

TSCA Chemical Data Reporting

Fact Sheet: Toll Manufacturing

This fact sheet provides information on existing Chemical Data Reporting (CDR) regulations to persons who are involved in toll 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.

How the CDR regulations apply to toll manufacturing

What is toll 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”).

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 toll manufacturers and contracting companies the co-manufacturers of a chemical substance?

The definition of “manufacture” at 40 CFR 711.3, includes toll manufacturers and at 40 CFR 711.3(2), 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. When a chemical substance, manufactured other than by import, is:

- (1) Produced exclusively for another person who contracts for such production and
- (2) That person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

EPA recognizes that there are situations where a manufacturer may have produced the same chemical for multiple contracting companies during the 2012 to 2015 time period (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”). Any required reporting of the chemical substance would be completed by the manufacturer: the entity physically producing the chemical substance.

In this information document, further references to “toll manufacturer” 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 toll manufacturer or the contracting manufacturer?

The CDR rule requires that only one report be submitted with respect to the manufacture of a reportable chemical at a site. See 40 CFR 711.22(c). Therefore, a toll manufacturer and the contracting company who are “co-manufacturers” of a chemical substance should determine among themselves who should submit the required report for the site to avoid duplicative reporting. At the same time, if neither party reports the co-manufactured chemical substance, then both the toll manufacturer and the contracting company are liable for the failure to report.

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

Regardless of whether the contracting company or the toll manufacturer files the Form U, there likely will be a need to share information. This is because certain information is more likely to be known by one party than the other. For some of the data elements, the co-manufacturers will need to decide whose company information to report.

Site: For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured (see definition of “site,” 40 CFR 711.3). Therefore, even if the contracting company and the toll manufacturer decide that the contracting company will prepare the Form U for CDR for the chemical substance that they co-manufactured, the site to be reported is still the location where the toll manufacturer physically produced the chemical substance.

Parent Company: The CDR regulations do not specify whose parent company information should be reported. EPA believes it generally makes the most sense to report the contracting company’s parent company, because it is the contracting company that specified the chemical identity and quantity. Ultimately, the decision is between the toll manufacturer and the contracting company.

Technical Contact: A different technical contact may be specified for each chemical reported (see 40 CFR 711.15(b)(2)(iii)). 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 toll manufacturing

Coordination among co-manufacturers

The CDR regulations allow the contracting company and the toll manufacturer to decide for themselves who should report, while making clear that both parties are liable if neither reports. It is up to the contracting company and the toll manufacturer to decide whether to make informal arrangements for sharing the necessary information and allocating reporting work, or whether to address these issues within the toll manufacture contract. The contracting company and the toll manufacturer 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 exemptions

Small manufacturers 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 (2015), combined with those of your parent company, domestic or foreign (if any), are less than \$4 million regardless of annual production volume.
- Your total sales during the principal reporting year (2015), combined with those of your 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 lb 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.

Difference in requirements for toll manufacturers under CDR and the PMN program

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

Different toll manufacturers for the same chemical

Under 40 CFR 711.15, reports are site-based, with a separate Form U completed for each site. And as noted earlier in this document, the CDR regulations define “site” in terms of the tolling site. See 40 CFR 711.3 (definition of “site”). Therefore, when a contracting company has used different toll manufacturers for the same chemical (either in the same year or different years during the 2012 to 2015 time period), a separate Form U would be required for each toll manufacturing site, assuming each site met the appropriate reporting volume threshold for the chemical. (See *Fact Sheet: Reporting Thresholds for 2016* for additional information on reporting thresholds for the 2016 reporting period).

Different contracting companies for the same chemical

When a manufacturer enters into contracts to produce the same chemical substance for multiple companies (either in the same year or different years during the 2012 to 2015 time 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 Toll Manufacturing Scenarios

- 1. ABC Company used MegaToll, a toll manufacturer, to manufacture 30,000 lb of Chemical K in each of the years 2013 and 2015. The toll manufacturing contract includes a provision that ABC Company will prepare and submit the Form U for the 2016 CDR. MegaToll produces no other chemical substances that are reportable under CDR. What information will ABC need from MegaToll to complete the Form U report for Chemical K?**

ABC Company would need information specific to MegaToll’s manufacturing site, including the location, number of workers potentially exposed, and other site-related information. ABC Company itself would provide information such as the chemical identity and physical form, as well as the processing and use information.

The co-manufacturers would need to determine among themselves which parent company and technical contact to include. Based on the information provided, EPA believes the ABC Company parent company and technical contact would be appropriate.

- 2. DEF Company used Omega Toll Manufacturer to manufacture 50,000 lb of Chemical J in each of the years 2014 and 2015. The toll manufacturing contract includes a provision that Omega will prepare and submit the Form U for the 2016 CDR. What information will Omega need from DEF to complete the Form U for Chemical J? Omega produces no other chemical substances that are reportable under CDR.**

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 toll manufacturer, would be using its own site and manufacturing information to complete the other sections. The co-manufacturers would need to determine among themselves what parent company and technical contact to include. Based on the information provided, EPA believes that the DEF Company parent company and technical contact would be appropriate.

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

Yellow and Company G, as co-manufacturers of Chemical Y, should determine amongst themselves which one of them will submit the Form U for Yellow's site. If the co-manufacturers decide that Yellow will submit the Form U, Yellow would report Chemical Y, Chemical X, and Chemical Z on its Form U.

If the co-manufacturers decide that Company G will submit the Form U for Chemical Y manufactured at Yellow's site, then both Company G and Yellow will submit a Form U, as follows:

- Company G will prepare a Form U using the Company G company information and the Yellow site information. This Form U will include manufacturing, processing, and use information for Chemical Y.
- Yellow will prepare a Form U using Yellow's company and site information. This Form U will include manufacturing, processing, and use information for Chemical X and Chemical Z.

- 4. Company XYZ used AlphaToll, a toll manufacturer, to manufacture 50,000 lb of Chemical Q in 2012 and 60,000 lb of Chemical Q in 2014. Company XYZ used BetaToll, a different toll manufacturer, to manufacture 70,000 of Chemical Q in 2013 and 80,000 lb of Chemical Q in 2015. How is this reported to the 2016 CDR (assuming that Company XYZ is handling the reporting for both toll manufacturers)? Neither AlphaToll or BetaToll produce other chemical substances that are reportable under CDR.**

Company XYZ would submit two reports: one report for its manufacture at AlphaToll's site and another report for its manufacture at BetaToll's site. The report for manufacture at Alpha's site would be limited to reporting total annual production volumes for 2012 and 2014, and would report zero for the 2013 and 2015 production volumes at that site. The report for manufacture at Beta's site would include total annual production volumes for 2013 and 2015 (and zero for 2012 and 2014) and would also include the additional manufacturing

and processing and use information based on the production volume for the principal reporting year of 2015.

In summary:

CDR Data Element		Site Reporting	
		AlphaToll	BetaToll
CDR reporting required?		Yes	Yes
Production Volume	2012	50,000 lbs	0 lbs
	2013	0 lbs	70,000 lbs
	2014	60,000 lbs	0 lbs
	2015	0 lbs	80,000 lbs
Manufacturing, Processing, and Use Information		NA	Report

5. **Company H contracted with Company A, whose facility is located in upstate New York, for Company A to manufacture Chemical Q in amounts of 40,000 lb in 2013 and 45,000 lb in 2014. 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 Chemical Q in amounts of 30,000 lb in 2012 and 50,000 lb in 2015, for shipment to the United States. How should this be reported to CDR?**

Company B is located outside of the United States and therefore would not be treated as a manufacturer subject to the CDR rule. In this case, Company H and Company B would not be considered co-manufacturers for the CDR rule. Instead, Company H would simply be considered the importer of Chemical Q. Company H would report as the importer of Chemical Q and the site would be the U.S. address used by Company H for the importation (See *Fact Sheet: Importers* for additional information on reporting imports under CDR). Because Chemical Q was imported in 2015, the principal reporting year (in addition to being imported in 2012), Company H would report the additional manufacturing and processing and use information based on the 2015 production volume.

Because Company A is located in the United States and therefore could be considered a toll manufacturer, Company H and Company A would be considered co-manufacturers for the CDR rule. Therefore, Company H and Company A would decide who should submit the Form U for the manufacture of Chemical Q at Company A's site in 2013 and 2014. Because the production volume of Chemical Q for 2015 at Company A's site would be zero, the additional manufacturing and processing and use data would not be reported.

- 6. For 2015, TopChem manufactured different amounts of Chemical D for four different contracting companies: Company M, 10,000 lb; Company N, 60,000 lb; Company O, 30,000 lb; and Company P, 1,000 lb. What are the options for reporting?**

For purposes of CDR, a company making the same chemical for multiple customers during the reporting period (2012-2015) does not have a 'co-manufacturer' relationship with any of its multiple 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 of Chemical D and it would be solely responsible for any reporting required by the CDR rule.

- 7. In 2012, Company K made 20,000 lb of Chemical Y and then contracted with Toll Manufacturer W to make another 10,000 lb of Chemical Y, also in 2012. The reporting threshold for Chemical Y is 25,000 lb and there was no other manufacture of Chemical Y at either site in any of the years from 2012 to 2015. How is Chemical Y reported?**

CDR reporting is based on the production volume at a particular site. Company K's site and Toll Manufacturer W's site are two different sites. Neither site's production volume exceeded the 25,000 threshold. Therefore, reporting would not be required for the 2016 CDR (unless Chemical Y is the subject of a TSCA action that would trigger the lower threshold of 2,500 pounds).

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.