

Washington Watch

The New Chemical Data Reporting Rule: It's More Than You Think

The successor to the Inventory Update Reporting (IUR) Rule will pose some challenges for industry

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Chemical data reporting under the Toxic Substances Control Act (TSCA) just got a lot harder. That's because on August 16, 2011, the United States Environmental Protection Agency (US EPA) issued its final Chemical Data Reporting (CDR) Rule,¹ previously referred to as the Inventory Update Reporting (IUR) Rule.

Summary of Key Changes from Proposed Rule

When US EPA proposed revisions to the IUR Rule in 2010, it telegraphed important changes that were expected to have a significant impact on industry's reporting burdens.² Now that the final rule is in place, the extent of those changes is becoming clear. Proposed revisions to the rule were the subject of considerable debate, which helps explain the rule's long gestation period and its extensive review by the Office of Management and Budget.

While the final CDR Rule is only modestly changed from the proposed rule, certain key modifications are of particular interest to impacted entities. In particular, US EPA has decided to:

- delay until 2016 a requirement for reporting of production volumes for each of the intervening years since the last reporting cycle;
- phase in a lower reporting threshold for processing and use information (to 100,000 pounds in 2011 and 25,000 pounds in 2016); and
- specify a reporting threshold of 2,500 pounds at a site for chemicals subject to certain TSCA rules and orders (e.g., rules issued under TSCA sections 5 and 6) starting with the 2016 reporting cycle; the proposed rule would have required reporting regardless of production volume.

After a brief background discussion, major components of the CDR Rule are highlighted below, followed by a discussion of key issues of which stakeholders should be aware. **Exhibit 1** summarizes some important provisions of the final rule (highlighting differences between the reporting requirements for 2012 and those for 2016).

Background: Controversy Over TSCA Chemical Reporting

TSCA detractors have long expressed concern about the limited utility of the IUR Rule, as the reporting requirement used to be called. The rule was established pursuant to TSCA section 8, which covers information reporting. The IUR Rule historically has been US EPA's primary tool under TSCA for obtaining information on chemicals in commerce. Such information is critically important in helping the Agency achieve TSCA's core goal of ensuring that chemicals do not pose risks to human health or the environment.

Concerns about US EPA's TSCA section 8 implementation efforts reached a new pitch within the last several years, and have been among the key drivers of TSCA legislative

reform efforts. Indeed, proposed legislative revisions to TSCA section 8 have figured prominently in discussions over the past few years among TSCA stakeholders and Congressional staff.

TSCA detractors have argued that IUR reporting elements require significant revision and expansion if they are to provide US EPA with the information it needs to identify and quantify potential risks posed by chemicals in commerce. Others argued that the Agency's proposed revisions to the IUR were unworkable and would burden industrial entities unnecessarily with reporting obligations — but still would not provide US EPA with useful information.

Faced with the political reality that TSCA legislative reform is unlikely to happen any time soon, administrative efforts to rehabilitate TSCA have taken on renewed urgency. TSCA stakeholders, regardless of their position on the merits of US EPA's proposed IUR modifications, have recognized the importance of demonstrating to an increasingly concerned public that the current TSCA program is not without clout. Similarly, the Agency is interested in demonstrating that TSCA has not lost its mojo, and that it still has teeth.

Given this reality, it is unclear whether judicial review will be in the final rule's future. Industry stakeholders may be reluctant to challenge administrative efforts to modernize TSCA. These business leaders may recognize that public backlash to an industry challenge might have more negative consequences than the new reporting requirements themselves — even if industry believes those requirements to be unreasonable.

Entities Required To Report

Under the final CDR Rule, for the next submission period (2012), entities must report if they manufacture for commercial purposes (including manufacture as a byproduct or import) chemical substances that are listed on the TSCA Inventory and produced in volumes of 25,000 pounds or more at a single site during the principal reporting year (i.e., calendar year 2011).³

Potentially affected entities include chemical substance manufacturers and importers, chemical substance manufacturing and processing facilities, and chemical substance users and processors who may manufacture a byproduct chemical substance (this may affect sectors such as utilities, paper manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing).

This requirement is significant in that only one calendar year of information must be reviewed to determine if reporting is required. In contrast, for the next reporting year of 2016, manufacturers and importers are required to review production volumes for all calendar years since the last principal reporting year (thus, they will have to review data for 2012 through 2015).

Reporting Period

The 2012 submission period (during which manufacturing, processing, and use information from 2011 and production volume information from 2010 would be reported), is scheduled to occur from February 1 to June 30, 2012. Subsequent recurring submission periods will run from June 1 to September 30 at four-year intervals, beginning in 2016.⁴

What this means is that US EPA has changed the reporting frequency back to every four years from every five years. That the reporting frequency was lengthened when the

Agency last substantively modified the IUR rule in 2005 was the subject of criticism by some who argued that the frequency should not have been relaxed.⁵ The CDR Rule returns the frequency to its pre-2005 status, requiring TSCA reporting every four years instead of every five years.

Manufacturing-Related Information To Be Reported in 2012

Manufacturing-related information required to be reported for the current principal reporting year (i.e., 2011), subject to the relevant reporting threshold, includes the volume of a chemical substance used on site, the volume directly exported, and the volume recycled, remanufactured, reprocessed, or reused.

Volume Used on Site

Companies must report the volume of a chemical substance manufactured (including imported) and used at a reporting site.⁶ This replaces the requirement to indicate that a chemical substance is site-limited (i.e., not distributed for commercial purposes outside the site at which it is manufactured and processed).

US EPA states that reporting the volume used on-site “provides valuable information related to potential exposures associated with the on-site volumes, providing the Agency with better information for exposure assessments.”⁷ The Agency also states that this type of information is similar to that required for premanufacture notification (PMN).

In response to requests for clarification as to what activities would be considered “used at the reporting site,” US EPA states:

For a domestically manufactured substance, if the volume would have been considered to be site-limited, then the chemical substance is used on site. If the chemical substance is domestically manufactured, temporarily stored, and then packaged for shipment off of the site, that volume would not be considered “used at the reporting site.” For an imported substance, any use at the importing site (e.g., consumed in a reaction or cross-linked or cured in an article) would be considered “used at the reporting site.”⁸

Volume Directly Exported

Companies must report the volume of a chemical substance that is directly exported and not domestically processed or used. US EPA states that a chemical substance that “is processed in any way (e.g., combined with other chemical substances to form a mixture)” or that is sent to a distributor who then exports it, is not considered “directly exported.”⁹

Volume Recycled, Remanufactured, Reprocessed, or Reused

Despite concerns that terms such as “recycle” are not well defined and will lead to difficulties in determining reporting obligations, US EPA will require manufacturers to check a box indicating whether a chemical substance they manufactured (such as a byproduct), which might otherwise be disposed of as waste, was or is expected to be recycled.

Rather than providing a precise definition of “recycle” or related terms, the rule asks submitters to “indicate, to the extent that they know or can reasonably ascertain, whether the reported volume of the chemical substance that they manufactured, which would otherwise be disposed of as waste, was or is expected to be recycled, remanufactured,

reprocessed, or reused, as those terms are understood by the submitter.” Because the term “reworked” could be applied too broadly, US EPA removed that term from the list of recycling synonyms.¹⁰

Production Volume

In addition to the 2011 information outlined above, companies must also report production volume for calendar year 2010.¹¹

Processing and Use-Related Information To Be Reported in 2012

US EPA has made some key changes to processing and use-related information reporting requirements, as highlighted in the following paragraphs.

“Known To or Reasonably Ascertainable By” Standard

Under the old IUR Rule, submitters were required to report only processing and use information that was “readily obtainable.” Under the new rule, submitters will be required to report information that is “known to or reasonably ascertainable by” them.¹²

Lower Threshold for Reporting

For 2012 reporting, the processing and use-related information that is required to be reported includes, for the principal reporting year only (i.e., 2011), processing and use information for all reportable chemical substances manufactured in quantities of 100,000 pounds or more per site, unless otherwise exempted. This means that US EPA is amending 40 CFR section 710.52(c) to reduce the reporting threshold for processing and use information from 300,000 to 100,000 pounds per chemical substance for the 2012 reporting period.¹³

“Consumer” and “Commercial” Categories

Among the other processing and use information changes in the new rule are requirements to report:

- consumer and commercial product categories separately to distinguish between the use types;
- consumer and commercial use information using a revised list of consumer and commercial product category codes; and
- the total number of commercial workers, including “those at sites not under the submitter’s control,” that are reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use.¹⁴

US EPA states that it has imposed these requirements because it had difficulty evaluating exposures to consumers and commercial workers based on the processing and use data it obtained from the 2006 IUR reporting cycle (that data did not differentiate between these two populations).

The Agency acknowledges, however, that it received comments opposing these new requirements. According to US EPA, opponents “stated that they were too removed from the consumer and commercial uses to have a clear understanding of the uses at that level

of distinction, especially for commodity chemical substances with a large number of uses.”¹⁵ The Agency has attempted to reduce the reporting burden regarding the number of commercial workers by requiring that this information be reported only in ranges.

US EPA’s decision to add a reporting requirement for commercial workers (even in ranges) is significant and may prove particularly challenging. While some of this information may be available on the Internet, for example, there may be many cases where it is not readily obtainable. If a chemical involves a wide range of uses, a large number of potential sites, and many customers, submitters might need to expend significant amounts of time, resources, and energy to collect the information, analyze it, and report it.

In addition, it is unclear how US EPA may react if companies opt simply to rely on “worst case scenario” values that may actually distort commercial uses — and thus may be viewed by the Agency as over-reporting. In past IUR reporting, the Agency has issued penalties to companies that reported higher than actual values. The “known to or reasonably ascertainable” standard noted above thus will be particularly instructive and important to understand with respect to these reporting elements.

Chemicals Exempt from Reporting

Certain chemicals are entirely exempt from reporting under the CDR rule. These include naturally occurring substances, microorganisms, polymers, certain forms of natural gas, and water unless they are subject to another TSCA rule. Certain other chemicals are partially exempt, and submitters are required to report only identification and manufacturing information for those substances. The partially exempt chemicals are listed at 40 CFR section 711.6(b). Chemical substances that are the subject of an enforceable consent agreement are no longer exempt from reporting.¹⁶

Information To Be Reported in 2016

After 2012, subsequent reporting periods will run from June 1 to September 30. As noted, the reporting cycles will be at four-year intervals, beginning in 2016.

The method by which manufacturers and importers must determine their reporting obligations will be different in 2016 compared to 2012. As noted above, for 2012 the only applicable timeframe for determining reporting requirements is the principal reporting year (i.e., 2011). The determining factor is whether the manufacture/import volume of a chemical substance on the TSCA Inventory during that year meets or exceeds 25,000 pounds per site during the year (i.e., calendar year 2011).

For 2016 and beyond, manufacturers and importers must review production volumes for all calendar years since the last principal reporting year. The Agency states in this regard:

EPA is finalizing this change because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. . . . This can result in the production volume of a chemical substance exceeding the threshold for several years, then falling below the threshold during the CDR principal reporting year. EPA believes that using production volume reporting for all years since the last principal reporting year to determine reporting obligations will yield a much more accurate picture of the chemical substances currently in commerce, ensuring proper review under EPA’s risk

screening, assessment, and management activities and providing better information to the public.¹⁷

The Agency also is delaying implementation of certain requirements until the 2016 submission period to allow submitters time to become familiar with the new requirements. For the 2016 CDR, the determination of the need to report will be based on whether, for any calendar year since the last principal reporting year, a chemical substance was manufactured (including imported) at a site in production volumes of 25,000 pounds or greater. For any such subject chemicals, manufacturers (including importers) will be required to report the production volume for each of the years since the last principal reporting year.

In general, the reporting threshold for processing and use information will be 25,000 pounds at a single site. But the threshold will be 2,500 pounds per site for any chemical substance that is the subject of:

- a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6,
- certain TSCA orders, or
- relief that has been granted under a civil action under TSCA sections 5 or 7.¹⁸

Information Must Be Submitted Electronically

Starting with the 2012 reporting period, US EPA will require the use of its electronic reporting tool, e-CDRweb, for submitting all CDR information. The Agency hopes that requiring the use of electronic reporting will reduce data entry errors and ensure that the information is available in a timely manner.

While there has been general support for moving toward electronic reporting, issues remain unresolved. In particular, there are concerns regarding protection of data claimed as confidential business information (CBI) and the use of electronic signatures. During the comment period, US EPA responded to concerns raised about the requirement for multiple notarized signatures on the electronic signature agreement (ESA) form. The Agency has decided that it is no longer necessary to require a notarized signature as part of the ESA form.

US EPA held an information workshop and webinar on November 30, 2010, to help entities develop a better understanding of the Agency's central data exchange (CDX) registration process and the e-CDRweb electronic reporting tool. The Agency hosted another webinar on September 23, 2011 to demonstrate the e-CDRweb tool. Recordings of the workshop and webinars and summaries of questions and answers are available on the IUR website.¹⁹

Key Issues for Reporting Entities

The following paragraphs highlight some key issues for entities that are required to report under the new CDR Rule.

2011 as Principal Reporting Year

An unexpected change from the proposed rule is the inclusion of 2011 as a principal reporting year. Presumably, US EPA deemed this change necessary given the long delay in

getting the final rule issued. What may appear to be a minor adjustment, however, could prove to have a significant impact on industry.

Those companies that dutifully collected processing and use information in 2010 with the understanding that such information would be required for reporting in 2011 may have wasted their time, effort, and resources. More importantly, unless those companies continued to collect information into 2011 as a precaution (given the uncertainty about when the final rule would be issued), they now have to expend further time, effort, and resources reviewing this year's files to identify and compile 2011 processing and use information.

Timing of Reporting

US EPA has actually *shortened* the timeframe within which industry must collect and report data in 2012. Specifically, for the 2012 report, the Agency has set the reporting period as February through June. Since processing and use information is to be collected through December 31, 2011, this means that US EPA has provided only two to six months between the last day of data collection and the submission deadline.

The timeframe originally proposed in the Agency's rule (which will apply for 2016 and subsequent reporting periods) was from June to September. The end result is that industry has lost three months to prepare the first reports under the new CDR Rule.

Byproduct Reporting

Certain changes will result from US EPA's definition of (and interpretative guidance statements on) the term "byproduct." The Agency states that it is providing "additional information on byproduct reporting" because "the scope of the CDR obligation to report byproducts is not well understood by industry."²⁰ US EPA does not note, however, that the reason this issue is not clear to industry is because the Agency's explanations over the years have lacked clarity and formality — in that its reporting "policy" has been issued in fragmentary and informal guidance documents. US EPA states in the CDR Rule:

Chemical substances that are byproducts of the manufacture, processing, use, or disposal of another chemical substance or mixture, like any other manufactured chemical substances, are subject to CDR reporting if they are listed on the TSCA Inventory, are not otherwise excluded from reporting, and their manufacturer is not specifically exempted from CDR reporting requirements.²¹

The Agency's guidance on and interpretation of "byproducts" raises many issues, including possible notice and comment deficiencies under the Administrative Procedure Act. In addition, it is by no means clear whether certain byproducts should be listed on the TSCA Inventory and/or subject to CDR reporting, and whether US EPA has interpreted the controlling TSCA provisions consistently and in a way supported by a fair reading of the Act. The Agency's interpretation regarding byproduct reporting is likely to impact metals reclamation and recycling operations most significantly.

Records Review Standard

Under the final CDR Rule, the "readily obtainable" standard that applied under prior IUR reporting has been replaced by the more rigorous "known to or reasonably ascertainable by" standard. On the whole, this is not likely to have a significant impact on

larger chemical producers, which probably have been employing the new standard all along. Less experienced entities may have difficulties, however.

Additionally, certain reporting obligations pose interesting questions. For example, it is not clear what level of effort companies will be required to make in identifying the number of commercial workers who are reasonably exposed to a reported chemical. Conceivably, there could be multiple sources of information that purport to provide such data, but it is not clear what criteria apply with regard to determining data quality or integrity. An Internet search on “jobs census, janitor, US” produces, for example, more than six million hits. Using information that is “reasonably ascertainable” to fulfill this reporting obligation will prove time intensive.

Upfront CBI Substantiation

Under the final rule, entities asserting CBI claims must provide upfront substantiation of their claims.²² This requirement comes as no surprise to those who have been following the development of the new rule. Now that the rule is in place, however, it is almost certain to diminish (perhaps greatly) the number of CBI claims asserted in connection with chemical data reporting.

Of particular interest (and on a more ominous note), in the final CDR Rule the Agency “cautions submitters that they may be subject to criminal penalties under 18 U.S.C. 1001 if they knowingly and willfully make a false statement in connection with the assertion of a CBI claim.”²³ The statute cited here is not TSCA. Instead, US EPA is referencing the general, catch-all provision for fraud and false statements found at 18 U.S.C. section 1001(a).²⁴

This reference to 18 U.S.C. section 1001 is not unique. The Agency has referenced the section in other contexts. For example, penalties under this section can apply to persons who file false or misleading “affirmation of non-multinational status” forms with US EPA under Federal Insecticide, Fungicide, and Rodenticide Act section 10(g), or false or misleading statements with regard to TSCA Good Laboratory Practice (40 CFR section 792.17). Nonetheless, the inclusion of this language in the preamble to the final CDR Rule may telegraph the Agency’s intent to apply heightened scrutiny to CBI substantiation claims, perhaps as part of US EPA’s enhanced chemical transparency campaign.

What US EPA Declined To Do

The Agency chose not to proceed with a number of proposals floated in the proposed rule. These proposals included: revising or eliminating exemptions; revising or eliminating the 25,000-pound threshold for general reporting; changes in reporting to more closely parallel that required on new chemicals under TSCA section 5 (i.e., the PMN form); and expanding the reporting universe to include processors. Many in industry applaud US EPA’s decisions in this regard.

Conclusion

The final CDR Rule is an extremely important new regulation that will increase US EPA’s understanding of the volumes, uses, and exposures of chemicals in commerce — beginning with 2012 reporting and increasing with the changes that will take place in the 2016 reporting cycle and in reporting years thereafter. The increase in the Agency’s understanding is in direct proportion to the enhanced reporting burden on industry under the new rule. Whether US EPA has the resources and staff to review and evaluate the

increased information (and use it as Congress intended) is unclear. The hope is that the information will be critically reviewed and beneficially and prudently applied.

As yet another year passes without TSCA legislative reform, the CDR Rule's importance to the Agency as a critical data-gathering tool will almost certainly increase. This means that industrial operations subject to its scope must take care in analyzing the rule's application and respond in a timely and accurate way to the data and information requirements captured under the rule. US EPA can be expected to enforce the CDR Rule aggressively as a means of ensuring that the information it receives under the rule is timely submitted and is as fully reflective of chemical production, processing, and use as possible.

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Exhibit 1
Summary of Key CDR Rule Requirements

Issue	2012	2016	Citation	Comment
Reporting Periods	February 1 to June 30, 2012	June 1 to September 30, 2016 (and same timeframes in subsequent reporting years, 2020, 2024, and beyond)	To be codified at 40 CFR § 711.20	US EPA determined that reporting every five years is too infrequent and does not provide enough data to sufficiently cover the needs of the Agency or the public.
Method to Determine Whether a Manufacturer/Importer Is Subject to CDR Reporting	For 2012, reporting is required if the manufacture/import volume of a chemical substance meets or exceeds 25,000 pounds per site during the principal reporting year (2011).	Starting with 2016, reporting is required if the manufacture/import volume of a chemical substance meets or exceeds 25,000 pounds per site for any calendar year since the last principal reporting year.	US EPA is amending 40 CFR § 710.48(a), to be codified in the new 40 CFR Part 711 as 40 CFR § 711.8(a)	The Agency believes that using production volume reporting for all years since the last principal reporting year to determine reporting obligations will yield a much more accurate picture of the chemical substances currently in commerce.
Manufacturing Threshold for Chemicals Subject to Certain TSCA Rules/Orders (Sections 5, 6, 7)	For 2012, there is a 25,000-pound per site threshold for specific chemical substances that are the subject of particular TSCA rules and/or orders.	Starting with 2016, the new reporting threshold for these chemical substances is 2,500 pounds per site.	US EPA is amending 40 CFR § 710.48(a), to be codified in the new 40 CFR Part 711 as 40 CFR § 711.8(b)	This new reporting threshold is different from the proposed rule, under which reporting would have applied regardless of production volume. The Agency decided to set a <i>de minimis</i> threshold and to delay its implementation for several reasons identified by commenters (e.g., "the expense and burden of collecting the information, and difficulty in knowing whether low-concentration chemical substances are present in formulated mixtures").
Production Volume	For 2012, only report production	Starting with 2016, report	US EPA is amending 40	The requirement to report volumes for

Issue	2012	2016	Citation	Comment
Reported	volumes for calendar year 2010.	production volumes for each year since the last principal reporting year (i.e., for 2016, report for 2012, 2013, 2014, and 2015).	CFR § 710.52(c), to be codified in the new 40 CFR Part 711 as 40 CFR § 711.15(b)	multiple years had been proposed to apply since 2005, but in the final CDR Rule it applies only for 2016 and beyond.
Processing and Use Threshold	Lowered for the 2012 reporting period from 300,000 pounds per site to 100,000 pounds per site.	Starting with 2016, the reporting threshold for processing and use information will be 25,000 pounds per site.	US EPA is amending 40 CFR § 710.52(c), to be codified in the new 40 CFR Part 711 as 40 CFR § 711.15(b)	There will be no separate threshold for the reporting of processing and use information after 2012. The applicable reporting threshold will be the same as for other types of information (25,000 pounds per site).

Notes

¹ US EPA (2011, August 16). TSCA Inventory Update Reporting modifications; Chemical Data Reporting; final rule, 76 Fed. Reg. 50816-50879.

² US EPA (2010, August 13). TSCA Inventory Update Reporting modifications, proposed rule, 75 Fed. Reg. 49655-49707.

³ 76 Fed. Reg. at 50871 (cols 1-2).

⁴ Ibid. at 50877 (cols 2-3).

⁵ US EPA (2005, December 19). TSCA Inventory Update Reporting revisions; final rule, 70 Fed. Reg. 75059-75070.

⁶ 76 Fed. Reg. at 50873 (col 2)

⁷ Ibid. at 50845 (col 1).

⁸ Ibid. (col 2).

⁹ Ibid. (col 3).

¹⁰ Ibid. at 50846 (col 1).

¹¹ Ibid. at 50873 (col 2).

¹² Ibid. at 50829 (col 1).

¹³ Ibid. at 50817 (col 1).

¹⁴ Ibid. at 50828 (cols 1-2).

¹⁵ Ibid. at 50847 (col 3).

¹⁶ Ibid. at 50824 (col 1).

¹⁷ Ibid. at 50822 (col 1).

¹⁸ Ibid. at 50823 (cols 1-2).

¹⁹ See <http://www.epa.gov/iur/index.html>.

²⁰ 76 Fed. Reg. at 50832 (col 1).

²¹ Ibid. (col 2).

²² Ibid. at 50817 (col 2).

²³ Ibid. at 50830 (col 1).

²⁴ The provision reads in pertinent part:

Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully --

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.