EPA Proposes TSCA CDR Revisions and Update to Small Manufacturer Definition for TSCA Section 8(a)

Monday, April 15, 2019

On April 12, 2019, the U.S. Environmental Protection Agency (EPA) released a proposed rule that would amend the Toxic Substances Control Act (TSCA) Section 8(a) Chemical Data Reporting (CDR) requirements and the TSCA Section 8(a) size standards for small manufacturers. The current CDR rule requires manufacturers (including importers) of certain chemical substances listed on the TSCA Chemical Substance Inventory (TSCA Inventory) to report data on chemical manufacturing, processing, and use every four years. EPA is proposing several changes to the CDR rule to make regulatory updates to align with new statutory requirements of TSCA, improve the CDR data collected as necessary to support the implementation of TSCA, and potentially reduce the burden for certain CDR reporters. Proposed updates to the definition for small manufacturers, including a new definition for small governments, are being made in accordance with TSCA Section 8(a)(3)(C) and impact certain reporting and recordkeeping requirements for TSCA Section 8(a) rules, including CDR. EPA states that the definitions may reduce the burden on chemical manufacturers by increasing the number of manufacturers considered small. Overall, according to EPA, the regulatory modifications may better address EPA and public information needs by providing additional information that is currently not collected; improve the usability and reliability of the reported data; and ensure that data are available in a timely manner. Publication of the proposed rule in the Federal Register will begin a 60-day comment period. A prepublication version of the proposed rule is available here.

Summary of Proposed Rule

EPA is proposing several amendments to the current CDR rule requirements. These amendments include:

- Changing requirements for making confidentiality claims, including to identify when upfront substantiation is required, update the substantiation questions, and identify data elements that cannot be claimed as confidential to align with the Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act);
- Replacing certain processing and use codes (industrial function and commercial/consumer product use) with codes based on the Organization for Economic Cooperation and Development’s (OECD) functional use and product and article use codes, including adding reporting of the OECD-based functional use codes for consumer and commercial use information;
- Adding the requirement to report the North American Industrial Classification System (NAICS) code(s) for the site of manufacture;
- Modifying the requirement to indicate whether a chemical is removed from the waste stream and recycled, remanufactured, reprocessed, or reused with the requirement to indicate whether a chemical is removed.
from the waste stream and recycled;

- Adding a requirement to identify the percent total production volume of a chemical substance that is a byproduct;

- Requiring that the secondary submitter of a joint submission report the chemical specific function along with the percentage of the chemical in the imported product;

- Adding a voluntary data element to provide a public contact;

- Modifying the definition of “parent company” to clarify the definition, add the requirement to report a foreign parent company, when applicable, and codify reporting scenarios;

- Simplifying the reporting process for co-manufacturers by enabling a multi-reporter process for reporters to separately report directly to EPA within the e-CDRweb reporting tool;

- Allowing reporting in specified metal categories for inorganic byproducts;

- Adding exemptions for specifically identified byproducts that are recycled in a site-limited, enclosed system and for byproducts that are manufactured as part of non-integral pollution control and boiler equipment; and

- Clarifying regulatory text by removing outdated text, consolidating exemptions, and making other improvements.

Additionally, EPA proposes to update the size standards definition for small manufacturers for reporting and recordkeeping requirements under TSCA Section 8(a).

EPA states that it is also giving notice of some aspects of the Lautenberg Act amendments that may impact, more broadly, TSCA submitters. For example, under TSCA Section 14(e)(1)(B), EPA is charged with implementing a ten year “sunset” provision for confidentiality claims. EPA states that, because the small manufacturer size standard under TSCA Section 8(a) impacts the CDR rule more than other TSCA Section 8(a) reporting rules at this time, EPA included these two actions as one proposed rule. EPA recognizes that the changes made to the small business definition will impact current and future TSCA Section 8(a) reporting rules, however, and intends to promulgate these amendments as two separate actions.

EPA states that it is taking “other, non-regulatory steps to minimize the burden on all reporters, including small entities, by improving the reporting application and database to be user-friendly and dynamic, consisting of straightforward questions that include fill-in-the-blank (number) fields, check boxes, and drop-down menus.” In addition, EPA is replacing the current preformatted Form U with a customized report based on the actual information submitted by a site through e-CDRweb, the electronic reporting tool. EPA notes that although these changes are not discussed further in the proposed rule, “they are an important component of the effort to reduce burden and modernize the data collection system.” EPA is adding an addendum to the current CDR rule Information Collection Request (ICR) (Office of Management and Budget (OMB) Control Number 2070-0162) for the regulatory changes proposed. In addition to the changes outlined in this proposed rule, if needed, EPA states that it will provide a second addendum to the ICR to address non-regulatory changes.

According to the proposed rule, as was done for previous CDR collections, EPA will provide industry with the opportunity to test and comment on the updated e-CDRweb prior to the 2020 CDR submission period. EPA states that it anticipates holding a webinar to introduce the revised e-CDRweb to the regulated community directly following promulgation of the final CDR revisions rule. During the webinar, EPA will issue a general invitation to interested parties to participate in a short testing period of the revised e-CDRweb. EPA will open the testing period within four months after issuing the final rule, and currently anticipates that testing will occur in the February to March 2020 timeframe. Because of resource constraints, the testing period will be limited to 25 participants. For additional information, contact Susan Sharkey, Chemical Control Division, Office of Pollution Prevention and Toxics, at sharkey.susan@epa.gov. EPA states that it will also post information to the CDR website.

Why EPA Is Taking This Action

According to the proposed rule, EPA is proposing revisions to the CDR rule for three primary reasons: to align with Lautenberg Act amendments to TSCA; to improve the CDR data collected as necessary to support the implementation of TSCA; and to reduce the burden for CDR reporters pursuant to TSCA Section 8(a)(5).

The Lautenberg Act amended the TSCA requirements associated with confidentiality claims, including identifying the data elements eligible for confidentiality claims and when substantiation of claims is required. EPA proposes
revisions to the CDR rule to address these changes.

EPA proposes to modify the definition for small manufacturers, as a result of the Lautenberg Act’s amendment of TSCA Section 8(a)(3)(C), which requires EPA, after consultation with the Administrator of the U.S. Small Business Administration (SBA), to review the adequacy of the standards for determining which manufacturers and processors qualify as small manufacturers and processors for purposes of TSCA Sections 8(a)(1) and 8(a)(3). EPA published a determination that revision of the TSCA Section 8(a) size standards for small manufacturers was warranted in a Federal Register notice published November 30, 2017 (82 Fed. Reg. 56824). EPA’s determination, supporting documents, and comments received can be found in Docket ID EPA-HQ-OPPT-2016-0675. This proposed change may reduce the burden for some manufacturers that would be considered small manufacturers under CDR and other TSCA Section 8(a) rules relying on the small manufacturer definition in 40 C.F.R. Part 704.3.

EPA states that it is also proposing to make some changes to the CDR data reporting so the information collected is tailored to meet better its overall information needs and align them with specific needs for prioritization and risk evaluation under TSCA Section 6. TSCA Section 2 specifies that “adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures” (TSCA Section 2(b)(1)). These proposed changes include the addition of data elements, such as a site-specific NAICS code and how much of a chemical is a byproduct; modification to multi-reporter submission requirements, including adding a process for jointly reporting co-manufactured chemicals; and changes to current data elements, such as codes used for reporting processing and use information. In addition, according to EPA, proposed changes to the parent company reporting requirements would increase EPA’s ability to protect confidential information while better enabling EPA to make information publicly available; and the addition of a voluntary public contact would direct inquiries from the public to a designated individual rather than to the technical contact. These changes would help to meet EPA’s requirement under TSCA Section 26(h), in carrying out TSCA Sections 4, 5, and 6, to make scientific decisions consistent with the best available science, improve the CDR data collected as necessary to support the implementation of TSCA, and improve EPA’s ability to provide effectively public access to the information. Furthermore, these changes would meet EPA’s objective to obtain new and updated information relating to potential exposures to a major subset of chemical substances listed on the TSCA Inventory.

EPA states that, at the same time, it is interested in reducing the burden on industry while maintaining EPA’s ability to receive the information it needs to understand exposure to these chemicals (TSCA Section 8(a)(5)). EPA used experiences from the 2016 CDR submission period, concerns identified by users of CDR information, and burden-reduction suggestions made as part of public comment opportunities, including public comments solicited in conjunction with Executive Order 13777, Enforcing the Regulatory Reform Agenda (Docket ID EPA-HQ-OA-2017-0190 and 82 Fed. Reg. 17793, April 13, 2017) and as part of the renewal of the ICR (Docket ID EPA-HQ-OPPT-2017-0648 and 83 Fed. Reg. 36928, July 31, 2018). In addition, EPA identified ways to reduce the burden specifically for manufacturers of inorganic byproducts as part of an extensive negotiated rulemaking effort, which included participation by all stakeholder groups, and subsequent public comment period in 2017 (Docket ID EPA-HQ-OPPT-2016-0597 and 82 Fed. Reg. 47423, October 12, 2017). Taking into account these experiences and stakeholder input, EPA proposes the following changes to reduce burden: the new ability to report alternatively inorganic byproducts within defined metal categories, the introduction of two new exemptions related to byproducts, a revised approach to reporting for co-manufactured chemicals, and the harmonization of function and product codes with those used by other countries.

Additionally, EPA received comments that modernizing the CDR data collection and public access to the database would reduce reporting burden and facilitate ease of use by reporters and the public (81 Fed. Reg. 90843 (Dec. 15, 2016); Docket ID EPA-HQ-OPPT-2016-0597 and Refs. 1, 2, and 3). These comments were used to develop this proposal and to inform other, non-regulatory changes that EPA plans to make to the reporting process.

**Estimated Incremental Impacts of This Action**

EPA states that it evaluated the potential costs and benefits of revising CDR reporting requirements and modifying standards for small manufacturers in CDR and other TSCA Section 8(a) reporting. Some aspects of the proposal increase the burden and cost while other aspects decrease the burden and result in cost savings. Overall, EPA estimates that the combined impact of all the proposed amendments would decrease the total burden and result in a cost savings to industry and government reporters. These analyses are briefly summarized below:

1. **CDR revisions economic impacts summary.** The proposed amendments are estimated to result in an overall net decrease in burden with associated cost savings. The estimated changes include increases in rule familiarization, compliance determination, and form completion. The future cycle burden and costs or cost savings are listed by type of change:
1. For changes to modify or add reportable data elements (e.g., processing and use codes, NAICS codes, byproduct percentage, chemical function, public contact, and parent company), the incremental burden is expected to increase by 45,000 hours with an associated cost increase of $3.5 million.

2. For changes to claiming confidentiality, the incremental burden is expected to decrease by 340 hours with an associated cost savings of $0.03 million.

3. For changes to add byproducts exemptions, the incremental burden is expected to decrease by 68,000 hours with an associated cost savings of $5.2 million.

4. For changes to implement consolidated category reporting for certain inorganic metals, the incremental burden is expected to decrease by 13,000 hours with an associated cost savings of $1.0 million.

5. For changes that affect CDR reporting eligibility (targeted to certain sites with varying reductions to the number of chemicals reported per site), the incremental burden is expected to result in a net decrease by 81,000 hours with associated cost savings at $6.3 million. There are increases in burden and costs for several requirements, such as the need to assess whether exemptions apply (compliance determination) and the need to familiarize oneself with modifications to the rule (rule familiarization), estimated at 3,000 hours with an associated cost of $0.24 million. The changes to form completion in the aggregate, however, are estimated to result in an overall net decrease in burden and cost savings due to decreases in the number of sites reporting and/or the number of chemical reports from a site. These decreases are due to the proposed byproduct exemptions and consolidated category reporting.

In sum, EPA states that the overall incremental impacts to industry and government reporters result in a net decrease in burden and cost savings. Estimates include rule familiarization, compliance determination, and CDR form completion. Note that estimated changes to recordkeeping burden and cost are negligible and estimated at zero. An estimated 5,660 sites are expected to report during the next CDR submission period in 2020. The total incremental burden reduction and cost savings are estimated at a 36,000 hour reduction and $2.79 million cost savings. On an annualized basis using a three percent and a seven percent discount rate over a ten-year period, the annualized incremental cost savings is estimated at $0.66 million and $0.65 million per year, respectively.

2. **TSCA Section 8(a) small manufacturer definition economic impacts summary.** The proposed modified standards for small manufacturers would affect TSCA Section 8(a) rules, including CDR. These rules use the TSCA Section 8(a) small manufacturer definition to identify the entities exempted from reporting or for other reduced reporting requirements. The impact from the proposal is focused on the CDR rule and may impact whether a site is required to report or the number of chemicals a site would report. There is no measurable impact to other TSCA Section 8(a) rules either because EPA has not received any chemical reports for the rule for an extended period of time or because the rule uses a different definition that is not being changed by this proposal. According to EPA, the proposed definition results in a cost savings.

   a. **Impact of proposed small manufacturer definition.** The proposal is estimated to eliminate reporting entirely for 93 industry sites and reduce reporting by eliminating the need to report at least one chemical for additional 129 industry sites. This reduction in reporting is in addition to the sites already not reporting because they meet the current small manufacturer definition.

Under this proposed definition, incremental future cycle burden reductions and cost savings are estimated at 64,000 hours and $5.0 million, respectively, over a four-year CDR reporting cycle. On an annualized basis, using a three percent and seven percent discount rate over a ten-year period yields net annualized incremental cost savings of $1.2 million and $1.2 million per year, respectively. This proposal also includes a small government exemption.

   b. **Impact of proposed small government definition.** The following government entities report under CDR: seven municipalities, one county-level public utility district, and one tribal entity. Under the proposed small government definition, four government entities would be exempted from the need to report. The burden and cost savings associated with the exempted entities, in future reporting cycles, are included in the estimates for the proposed definition with incremental future cycle burden reduction and cost savings estimated at 500 hours and $39,000 respectively, over a four-year CDR reporting cycle.

3. **Total economic impacts summary for proposal.** The amendments in the proposed rule may affect the number of reports submitted during a submission period and the burden to prepare a report. EPA estimates that
the combined impact of all of the proposed amendments would decrease the total burden and cost to
industry associated with CDR reporting. Tables 1A and 1B in the proposed rule present the summaries of
burden and cost impacts, respectively, for the proposed CDR revisions and TSCA Section 8(a) small
manufacturer definition update. In the tables, EPA presents estimates for the CDR four-year first cycle and
the future cycle. In the first cycle, higher burdens and costs are incurred, because all reporters need to
familiarize themselves with the changes and may take longer to complete reporting activities. After the
first cycle, and for future cycles, experienced reporters (85 percent) are familiar with the changed
requirements. In addition to estimates that cover the four-year CDR cycle, Tables 1A and 1B present annual
estimates. These annual estimates are the four-year estimates divided by four. EPA acknowledges that
activities may be spread unevenly across the four years. On an annualized basis, using a three percent and
seven percent discount rate over a ten-year period yields a net annualized incremental cost savings of
$1.85 million and $1.83 million per year, respectively, for the overall proposed rule.

Commentary

As we noted in our “Forecast for U.S. Federal and International Chemical Regulatory Policy 2019” document, EPA
has made changes in the last four cycles of CDR (or its predecessor, the Inventory Update Reporting (IUR) rule).
This is the fifth set of modifications in as many reporting cycles, and the final changes will be implemented less
than a year before reporting is required in 2020. So while these proposed changes may ultimately prove helpful
to the reporting community, the reality is that regulated stakeholders will bear an increased burden in the near
future.

The exception to this will be those entities captured under the existing definition of “small business.” The current
monetary thresholds for determining small business status under CDR are $40 million in sales if the subject
chemical volume is less than or equal to 100,000 pounds; or $4 million in sales regardless of volume. EPA is
proposing to adjust the $40 million standard to $110 million and the $4 million standard to $11 million. While EPA
indicated that it considered different options for defining small businesses under CDR, we applaud the decision to
propose an approach that simply updates the numbers in the current standard, as that will make it easier for
stakeholders to understand and apply within their own businesses.

In terms of other changes proposed, while we recognize EPA’s general desire to harmonize reporting codes with
OECD, we note that one of the more challenging aspects of CDR reporting is identifying the “top ten,” the unique
three code combinations for the subject chemicals’ process or use, industry sector, and industrial function under
Form U, Part IIIA. With the proposed change to align reporting codes with OECD codes, companies cannot rely on
code combinations reported in the past. EPA also intends to add function code reporting for commercial and
consumer products under Part IIIB; these codes would also align with OECD codes. In the notice, EPA mentions
that the OECD codes are more specific than the current CDR codes. Whether this specificity will help or hinder
companies’ efforts is yet to be seen.

The notice also covers issues related to confidential business information (CBI) reporting and substantiation
requirements under amended TSCA. While EPA’s review of the CBI substantiation process expected under CDR is
not unexpected, stakeholders should take note that EPA believes the following reporting elements under CDR are
NOT eligible for CBI protection:

- Use, sector, and function of reported chemical in industrial processing;
- Whether the reported chemical is used in commercial or consumer products;
- Commercial or consumer product category for reported chemical;
- Function of chemical in commercial or consumer products; and
- Whether the reported chemical is used in children’s products.

There is also a proposal to change the current approach for joint submissions between U.S. companies and their
foreign suppliers, in which the foreign suppliers would also need to report chemical-specific function information
along with chemical composition. While a relatively minor change, we note that this would require outreach
education by U.S. entities to ensure their foreign partners appreciate this change.

Most of the remaining proposed modifications focus on reporting of byproducts that would not be exempted from
CDR. As EPA and others came to appreciate during the negotiated rulemaking efforts in 2016, the recycling of
byproducts that would otherwise be disposed of as waste cuts across many industries and is very complicated.
A one-size-fits-all approach is simply unworkable.

We applaud EPA’s consideration of exempting certain byproduct recycling processes that occur within enclosed
systems from reporting obligations. We support the concept of a petition process to request consideration of other exemptions in the future.

We appreciate the option of reporting of recycled inorganic metal byproducts by category. We note, however, that the additional stipulations for this option (reporting in weight versus volume and exclusions from category listing) may impact stakeholders’ interest.

We anticipate that EPA’s proposal to require total percentage of product volume of a reported chemical from byproduct recycling processing could be of concern to the reporting community. As noted, recycling of byproducts that would otherwise be disposed of as waste is complicated and often involves extraction of chemicals from mixtures with complex and variable components. Impacted stakeholders should consider carefully this proposed modification and provide EPA with clear and concise input as to any challenges or difficulties associated with it.

Given that the next CDR reporting cycle is coming up next year, we hope EPA staff can move quickly to issue a final rule and complete testing on the new electronic system. We also hope that this upcoming adjustment in CDR will be the last for a while, so companies can set their internal processes with the confidence that no further changes are forthcoming.

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