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Effectively Managing Supply Chain Communications Under TSCA

By Lynn L. Bergeson

The EPA's amendments to the Toxic Substances Control Act reporting requirements have increased the need for chemical stakeholders to manage actively supply chain communications. Lynn L. Bergeson, owner and managing partner of Bergeson & Campbell P.C., explores the upsides to be realized through these communications and the perils of failing to seize them.

The Environmental Protection Agency on March 17, 2020, issued final amendments to the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) requirements. The amendments reflect a growing trend in the chemical community to compel communications among chemical stakeholders regarding chemicals produced and used in the U.S., by whom, and in what applications and quantities. The EPA's recent action relies upon broad authority under TSCA Section 8(a) to obtain such information. State authorities and supply chain partners are also seeking more granular information for any number of reasons, and the trend is not abating.

Understanding this trend is essential from a compliance perspective. Equally important, however, and often overlooked is the need to understand and manage these supply chain communications and strategically optimize the commercial interactions and exchanges of information they elicit.

The Chemical Industry Supply Chain Is Complicated

The chain includes raw material manufacturers, product formulators, toll manufacturers, distributors, retailers, and end-use customers in a wide variety of manufacturing sectors that rely

on chemicals, including automotive, electronics, consumer products, textiles, and many more. The information that must be shared is uniquely challenging and must be managed carefully.

In keeping with increasing demands over the years for more information about the chemical components to which workers are exposed and that are embedded in the products consumers purchase and use, federal and state regulators have significantly stepped up regulatory efforts to compel the disclosure of chemical component information to supply chain partners. Other initiatives urge voluntary disclosure of such information as a matter of good product stewardship and/or corporate governance, perhaps motivated in part by a desire to exert more control over the timing, optics, and content of such disclosures.

Amendments to the TSCA have significantly enhanced both the need for and the opportunities available to chemical stakeholders to manage supply chain communications smartly and in a way that offers considerable commercial value.

TSCA and Supply Chain Communications

The amended TSCA is structured in a way that requires a high degree of communication among chemical value chain partners. Even before the 2016 amendments, the EPA's implementation of the TSCA increasingly required chemical manufacturers to be more aware of how their products were being distributed, formulated, and used, and by which manufacturing sectors. TSCA Section 8 CDR obligations are a case in point.

Early on, the EPA requested fairly minimal information. Current CDR reporting requirements, and the recent amendments, are much more extensive and include chemical identity, where the chemical is produced, manufacturing information, and certain

processing and downstream user and use information.

While the legal standard that applies to providing this information is “known to or reasonably ascertainable by,” more sophisticated entities appreciate that it is in the manufacturer’s best interests to provide accurate and high-quality information, given the EPA’s reliance upon CDR information for regulatory prioritization purposes.

Revisions to TSCA Section 5 (new chemicals) have, in particular, greatly heightened the need for enhanced communication among supply chain entities. Chemical innovators today design new molecules to achieve functionalities in targeted commercial applications. The utility of a particular new chemical, and thus its commercial success, will, in part, be measured by the relative ease with which the chemical can be used in commercial settings with as few use restrictions as possible.

Since the TSCA was amended, the EPA is now required to make one of three alternative determinations under Section 5. These are the new chemical (or new use): presents an unreasonable risk (the (A) finding); information is insufficient to permit making a reasoned evaluation of the chemical’s health and environmental effects or the chemical may present an unreasonable risk or it has substantial production and exposure (the (B) finding); or the new chemical is not likely to present an unreasonable risk (the (C) finding).

If the EPA makes the (B) finding, it issues a Section 5(e) order that sets out the control measures the EPA deems necessary to protect against the unreasonable risk the EPA’s review identified.

Standard Section 5(e) provisions include some or all of the following: specific use (“use other than”) prohibitions, restrictions on consumer use, no releases to water, worker protections (impermeable gloves, respiratory controls),

limits on production volume, prohibitions on domestic production, prohibitions on formation of respirable forms (spray, dust, mist, aerosol), and recordkeeping requirements.

It is the Section 5(e) order that can be avoided entirely in some instances as a result of clear communication between the chemical innovator and the downstream processor or user prior to the submission of the premanufacture notification.

At the least, clear communication results in an order that is better tailored to the commercial realities that prevail and the issuance of which does not come as a surprise to downstream users.

Create and Curate Effective Supply Chain Communications

The amended TSCA has had a far more profound impact on the chemical community than its members appreciate. Our experience suggests that commercial behaviors and courses of conduct have been slow to adapt.

Chemical innovators may wish to consider embracing a business strategy that focuses on developing and curating a proactive supply chain communication strategy. Here are a few tips.

Identify and Prioritize Stakeholders/Suppliers

Chemical producers need to know their customers and accommodate their customers’ needs. A new chemical notice requires information from entities throughout the supply chain, and accurately portraying the conditions of use in the supply chain is critical to understanding commercially feasible regulatory controls.

The only way to elicit this information is to know your customers’ manufacturing operations, intended uses, and appetite for regulatory control.

Include EPA in Your List of Stakeholders

Chemical producers and formulators often overlook EPA as a critical supply chain stakeholder. This is a mistake. Include EPA in your business planning. Let the new chemicals staff in on important product rollouts so that both parties can anticipate the regulatory trajectory, resource needs, and/or data development requirements.

Communicate Often and Clearly

Ensuring that your customer base is aware of regulatory requirements with the products you manufacture and how those requirements can be addressed are considerations as important as the product itself. Routine, candid communications are foundational to all relationships, and commercial relationships forged by the TSCA are no exception.

[Lynn L. Bergeson](#) is owner and managing partner of Bergeson & Campbell P.C. She has earned an international reputation for her deep and expansive understanding of the TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and especially how these regulatory programs pertain to nanotechnology, industrial biotechnology, synthetic biology, and other emerging transformative technologies.