Toxic Substance Control Act Reform and Chemical Data Reporting Requirements: A Roadmap for TSCA CDR Compliance
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Executive Summary

The United States Environmental Protection Agency (EPA) requires every manufacturer, processor and importer to provide a snapshot of chemicals in commerce in the United States. Under the auspices of the Chemical Data Reporting (CDR) Rule, issued under the Toxic Substances Control Act (TSCA), the EPA requires companies to keep a detailed inventory of the listed substances they domestically manufacture, process or import into the United States. Under the CDR, companies are also tasked with reporting the quantities, type and method of use for each site every four years.

The June 1 to September 30, 2016 TSCA CDR reporting deadline covering the years 2012-2015 has been extended to October 31, 2016. With the reform of TSCA effected by the Frank R. Lautenberg Chemical Safety for the 21st Century Act signed into law on June 22, 2016, both new and established businesses will have increased chemical reporting requirements added to the stringent list of compliance obligations.

This white paper details the TSCA compliance requirements under the CDR Rule. It also examines changes within the recently signed 2015 TSCA Reform Bill and how they impact chemical use and reporting within domestic businesses. This piece also offers guidelines for proper filing and best practices for compiling data necessary for daily operation as well as regulatory compliance.

Introduction

Chemical manufacturers, importers and processors in the United States face a unique set of challenges. In addition to their own complex organizational issues, businesses must remain aware and compliant within the arduous domestic regulatory landscape. Evolving authority within the EPA and ongoing reforms, specifically the recently signed 2015 TSCA Reform Bill, will place ever increasing responsibilities upon chemical companies. Preparation, organization and comprehensive planning are the keys to compliance.

The TSCA Reform Bill places renewed emphasis upon the submission and compliance guidelines of the Chemical Data Reporting (CDR) requirement. With
an expanded role for the EPA and tightening regulations on businesses, accurate documentation and timely reporting has never been more vital.

TSCA compliance rests upon a foundation of sound organization, preparation and quality data collection and processing. A detailed account of a company’s operations and its chemical compounds, sources and uses is the difference between a successful report and the potential for costly penalties.

TSCA CDR requires reporting every four years; 2016 being a current reporting year. The upcoming reporting period began June 1 and remains open now until October 31, 2016. Well-prepared businesses may already have their TSCA compliance strategy in place. The rest will either need to catch up, which at this point may warrant professional TSCA services consultants, or prepare for potentially costly repercussions of noncompliance.

**TSCA Regulations and Responsibilities**

Proper CDR TSCA reporting requires active planning, preparation and continuous monitoring across your entire operation. Businesses engaged in the manufacture, import or processing of products and substances are required by the EPA to determine the levels of specific reportable chemicals and formally catalog their use. With the passage and adoption of the 2015 TSCA Reform Bill, diligence and accurate recording are even more vital as the EPA tightens toxic substance reporting requirements.

**Changes Under the TSCA Reform Bill**

The TSCA Reform Bill increases the EPA’s role in the areas of chemical monitoring, controls and risk assessment. It broadens their authority to ban chemicals and require testing on new and existing chemicals. The changes mandate businesses maintain comprehensive and accurate chemical data.

With passage of the bill, the EPA will review all chemicals currently in commercial use and update the confidential TSCA inventory. A list of high priority chemicals is being created to undergo full Safety Assessment, Safety Determination and review against current Safety Standards. The bill will require the EPA to determine a list of active chemicals in commerce and require companies to give notification
when using previously determined inactive chemicals. The EPA will also develop a new fee-based review system.

During the 2012 CDR reporting period 1,626 separate companies reported, submitting 7,674 chemicals and 4,785 filings for Form U, the EPA-required report form. The compiled data was leveraged to create the 2014 TSCA Work Plan for Chemical Assessment. This current plan has roughly 90 chemicals and will be used as the basis for determination of High-Priority substances under the TSCA Reform Bill; chemicals deemed by the EPA to be highly toxic or to which there is widespread exposure.

2016 TSCA Chemical Reporting Requirement

All chemical manufacturers, processors and importers of chemicals from outside the U.S. with total annual sales of at least $40 million are required to report under the CDR Rule unless the chemical is considered exempt. Chemical manufacturers, processors and importers of chemicals from outside the U.S. with total annual sales of <$4 million are exempt from reporting under CDR. Chemical manufacturers, processors and importers of chemicals from outside the U.S. with total annual sales of <$40 million and chemicals with volumes <100,000 pounds are exempted from reporting under CDR. Suppliers that have not released a chemical identity of a material are required to submit supporting information for the CDR. Any toll manufacturers that have not released processing information must provide supporting information as a joint submitter in addition to its own company report.

The threshold maximum for TSCA 8b listed substances not subject to a TSCA action, in place through the 2012 reporting period, will be reduced from 100,000 pounds of production volume to 25,000 pounds (or 11,340 kilograms). If you import or manufacture greater than 25,000 pounds per year, you are required to submit during the 2016 CDR reporting period. If your threshold limit is exceeded in any year of the current reporting period (i.e. 2012 through 2015), you must report the production volume in each year, not simply the year of excess. For any chemicals subject to a TSCA action in effect June 1, 2016, the threshold maximum is 2,500 pounds (or 1,134 kilograms).
In addition to volume reporting you will need to collect the additional data for the principle reporting year, which is 2015 for the current period. You will need to document how each chemical was used, how the chemical is processed and the concentration. In addition, companies will need to identify the number of workers who are potentially exposed and the anticipated duration of exposure. The industrial sector and function must be specified, as well as the typical usage of the chemical (consumer or commercial) and whether the material is, or is intended to be, a component in a product for use by children. For partially exempt chemicals, only volume reporting is required.

Reports must be filed for each legal site within your company, not simply for the company as a whole. If you maintain multiple manufacturing sites in the U.S. above the production threshold, each site must report. Sites must also report if they exceed $40 million in annual sales. Volumes only need to be reported if the material is for commercial use. You are not required to report TSCA listed substances if used for R&D. Other materials exemptions apply depending upon substance composition, usage, and physical exposure at your site and may require certification.

The burden of determining reporting levels or securing exemptions lies upon the manufacturer, importer and processor. Improper reporting or failure to comply carries significant penalties and financial risk.

Your authorized representative/official is responsible for the accuracy of your company’s information. Each submission must be complete with all claims of confidentiality validated. There are civil and criminal penalties for failing to submit or knowingly submitting incorrect reports.

The Significant New Use Rule (SNUR) section of TSCA may have a substantial impact upon your company processes. The EPA retains the discretion to determine when/if the manufacture, use or import of a chemical substance represents a “significant new use”. Upon review, the EPA may report the substance in the federal registry to limit potentially adverse exposure to, or effects from, said chemicals or prevent use outright. ("EPA Actions to Reduce Risk for New Chemicals under TSCA")
Recent SNUR activity reflects a renewed emphasis on reducing the specific environmental impact in the event of an accidental substance release. The EPA is continuing to lower the amounts of substances that are allowed to be released to water (<5 parts per billion). Any new premanufacture notice (PMN) submissions are being stringently regulated. Compliance efforts affected by SNUR activity may become a liability if not understood or addressed.

**Best Practices: Your Path to TSCA CDR Compliance**

The current TSCA CDR reporting period begins on June 1, 2016. A complete CDR Form U must be filed using e-CDR for each applicable site by October 31, 2016. The best practice is to make your business submission-ready as early as possible. It is important to develop a plan for chemical data collection wherever the requisite amounts of listed substances are commercially employed. Data for the reporting years 2012-2015 should be currently available, either on hand or at your suppliers or toll manufacturers. With multiple sites and outside entities, data takes time to locate and verify. The more time you can dedicate to the process, the more likely you are to compile a complete, correct and TSCA-compliant report.

Assign an authorized CDR official within your company to streamline CDR filings. From understanding what information is needed and knowing where and how to locate it, to a familiarity with the EPA requirements and the submission process, a practiced representative is a valuable key to your CDR compliance. You will want someone with access to necessary information and the ability to process and perform regular audits. Maintain open channels between the official and active sites regarding process, data as well as requirement updates.

Use any previously filed CDR data from your company’s manufacturing, importing or processing sites to create an informational benchmark. Even if your company has undergone developmental or organizational changes, past data is a useful roadmap of active sites, high-volume substances and commercial activity.

Create a master materials list from historical and current data. For convenient reference and CDR compliance, include each chemical identity, the Chemical Abstract Service (CAS) name and number, site locations, commercial use, and
total manufacture and import volumes. It is your obligation to determine whether any of your chemicals are subject to SNUR or other TSCA actions. Current, properly formatted information will help identify areas of potential and required action, ease the reporting process, reduce errors and minimize your company’s exposure.

Depending upon the scale of your business, required CDR data may come from multiple sources. EH&S, manufacturing and production departments will all have separate and necessary input. It is important to compile a complete internal and external inventory. Review any and all toll-manufacture agreements, and ensure their data is available, accessible and accurate. Each site must include all present reportable chemicals, including intermediates, mixture components and by-products. The EPA CDR website allows NKRA, that is, not known or reasonably ascertainable figures. The burden to file accurately lies within.

If your business manufactures as well as imports chemicals, the EPA maximum threshold is based upon a substance’s combined volume. Past filings and a master list will enable your CDR official to understand the scope of your business and your reporting requirements. Gathering and auditing information for multiple chemical and site reports requires additional time and effort. Arrange your master list to reflect each of these historical, existing and, where possible, evolving elements.

**CDR Enforcement Concerns**

It is also critical to save all documentation. The EPA requires records to be kept for five years. 2012 data must be kept until June 30, 2017 and 2016 data must be kept until September 30, 2021. It is recommended you keep documents for extended periods for reference purposes during future reporting.

The 2016 CDR follows all earlier TSCA regulations when it comes to enforcement. Failing to submit the 2016 CDR for your organization, failing to keep required records and failing to comply with an EPA audit if requested or desired is illegal. The EPA can impose civil and criminal penalties up to $37,500 for each civil or criminal violation. Not being aware of regulations or the proper reporting process is not an acceptable reason for failing to report.
SNUR Best Practices

Company officials must remain aware of the current contents of the federal registry. If involving substances vital to your processing, ongoing TSCA reform and SNUR activity could result in major disruptions, even cessation of business. When a SNUR is promulgated, you do have an option to submit comments, with the potential of having them withdrawn by the EPA. Regular audits of your site inventories and monitoring the federal registry vastly increase the chances of a successful appeal should the need arise.

Conclusion

The recently signed TSCA Reform Bill reinforces the need for thorough and accurate company-wide record keeping. The process, to include data accumulation, documentation and regular auditing, is ongoing and should become a permanent, auditable facet of your business. Diligence in a reporting year and beyond increases your company’s compliance potential as well as its internal efficiency.

For a manufacturer, importer and processor of chemical substances, diligence regarding existing and evolving law is vital to efficiency and profitability. Knowledge of the legal and regulatory landscape should be as ingrained as the intricacies of your operation. Failure to understand your processes, responsibilities and your company’s exposure can result in significant penalties.

Site inspection and diligent record keeping are key to fulfilling a company’s legal reporting requirements. The assignment of an internal or, if necessary, external expert simplifies the filing process while reducing uncertainty. But beyond chemical and material inventories, greater awareness of your operations and responsibilities puts your business on a stronger legal and operational foundation for proactive compliance.

Should you need assistance with TSCA CDR compliance, 3E Company stands ready to help. Learn more about 3E Company’s TSCA CDR services at 3ecompany.com.
About 3E Company

3E Company, a Verisk Analytics business, is a global provider of data and information services which enable companies to improve compliance with EH&S regulations and supply chain obligations through the entire lifecycle of chemicals and products. Whether you are a manufacturer, distributor or corporate user of chemical products, 3E can tailor a program specific to the compliance information and management needs of your organization. For more than 25 years we have led the industry in obtaining and managing content, offering unique insights and solutions that enable customers to reduce cost and risk while improving processes across the enterprise and throughout the supply chain.

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