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In-House Counsel Beware: TSCA Reform Impacts Everyone

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In-house counsel unfamiliar with the tsunami-like changes in domestic chemical management headed our way soon may wish to read this article. If you think for a second that the extensive revisions to the Toxic Substances Control Act (TSCA) expected to be enacted imminently do not impact your legal practice or your client's business operations, think again. TSCA reform impacts virtually every business sector in the United States, and will continue to do so for years to come. Here are the reasons why you should care.

TSCA Reform: What Just Happened?

The TSCA is the federal law that authorizes the U.S. Environmental Protection Agency to regulate the import, manufacture and processing of industrial chemical substances, generously defined to include just about every industrial chemical going into a manufacturing process for the manufacture of a finished good. Chemical substances are the feedstocks of manufacturing operations, quite literally the "stuff" that makes a finished good the unique and profitable commodity that enables companies to remain in business.

Historically, the EPA's implementation of the TSCA has been hampered by the lack of a clear mandate in the law to prioritize, evaluate and regulate the 62,000 plus chemicals originally grandfathered under the TSCA (and, thus, beyond the EPA's scope for precommercialization review). The TSCA also lacks clear legal authority, effectively compelling the testing of these chemical substances. This means that thousands of chemical substances used daily in as many manufacturing processes have never been assessed by the EPA under TSCA for their impacts on human health or the environment. This fact has allowed manufacturing processes to develop and complicated chemical supply chains to evolve, largely unfettered by serious EPA inquiry into whether any chemical substance used in that manufacturing process, or the ultimate finished good that emerges from it, might pose risks to human heath or the environment. This is not to suggest that any particular chemical or product into which a chemical ingredient might be formulated necessarily poses such a risk. It is to suggest, however, that the current TSCA neither invites nor rewards meaningful inquiry into exactly that question, and EPA has lacked the legal authority and, unsurprisingly, the political will to ask for it.

Similarly, the TSCA as it now reads affords chemical manufacturers and processors, their upstream suppliers and downstream customers a good deal of privacy in selecting the chemical substances used in their manufacturing operations and to maintain as confidential for many years the precise chemical identities of these selections. Under current law, those entities asserting confidential business

information (CBI) have largely done so without question, or the need for upfront substantiation of those CBI claims. The EPA is disallowed from sharing such CBI, which often consists of the precise chemical identity of a chemical substance, with state and tribal governments, health and environmental professionals and first responders.

The New TSCA and the New Normal

The rules of engagement in the chemical world as we know it are set to change dramatically and imminently. In-house counsel who may be laboring under the dangerously wrong impression that the TSCA is for "chemical producers" only and that they need not concern themselves with that "chemical law" are gravely mistaken. This misimpression is likely rooted in the largely accurate view that the current law has had its greatest (but not exclusive) impacts on chemical producers, and not on formulators, processors or finished good manufactures. After all, for the past 40 years, the objects of the EPA's affection under the TSCA have been the manufacturers of "new" chemical substances and the manufacturers of grandfathered chemical producers, largely only in the form of recordkeeping and reporting requirements. The practical impact of TSCA's narrowly focused attention on chemical producers has reinforced the perception that TSCA's reach and relevance extends only to this sector, leaving the rest of the manufacturing sector largely off the hook.

Think again. Congress passed on June 7, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act and President Obama is poised to sign the measure into law. It fundamentally revises the TSCA, greatly expands the EPA's authority, and, if stakeholders and the EPA can get its implementation right, will improve public health protection and restore much of the public's confidence in chemical safety, a regrettable victim of the TSCA's deficits. In doing so, the law shifts the burden of demonstrating chemical safety — all chemicals, old and new — to chemical manufacturers, processors and manufactures of the finished goods that contain them, away from the EPA proving the opposite. A quick run down of key provisions include:

- Mandating safety reviews for chemicals in commerce;
- Eliminating the challenging "least burdensome" requirement for assessment of chemicals in commerce, which for years prevented the EPA from taking meaningful action on chemicals in commerce;
- Establishing a health-based safety standard, and authorizing the consideration of cost in developing risk abatement measures;
- Requiring the protection of vulnerable populations, including children and pregnant women;
- Limiting the ability of entities to claim information as confidential, thus preventing disclosure, and authorizing the sharing of needed confidential information with states and first responders, as necessary, to fulfill their duties;
- Establishing judicially enforceable deadlines by which the EPA must act to implement the law;

- Preserving the role of states to regulate chemicals as balanced against the need for a clear and centralized federal chemical management law; and

- Requiring the EPA to prioritize its review of chemicals that are persistent and bioaccumulative, and that are known carcinogens and highly toxic.

How the New TSCA Will Impact Product Manufacturers

The erosion of public confidence in chemical safety has already left an indelible mark on the product manufacturing sector, particularly the consumer products market. The American public is far savvier today in making its purchasing decisions, and in supporting brands that are believed to care about human health, the environment and the goal of sustainability, and deselecting those brands that do not. The public's selection choices have been predetermined to some extent by a highly energized retailer community, keen to promote sustainability while also limiting its exposure to liability for distributing products believed potentially to cause harm.

Given this, here is what in-house counsel needs to know about how the new law works, when will these impacts will occur and how best to be prepared for them.

First, know the law. While long and detailed, nothing beats reading the original text of that which Congress has penned. Here is a link to the "enrolled bill."

Second, know which chemicals are core to the business. The new law mandates that the EPA prioritize and evaluate "high priority" chemicals according to an aggressive and judicially enforceable schedule. The EPA's Work Plan for Chemical Assessments' list of chemicals is a must-read for counsel and, if this program is unfamiliar to you, it would be helpful for you to review the EPA's TSCA Work Plan for Chemical Assessment website. EPA's review and evaluation of these chemicals, and many others determined to be "high priority," will have significant impacts on the chemicals reviewed, their uses and applications and even their availability. In-house counsel need to know which chemicals core to the business are being reviewed. Unsurprisingly, evaluations of existing chemicals will inevitably lead in some cases to chemical deselection and product reformation. As any manufacturer knows well, reformulation takes a long time, particularly for markets that must qualify formulations for use in procurement-driven markets that are highly susceptible to federal "green" purchasing mandates.

Third, reassess confidential business information claims and qualify new claims carefully. Transparency is the name of the game and the new law embraces the right-to-know mindset, which makes it harder to assert and sustain CBI, and requires claims substantiation. This process is not a gimme and will take time and resources to do it well and comprehensively. The intensely competitive nature of product manufacturing makes it all the more important to protect CBI, and counsel will need to be diligent and thoughtful in developing suitable protocols and systems to comply with the new law's mandate.

Fourth, expect more chemical testing. Even if your company is not actually conducting the testing or paying for it, your product line will not be immunized from the consequences of testing done on chemicals core to the business. In other words, if an upstream supplier is subject to robust toxicological or environmental fate testing of a chemical critical to your product line, you need to know that this testing is ongoing and anticipate the consequences of it. This could include managing the optics inspired by test results that are unexpected and may portray the product in an unfavorable light, or having to consider product reformulation in the event the supplier discontinues production or import of the test

chemical or determines your client's use is not sustainable. Under these circumstances, it will be important to assess product liability coverage and related insurance issues, among many other legal and business considerations.

Fifth, focus on the upside and seize opportunities to innovate new products to fill the inevitable chemical product deselection void. With change comes opportunity, and new products with a distinctly sustainable profile will do well under the new law. In-house counsel can be instrumental in using the new law to encourage innovation and favorable marketing that accompanies product ingredients that are more sustainable and less environmentally consequential than incumbent chemicals, and to help inspire the business benefits that derive from these actions.

Sixth, be mindful of the competitive consequences of the law's implementation. The new law requires dozens of new rules, the implications of which will be vast and consequential for domestic product manufacturers. Savvy in-house counsel appreciates that some rulemaking can be zero sum games with distinct winners and losers. Stakeholders in the rulemaking process need to begin now to think strategically and tactically about the implementation process and influence that process in ways that ensure your company's products are appropriately considered, or at least not inadvertently victimized because you have been outmaneuvered.

Seventh, be a good product steward and engage robustly in the many rulemakings that the new law requires. Implementation will take years and require dozens of rulemakings. For example, within one year of enactment (or about June of 2017), the EPA must reset the TSCA chemical Inventory. In-house counsel need to understand what this important initiative means for the business, which chemicals are essential, how these chemicals will be notified for inventory reset purposes and who will make the notifications. It is important to know which milestones are critically important to the business, and how each will impact the bottom line.

Conclusion

TSCA reform has been a work in progress for over a decade. As the TSCA has now been reformed, it is time to think strategically and prepare to engage in the many initiatives that the new law requires and the collective result of which will fundamentally revolutionize chemical management in the U.S. Smart in-house counsel will see this for what it is — a critically important business challenge and opportunity that requires counsel to take stock in your client's manufacturing processes, to critically assess your client's product lines' chemical feedstocks, to prepare for the impacts of the new law and to seize opportunities for change by innovating in ways that improve product safety and your client's bottom line.

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