President Obama Signs Landmark TSCA Reform Legislation into Law

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On June 22, 2016, President Barack Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Chemical Safety Act). The landmark legislation was the first substantive update of the Toxic Substances Control Act (TSCA) since it was passed 40 years ago in 1976. The revision received bipartisan support in both houses of Congress; passing by a 403-12 margin in the U.S. House on May 24, 2016 and by a unanimous voice vote in the U.S. Senate on June 7, 2016.

The Chemical Safety Act was passed in order to address many of the widely acknowledged deficiencies of TSCA. Historically, EPA’s implementation of TSCA has been hampered by the lack of a clear mandate or authority to test and regulate chemicals. Since TSCA’s enactment, EPA has required testing on approximately 200 of the 84,000 chemical substances in TSCA’s inventory. When EPA did seek to ban or regulate the use of a chemical, TSCA required EPA to show that its action provided the “least burdensome” regulation. The high burden of this standard was highlighted when EPA’s attempt to ban asbestos was overturned by a federal appellate court because it was not sufficiently supported under the onerous requirements of TSCA. Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991). The Chemical Safety Act seeks to correct TSCA’s weaknesses by giving EPA additional teeth in its regulation of chemicals. The reform brings several substantial changes to the old law, many of which will have immediate effects on EPA’s review of chemicals.

Early Reaction to Reform

The Chemical Safety Act has been met with enthusiasm from both industry and environmental groups:

“The updated law gives EPA the authorities we need to protect American families from the health effects of dangerous chemicals.” - Gina McCarthy, EPA Administrator

“This legislation will offer the kind of predictability, consistency and certainty that manufacturers and the national marketplace need…” - Cal Dooley, President of the American Chemistry Council

“The Chemical Safety Act begins the process of regaining the public’s confidence in everyday products made possible by our industry.” - The Society of Chemical Manufacturers and Affiliates

“A strong new TSCA.” - Richard Denison, a lead scientist at the Environmental Defense Fund

However, some environmental groups have expressed displeasure with the reform, particularly because of its higher level of preemption of state chemical laws.

“The failure to include a bulletproof safety standard or sufficient resources, along with the uncertain effects of new restrictions on state action, could ultimately result in less regulatory action than supporters claim.” - Scott Faber, Vice President of Government Affairs, Environmental Working Group

Key Changes Brought by the Chemical Safety Act

New Chemical Review Process Requiring Affirmative Approval: EPA has stated, “The most immediate effects [of the Chemical Safety Act] will be on the new chemicals review process.” Under Section 5 of the Chemical Safety Act, EPA must make an affirmative safety review of every new chemical or significant new use (SNU) of an existing chemical and make one of three types of determinations:
(1) The new chemical or SNU presents an unreasonable risk, in which case EPA must regulate under §5(f), and promulgate a Significant New Use Rule (SNUR) or explain why it has chosen not to do so.

(2) There is insufficient information to permit a reasoned evaluation of the chemical, OR in the absence of sufficient information, the chemical may present an unreasonable risk, OR the substance will be produced in substantial quantities and that it may enter the environment in substantial quantities or cause significant human exposure. If any of these three conditions are satisfied, EPA must issue an order under §5(e) and implement a SNUR or explain why it has chosen not to do so.

(3) The new chemical is not likely to present an unreasonable risk, in which case, the production or use of the chemical may begin.

Unreasonable Risk Determination: In determining if a chemical poses an unreasonable risk, EPA can no longer consider costs or any other non-risk factors, and must consider risks posed to susceptible populations. Once a chemical or use has been deemed to pose an unreasonable risk, however, EPA may consider cost and availability of alternatives when evaluating its risk management options. The reform eliminates TSCA’s requirement that the chosen regulation be the “least burdensome” option.

Prioritization and Regulation of Existing Chemicals: The Chemical Safety Act requires EPA to establish a priority system to test and regulate existing chemicals. EPA must identify existing chemicals “which may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations.” The agency must then designate these chemicals as “high priority” and perform a full risk evaluation within three years. It is important to note that unless EPA can conclusively classify a chemical as “low priority,” the default presumption will require the chemical to be designated “high priority.”

State Preemption: One of the significant obstacles to passing TSCA reform was the issue of state preemption, specifically, whether a TSCA reform bill would prohibit states from having more stringent chemical regulations. The Chemical Safety Act presents a compromise by creating national uniform regulations, while still allowing states to fill in regulation gaps. However, when EPA takes final action, either by determining a chemical is safe or by issuing a chemical specific rule, state laws in conflict with EPA’s determination are preempted. Moreover, any new state action is preemptively “paused” during the time EPA performs its risk evaluation of a high priority chemical. This preemption will end on the date EPA’s deadline to complete its risk evaluation expires, or, on the date that EPA publishes its risk evaluation findings. This preemption occurs only on a chemical-by-chemical basis, and does not preempt state environmental laws focused on other areas of environmental protection. Further, any chemical specific state regulation in existence as of April 22, 2016, or any state law in effect as of August 31, 2003 (including California’s Proposition 65) have been expressly preserved. States may apply for waivers from EPA preemption by asserting “compelling conditions” that warrant a waiver to protect health or the environment.

Confidential Business Information: The Chemical Safety Act imposes more stringent requirements on companies asserting Confidential Business Information (CBI) claims. EPA must now substantially evaluate all new chemical CBI claims and screen 25% of all non-chemical CBI claims. Additionally, EPA may retrospectively review past CBI claims to determine if the claims were adequately substantiated.

Fees and Penalties: Section 26 of the Chemical Safety Act provides the necessary funding for EPA’s larger regulatory role by allowing for increased collection of user fees from industry. The law allows EPA to collect up to $25 million in fees each year to help defray the costs of chemical regulation. The reform also increases the penalties EPA can administer. Civil fines for violations have increased from $25,000 to $30,000, and fines for violating “imminent danger” restrictions have increased from $25,000/day to $50,000/day.

Key Deadlines for EPA Implementation

- Implementation of the law began immediately upon the President’s signature.
- EPA announced its first-year implementation plan on June 29, 2016.
- EPA has 180 days to begin (or continue if already underway) risk evaluations on the first 10 high priority chemicals, which will be pulled from an existing EPA list of chemicals designated to undergo risk evaluations.
- Within one year, EPA must establish its process for identifying additional high vs. low priority chemicals, and establish a process for evaluating the risk of chemicals designated as high priority.
Within one year, chemical manufacturers must report to EPA all chemicals that they are currently producing or processing in order to establish an accurate accounting of the number and kinds of chemicals currently in use in the marketplace.

Within 42 months (or three and a half years), EPA must have risk evaluations underway for at least 20 chemicals.

**Recommendations to In-House Counsel**

As EPA moves to implement the new legislation, there are a number of items that all companies should consider to properly anticipate the effects of the new law.

- **Identify chemicals that are critical to your business.** Section 6(b)(2) of the new law requires EPA to conduct risk evaluations on 10 chemicals from the 2014 update of the “TSCA Work Plan for Chemical Assessments” (TSCA Work Plan). EPA will add additional high priority chemicals to this plan according to the judicially enforceable schedule. Counsel should identify any critical chemicals on the TSCA Work Plan list or identified by EPA as potential additional high priority chemicals. These include not only chemicals produced by your company, but also, any chemicals used by your company, or any used by other companies in the business’ supply chain. A high priority designation and subsequent risk evaluation may have a significant impact on the allowed uses or even availability of the chemicals.

- **Identify if your company has submitted any premanufacture notices (PMNs) prior to the enactment of the law, which are currently undergoing EPA 90-day review.** EPA will require an affirmative safety finding on all new chemicals and significant new uses, even if the PMN was submitted prior to the law’s enactment. EPA has stressed that it will “make every effort” to complete an affirmative finding on these new chemicals under their original submission deadline, but that it has interpreted the new law to effectively reset the 90-day review window.

- **Assess any confidential business information (CBI) claims made by your company, and invest time and resources to properly qualify new claims.** Section 14 now requires EPA to “substantively” evaluate all new chemical CBI claims and 25% of non-chemical CBI claims. Record keeping will be important, as CBI claims now automatically dissolve after 10 years if a company does not affirmatively reapply.

- **Communicate significant concerns with EPA.** The Chemical Safety Act requires EPA to establish a process and criteria for identifying and evaluating the risk of high priority chemicals. EPA has affirmatively stated that input from interested stakeholders “is critical to successful implementation of the new law.” Based on the aggressive timetable for implementation, industry should engage EPA as early as possible to help ensure these regulations are sufficient and practical.