

TSCA Chemical Data Reporting

Fact Sheet: Reporting for Co-Manufactured Chemicals

This fact sheet provides information on existing Chemical Data Reporting (CDR) regulations to persons who are involved in co-manufacturing of chemical substances which may be subject to the CDR rule.

The primary goal of this document is to help the regulated community comply with the requirements of the CDR rule. This document does not substitute for that rule, nor is it a rule itself. It does not impose legally binding requirements on the regulated community or on the U.S. Environmental Protection Agency (EPA).

The CDR rule, issued under the Toxic Substances Control Act (TSCA), requires manufacturers (including importers) to give EPA information on the chemicals they manufacture domestically or import into the United States. EPA uses the data, which provides important screening-level exposure related information, to help assess the potential human health and environmental effects of these chemicals and makes the non-confidential business information it receives available to the public.

In the instructions, guidance, and other communications with submitters, EPA may have previously referred to co-manufacturing as toll manufacturing, and more specifically to the two parties as the contracting manufacturer and the toll manufacturer. EPA does not specifically define the term “toll manufacturer,” and it is relying instead on terms associated with the CDR definition of manufacturer in 40 CFR 711.3; namely, EPA is using the terms co-manufacture, contracting company, and producing company.

How the CDR regulations apply to co-manufactured chemicals

What is co-manufacturing?

For CDR purposes, co-manufacturing refers to a particular kind of manufacturing situation involving two parties, in which one company contracts with a second company to domestically produce a chemical substance exclusively for the first company. The first company, or the 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 the producing company, physically manufactures the chemical substance and generally provides the site, staff, and equipment necessary to manufacture the chemical substance.

The definition of “manufacture,” at 40 CFR 711.3, includes producing companies and contracting companies as co-manufacturers:

Manufacture means to manufacture, produce, or import, for commercial purposes.

Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. A chemical substance is co-manufactured by the person who

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

- (1) Produced exclusively for another person who contracts for such production, and
- (2) That other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process.

When the physical production occurs outside of the United States and the contracting company is located in the United States, a different situation exists. In that situation, the contracting company would likely be considered an “importer” under CDR. (See [Fact Sheet: Importers](#) for information on CDR requirements specific to Importers).

When are producing companies and contracting companies the co-manufacturers of a chemical substance?

Producing companies and contracting companies are co-manufacturers of a chemical substance when they meet the requirements under the definition of “manufacture,” specifically: (1) the chemical substance is produced exclusively for the contracting company and (2) the contracting company specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process. See 40 CFR 711.3.

EPA recognizes that there are situations where a manufacturer may have produced the same chemical for multiple contracting companies during the reporting period¹ (i.e., either for multiple companies in a single year or for different companies in different years of the reporting period). In such situations, the chemical substance was not “[p]roduced exclusively” for any one contracting company and, therefore, the manufacturer and the two or more contracting companies are not considered to be co-manufacturers for CDR purposes. See 40 CFR 711.3 (definition of “manufacture”). Because the companies do not meet the requirements of co-manufacturing, the required reporting of the chemical substance would be completed by the entity physically producing the chemical substance.

In this fact sheet, further references to “producing company” assume that the manufacturer in question is, in fact, one of two co-manufacturers, consistent with the definition of “manufacture” at 40 CFR 711.3.

Who reports under CDR – the contracting company or the producing company?

When a company contracts with a producing company to manufacture a chemical substance and the criteria for co-manufacture are met (each party meets the definition of *manufacturer* as set forth in 40 CFR 711.3), there are two procedures available for the reporting of the co-manufactured chemical.

Procedure 1: Both the contracting company and the producing company report information. The contracting company (as the initiating submitter) has the responsibility to initiate a co-manufacturer report that triggers the reporting requirements for the producing company (as the completing submitter). The contracting company reports both its site information (as the site controlling the contract) and the producing company’s site information (as the site physically manufacturing the chemical substance). The contracting

¹ For example, the reporting period for the 2020 CDR is 2016 to 2019.

company also provides information including the chemical identity, the production volume and the processing and use information. The contracting company then initiates the co-manufacturer report and, from within e-CDRweb, sends a notification to the producing company to complete the reporting.

Upon receipt of the email notification to complete the reporting, the producing company has the responsibility to begin its portion of the co-manufacturer report. The producing company provides the manufacturing information, including the production volume. Each party will complete its part of the co-manufacturer joint report as part of its overall CDR submission and will not have access to the information submitted by the other party.

Table 1: Procedure 1 Reporting:

Data Elements	Contracting Company	Producing Company
Chemical Identity	✓	
Production Volume	✓	✓
Manufacturing Information		✓
Processing and Use Information	✓	

Procedure 2: The producing company, as specified in the written agreement between the contracting and producing company, completes the full report for the co-manufactured chemical. The contracting company would supply the information not otherwise known to or reasonably ascertainable by the producing company.

Table 2: Procedure 2 Reporting:

Data Elements	Contracting Company	Producing Company
Chemical Identity	✓ (provide to producing company)	✓
Production Volume		✓
Manufacturing Information		✓
Processing and Use Information	✓ (provide to producing company)	✓

Note that, in all cases, both the producing company and the contracting company are liable if no report is made. See 40 CFR 711.22(c).

How do co-manufacturers identify and report the site, parent company, and technical contact data elements?

Under Procedure 1, the reporting is as follows:

Site: The contracting company reports its own site (in Part I of Form U) AND the producing company site in (Part II of Form U), when it indicates that the chemical substance is co-manufactured and initiates the co-manufacture report. The producing company reports its own site in Part I of Form U. For users of the data, the producing company site will be identified as the manufacturing site, because it is the location where the chemical substance is physically manufactured (see definition of “site,” 40 CFR 711.3).

Parent Company: Both the contracting company and the producing company will report their respective parent companies, including foreign parent companies, if applicable, in Part I of Form U.

Technical Contact: A different technical contact may be specified for each chemical reported (see 40 CFR 711.15(b)(2)(ii)). Both the contracting company and the producing company have the opportunity to identify a technical contact for the chemical. The technical contact should be the person who can best answer questions about the specific chemical and may be an employee of one of the co-manufacturers, or a consultant, as appropriate.

Under Procedure 2, the reporting is as follows:

Site: The producing company reports its own site in Part I of Form U. For chemical substances manufactured under contract, the site is the location where the chemical substance is physically manufactured (see definition of “site,” 40 CFR 711.3).

Parent Company: The producing company will report its parent company, including foreign parent company if applicable, in Part I of Form U.

Technical Contact: A different technical contact may be specified for each chemical reported (see 40 CFR 711.15(b)(2)(ii)). The technical contact should be the person who can best answer questions about the specific chemical and may be an employee of one of the co-manufacturers, or a consultant, as appropriate.

Reporting issues specific to co-manufacturing

Coordination among co-manufacturers

The CDR regulations allow the contracting company and the producing company to decide for themselves who should report by using Procedure 1 or Procedure 2, while making clear that both parties are liable if no report is made. The contracting company and the producing company may wish to make arrangements among themselves for the reporting party to verify to the other party that it completed the CDR submission on behalf of both parties.

Impact of the small manufacturer and small government exemptions

Small manufacturers and small governments are exempted from CDR reporting requirements, unless the chemical substance is subject to certain TSCA actions (40 CFR 711.9). When

determining reporting requirements for co-manufacturers, it may happen that one company meets the conditions for the small manufacturer exemption and the other company does not. In such cases, only the non-small manufacturer bears the liability for reporting under CDR. However, the two companies may continue to decide among themselves who will file the report (i.e., the small manufacturer may elect to voluntarily report on behalf of the other manufacturer).

Small manufacturer means a manufacturer (including importer) that meets either of the following standards (40 CFR 704.3, referenced by 40 CFR 711.3):

- Your total sales during the principal reporting year (e.g., for 2020 CDR, 2019), combined with those of your parent company, domestic or foreign (if any), are less than \$12 million regardless of annual production volume.
- Your total sales during the principal reporting year (e.g., for 2020 CDR, 2019), combined with those of your parent company, domestic or foreign (if any), are less than \$120 million and your annual production volume of the chemical substance subject to reporting does not exceed 100,000 lbs at your plant 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.

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000 (40 CFR 704.3, referenced by 40 CFR 711.3).

Difference in requirements for producing companies under CDR and the PMN program

Under the relevant regulations governing the new chemicals program, 40 CFR 720.22(a)(2), the obligation to file a Premanufacture Notice (PMN) always rests with the contracting company². The producing company does not file a PMN. By contrast, the CDR regulations (40 CFR 711.22(c)) allow the contracting company and the producing company more flexibility, to determine among themselves who will report.

Different producing companies for the same chemical

Under 40 CFR 711.15, reports are site-based, with a separate Form U completed for each site. The method for reporting varies depending upon which company is initiating the reporting (Procedure 1 or Procedure 2). If the contracting company initiates the report (Procedure 1), they will be able to list all of the producing companies on the contracting company Form U and send a request to each of the producing companies to report their portion of information directly to EPA. If the producing companies are doing the reporting (Procedure 2), then EPA will receive a separate report from each producing company site.

Reporting past years' production volumes: Under Procedure 1, the contracting company reports the past years' production volumes (for 2020 CDR, the past years' production volumes are 2016

² Regulatory requirement under the new chemicals program: If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice. 40 CFR 720.22(a)(2)

2018) for all of the producing companies as a total volume for each of the years.³ Under Procedure 2, each producing company reports the past years' production volume for its own site.

Alternately, the contracting company may have different agreements with different producing companies (of the same co-manufactured chemical), with some of the co-manufactured chemical reported under Procedure 1 and some under Procedure 2. However, each relationship between contracting company and producing company should use only one procedure (and not split the volume of the same chemical from the same producing company between two reports).

See [Fact Sheet: Reporting Thresholds](#) for additional information on reporting thresholds.

Different contracting companies for the same chemical

When a manufacturer enters into contracts to produce the same chemical substance for multiple different companies (either in the same year or different years during the latest reporting period), that manufacturer is not making the chemical substance exclusively for any one contracting company. Therefore, the manufacturer and the contracting company are not co-manufacturers, as defined in 40 CFR 711.3. In this situation, the manufacturer that is physically producing the chemical substance bears the whole responsibility of reporting for CDR.

Applying CDR Requirements to Specific Co-Manufacturing Scenarios⁴

- 1. ABC Company contracts with MegaCorp to manufacture 30,000 lbs of a chemical in each of the years 2018 and 2019. ABC Company specifies the chemical and the technology to manufacture the chemical, such that the companies meet the definition of "co-manufacture." The contract between the companies includes a provision that ABC Company will prepare and submit the Form U for the 2020 CDR. MegaCorp produces no other chemical substances that are reportable under CDR. What information will ABC need from MegaCorp to complete the 2020 CDR Form U report for the chemical?**

Although the contract between ABC Company (the contracting company) and MegaCorp (the producing company) specifies that ABC Company will prepare and submit the CDR Form U, there is not a provision in the CDR rule for the contracting company to report all of the required information. Therefore, in this situation ABC Company will use Procedure 1 to initiate the co-manufactured chemical report, using e-CDRweb to send an email notification to MegaCorp, as the producing manufacturer, of the need to complete its part of the co-manufacturer report. ABC Company will need information specific to MegaCorp's address and email to send the notification. On the ABC Company Form U, ABC Company will include the chemical identity, production volume, and processing and use information for the co-manufactured chemical and on the MegaCorp Form U, MegaCorp will include the production volume and other manufacturing information for the same co-manufactured chemical. Each company will submit its share of the information directly to EPA.

³ Under Procedure 1, For the past production volume, the site associated with the past reporting would be the contracting site.

⁴ Years given in these scenarios are used only as examples for the particular submission periods.

- 2. DEF Company contracted with Omega Producing Company to manufacture 50,000 lbs of a chemical in each of the years 2018 and 2019. The arrangement meets the other requirements to be considered co-manufacturing. The contract includes a provision that Omega will prepare and submit the Form U for the 2020 CDR. What information will Omega need from DEF to complete the Form U for the chemical? Omega produces no other chemical substances that are reportable under CDR.**

In this situation the two companies meet the requirements for co-manufacturing and have a contract that the producing company will complete the CDR reporting requirements. Therefore, using Procedure 2 would be appropriate, where Omega as the producing company completes the full report for the co-manufactured chemical. The DEF Company would provide to Omega the information not otherwise known to or reasonably ascertainable by Omega. Omega would need information about the specific chemical identity, if it had not already been completely disclosed, and would need information to complete the processing and use section of the Form U. Omega, as the producing company, would be using its own site and manufacturing information to complete the other sections. The technical contact could be from either company.

- 3. Company G and Yellow Company are co-manufacturers of 30,000 lbs of Chemical Y, produced at Yellow Company's site. Yellow Company also produces Chemical X and Chemical Z, both CDR reportable chemical substances, in volumes of 100,000 lbs and 75,000 lbs, respectively. What are the options for reporting Chemical Y?**

In this situation the companies could agree to report using either Procedure 1 or 2 of the reporting methodology for co-manufacturers.

Procedure 1: If the co-manufacturers decide that Company G will initiate the Form U chemical report for Chemical Y, then both Company G and Yellow Company will provide information, as follows:

- Company G will initiate reporting for Chemical Y in the e-CDRweb reporting tool by sending a notification to Yellow Company asking them to report the manufacturing-related information directly to EPA. Company G will report the chemical identity, production volume, and processing and use information for Chemical Y and will identify that Yellow Company is the producing site. Company G's Form U will report its own company and site information and will include other chemical reports as necessary for its site.
- Upon receipt of the email, Yellow Company will provide the principal year production volume and other manufacturing-related information. In the same Form U but in separate chemical reports, Yellow Company will also report all information for Chemical X and Chemical Z. The form will use Yellow's company and site information.

Procedure 2: If the co-manufacturers agree in writing that Yellow Company will submit the Form U, Yellow Company would report Chemical Y, Chemical X, and Chemical Z in three separate chemical reports on its Form U. Company G would supply Yellow Company with the information not otherwise known to or reasonably ascertainable by Yellow Company (e.g., the processing and use information for Chemical Y).

- 4. Company Q contracted with Alpha Corp, a producing company, to manufacture Chemical M: 50,000 lbs in 2016, 60,000 lbs in 2017, and 10,000 lbs in 2018. Company Q also contracted with Beta Corp, a different producing company, to manufacture the same chemical (Chemical M): 60,000 lbs in 2018 and 80,000 lbs in 2019. How is this reported to the 2020 CDR? Neither Alpha Corp nor Beta Corp produce other chemical substances that are reportable under CDR.**

There are multiple options for reporting in this scenario, and Company Q will need to work with Alpha Corp and Beta Corp to ensure the reporting is done properly. The choice between Procedure 1 or Procedure 2 may depend on the contract between the contracting company and each producing company.

Using Procedure 1: Company Q will initiate the chemical report for Chemical M and will indicate that there are two producing companies, using the eCDRweb reporting tool to send separate requests for each producing company to provide the manufacturing-related information on their own Form U submissions. The companies will report as indicated in Table 4-1:

Table 4-1: Scenario 4 Reporting using Procedure 1				
CDR Data Element		Contracting Company	Producing Companies	
		Company Q	Alpha Corp	Beta Corp
Submitting a CDR report for Chemical M?		Yes	Yes	Yes
Chemical identity		Chemical M	NA	NA
Production Volume	2016	50,000 lbs	NA*	NA*
	2017	60,000 lbs	NA*	NA*
	2018	70,000 lbs	NA*	NA*
	2019	80,000 lbs	NA	80,000 lbs
Manufacturing-related Information		NA	NA	Report**
Processing and Use Information		Report	NA	NA
<p>* Under Procedure 1, the past production volume (i.e., for years 2016-2018) is reported by the contracting company.</p> <p>** The manufacturing-related information, except for the chemical identity, is only reported for the 2019 production. Because Alpha Corp did not manufacture Chemical M in 2019, Alpha Corp has no manufacturing-related information to provide other than the prior-year production volumes.</p>				

Using Procedure 2: Company Q has a contract or other written agreement with Alpha Corp and with Beta Corp that specifies that the producing companies will complete the CDR submissions for the co-manufactured chemical, Chemical M. The companies will report as indicated in Table 4-2:

Table 4-2: Scenario 4 Reporting using Procedure 2				
CDR Data Element		Contracting Company	Producing Companies	
		Company Q	Alpha Corp	Beta Corp
Submitting a CDR report for Chemical M?		No	Yes	Yes
Chemical identity		NA	Chemical M	Chemical M
Production Volume	2016	NA	50,000 lbs	0 lbs
	2017	NA	60,000 lbs	0 lbs
	2018	NA	10,000 lbs	60,000 lbs
	2019	NA	0 lbs	80,000 lbs
Manufacturing-related Information		NA	NA**	Report
Processing and Use Information		NA	NA**	Report***
<p>* Under Procedure 2, the past production volume (i.e., for years 2016-2018) is reported by the producing company.</p> <p>** The manufacturing-related and processing and use information is only reported for the 2019 production. Because Alpha Corp did not manufacture Chemical M in 2019, Alpha Corp only reports the past production volume information. Alpha has no other manufacturing-related information or processing and use information to report.</p> <p>*** Company Q will provide Beta Corp with processing and use-related information that is not known to or reasonably ascertainable by Beta Corp.</p>				

- 5. Company H contracted with Company A, whose facility is located in upstate New York, for Company A to manufacture a chemical: 40,000 lbs in 2017, 45,000 lbs in 2018, and 10,000 lbs in 2019. Company A produces no other chemicals substances that are reportable under CDR. Company H contracted with Company B, whose facility is located in Ontario, Canada, for Company B to manufacture the same chemical: 30,000 lbs in 2016 and 50,000 lbs in 2019, for shipment to the United States. How should this be reported to CDR?**

Because Company A is located in the United States and therefore could be considered a producing company, Company H and Company A would be considered co-manufacturers for the CDR rule (assuming the other requirements for a co-manufacturing relationship exists). Therefore, Company H and Company A would decide whether to use Procedure 1 or Procedure 2 for reporting the manufacture of Chemical Q at Company A's site in 2017, 2018, and 2019. Table 5-1 provides a summary using Procedure 1. Table 5-2 provides a summary using Procedure 2, which will depend on whether Company H and Company A have a written agreement specifying that Company A (the producing company) will complete the CDR submission for the co-manufactured chemical.

For Company B's Canadian site production, Company H reports Chemical Q as the importer. Because Company B's site is located outside of the United States, it is not a manufacturer subject to the CDR rule.

Table 5-1: Scenario 5 Reporting using Procedure 1					
CDR Data Element		Company H*		Company A	Company B
		Contracting	Importing	U.S. Producing	Non-U.S. Producing
Submitting a CDR report for Chemical?		Yes		Yes	No
Chemical identity		Chemical		NA	NA
Production Volume	2016	0 lbs	30,000 lbs	0 lbs	NA
	2017	40,000 lbs	0 lbs	40,000 lbs	NA
	2018	45,000 lbs	0 lbs	45,000 lbs	NA
	2019	10,000 lbs	50,000 lbs	10,000 lbs	NA
Manufacturing-related Information		NA	Yes	Yes	NA
Processing and Use Information		Yes*		NA	NA
* Company H submits one report for this chemical, indicating the amounts that are imported and the amounts that are co-manufactured. The processing and use information is reported by Company H for the total of 60,000 lbs (combining the volumes co-manufactured and imported for the principal reporting year).					

Table 5-2: Scenario 5 Reporting using Procedure 2					
CDR Data Element		Company H*		Company A	Company B
		Contracting	Importing	U.S. Producing	Non-U.S. Producing
Submitting a CDR report for Chemical?		Yes		Yes	No
Chemical identity		Chemical		Chemical	NA
Production Volume	2016	NA	30,000 lbs	0 lbs	NA
	2017	NA	0 lbs	40,000 lbs	NA
	2018	NA	0 lbs	45,000 lbs	NA
	2019	NA	50,000 lbs	10,000 lbs	NA
Manufacturing-related Information		NA	Yes	Yes	NA
Processing and Use Information		NA	Yes**	Yes**	NA
* Company H submits only production volume information about the import of this chemical. ** Company H reports the processing and use information only associated with the imported 50,000 lbs that it imported during the principal reporting year and supplies the processing and use information associated with the co-manufactured portion to Company A for the 10,000 lbs it reported during the principal reporting year, insofar as the information is known to or reasonably ascertainable by Company H.					

- 6. In 2019, TopChem contracted with four different companies to manufacture the same chemical: Company M, 10,000 lbs; Company N, 60,000 lbs; Company O, 30,000 lbs; and Company P, 1,000 lbs. What are the options for the 2020 CDR submission period?**

For purposes of CDR, a company making the same chemical for multiple customers during the reporting period (e.g., for 2020, years 2016 to 2019) does not have a co-manufacturer relationship with any of its customers, with respect to that chemical substance. This is regardless of whether or not there is a contractual arrangement between the chemical producer and the customers. In this situation, TopChem is considered the only manufacturer and it would be solely responsible for any reporting required by the CDR rule.

- 7. In 2016, Company K made 20,000 lbs of a chemical onsite, and then contracted with Producing Company W to make another 10,000 lbs of the same chemical at another site, also in 2016. This chemical is not the subject of any TSCA actions that impact the reporting threshold, therefore its reporting threshold is 25,000 lbs. In addition, there was no other manufacture of the chemical at either site in any of the years from 2016 to 2019. How is this chemical reported in the 2020 CDR submission period?**

CDR reporting is based on the production volume at a particular site. Company K's site and Producing Company W's site are two different sites. Neither site's production volume exceeded the 25,000 lbs threshold. Therefore, reporting would not be required for the 2020 CDR.

For further information:

To access copies of additional fact sheets and other CDR information, log onto www.epa.gov/cdr.

If you have questions about CDR, you can contact the TSCA Hotline by phone at 202-554-1404 or e-mail your question to eCDRweb@epa.gov.