

WASHINGTON WATCH

Off to the Races -- CDR Reporting Begins!

By Lynn L. Bergeson

As the expression goes, it is that time of year again. Section 8 of the Toxic Substances Control Act (TSCA) requires manufacturers, including importers, to provide the U.S. Environmental Protection Agency (EPA) with information on the production and use of chemicals in commerce at four-year intervals. The last reporting cycle for the requirement, known as the Chemical Data Reporting (CDR) requirement, was in 2016, so TSCA stakeholders have been gearing up since then for the current quadrennial reporting obligation, which commenced on June 1, 2020. This column provides an overview of what is new and different since 2016.

Background

The CDR reporting obligation has been around a long time. It requires industrial chemical manufacturers to provide EPA with information on the production and use of chemicals in commerce. Under the CDR rules implementing Congress's statutory mandate, EPA collects basic, exposure-related information on the types, quantities, and uses of chemicals produced domestically or imported into the United States.

EPA takes this reporting requirement very seriously. Without question, the CDR database represents the most current and comprehensive source of basic screening-level and exposure-related information on active chemicals in commerce available to EPA. EPA uses often and relies extensively upon the data collected under the CDR rule, as do other federal and state regulatory agencies and private entities. With each passing year, the CDR database's influence grows, and the data the reporting requirement elicits become even more important.

Congress amended TSCA in 2016, and EPA has been required to revise the CDR rule several times since 2016 to reflect legislative changes. Some might regard these changes as challenging to follow (from an industry submitter perspective) and a bit of a nuisance. A more generous view is

that the many changes reflect the importance EPA places on the CDR reporting functionality. Through the data reported under the CDR rule, EPA is able to track the identities, volumes, uses, and potential exposures of chemicals in commerce. These data are critically important and provide vital metrics to EPA across a broad expanse of programmatic functions and EPA's commitment to keep the data relevant and the process efficient. EPA uses CDR data for many purposes, including to support risk screening, risk assessment, chemical prioritization, risk evaluation, and risk management functions. EPA relies upon CDR data for rulemaking purposes, and EPA often cites CDR data in a rulemaking's administrative record as a basis for taking regulatory action or declining to take such action. EPA enforcement offices rely upon CDR data to confirm alleged violations of other federal laws under EPA's purview to administer. As readers likely know well, EPA vigorously enforces CDR reporting requirements, and administrative enforcement actions brought against CDR submitters are a popular and seemingly target-rich area for enforcement activity.

Beyond EPA, state regulators and nongovernmental organizations (NGOs) rely upon CDR data for enforcement and priority-setting purposes. Industrial stakeholders, business competitors, NGOs, corporate shareholders, and others routinely scrutinize CDR data to assess a company's commitment to compliance, sustainability, and commitment to good corporate governance and to hold entities accountable.

New CDR Rule

On March 17, 2020, EPA released a new final CDR rule, well in advance of the June 1, 2020, start of the 2020 reporting cycle. The revisions are intended to lessen the burden for certain CDR reporters, improve the quality of CDR data collected, and align reporting requirements with the 2016 TSCA amendments. Importantly, EPA also extended the reporting period for CDR data submitters from September 30, 2020, to November 30, 2020, to provide additional time for the regulated community to familiarize themselves with the amendments and with an updated public version of the reporting tool. Key changes are discussed below.

Confidentiality: EPA revised the requirements for making confidentiality claims, and these changes are among the most important changes to the rule. The good news is that CDR reporting allows for the non-disclosure of certain proprietary information, and most information elements in Form U can be claimed as confidential business information (CBI). EPA is requiring manufacturers and importers to substantiate any CBI claim up front and at the time the CDR submission is made to EPA unless the claim is not required to be substantiated under TSCA Section 14(c)(2).

In addition, EPA is requiring more information to support a CBI claim. In particular, if a company claims that release of certain information could harm its competitive position, EPA is requiring specific information on how that competitive harm might arise. EPA is also seeking more information about whether information claimed as CBI might have been disclosed previously in other contexts. Amendments also include updating the substantiation questions and identifying data elements that cannot be claimed as CBI to align with the 2016 amendments. Here are some of the questions that are asked:

1. Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information and the causal relationship between the disclosure and the harmful effects.
2. To the extent your business has disclosed the information to others (both internally and externally), has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential.
3. Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.
4. Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data

sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential.

5. Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.
6. Does any of the information that you are claiming as confidential constitute a trade secret? If yes, please explain how the information you are claiming as confidential constitutes a trade secret.
7. Is the claim of confidentiality intended to last less than 10 years (see TSCA Section 14(e)(1)(B))? If yes, please indicate the number of years (between 1-10 years) or the specific date after which the claim is withdrawn.

Responding to these questions is not for the faint of heart. Entities wishing to assert CBI will need to be committed to preparing a compelling narrative in offering substantiation and to ensuring that a coherent, consistent system is created internally to enable these questions to be answered appropriately.

Use Codes: The final rule replaces certain processing and use codes (industrial function and commercial/consumer product uses) with codes based on the Organization for Economic Cooperation and Development's (OECD) functional use, product, and article use codes. The new industrial function and commercial/consumer product use codes will be codified in the Code of Federal Regulations rather than listed in guidance. Codes associated with non-TSCA uses will be folded into the overarching non-TSCA use code. Reporting using the OECD-based codes will be required during the 2020 CDR submission period for the 20 chemical substances designated in 2019 by EPA as high-priority chemicals for risk evaluation and will be required for all chemical substances during the 2024 CDR submission.

NAICS: The final rule adds the requirement to report the North American Industrial Classification System (NAICS) code(s) for the site of manufacture. The final rule also modifies the requirement to indicate whether a chemical

is removed from the waste stream and recycled, remanufactured, reprocessed, or reused. The final rule changed this requirement to require an indication of whether a chemical is removed from the waste stream and recycled only.

Voluntary Data Element: The final rule added a voluntary data element to identify the percent total production volume of a chemical substance that is considered a byproduct. EPA modified the proposed requirement by including that percent byproduct reporting be in ranges and making the reporting of the data element voluntary. The final rule implements the proposed requirement that the secondary submitter of a joint submission report the specific function of the chemical, along with the percentage of the chemical in the imported product.

Parent Company: The final rule modifies the reporting of the “parent company” to require the use of a naming convention; adds the requirement to report a foreign parent company, when applicable; and codifies reporting scenarios in a new definition for “highest-level parent company.” The final rule simplifies to some extent the reporting process by providing two reporting mechanisms for co-manufacturers by enabling a multi-reporter process for reporters separately to report directly to EPA within the e-CDRweb reporting tool.

New Exemptions: The final rule adds certain exemptions, including: for specifically identified byproducts that are recycled in a site-limited, enclosed system (which is being adopted as proposed with the addition of another chemical substance); and for byproducts that are manufactured as part of non-integral pollution control and boiler equipment (which is implemented as proposed).

Discussion

EPA’s efforts are commendable for recognizing that certain changes, such as the adoption of the OECD function codes, could result in additional burden for companies hoping to rely on codes used during the latest reporting cycle. Requiring the new OECD codes for the 20 high-priority chemicals and allowing voluntary reporting with those codes for other chemicals is a reasonable and pragmatic approach.

The adjustments in the CBI substantiation requirements will likely be the biggest and most challenging change from 2016 to 2020. As noted above, these changes require a much more disciplined approach to asserting and supporting CBI claims, and CDR Form U submitters are urged to be mindful of these new requirements and to be internally prepared to address them. As is always the case, the sooner reporting entities are able to get started and complete their CDR reporting obligations, the better off each will be.