2016 TSCA Chemical Data Reporting – Are You Prepared?

The Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) rule (40 C.F.R. Part 711) will require U.S. manufacturers and importers of certain chemical substances to report information on these substances to the U.S. Environmental Protection Agency (EPA) by September 30, 2016. Industry should be well aware of and theoretically has ample time to meet this deadline, but the 2016 CDR is more complicated, more onerous, and requires more information than the 2012 CDR. Particularly given the significant penalties for CDR noncompliance (up to $2-5,000 per chemical per site), companies should devote significant time and effort to ensuring full compliance with this requirement.

Companies should be preparing now for the CDR submission period in 2016.

- CDR reports must be submitted between June 1 and September 30, 2016.
- Companies must report if they manufactured in or imported into the U.S. at least 25,000 pounds (lbs.) of a TSCA Inventory listed substance at any one U.S. site during any one of the following calendar years - 2012, 2013, 2014, or 2015.
- Certain regulated chemicals (e.g., chemicals subject to TSCA section 5 significant new use rules (SNUR)) are subject to a lower, 2,500 lbs./year, manufacture / import volume threshold for these calendar years. ---
- CDR reports must include detailed, chemical-specific and site-specific manufacture / import and processing / use information for calendar year 2015 (the “principal reporting year”), and production volume information for each calendar year from 2012 to 2015.
- Information reported for the CDR can be claimed as TSCA confidential business information (CBI) only if “upfront” substantiation is provided.

EPA regulations governing CDR appear at 40 C.F.R. Part 711. For additional information, visit http://www.epa.gov/cdr.

The CDR Program

Since 1986, U.S. manufacturers and importers have been required to periodically submit under TSCA certain basic information on many of the now over 85,000 chemicals appearing on the TSCA Chemical Substance Inventory (Inventory). Information submitted to EPA under this reporting requirement has been used as a tool for regularly updating the Agency and the public as to potential human and environmental exposure to substances in U.S. commerce.

In 2011, EPA overhauled this reporting requirement, which was originally known as the TSCA Inventory Update Rule (IUR) rule. The new “CDR” rule ushered in significant changes to reporting requirements beginning with the first CDR submission period, which ended in August 2012. For the 2012 CDR, about 1,600 U.S. companies reported activities for about 7,700 chemicals at about 4,800 sites. The second CDR reporting period will occur between June 1 and September 30, 2016 (to recur at 4-year intervals thereafter). Given the broader time period beginning in 2016 during which chemical production can trigger CDR reporting, in the future even more companies will likely be subject to and have to report on more chemicals.

Basic Thresholds and Reporting Requirement

For the 2016 submission period, companies must report for the CDR if, at one or more U.S. sites, they manufactured in or imported into the U.S. at least 25,000 pounds (lbs.) of a reportable chemical substance during any one of the calendar years 2012, 2013, 2014, or 2015. The CDR reporting form is known as the “Form U.”
The Form U requires companies to provide a variety of information, including technical contact information, and a Chemical Abstracts (CA) Index Name and corresponding Chemical Abstracts Service (CAS) Registry Number (CASRN) (if available) for each reportable substance.

To the extent that it is known or reasonably ascertainable, the Form U requires reporting of the following information on manufacture / import activities for each reportable substance at each site:

- Volume of the substance that is manufactured or imported;
- Number of workers reasonably likely to be exposed to the substance at each site;
- Physical form(s) of the substance as it leaves the submitter's possession, along with the associated percent production volume; and
- Maximum concentration of the substance as it leaves the submitter's possession;
- Volume of a substance used on site;
- Volume of a substance that is directly exported and not domestically processed or used;
- Whether an imported substance is physically at the reporting site; and
- Whether a substance is being recycled, remanufactured, reprocessed, or reused.

For the 2016 submission period, companies must also report production volume, by substance and site, for each of the calendar years 2012, 2013, 2014, and 2015.

**Processing and Use Information**

As was the case under the 2012 CDR, companies are required under the 2016 CDR to report detailed "processing and use" information associated with downstream domestic customer facilities regardless of whether the facilities are controlled by the manufacturer or importer. For the 2012 submission period, information on processing and use activities was required only for substances manufactured or imported in quantities ≥ 100,000 lbs. in the principal reporting year. This higher threshold, however, has been eliminated such that, other than substances specifically exempted from this required as described and listed at section 711.6, this extensive processing and use information is now required for all CDR-reportable substances.

Required processing and use information includes the following:

- Type of industrial processing or use operations at downstream sites;
- Approximate number of sites and estimated number of industrial processing and use workers reasonably likely to be exposed to each substance for each combination of processing or use code and industrial function category;
- Estimated percentages of the submitter's production volume for each processing or use code and corresponding industrial function category;
- Whether the products are intended for use by children; and
- Maximum concentration of the reportable chemical substance in each commercial and consumer product category.

Processing and use information must be reported if it is "known to or reasonably ascertainable by" the manufacturer or importer. This is a considerably lower standard compared to the previous IUR requirement to report information that was "readily obtainable."

**Exemptions from CDR Reporting**

Several categories of substances are exempt from CDR - certain polymers, microorganisms, and certain natural gas streams - so long as the specific substance is not subject to certain specified TSCA actions, such as proposed or final rules issued under section 4, 5(a)(2), 5(b)(4), or 6 of TSCA (e.g., test rules, significant...
new use rules), or to orders issued pursuant to section 5(e) or 5(f). Note that substances that are subject to an enforceable consent agreement (ECA) are similarly ineligible for these exemptions, even if the CDR reporter is not a signatory to the ECA. Also, otherwise polymeric substances resulting from hydrolysis, depolymerization, or chemical modification of polymers must be reported if the hydrolysis, depolymerization, or chemical modification occurs to such an extent that the resulting product is no longer totally polymeric in structure.

Exemptions also exist for substances that are produced or imported in small quantities for research and development, substances imported as part of an "article," and substances manufactured or imported as an "impurity" or "non-isolated intermediate." Other types of substances that are described at 40 C.F.R. § 720.30(h) are also excluded from CDR.

"Byproducts" are excluded from CDR if their only commercial purpose is to be burned as a fuel, disposed as a waste, or from which component chemical substances are extracted for a commercial purpose. Note, however, that any extracted component substances are potentially reportable for CDR.

Under section 711.6, certain petroleum process streams and other specifically listed "low interest" substances are exempt from the requirement to submit processing and use information. Manufacturers and importers of partially exempt substances, however, are still required to provide the traditional information required on the Form U if the general 25,000 / 2,500 lbs. production volume threshold is exceeded. EPA has established a process for revising these "partially exempt" substance lists.

Electronic Reporting

CDR reports must be submitted electronically using e-CDRweb, EPA's free electronic reporting tool, to EPA's Central Data Exchange (CDX).

CDR Violations, Penalties

EPA can assess substantial monetary penalties (up to $25,000 per chemical per site) for failure to comply with the CDR. Violations subject to penalties include seemingly minor CDR reporting violations such as late reporting, or reporting a slightly inaccurate manufacture or import volume. Companies would be well-advised to carefully review their production / import records and their prior CDR filing before preparing and submitting the 2016 report. If non-compliance occurs, companies may be able to rely on EPA's "Audit Policy" (65 Fed. Reg. 19,618 (April 11, 2000)) to mitigate or eliminate penalties for past reporting errors or omissions, but companies should consult with legal counsel before examining past CDR compliance.

Confidentiality and Records Retention

To claim the chemical identity, site identity, or processing and use information as confidential business information (CBI), reporting companies must substantiate such CBI claims at the time of reporting. Submitters cannot claim information as CBI when it is identified as "not known to or reasonably ascertainable." CDR records must be kept for 5 years.

Small Business Exemption

Certain small manufacturers are exempt from the CDR. A company may qualify for a small business exemption from reporting if it either: (1) produces less than 100,000 lbs. of the otherwise reportable substance and has total annual sales of less than $40 million (including those sales of the parent company); or (2) has annual sales of less than $4 million regardless of production / import volume.
This exemption does not apply for any substance that is the subject of a proposed or existing rule issued under sections 4, 5(b)(4), or 6; an order in effect under section 5(e); or relief that has been granted under a civil action under sections 5 or 7.

**CDR Non-Compliance Issues**

In our experience, many factors contribute to CDR non-compliance. These can include:

- inaccurate manufacture and import volume tracking
- failure to report / file all or some reportable substances
- incorrect conclusions as to who is the "importer" of a substance
- failure to report production volume to the required two significant figures of accuracy
- nomenclature issues
- "toll" manufacturing issues
- misinterpretation of exemptions
- failure to account for reportable "byproduct" and related stream manufacture
- fractionation issues

As noted above, CDR violations are potentially eligible for EPA’s “Audit Policy,” and companies should strive to preserve their ability to use the Audit Policy to the extent possible and seek legal advice when necessary.

For further information regarding Chemical Data Reporting CDR, please contact Tom Berger (202.434.4285, berger@khlaw.com).