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Chemical Industry: Significant Changes to Toxic Substances Control Act (TSCA) Require Attention

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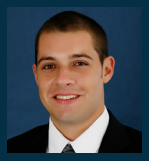

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On June 22, 2016, President Barack Obama signed into law, effective immediately, the first substantive amendments to the Toxic Substances Control Act (TSCA) since it was enacted forty years ago. The new public law, known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, gives the U.S. Environmental Protection Agency (EPA) broader authority to regulate new and existing chemicals in U.S. commerce to better protect human health and the environment. The amendments impose fundamental changes to TSCA; therefore it is important that all companies that manufacture, use, process, import, export or sell products containing covered substances become familiar with TSCA's new provisions and ensure tracking of EPA developments and promulgation of new and/or revised regulations to satisfy the mandates of the TSCA amendments.

The Toxic Substances Control Act

TSCA, originally passed in 1976, is the federal law that affords EPA broad authority to regulate chemical substances. 15 U.S.C. §§ 2610 *et seq.* Under TSCA, EPA is authorized to require the generation of data, review new chemical substances before commercialization, and regulate existing chemical substances for which EPA identifies risks to the environment and human health.

The first TSCA Inventory, a list of chemical substances in U.S. commerce, was published in 1979. With the original list, EPA grandfathered approximately 62,000 chemicals already in U.S. commerce and did not subject the 62,000 grandfathered substances to EPA's requirements for safety assessment. Since then, EPA has reviewed approximately 22,000 chemicals through the Premanufacture Notice (PMN) process for new chemicals, and the current TSCA Inventory lists more than 84,000 chemicals allowed in U.S. commerce (in some cases, with restrictions). Approximately 68,000 of these chemicals are listed on EPA's publicly-available TSCA Inventory. The remaining chemicals are listed separately on a confidential portion of the TSCA Inventory.

Until now, EPA has faced difficulties regulating existing chemicals under TSCA's authority. For example, EPA was unable to use TSCA to impose controls over asbestos after the Fifth Circuit Court of Appeals overturned EPA's ban on the substance in 1991. Similarly, although EPA was able to review and restrict chemicals in existence at the time the first TSCA Inventory was published, EPA had no direct charge (or resources) to do so and has only addressed a

handful of existing chemicals over the past 40 years. These are but a few of the scenarios used by legislators to spur TSCA reform to better protect human health and the environment. The reforms focus on regulating chemicals based on their impact to health and safety alone, with less consideration on the costs to industry, the burden of which will primarily fall on manufacturers and importers.

Congress has imposed multiple deadlines for EPA to complete its rulemaking processes, and many deadlines are within one or two years from the date of the law's enactment. Additionally, EPA is now required to submit a report every five years, beginning in December 2016, on resources needed to conduct risk evaluations and issue additional rules to address unreasonable risks. EPA must also report its anticipated schedules for accommodating the demand for risk assessments.

TSCA Title I is organized into 31 sections and this Environmental Client Alert briefly outlines the significant changes in several critical TSCA sections.

Testing of Chemical Substances and Mixtures (TSCA Section 4)

The revised TSCA continues to provide EPA with broad authority to require testing of *new* chemicals, and now supplements similar authority for testing *existing* chemicals, if EPA has a reasonable basis for concern about the chemical. EPA maintains the authority to issue rules requiring testing and received expanded authority to alternatively require such testing via orders or consent agreements. To impose a testing requirement, EPA must show that the findings of the desired testing do not currently exist, and that requiring new testing is the only way to acquire that information. This means manufacturers and importers may be subject to more frequent and costly testing because of EPA's increased authority.

Manufacturing and Processing Notices (TSCA Section 5)

In contrast to the prior framework, the revised TSCA requires EPA to make an *affirmative* finding about the level of risk imposed by a new chemical before its commercialization. EPA is required to make such determinations within 90 days of receipt of a PMN (or up to 180 days with extensions). This is a significant change from the original TSCA, which allowed commercial manufacturing or imports to begin by default if EPA took no explicit action within 90 days from date of submittal, although mutually agreed upon extensions were, and may continue to be, common under the prior TSCA timelines. The new law effectively resets the 90-day timeline for PMNs that were in process at the time the bill was signed into law.

Companies with ongoing PMN reviews should confirm their new PMN review periods with EPA. Manufacturers and importers planning to introduce new chemicals into the market should be aware that they will now need explicit EPA approval before any commercialization of chemicals in the United States.

Prioritization, Risk Evaluation and Regulation (TSCA Section 6)

The new TSCA fundamentally changes the regulation of chemicals by providing EPA with a clear mandate to conduct safety reviews of existing chemicals in U.S. commerce. The prioritization process is organized into two phases: (1) risk evaluation; and (2) risk management.

Within one year of the law's enactment (June 2017), EPA is required to establish a rule for its prioritization process -- identifying chemicals as either high-priority or low-priority -- and a rule for its risk evaluation process, assessing the risk of identified high-priority chemicals.

During the risk evaluation phase, EPA must use a health-based standard and must not consider cost or other non-risk factors. The revised TSCA also imposes a requirement that EPA explicitly protect potentially exposed or susceptible subpopulations, such as children and pregnant women. If the chemical under review indicates an unreasonable risk of injury to human health or the environment, EPA must consider it as "high-priority" and must turn to the second phase: risk management.

During the risk management phase, EPA must determine the appropriate method for managing the chemical, ranging from minimum labeling or notice requirements to an outright ban. EPA must consider the effects of the chemical on human health and the environment, the chemical's benefits and economic consequences of the regulation.

EPA must publish a list of ten high priority substances drawn from the 2014 "TSCA Work Plan for Chemicals Assessment," and must formally initiate risk evaluations on those chemicals within 180 days after enactment (December 2016). Subsequently, EPA must publish within six months of the risk evaluation (June 2017) the scope of each assessment, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider.

Reporting and Retention of Information (TSCA Section 8)

Approximately 84,000 chemicals are currently listed in TSCA Inventory, of which many are no longer used in U.S. commerce. In an effort to condense the inventory to pertinent chemicals, EPA must propose a rule charting a "reset" of the existing TSCA Inventory within one year after enactment (June 2017). The inventory reset will require manufacturers, importers and processors to provide EPA notifications as to which chemicals have been used in U.S. commerce in the past decade. Results will be used to designate active and inactive chemicals on the TSCA Inventory of existing chemicals. EPA will then focus its required risk assessment efforts exclusively on active chemicals.

Relation to Other Federal Laws (TSCA Section 9)

The revised TSCA clarifies the state-federal relationship regarding the regulation of chemicals. As a general rule, Congress prohibits states from establishing or continuing to enforce state statutes and/or regulations if EPA has taken a final action on a specific chemical. The prohibition applies if the state law or regulation: (1) restricts a chemical after EPA has determined that a chemical does not present an unreasonable risk to human health or the environment, or after EPA has published a risk management regulation; (2) duplicates information requirements under certain provisions of TSCA; or (3) subjects a chemical to the same notification of use already established by TSCA.

There are multiple exceptions to the general preemption rule. For example, the revised TSCA grandfathers states' actions taken before April 22, 2016, as well as any action taken pursuant to a state law that was in effect as of August 31, 2003. The regulated community should

be aware of the new preemption provisions, review relevant state laws and regulations and examine the exceptions allowed under TSCA.

Confidential Information (TSCA Section 11)

The TSCA amendments also alter the process for the handling of Confidential Business Information (CBI). Companies seeking to maintain the confidentiality of a chemical substance must submit a notice to EPA substantiating the confidentiality of the substance. Absent such a notice, chemical substances are placed in a non-confidential portion of the TSCA Inventory after a PMN for the substance is approved. Under the revised TSCA, EPA must now evaluate whether chemicals on the existing confidential portion of the TSCA Inventory legitimately require continued CBI protection or whether they can (or should) be placed on the non-confidential portion.

EPA is required to finalize a CBI Review/Substantiation rule within one year after publication of the inventory reset of active chemicals (expected no later than June 2018). The regulated community should be mindful that current claims of confidentiality may "sunset," meaning that claims of confidentiality will eventually expire absent re-substantiation. Companies should track EPA's rulemaking to ensure they are aware of additional deadlines that the CBI Review/Substantiation rule may establish requiring re-substantiation of such claims.

Increased Fees (TSCA Section 26) & Penalties (TSCA Section 16)

The revised TSCA establishes the "TSCA Service Fee Fund" as part of the U.S. Treasury. The fund will consist of fees that EPA collects from the regulated community to defray a portion of EPA's costs of complying with the law. The amendments eliminated the $2,500 per-company cap and mandate that the fees must be "sufficient and not more than reasonably necessary" to defray the costs incurred by EPA to administer the law with respect to the particular substance under review.

EPA must structure the fees so that the new fund will be able to defray an annual cost of $25 million or 25 percent of EPA's costs in administering TSCA sections 4, 5 and 6, whichever is less. To meet this TSCA requirement, it is not surprising that EPA is expected to increase the financial burden on the chemical industry, including increasing fees beyond the prior $2,500 limit, specifically requiring regulated persons to pay the full cost of their substance's risk evaluation. Congress authorized EPA to create a rule to require additional fees, but did not set a firm deadline to do so. EPA has confirmed that it is nevertheless working to develop a revised fee structure to be effective by June 2017.

Furthermore, the revised TSCA increases the statutory civil penalties from $25,000 to $37,500 per day for each violation. Similarly, statutory criminal penalties are increased from $25,000 to $50,000 per day, per violation. In cases where a violation is willful and knowing, and imposes an imminent danger of death or serious bodily injury, EPA prescribes a fee of $250,000 or imprisonment of up to 15 years (or both). An organization that commits such violations can be subject to up to $1,000,000 for each violation.

Rulemaking Timeframe Under the Revised TSCA

- Month One: EPA will continue to assess hundreds of "in process" PMNs that were submitted before the new law was ratified. The review period for such PMNs will be reset for a new 90-day period. In addition, EPA is prioritizing the risk of existing chemicals (into high-risk or low-risk categories), as well as assessing claims of CBI.
- Year One: EPA will engage in internal policymaking, public rulemaking pursuant to delineated deadlines and adjusting its regulations, procedures and fees pursuant to the revised TSCA.
- Year Five and Beyond: EPA will complete the initial risk evaluation of new and existing chemicals, and will have in place new regulatory procedures with guidance developed based on industry feedback. The full-scale risk evaluation and risk management efforts are expected to take over ten years, given sheer volume, expected EPA resource limitations, and mandated timelines imposed by Congress.

For more details on EPA's current implementation plan, please visit EPA's website: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-2

Conclusion

The 2016 TSCA amendments portend the most significant change to EPA's regulation of chemical substances in commerce in four decades. To remain in compliance, the regulated community of chemical manufacturers, importers, distributors, and employers should take the time to review the new law and work with knowledgeable legal professionals who will aid them in adjusting to the amended statute and EPA's regulatory changes as they are promulgated over the next decade.

Questions or Information:

For further information and/or to discuss how these issues may impact you or your clients, please contact: Andrew N. Davis at (860) 251-5839 or adavis@goodwin.com, Matthew Ranelli at (860) 251-5748 or mranelli@goodwin.com, or Alfredo G. Fernandez at (860) 251-5353 or afernandez@goodwin.com. The authors acknowledge 2016 Summer Associate Martha R. Adams (University of Connecticut School of Law) for her valuable research and assistance in developing this Environmental Client Alert.

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