU — indicates a substance exempt from reporting under the CDR Rule, (40 CFR 711).
- Y1 — indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
- Y2 — indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

The “E”, “F”, “R”, “S”, and “T” flags identify those chemical substances that are subject to specific types of TSCA regulatory activities. These flags are useful for CDR, because they identify chemical substances subject to TSCA regulatory activities that make them ineligible for other CDR exemptions and subject to a lower production volume reporting threshold.

The “XU” flag identifies those chemical substances on the TSCA Inventory that are the subject of full exemptions from CDR requirements. The “Y1” and “Y2” flags identify polymers that were exempted from full PMN reporting under TSCA Section 5 according to the original Polymer Exemption rule of 1984, and most polymers are exempt from CDR.

These flags are embedded into the Substance Registry Services (SRS) chemical lookup within the current edition of e-CDRweb reporting tool and have been updated to reflect the 2016 reporting requirements. When the chemical lookup function is used, and the selected chemical has been assigned a special flag, the reporting tool will display a notice on the screen 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 Help with Chemical Data Reporting: How to Search for Chemicals Subject to Certain TSCA Actions 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, 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?

Solid solutions that are really mixtures of chemical substances should be reported in the same manner in which 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 TSCA 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, 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 MgSO₄, MgO, and MgCl₂. They are 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 actually 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 40 CFR 710.3(d).

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 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, or combination of chemicals from a reaction, to be listed as a single chemical substance, using one name that collectively describes the products or, if that is not feasible, describes the reactants used to make the products. This type of byproduct is often identified as a single chemical substance using nomenclature for substances of Unknown or Variable composition, Complex reaction products and Biological materials (a “UVCB” substance) to represent what is often a 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 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 reported 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 the process stream. Approximately one-third of the more than 85,000 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:

- [Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials: UVCB Substances](#) and
- [Combinations of Two or More Substances: Complex Reaction Products](#)

10.4. When is a byproduct reportable for CDR purposes?

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 both byproducts...”

While byproducts may or may not, in themselves, have commercial value, they are nonetheless produced for the purpose of obtaining a commercial advantage because they are formed as part of the manufacture of a chemical product for a commercial purpose. Thus, chemical substances that are the byproducts of 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, and (4) their manufacturers are not specifically exempted from CDR requirements. If the reporting threshold of 25,000 pounds 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. A byproduct may be subject to the lower

2,500 pound threshold if it is the subject of certain TSCA actions. See the [Reporting Thresholds for 2016](#) fact sheet.

A byproduct may have a separate commercial purpose even if its manufacturer does not intentionally commercialize it. 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, then the byproduct's 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; however, under 40 CFR 711.10(c), chemical substances are not subject to reporting when they meet the requirements of 40 CFR 720.30(g) or (h).

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

Under 40 CFR 720.30(g) a byproduct is exempt from 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.)"

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. In interpreting Section 40 CFR 720.30(g), one needs to consider the following important points:

- Regarding 40 CFR 720.30(g)(1), note that where the same quantity of a byproduct is burned as a fuel, and is also being burned for a non-exempt commercial purpose (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. However, if a certain portion of a byproduct was burned solely as a fuel and a separate portion of the byproduct was used for a non-exempt commercial purpose, the exemption under 40 CFR 720.30(g)(1) would apply to the portion burned solely as fuel (but not to the portion burned for the non-exempt purpose). Also note that if a substance is normally manufactured for use as a fuel, then it would not be considered a byproduct. Furthermore, if a byproduct were to end up being used as a fuel by individuals (such as in a consumer product), it would not qualify for this exemption (because 40 CFR 720.30(g)(1) only covers use by "public or private organizations").
- Regarding 40 CFR 720.30(g)(2), note that although the manufacture of a byproduct is not reportable if the byproduct is subsequently disposed of as a waste for purposes of enriching the soil (e.g., to change the soil properties in a desirable way, such as by serving as a filler to make the soil less dense or enhancing moisture retention), a substance used as a fertilizer is not necessarily an excluded byproduct. For instance, if the substance's ordinary manner of use is as a fertilizer, then the substance is not a byproduct in the first place, and the provisions at 40 CFR 720.30(g) are inapplicable.

- Regarding 40 CFR 720.30(g)(3), Note that a “component chemical substance” means a chemical substance that already specifically exists in the byproduct. While heat or chemical reactions can be used to extract a component chemical substance, the component chemical substance extracted must be left chemically unchanged by the extraction process for the byproduct manufacturer to claim a CDR exemption under 40 CFR 720.30(g)(3). That is, the chemical changes can only occur on substances other than the one being extracted. Note also that individual component chemical substances extracted from a UVCB byproduct are reportable substances if they are extracted for a commercial purpose, even in cases where the manufacture of the UVCB byproduct itself is exempt from reporting pursuant to 40 CFR 720.30(g)(3).

10.6. 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 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 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 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 subject to CDR.

Note also that the component chemical substance must be viewed as a particular chemical substance.

For instance, elemental Nickel (Ni^0) and nickel hydroxide $\text{Ni}(\text{OH})_2$ have different molecular identities and are not the same chemical substance. Additionally, because the Ni^{+2} ion cannot exist on its own and is therefore not considered a chemical substance, the Ni^{+2} ion is not considered a component chemical substance of the byproduct. Consider the following scenarios:

- Scenario 1: If (Ni^0) is recovered from a UVCB byproduct containing $\text{Ni}(\text{OH})_2$ as a component chemical substance, then an extraction of a component chemical substance has NOT occurred. Rather, the byproduct has been used as a chemical

feedstock to manufacture Ni⁰, and both the byproduct and (Ni⁰) are therefore subject to CDR.

- Scenario 2: If Ni(OH)₂ is recovered from a UVCB byproduct containing Ni(OH)₂ as a component chemical substance, then 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)₂ 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](#).

10.7. 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 Sections 720.30(h), which says in part:

The chemical substances described below: (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.)

1. Any impurity.
2. Any byproduct which is not used for commercial purposes.
3. Any nonisolated intermediate.

In interpreting Section 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, 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 (Although the component was produced coincidentally with the intended product, it has been separated from the intended product. Thus, it is not “present with” the intended product and it is not “unintentionally present with” the 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 back 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 III 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).

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

10.8. 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 or 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.

10.9. It is unclear to me whether I am burning my byproduct for energy recovery or destruction. Is this an issue I need to resolve in order 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 side product you manufacture is normally intended to be used as a fuel product, it would be considered a co-product instead of a byproduct.

10.10. How could a byproduct be manufactured in the course of 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.

10.11. 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 Inventory listing and 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, both are required to be listed on the Inventory unless otherwise excluded and, unless exempted from CDR, both are subject to the CDR requirements if listed on the Inventory.

10.12. How does a submitter report under the data element “Is chemical substance being recycled, remanufactured, reprocessed, or reused?”

For purposes of CDR, a manufactured chemical substance is being recycled, remanufactured, reprocessed, or reused when that substance or a component of a UVCB substance is recovered and reused. EPA generally expects that this data element would

apply to many byproduct substances, but that product finishing, which does not involve removing a chemical substance from a waste stream, would not qualify as recycling for purposes of this data element.

10.13. EPA has a lot of programs encouraging recycling. If I am recycling my byproduct, do I need to be concerned about Inventory listings or 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 manufactured substances are being recycled, you need to consider whether those substances must be listed on the TSCA Inventory. In addition, those substances listed on the TSCA Inventory may be subject to the CDR.

10.14. 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.

10.15. 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.”)

10.16. 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 and PMN 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)).

10.17. 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.

10.18. 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. 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 recycled 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.

10.19. 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?).

10.20. 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?

The baghouse dust is a byproduct of your manufacturing process. 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?).

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 just melts out of the ore or baghouse dust. However, if you just 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 (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 the CDR.

10.21. 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 manufacturer of the baghouse dust.

10.22. 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)(1).

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.

10.23. 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 recovered to begin the process to make white liquor. Since the black liquor is used as a fuel, do I need to report it under the CDR? How about the smelt?

Both the manufacture of the black liquor byproduct and the manufacture of smelt from the black liquor byproduct are reportable under CDR.

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.)"

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.

10.24. Our company purchases a cation resin (H+-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: $[G^+][\text{anions}^-] + [H^+][\text{Resin}] \rightleftharpoons [G^+][\text{Resin}] + [H^+][\text{anions}^-]$; (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⁺][Resin] complex). As the performance of the resin declines, an acid solution ([H⁺][Y⁻]) is typically used to regenerate the cation resin. A subsequent drying step results in the metal salt [G⁺][Y⁻]. 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⁻] 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 non-isolated 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.

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 exempted in TSCA Section 3(2)(B) need not be reported. Substances exempted in TSCA Section 3(2)(B) 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 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 exempt from TSCA in Section 3(2)(B).

11.3. 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.

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?

Water and naturally occurring substances are exempt from CDR requirements. Three other groups of chemical substances (polymers, microorganisms, and certain forms of natural gas) are also generally exempt from CDR requirements. These general exemptions are further defined at 40 CFR 711.6 (a). Note that a particular polymer, microorganism, or form of natural gas is no longer covered under this exemption if the chemical substance becomes the subject of any of certain TSCA actions. The relevant TSCA Sections are: 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 5(e) or 5(f), or relief under TSCA Section 5 or 7.

12.2. 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.

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

Substances that 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) are not considered to be polymers and must be reported to CDR if they are not otherwise excluded.

12.4. 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.

12.5. 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)).

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 domestically manufacture (including import) 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 [Instructions for Reporting](#) for help with each of these steps.

13.2. 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.

- 13.3. 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.

- 13.4. If a company began producing a chemical substance in January 2016, does the company need to send EPA a CDR report for 2015 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 2012-2015, the company has no reporting obligations for that chemical for the 2016 CDR submission period.

- 13.5. 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 chemical substance in any calendar year since the last principal reporting year. If the chemical does not trigger a reduced 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.

- 13.6. 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 threshold has been met.

- 13.7. 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.

13.8. 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; complete Parts I, II, and III of Form U.
- Chemical B: 90,000 pounds imported; complete and submit Parts I, II, and III of Form U.
- 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; in this case the company would complete Parts I, II, and III of Form U.)

13.9. 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
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 criteria (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 \$4 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 \$40 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.

Note that under this criterion, 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.

14.2. 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 5(e) or 5(f) 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.

14.3. 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. Therefore, if your company has 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.

14.4. 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.

14.5. 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 2015?

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 CDR 711.6 or 40 CFR 711.9. The fact that Company B did not start to manufacture the chemical substance until 2015 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?

Chemical substances which are the subject of final TSCA Section 4 test rules 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 year. Consider the TSCA regulatory status of the chemical substance at the beginning of the reporting period, e.g., June 1, 2016.

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 substances for industrial uses. Is CDR reporting required? The chemical substance is not otherwise exempted from CDR requirements.**

Yes. 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. For example, a pen is considered an article and is 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 is 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 [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) 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 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 are 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.

19. Non-Isolated Intermediates

- 19.1. 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.

- 19.2. 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 Threshold

- 20.1. What is the threshold for processing and use reporting?**

There is no separate threshold for 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., 2015).

- 20.2. 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 III of the form?**

Yes. The need to complete the processing and use information for Part III 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.

20.3. Must processing and use activities be reported for an inorganic chemical substance that meets the reporting threshold?

Yes. Manufacturers (including importers) of inorganic substances have the same reporting obligations as manufacturers (including importers) of organic substances. Some substances which are defined as inorganic (e.g., water, certain ores and minerals) will still receive a full or partial exemption as they are classified under other exemption categories.

21. Full Reporting for Chemical Substances

21.1. What is full reporting under CDR?

Full reporting means that Parts I, II, and III 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 (i.e., 2012-2015) are subject to full reporting for the principle reporting year (i.e. 2015). Full reporting means that all data elements (Parts I, II, and III) 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 III 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 [TSCA Chemical Data Reporting Fact Sheet: Chemical Substances which are the Subject of Certain TSCA Actions](#) 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 Parts I and II 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 III 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 under the Petition Results tab of the [How To Report Under Chemical Data Reporting](#) page of the CDR website.

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 (manufacturing information) of Form U. Part III (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 Parts I and II 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. What do I need to do differently now that the Frank R. Lautenberg Chemical Safety for the 21st Century Act has become law?

If you submit a CBI claim, you will need to agree to the new certification statement which appears in the reporting system. As in the past, the certification statement must be electronically signed and dated by an authorized official at the company. The authorized official typically is a senior official with management responsibility for the person (or persons) completing the form.

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. What is the purpose of the certification statement and how has the Frank R. Lautenberg Chemical Safety for the 21st Century Act impacted it?

The certification statement applies to all the information supplied on the Form U and should be signed only after the form has been completed. The CDR submission must be certified, indicating that the submitted information has been completed in compliance with the CDR requirements and that any confidentiality claims are true and correct. The new law requires the addition of specific language. On June 24th, 2016, the certification statement was updated to include the required language to conform with the new law and is now:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim 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 my competitive position; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 USC § 1001.

The certification statement must be electronically signed and dated by an authorized official at the company. The authorized official typically is a senior official with management responsibility for the person (or persons) completing the form.

23.5. 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.

23.6. 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 2012 CDR Form U, please submit a notarized request on company letterhead to EPA. The company letterhead must be from the company that owns the site. 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.

Please send the request to one of the following addresses:

By U.S. Postal Service

CDR CDX Registration Coordinator (7407M)
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
William Jefferson Clinton Building East
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

By Hand Delivery or Courier
CDR CDX Registration Coordinator
U.S. EPA – OPPT/CBIC
WJ Clinton Building East, Room 6428
1201 Constitution Ave., N.W.
Washington, D.C. 20004-3302

Telephone: (202) 564-8930 or (202) 564-8940

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 does not even cover all the information in a submitter’s possession or control. As defined for the 2006 IUR, 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 therefore 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 situation 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 (Blocks 1.A.1-1.A.8)

25.1. 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 [Reporting After Changes to Company Ownership or Legal Identity](#) fact sheet for further information.

25.2. During the first six months of the current CDR reporting year (e.g., 2015), 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., 2015), 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 [Reporting After Changes to Company Ownership or Legal Identity](#) fact sheet.

- 25.3. On January 1, 2016, Company A will sell the portion of its business that conducted manufacturing in 2015. 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 2016, Company B owns the entity that conducted the manufacturing in 2015. 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 [Reporting After Changes to Company Ownership or Legal Identity](#) fact sheet on the CDR website.

- 25.4. 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.

- 25.5. 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.

- 25.6. 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.

25.7. On January 1, 2016, 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 2015?

By the time of the CDR submission in 2016, Company XYZ is the current name of the business entity that conducted the manufacturing in 2015. Company XYZ should report its current name, not a prior name that it used when manufacturing in 2015.

Section B. Site Information (Blocks 1.B.1-1.B.8)

25.8. 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).

25.9. 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.

- 25.10. 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 (1.A.2) and the site Dun & Bradstreet block (1.B.2) on Form U or should the 1.B.2. block be left blank?**

The D&B number of the corporation that owns the site should be reported as the site D&B number (block 1.B.2). 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 (block 1.A.2). 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.

- 25.11. 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.

- 25.12. 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.

- 25.13. 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.

- 25.14. A company has portable tanks for slurring 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.

Section C. Technical Contact Information (Blocks 1.C.1-1.C.10)

25.15. 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.

25.16. 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.

25.17. 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.

25.18. 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.

26. Part II — Section A. Chemical Substance Identification (Blocks 2.A.1-2.A.4)

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 [Agency's Substance Registry Services \(SRS\)](#) 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.

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 (Block 2.A.2) or the specific name of the chemical substance (Block 2.A.4) 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 contact EPA, in writing or via fax on company letterhead, well before initiating CDR reporting to obtain the Accession Number assigned when the Notice of Commencement (NOC) was submitted to the Agency. Individuals are urged to submit a complete and accurate TSCA Inventory Correspondence via fax or by U.S. mail 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 [Substance Registry Services \(SRS\)](#) 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 tsc-hotline@epa.gov.

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 ₃ H ₈	68476-49-3 Hydrocarbons, C2-4, C-3
106-97-8, Butane, C ₄ H ₁₀	68476-42-6 Hydrocarbons, C4-5
74-84-0, Ethane, C ₂ H ₆	68606-25-7 Hydrocarbons, C2-4

The company wants to know whether or not 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. The Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that when a CBI claim is made for specific chemical identity, the claim shall include a structurally descriptive generic name, developed consistent with EPA guidance. Will the CDR reporting process be modified to comply with this requirement?

For the 2016 CDR submission cycle there will be no change. In general, the CDR processes now in place automatically incorporate existing generic chemical names that are associated with chemical substance listings on the confidential version of the TSCA Inventory. These processes provide the greatest degree of structural specificity that is practicable to afford for the 2016 CDR reporting cycle, given that the submission period is already ongoing. EPA will develop guidance regarding generic names as required by the new law, and will determine appropriate procedures regarding their use and submission.

27. Part II — Section B. Manufacturing Information

27.1. 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.

27.2. 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 industrial 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 industrial 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 industrial 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)(ii)(D))).

27.3. 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.

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

Yes. Block 2.B.8 (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 in 2.B.8. 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 in Block 2.B.8.

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 [TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates](#).

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

Report the total volume of the 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 (i.e., $\text{Block 2B.8} = (\text{Block 2.B.5} + \text{Block 2.B.6}) - \text{Block 2.B.9}$).

27.6. 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 Block 2.B.8 of the CDR Form U for this chemical substance.

27.7. 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 in Block 2.B.6 for volume imported and indicate in Block 2.B.7 that the imported chemical substance is never physically at the reporting site.

27.8. 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 the volume used on-site 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 2015.

27.9. I manufacture a product for sale within the United States as well as for export. Does the Production Volume Exported (Block 2.B.9) apply to exports out of the United States or does it apply to the production volume that is not used on site?

In Block 2.B.9 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 III of Form U.

Physical Form (Blocks 2B.13-2.B.19)

27.10. 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 in Block 2.B.15 as a “water- or solvent-wet solid.”

27.11. 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.

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

No. For purposes of CDR, pellets and granules should be reported in Block 2.B.14 as “pellets or large crystals.”

27.13. 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” (Block 2.B.18) and “pellets or large crystals” (Block 2.B.14) because the chemical substance may leave the site in either form.

27.14. 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 (Block 2.B.18) and 0 percent for the gas or vapor (Block 2.B.17).

27.15. 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 in Block 2.B.18.

Other: Maximum Concentration, Recycling (Blocks 2.B.11-2.B.12)

27.16. 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 in Block 2.B.11?

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

27.17. How does a company report the maximum concentration in Block 2.B.11 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.

27.18. 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 Block 2.B.11 of 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.

27.19. 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.

27.20. 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 in Block 2.B.11?

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 (Block 2.B.20)

27.21. 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 any 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 the 2016 CDR, report production volumes for 2012, 2013, 2014, and 2015.

28. Part III — Processing and Use Information General

Section A. Industrial Processing and Use Data (Blocks 3.A.1-3.A.10)

28.1. 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.

28.2. All of a company’s products are used to make commercial products through various process steps by different manufacturers. For Part III, 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 III 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 III relate to what subsequent users and processors are doing with the product.

Information on subsequent industrial users and processors is reported on Part III, Section A, and on commercial and consumer uses of the chemical substance would be reported on Part III, Section B of CDR Form U to the extent the information is known to or reasonably ascertainable by the manufacturer or importer of the subject chemical substance. A company which is a manufacturer or importer should report information about the distribution 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”).

28.3. 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 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, a submitter should, for CDR purposes, consider this site’s 100,000 tons to have only been extracted from the pipeline by its customer. Thus, the submitter does not have to account for all potential downstream processing and use scenarios for all persons drawing ammonia from the common pipeline. Instead, the 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.

- 28.4. 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 III 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)).

- 28.5. 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 III of Form U be completed for the original chemical substance?**

The company would complete Part III, Section A 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)).

- 28.6. 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 III 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.

28.7. How is the use of an organic fertilizer reported in Part III 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.

28.8. 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 III 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 A. of Part III 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 information in Section B. of Part III to the extent that it is reasonably ascertainable.

28.9. 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 III Section B reporting.

Assuming that the use of a substance by an oilfield service company means that the product will be used in an oilfield or a related production facility, selling a substance for such an application would constitute an industrial use operation and would be reported in Section A. of Part III. 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 B. of Part III.

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

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

28.11. Is there a crosswalk between the North American Industrial Classification System (NAICS) codes used in 2006 and the 2016 Industrial Sector (IS) codes?

Yes. This information can be located on the [Replacement of 5-digit NAICS Codes with Industrial Sector Codes](#) page of the CDR website. Submitters who do not know a specific NAICS code may be able to identify a more general category.

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

For Part III 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 of Form. The IS codes are included in the e-CDRweb reporting tool.

28.13. How does a company determine the top 10 combinations of TPU, IS, and IFC 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 IFC, 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 substances 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.

28.14. How is Part III of Form U completed for Chemical A when it is used as an intermediate to manufacture Chemical B?

If Chemical A is used solely as a chemical intermediate to manufacture Chemical B, report “PC” for the Type of Processing or Use (TPU) code for Chemical A, including the associated Sector code, Industrial Function Category, 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 Section B of Part III, if 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 B is subject to CDR, whoever manufactures it may need to complete all of Part III.

28.15. 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 IFC codes but doesn’t know what percentages of the volumes go to the customer’s various IFC codes or how many IFC codes apply. Should the company report the TPU and NAICS codes and leave the IFC code blank or put in “U999” for “Other”?

The company should fill out the portion of the Part III information that it knows (that is, the TPU, IS, and IFC 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.

28.16. Both the Industrial Sector Code and Industrial 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 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. The written description should be used to provide a description at a comparable level of specificity as found with the current codes. It should not be used to add additional, more specific detail.

Section B. Consumer and Commercial Use Data (Blocks 3.B.1-3.B.10)

28.17. The Consumer and Commercial Category code allows a submitter to report C909 “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 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. The written description should be used to provide a description at a comparable level of specificity as found with the current codes. It should not be used to add additional, more specific detail.

28.18. 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.

28.19. 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 Section A. of Part III of Form U to denote that there is no industrial processing of the chemical substance. Complete Section B. of Part III to reflect the manner in which consumers use the chemical substance.

28.20. 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.

29. Parts II and III — Estimating Number of Workers Reasonably Likely to be Exposed to a Chemical Substance (Block 2.B.10 and Sections 3.A. & 3.B.)

What to Consider When Estimating

29.1. 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.

29.2. 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.

29.3. 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.

29.4. 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.

29.5. 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 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.

29.6. 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.

29.7. 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.

29.8. 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.

Estimating Workers in Part II and Part III

29.9. 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 information, a company only reports the number of workers associated with the site of manufacture and/or import identified in Part I. Part II 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 in Block 2.B.10.

For Part III 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 III 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 industrial function category identified in Section 3.A. This would include workers at sites controlled by the manufacturer or importers 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 3.B.

29.10. A company imports reportable chemical substances that are not actually received at the reporting site. How does this company fill in Part II Block 2.B.10 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, Block 2.B.10 for less than 10 workers reasonably likely to be exposed to the chemical substance.

29.11. 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 Block 2.B.10 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, Block 2.B.10 on Form U.

29.12. 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, Block 2.B.10 to reflect at least 10 but fewer than 25 workers.

29.13. 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. 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.

30. Part IV — Joint Submissions (Sections 4.A.-4.D.)

30.1. When are joint submissions allowed?

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 confidential component of the mixture. 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 Part IV of Form U (see 40 CFR 711.15(b)(3)(i)(A)).

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 Part IV of 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 their own sections of the same 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.

30.2. 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 Part IV of Form U and send the information to EPA by the end of the submission period. It is also the responsibility of the primary submitter to include a copy of the request to the secondary submitter with the portion of the Form U that the primary submitter sends to EPA. (See 40 CFR 711.15(b)(3)(i)(B)).

30.3. 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 Part IV of Form U.

30.4. 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 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)(i) accommodates consideration of harm to the submitter’s competitive position “or to your supplier’s competitive position.

Asserting Confidential Business Information (CBI) Claims and Certification Statements

31. General

31.1. What are the restrictions on submitting confidential information under CDR?

Information submitted under CDR may be claimed as confidential at the time the Form U is submitted. Submitters must provide upfront substantiation of confidentiality claims for processing and use information as well as for confidentiality claims for site or chemical identity. Confidentiality claims for data elements identified as “not known or reasonably ascertainable by” are not allowed (40 CFR 711.30(b)).

31.2. Does the Frank R. Lautenberg Chemical Safety for the 21st Century Act change the requirements for substantiation of CBI claims asserted with submission of CDR forms?

For the 2016 CDR, there is no revised or new substantiation beyond what the current regulations at 40 CFR 711.30 require. Although the Agency may revise CBI substantiation requirements by subsequent rulemaking, EPA has determined that the retention of current CBI substantiation requirements is the most practicable approach for the 2016 CDR reporting cycle, given that the submission period is already ongoing. EPA will use the answers to the CDR substantiation questions to inform the confidentiality determinations for chemical identity.

31.3. TSCA section 14(c)(2) now provides that certain information 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 substantiation requirements of 40 CFR 711.30?

No. The information 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 that TSCA section 14(c)(2) is referring to.

31.4. What must generally be considered in making a claim of confidentiality under TSCA?

EPA’s procedures for processing and reviewing confidentiality claims are set forth at 40 CFR Part 2, Subpart B and 40 CFR 711.30. When claiming information confidential, a submitter must ensure that the information meets the regulatory criteria found at 40 CFR 2.208. Under this regulation, business information is entitled to confidential treatment if:

- a. The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived, nor withdrawn;
- b. The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information and that it intends to continue to take such measures;
- c. The information is not, and has not been, reasonably obtainable without the business’s consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);
- d. No statute specifically requires disclosure of the information; and,
- e. Either –
 - i. The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business’s competitive position, or

- ii. The information is voluntarily submitted information and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future.

In addition, the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that for all claims for protection for any confidential information made with this submission the submitter certify they have:

- (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 my competitive position; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).

Additional requirements apply when chemical identity, site identity, or processing and use information is claimed to be confidential (See 40 CFR 711.30).

31.5. How does a submitter make CBI claims and provide the required substantiation in e-CDRweb?

CBI claims are made for CDR reporting by checking a box next to the data element. For those data elements that require upfront substantiation, checking the CBI box automatically triggers the substantiation questions. The answers must be complete and specific to the chemical substance in question.

31.6. Did the Agency install a warning system in the reporting tool to remind submitters to complete required substantiation before submitting Form U?

Yes. When a user checks a field that requires up front substantiation, a pop-up window will appear containing the substantiation questions a user needs to complete. If a user tries to save the substantiation questions without entering information into each of the required questions, the tool will show a validation warning that will require a user to enter information into the text fields. If a user clicks on the 'X' button to close the pop-up window, or on the 'Cancel' button to close the pop-up window, the check will be removed from the CBI box.

31.7. Can information that is “not known or reasonably ascertainable” be claimed as confidential?

No. Entries designated as “not known or reasonably ascertainable” (i.e., “NKRA”) may no longer be claimed as confidential (40 CFR 711.30(a)).

31.8. Does the Agency contact submitters after it determines the data is non-CBI and releases it as public information?

CBI claims made under the CDR rule must comply with certain procedural provisions in order to be recognized, 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 declassified pursuant to specific regulatory provisions. EPA has long established procedures for the protection of properly asserted CBI claims and also the review of these claims. Regarding those instances where a substantiation is required for a CBI claim but EPA concluded that it was insufficient, the Agency has procedures in place in 40 CFR part 2, subpart B that provide for notification to the submitter prior to disclosure.

31.9. 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.

31.10. How do I claim my CBI substantiation answers as CBI themselves?

In order to claim information in your answers to the required CBI substantiation questions as CBI, you must clearly identify the information that is claimed confidential by marking the specific information in each answer with a label such as "confidential business information," "proprietary," or "trade secret."

32. Part I — Company and Site Information (Blocks 2.B.1-2.B.3)

32.1. Can the identity and contact information for the person listed as the technical contact for a site be claimed as confidential?

Yes. Check the CBI box adjacent to block 2.B.3. Note that this CBI claim is a chemical-specific claim and must be made for each reported chemical substance for which the technical contact information is being claimed as confidential.

32.2. 32.2. How does a submitter claim the link between the identity of the company and the information submitted under CDR to be confidential?

To claim the link between the company and the information being reported on CDR Form U as confidential, check the box next to the CBI for Company Identification field (Block 2.B.1). Also mark as confidential any correspondence that may link the company name or site to the reported.

32.3. How does a submitter claim site information as CBI?

Under CDR, a submitter may assert a confidentiality claim for the site identity (site information) 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 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, check the site information CBI box (Block 2.B.2) on Form U. Note that written substantiation is required to claim site information as CBI.

32.4. 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 is confidential and not publicly available. Selecting the CBI box for site information protects the link between a specific chemical substance and the information reported in Part I, Section B of Form U and automatically triggers substantiation questions which must be answered and submitted as part 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, Section A of Form U and does not 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.

33. Part II — Chemical Substance and Manufacturing Information (Block 2.A.1 and Blocks 2.B.4-2.B.20)

33.1. When is written substantiation required for claiming confidentiality under Part II of Form U?

Checking any CBI box for chemical identity or site identity automatically triggers the appropriate substantiation questions. In addition to signing the Certification on page one

of CDR Form U, an Authorized Official must also 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.

33.2. A company plans to report a chemical substance on the CDR using the confidential Inventory Accession Number and the generic name that goes with the Accession Number. To maintain the listing of this substance on the confidential Inventory does the chemical identity information need to be claimed CBI on the CDR form and must written responses be provided to the CBI questions up front with the CDR report?

Yes to both questions, except in the special case of secondary and tertiary submitters participating in joint submissions. In other cases, in order to maintain the chemical substance on the confidential inventory, the company would need to claim chemical substance identity as confidential and provide written answers to the substantiation questions when submitting the CDR report.

33.3. 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 the company may assert new CBI claims, even ones which are inconsistent with previous data collection submissions. Please note, though, that the fact that a particular data element was not claimed as CBI previously may call into question the validity of the now-asserted CBI claim and trigger a CBI review consistent with the regulations. CBI claims for information in a CDR submission must be made at the time the information is submitted. 40 CFR 711.30(a). Also please note that EPA will not consider reclassifying non-CBI data elements in previous data collections, based on this year's collection CBI assertions, without an amendment of the earlier filing(s). Any reclassification effort will be done in accordance with 40 CFR 2.203(c) and the Agency cannot assure that a reclassification to CBI will be authorized or that such efforts will be effective.

33.4. 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 Form U submission. However, any claim still needs to qualify for confidential treatment (40 CFR 2.208), and submitters should be prepared to provide such substantiation in the event the CBI claim is challenged.

33.5. 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?

Because the chemical substance is listed on the public version of the TSCA Inventory, the chemical identity cannot be claimed CBI. However, the company can claim as confidential the connections between the chemical substance and the company name and between the chemical substance and the site by checking the appropriate CBI boxes. The company can also make confidentiality claims for processing and use information that it reports in Part III of Form U.

34. Part III – Processing and Use Information (Sections 3.A. and 3.B.)

34.1. Do all CBI claims made in Sections A and B of Form U Part III need to be accompanied by answers to substantiation questions?

Upfront substantiation of CBI claims is needed for all data elements except production volume. A claim of confidentiality may be asserted for data associated with the processing and use information reported in Part III of Form U if a submitter has reason to believe that release of the information would reveal trade secrets or confidential commercial or financial information, as provided by Section 14 of TSCA and 40 CFR part 2.

A submitter may check the CBI box next to each data element to claim data as confidential. Checking a CBI box for a specific data element automatically triggers the substantiation questions. The written answers must be complete and specific as to the chemical substance and each data element in question. If a chemical substance is not used in products intended for use by children and a submitter answers “No” in Part III.B, the submitter is encouraged not to claim that designation as confidential.

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.

34.2. If a chemical substance is not used in products intended for use by children, can the manufacturer claim that lack of use as confidential?

Yes, such claims can be made, but the submitter is encouraged not to claim the information as confidential.

35. Part IV — Joint Submissions (Sections 4.A-4.D.)

35.1. How are confidentiality claims for chemical identity treated differently for submissions made directly by suppliers in a joint submission?

When a supplier in a joint submission (i.e., a secondary or tertiary submitter) reports a chemical substance listed on the confidential portion of the TSCA Inventory, EPA will presume that the chemical identity associated with the Accession Number is subject to a

confidentiality claim. In such instances, the secondary or tertiary submitter does not need to claim the underlying chemical identity CBI or provide upfront substantiation.

35.2. What assumptions about CBI claims does EPA make with respect to information submitted in Part IV of Form U and the participants in joint submissions?

EPA will presume that the information reported in Section 4.D. (Trade Product Identification Information) of Form U and the connection between the chemical identity and the primary company associated with the joint submission is subject to a confidentiality claim when it is reported by a secondary submitter.

Similarly, EPA will presume that the information reported in Section 4.D. of Form U and the connection between the chemical identity and the secondary company associated with the joint submission is subject to a confidentiality claim when it is reported by a tertiary submitter.

Other Issues

36. Recordkeeping Requirements

36.1. 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 is 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.

36.2. 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.

36.3. 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.

36.4. 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.

37. Penalties for Not Submitting a Report

37.1. 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 5 and may subject you to penalties (40 CFR 711.1(c)).

For additional information, see [EPA's Audit Policy](#) and [Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13](#).

37.2. 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.

38. Additional Regulatory Information for CDR Chemical Substances

38.1. Where can I find more information about TSCA Section 4 proposed or final rules?

For chemical substances subject to a final test rule, you can learn more about the requirements by viewing [test rule requirements \(Subparts B and D\)](#), as well as EPA's [sunset table](#) 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, contact the TSCA Hotline at (202)-554-1404.

To determine whether your chemical substance is in an active proposed or final test rule under 40 CFR 790.45 for 2016 CDR purposes, visit [Substance Registry Services](#) and view the "2016 CDR TSCA 4 TR" list.

38.2. 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 [40 CFR 799.5000 and 5025](#), as well as EPA's [sunset table](#) 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 2016 CDR purposes, visit [Substance Registry Services](#) and view its “2016 CDR TSCA 4 ECA” list.

38.3. 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 [ChemView](#). To determine whether your chemical substance is in a proposed or final SNUR for 2016 CDR purposes, visit [Substance Registry Services](#) and view the “2016 CDR TSCA 5(a) SNUR.”

If your company is not following the requirements in the SNUR, then a significant new use notice (SNUN) may need to be submitted pursuant to 40 CFR 721.5. 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.

38.4. 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 2016 CDR purposes, visit [Substance Registry Services](#) and view its “2016 CDR TSCA 5(e) Consent Orders” list.

38.5. 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 2016 CDR purposes, visit [Substance Registry Services](#) and view its “2016 CDR TSCA 5(f) Specific Labeling” list.

38.6. 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 2016 CDR purposes, visit [Substance Registry Services](#) and view its “2016 CDR TSCA 6 Unreasonable Risk” list.

38.7. What do I do if my chemical substance is not on the TSCA Inventory?

In order to manufacture (including import) a chemical substance for a non-exempt commercial purpose, it must be: on the [TSCA Inventory](#), a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.4(b)), or excluded by TSCA Section 3(2)(B)*. You can visit [Substance Registry Services](#) and view its “2016 CDR TSCA Inv” list to determine whether your chemical substance is on the TSCA Inventory for 2016 CDR purposes.

If your chemical substance is not on the TSCA Inventory, please see EPA’s [Pre-Manufacture Notice \(PMN\) Requirement](#) flowchart to determining 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.

A chemical substance that is not on the [TSCA Inventory](#), a naturally occurring chemical substance as defined by TSCA, or exempted in TSCA Section 3(2)(B)) must be submitted with a notice as per 40 CFR 720.22(a)(1), prior to manufacture (including import).

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 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, contact the Agency at the following address: <https://www.epa.gov/compliance/epas-edisclosure>.

[Significant reductions](#) in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a company has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the CDR.

**Substances exempted in TSCA Section 3(2)(B) 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.*