KING & SPALDING

Client Alert

Environmental, Health & Safety Practice Group

June 23, 2016

Toxic Substances Control Act Overhauled
Chemical Risk Regulation in the U.S. Joins the 21st Century

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Act). Passed with significant bipartisan support, the Act is the first major update to a federal environmental statute in more than 20 years and the first update ever for the Toxic Substances Control Act (TSCA) of 1976.[1] This Alert provides an overview of the new law, and forthcoming alerts will dive deeper into aspects of the Act, including potential impacts to specific industries and implementation considerations.

TSCA is the federal statute that governs the manufacturing, import, and processing of virtually every chemical substance that is, or is used to make, a finished product. The new requirements of the Act will impact U.S. businesses in nearly every sector of the economy – including energy, consumer products, plastics, pharmaceuticals and medical devices, and chemicals. Even companies not directly required to report, test, or restrict substances under the Act will see effects throughout their supply chain. As the *Washington Post* emphasized – "The president just signed a law that affects nearly every product you use."[2]

Background

As originally enacted, TSCA required the Environmental Protection Agency (EPA) to evaluate the safety of new chemical substances introduced into commerce. But the statute gave roughly 65,000 substances the status of "existing chemicals," which exempted them from these safety reviews, unless and until EPA could demonstrate that a chemical presented an "unreasonable risk," and even then, EPA could impose only the "least burdensome" restrictions. Judicial interpretations of these terms created a high bar for the Agency to overcome, effectively thwarting EPA's efforts to regulate existing chemicals for more than 25 years. Irritated with federal inaction, several states enacted their own chemical regulation regimes, requiring companies to manage a complex and sometimes inconsistent array of requirements. The new law provides a compromise that satisfies, enough to achieve passage, both the desire of companies to have nationwide standards and the objective of environmental organizations to have stronger chemical safety rules.[3]

Significant Revisions

As discussed further below, significant revisions to TSCA in the Act focus on evaluating risks of existing chemicals, testing, preemption of state laws and regulations, and protections for (or disclosure of) confidential information.

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Evaluating Risks of Existing Chemicals

The law grants EPA new authority to assess and manage the risk of existing chemicals. Within one year, EPA must create a risk-based screening process designate existing chemicals as either high or low priority. High priority chemicals are those that "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation."[4] Low priority chemicals are those that do not meet the standard for a high priority designation. EPA may not consider costs or other non-risk factors in the risk assessment decision, and EPA is no longer constrained to use the "least burdensome" mechanisms to reduce risk.

Designating a chemical as high priority triggers a new risk evaluation process.[5] Shortly after initiating this risk evaluation process, EPA must publish the "scope" of its intended risk evaluation.[6] EPA will review whether a chemical substance "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation [by EPA], under the conditions of use." If EPA answers this inquiry in the affirmative, it must impose prohibitions or restrictions to manage the risk, such as production limits, end use restrictions, or other limitations. While EPA may not consider cost in making the "unreasonable risk" determination, it may consider costs in selecting the risk management mechanisms for any substance determined to present an unreasonable risk. EPA may also exempt specific uses from risk management requirements if they are critical or essential uses, or if the risk management requirements would significantly disrupt the national economy, national security, or critical infrastructure.[7] EPA then has up to three years to complete the evaluation.

The Act also establishes a timeline for at least the first phases of the new program for existing chemicals. Within the next 180 days, EPA must launch evaluations for at least 10 substances on EPA's TSCA Workplan 2014 Update list (Workplan List).[8] Moreover, no later than January 2020 (3.5 years after the Act's enactment), EPA must have started risk evaluations for at least 20 high priority chemicals, and it must have designated at least 20 chemicals as "low priority." At least half of the chemicals evaluated in this initial stage must be drawn from the Workplan List. The Act's timetable also extends past these initial phases, because when EPA completes a risk management rule for a high priority chemical, EPA must then designate another high priority chemical, thus starting another cycle of evaluation.

Testing

As originally enacted, TSCA provided limited authority for EPA to mandate testing of chemicals by manufacturers (including importers) and processors. Under the new law, EPA can require testing of a chemical when it conducts a risk evaluation. In addition to rulemaking, the new law clarifies that EPA has the authority to enter into a consent agreement or order with manufacturers (including importers) and processors to conduct testing.

Preemption of State Laws and Regulations

As revised, TSCA now preempts state regulation of chemicals when either of two events occurs. For chemicals determined to satisfy TSCA's safety standard, preemption begins on the date that EPA issues its determination. For chemicals that EPA determines do not meet TSCA's safety standard, preemption begins on the effective date of EPA's rule prohibiting or restricting the chemical's use. Also, while EPA is conducting a risk evaluation, states may not initiate legislation or rules that would impose restrictions within the scope of EPA's evaluation. This "moratorium" or "pause" lasts until the earlier of EPA completing its evaluation the expiration of EPA's three-year period for completing the evaluation. A caveat on preemption (and it is a big one) State laws enacted before April 22, 2016, actions under State laws in effect on August 31, 2003, and common law tort claims are *not preempted*. This was perhaps the most important compromise necessary to gain bipartisan support for the Act. It is intended to reward those states with

existing programs, particularly California's Proposition 65. States may also adopt provisions identical to EPA rules or seek a waiver of the preemption provision.

Other Provisions of Note

Definitions – The Act adds two key terms "conditions of use" and "potentially exposed or susceptible subpopulation" that will factor into any EPA review. Intended "conditions of use" are "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of"[9] and must be considered in the risk evaluation. A "potentially exposed or susceptible subpopulation" is "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly,"[10] and EPA cannot conclude that a substance does not present an unreasonable risk based on its general exposure if it would present an unreasonable risk to any such subpopulation.

Testing Methods – The Act directs EPA to focus on testing methods that reduce and replace the use of vertebrate animals. Within the next two years, EPA must develop a strategic plan to promote the development of alternative test methods, and within five years (and after each subsequent five year period), EPA must report to Congress on its progress in implementing the strategic plan, as well as goals for future alternative test methods and strategies.

Safer Chemicals – The Act does not require businesses to substitute safer chemicals, which was a significant "win" for businesses in the legislative process. However, it does require EPA to take into consideration in setting risk management measures whether "technically and economically feasible alternatives" that benefit the environment are "reasonably available as a substitute."

Confidential Business Information (CBI) – As originally enacted, TSCA allowed fairly generous CBI claims for chemical identities and other information submitted to EPA. The Act substantially reduces the extent of CBI coverage, requiring upfront substantiation of any claim and renewal of CBI claim substantiation every ten years.

The "Inventory" – The Act requires EPA to designate all chemicals on the TSCA Inventory of chemicals in commerce as either active or inactive. Within one year, EPA must require manufacturers (including importers) and processors to identify all Inventory substances that they have manufactured, imported, or processed in the past ten years. EPA will then designate all such identified chemicals as "active" and deem all other substances on the Inventory as "inactive".

Articles – The Act grants EPA authority to regulate articles. However, if EPA regulates articles due to substances they contain, restrictions must be only as stringent as necessary to address the unreasonable risk of the article.

Fees – The new law authorizes EPA to impose fees on manufacturers (including importers) and processors to defray the cost of the risk evaluation, testing, and CBI programs.

Public Participation – The rules mandated under the Act will provide stakeholders with regular opportunities to weigh in on EPA's actions. Moreover, the determination that a chemical does not present an unreasonable risk and the promulgation of risk management rules are final agency actions subject to judicial review.[11]

Persistent, Bioaccumulative, and Toxic (PBT) Chemicals – If, by June 2019 (three years after the Act's enactment), EPA has not addressed PBT chemicals on the Workplan List that meet certain exposure and severity thresholds, EPA must propose rules to mitigate the risks of all such substances.[12]

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The programs and requirements established by the Act will undoubtedly face various challenges in implementation. The timing and scope of both the expected and unexpected impacts to businesses will vary, in part because of EPA's efforts

and priorities. King & Spalding's Environmental, Health & Safety Practice is ready to help. We have represented clients in TSCA compliance and enforcement matters for roughly twenty years, including risk assessments and other analysis of thousands of chemicals and products, and we are actively assisting clients in understanding the implications of the revised TSCA and developing strategies for managing its impacts on their businesses.

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[1] 15 U.S.C. § 2601 et seq.
[2] *Washington Post* (June 22, 2012).
[3] As many know, such compromise is rare. According to Congress.gov, less than two percent of the 9524 bills introduced in the 114th Congress have been enacted.
[4] TSCA Section 6(b)(1).
[5] Risk evaluations may also be requested by manufacturers, although the requesting party must pay for the evaluation.
[6] Substances on the TSCA Workplan list are presumed to be high priority.
[7] EPA must set a case-by-case time limit for exempted uses (renewable if a new justification is presented) and must include conditions to protect health and the environment from the exempted use.
[8] The Workplan List includes many substances widely used in finished products, including many phthalates, styrene, acetaldehyde, acrylonitrile, benzene, 1,3-butadiene, various pigments, 1,4-dioxane, formaldehyde, long- and medium-chain chlorinated paraffins, naphthalene, nonylphenol, xylenes, and a range of metals and metallic compounds.
[9] TSCA Section 3(4).
[10] TSCA Section 3(12).
[11] TSCA Section 6(i).
[12] TSCA Section 6(h). In doing so, EPA does not need to undertake a risk evaluation, but must presume that the PBT substances present an unreasonable risk. *Id.*