TSCA tips for European chemical stakeholders

Changes to the Toxic Substances Control Act (TSCA) occasioned by enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act have fundamentally changed the way the US Environmental Protection Agency (EPA) reviews new and assesses existing chemical substances in surprising and subtle ways. Our 26-professionals TSCA practice in Washington, D.C. has been "doing TSCA" for a very long time. We offer our European colleagues practical insights into the new law and EPA's implementation efforts. As we represent many European companies that have business interests in the U.S., our views are offered from a practical perspective.

Be familiar with new TSCA's term - Just as US stakeholders familiarized themselves in 2007 with the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, it is important to know and understand new TSCA. Yes, the new law retains core elements of old TSCA, but much has changed. Importantly, new terms, including "reasonably foreseeable," "conditions of use," and "potentially exposed or susceptible subpopulation," are now part of TSCA parlance. These terms are placeholders for new concepts, the application of which profoundly affects the commercialisation of new and existing chemicals. TSCA stakeholders, including European entities, need to be familiar with the law to understand the contextual relevance of these terms, the mischief that can arise from their application, and the real-world implications of their interpretation by EPA. Informed decision-making demands no less.

Expect new chemical review delays - New chemical review is dramatically different. This fact is catching many businesses off guard, and is equally surprising to European entities submitting new chemical notifications. Gone are the days when the 90-day clock was a reliable estimate of the time between new chemical notification and commercialisation. Europeans need to embrace the new normal -- 180 days and quite possibly longer. The best strategy is to seek expert assistance with preparing a notification carefully, thoughtfully, and strategically, and to base commercialisation plans on a conservative estimate that assumes the worst. This is not to say every notification will take an indeterminate period of time to process. Many chemical notifications are, however, proving challenging and the absence of a predictable process for commencing commercialisation will continue to confound the business community. We have written much on this topic and sponsored a one-day work shop on how best to prepare Section 5 notifications under new TSCA, the materials of which are available upon request.

Work with your supply chain - Changes in the law make it imperative that European entities work closely with their U.S. processors, distributors, and customers to ensure all parties are aligned regarding chemical uses, applications, and markets. European chemical manufacturers and the US importers of record are considered "manufacturers" for TSCA purposes and are responsible for complying with TSCA. Recent changes regarding TSCA Inventory notification, changes in what can be claimed "confidential," and new requirements regarding substantiating confidentiality claims are especially important. It is essential that foreign companies understand these changes and prepare accordingly.

Be prepared for more testing - We have stated many times that chemical data are the new currency of the 21st century. New chemical notifications need data to rebut inferences that EPA can be expected to make in its decision-making process. Data may not be available on a new substance, but submitters should identify or provide data on suitable analogs. While the chemical may ultimately be commercialised, the absence of data can result in diminished market opportunities and enhanced customer use restrictions that invite commercial complications and diminished market potential. Similarly, EPA has new authority under TSCA Section 4 unilaterally to issue testing orders compelling the development of data. Unlike REACH, under TSCA there is no specific data set that is required. It is important to understand what the key data gaps are for a new substance before embarking on testing. Certain chemical classes can be expected to invite testing orders and it is important to know what those are and who will be subject to testing before investing heavily in new products destined for U.S. commercialization.

Bottom Line

New TSCA is extremely consequential. Knowing its terms, monitoring its implementation, and strategically preparing for changes under new TSCA offer the greatest opportunity for commercial success.

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