Ready or Not—EPA's Final Chemical Data Reporting Rule Has Arrived

On August 16, 2011, the US Environmental Protection Agency (EPA or Agency) published its long-anticipated final rule amending the reporting requirements of the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) rule under 40 C.F.R. Part 710, and changing its name to the Chemical Data Reporting (CDR) rule.[1] The CDR rule, now codified at 40 C.F.R. Part 711, requires manufacturers and importers of certain chemical substances listed on the TSCA Chemical Substances Inventory to report information about the manufacturing, processing, and use of those chemical substances. Reporting under the CDR rule for production that occurred during calendar years 2010 and 2011 will commence February 1, 2012 and conclude June 30, 2012. Given that EPA made a number of significant changes to the IUR rule, entities that have reporting obligations must begin now to become aware of and compile information needed to meet their expanded chemical reporting obligations.

Notable Changes to the Rule

The changes to the IUR rule relate generally to the method used to determine whether a manufacturer (or importer) is subject to CDR reporting, the frequency with which CDR reports must be submitted, the method of reporting, and the type of information that must be reported.

One significant modification to the rule is the introduction of new production volume thresholds to determine whether a manufacturer is required to submit a CDR report. Previously, manufacturers were required to file an IUR report with EPA only if production volume exceeded 25,000 pounds during the principal reporting year at a particular site. Under the new CDR rule, manufacturers (including importers) are required to file a report with EPA if the production volume of a chemical substance meets or exceeds 25,000 lbs. in *any* calendar year since the last principal reporting year.[2] The new production threshold will apply to reports filed during the 2016 submission period. In the preamble to the final rule, EPA explained that the requirement to collect and analyze historical data over a multiyear period would increase the reporting burden on industry, but stated that it believed that past IUR reporting was not accurately characterizing chemical production and that a multiyear threshold is needed to capture important information.[3]

1 76 Fed. Reg. 50,816 (Aug. 16, 2011).

2 40 C.F.R. 711.8(a).

3 76 Fed. Reg. 50,837.

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Another significant amendment was made to the threshold volume at which reporting entities are required to gather and report processing and use information. EPA replaced the 300,000 lbs. threshold for processing and use information by phasing in a lower threshold triggering when processing and use information must be reported. Thus, for the 2012 submission period, companies are required to report processing and use information if they manufactured or imported 100,000 lbs. or more of a chemical substance in 2011.[4] Subsequent to the 2012 submission period, the reporting threshold for processing and use information will be further reduced to 25,000 lbs.[5]

Finally, EPA significantly reduced the reporting threshold for chemical substances that are the subject of certain TSCA rules and/or orders from 25,000 lbs. to 2,500 lbs.[6] EPA explained that receipt of up-to-date exposure and use information on these chemical substances, which are of particular interest to the Agency, will help EPA develop risk management strategies for those chemical substances and monitor compliance with existing rules.[7] EPA initially proposed to eliminate the production volume threshold entirely, which would have required manufacturers of such chemical substances to report *any* production, no matter how insignificant.[8] Upon receiving numerous comments expressing the view that such a requirement would place an untenable burden on industry without any appreciable benefit, EPA opted instead to adopt a *de minimis* production volume threshold of 2,500 lbs. EPA explained that it believes that the *de minimis* threshold will sufficiently decrease the burden on submitters, yet still provide the data the Agency needs on chemical substances of concern.[9] EPA made a number of additional changes to the rule that are important to note.

- EPA increased the reporting frequency from five years to four years, explaining that more frequent reporting is necessary because of wide fluctuations in manufacturing volume from year to year.[10]
- EPA replaced the "readily obtainable" standard used for the reporting of processing and use information with a broader "known to or reasonably ascertainable by" standard.[11] Reporting entities are thus required to report all processing and use information that is in their "possession or control" or that "a reasonable person similarly situated might be expected to possess, control, or know."[12]
- EPA amended the rules to require reporting entities to report the volume of each chemical substance produced in each of the years since the last IUR principal reporting year.[13] This requirement goes into effect after the 2012 reporting cycle (*i.e.*, for the 2016 submission period and subsequent submission periods). For the 2012 submission period, reporting entities are only required to report production volume for calendar years 2010 and 2011.[14]
- EPA implemented a new requirement that reporting entities must use its electronic reporting tool, e-CDRweb, to submit all CDR information.[15] Information on how to use the reporting tool, including a recorded webinar workshop and accompanying slides, is provided on EPA's website.[16]
- Finally, EPA amended the rule to require companies to provide upfront substantiation when asserting confidential business information (CBI) claims for processing and use data.[17] Although EPA acknowledged the burden associated with providing written explanations

4 40 C.F.R. 711.15(b).
5 *Id.*
6 40 C.F.R. 711.8(b).
7 76 Fed. Reg. at 50,840.
8 75 Fed. Reg. 49,656, 49,664 (Aug. 13, 2010).
9 76 Fed. Reg. at 50,842.
10 40 C.F.R. 711.20; 76 Fed. Reg. at 50,854.
11 40 C.F.R. 711.15(b)(4).
12 40 C.F.R. 704.3.
13 40 C.F.R. 711.15(b)(3)(iii).
14 *Id.*
15 40 C.F.R. 711.35.
16 This information is *available at* http://www.epa.gov/iur.
17 40 C.F.R. 711.30.

to support CBI claims, the Agency explained that it believes a substantiation requirement is necessary to ensure that CBI claims are carefully considered and only made for information that is truly confidential.[18]

Conclusion

The modifications to the CDR rule, which went into effect on September 15, 2011, will impose new and additional reporting burdens on manufacturers and importers of chemical substances. Companies should be aware that a number of the changes discussed above apply to the upcoming CDR filing, which is due between February 1, 2012 and June 30, 2012. Having a comprehensive understanding of how these recent changes will affect the information that entities subject to CDR are required to submit will be essential to effectively preparing reports for the 2012 submission period and to avoiding compliance problems with the Agency.

We hope that you find this brief summary helpful. If you would like more information or assistance in addressing the issues raised in this Advisory, please feel free to contact:

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18 76 Fed. Reg. at 50,853.