



Environmental Update

June 22, 2016

TSCA Overhaul Will Have Major Impact on Chemical Manufacture & Use

Today President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, ushering in the first significant legislative reform of the Toxic Substances Control Act since its enactment in 1976. As its provisions are implemented by U.S. EPA, the new TSCA will give rise to significant changes in the way chemicals are manufactured, processed, imported and used. After decades of fruitless efforts to advance TSCA reform legislation and various compromises on thornier issues achieved just this year, the reconciled bill passed both houses of Congress with notable bipartisan support and largely positive comments from many stakeholders affiliated with both industry and environmental advocacy groups.

The new TSCA will require EPA to evaluate new and existing chemicals in commerce utilizing a new risk-based standard that will take into consideration factors such as risks to vulnerable populations. The EPA's authority to require testing and information collection needed to conduct those evaluations will be expanded. The Agency will face statutory deadlines to complete evaluations of prioritized groups of chemicals and subsequently to take regulatory action where needed on the risks identified. The new legislation will also limit states' authority to impose their own regulations on chemicals governed by TSCA, providing manufacturers more certainty and somewhat curbing the business community's difficulty in addressing a patchwork of state-specific and federal controls on individual chemicals. The bill will also impose new limitations on the confidentiality claims businesses can assert when providing chemical and process information to the EPA.

Factions within Congress as well as industry and environmental groups have advanced various efforts to amend TSCA for many years. The existing law has been at times described as perhaps the least effective and least successful of the major federal environmental statutes. These criticisms have been leveled by both industry and environmental advocacy stakeholders. A common complaint from industry has been the lack of effective federal preemption, depriving the business community of regulatory certainty where individual states were free to enact more stringent chemical-specific controls than those required under TSCA. Environmental stakeholders have commonly pointed to deficiencies such as the old statute's weak authorities for EPA to promulgate rules regulating individual toxic chemicals.

Reconciling the House and Senate bills, which differed markedly in their level of detail and specific mandates, required Congress to hammer out some difficult and significant compromises. For example, a diligent effort was required to find middle ground on the critically important issue of what standard to apply when assessing risk presented by chemicals and selecting a means of regulation where needed. While the House bill followed the original TSCA, retaining the opaque "unreasonable risk" standard and allowing the Agency's inaction on a review to allow entry to market, the Senate bill would have established a much more onerous "safety standard," disallowed cost and other non-risk considerations, and required the EPA to issue a review decision before market entry was allowed. In the end, the "unreasonable risk" standard from the House bill was retained. However, various concepts from the Senate bill were integrated, including mandating an affirmative EPA

risk decision before market entry will be permitted and a requirement to consider risks to exposed subpopulations. Another compromise related to the consideration of costs gave rise to decoupling the risk assessment phase (where costs will not be considered) from the risk management phase (where costs can be considered in selecting a mechanism for addressing risk).

EPA's existing resources will be heavily strained to implement the new TSCA, as the mandated pace of developing new programs and procedures is quite rapid, with many statutory deadlines falling within the first two years after enactment. For example, the Agency will be required to designate its first group of high-priority chemicals for evaluation within six months. Within one year, the EPA must establish the process it will utilize for the risk-based screening and corresponding criteria to designate chemicals as high or low priority for evaluation. Also within a year, the Agency must establish rules to govern a reboot of the TSCA Chemical Inventory of existing chemicals in commerce, which exists under the current statute but is considered out of date and not entirely accurate. This to-be-developed rule, known informally as the Inventory Reset rule, will impose important duties on industry as early as six months after it is promulgated. Since the EPA's new chemicals program will be burdened by substantial new obligations and eventually will be evaluating chemicals utilizing more demanding criteria, businesses seeking to bring new substances to market may wish to expedite commencing those regulatory reviews. Chemical manufacturers, processors and users should stay abreast of these looming changes, consider how the new TSCA will affect them and begin preparations to address those impacts promptly.

In addition, affected businesses should not lose focus on state efforts to regulate individual chemicals since the preemption provisions of the new TSCA only go so far. While the new bill will preempt most new state regulation where EPA is addressing a given chemical, long-established state regimes such as California's Proposition 65 are generally grandfathered. Also, limited mechanisms to allow preemption to be circumvented are being established whereby, for example, states may petition for a waiver to regulate where certain criteria are satisfied.

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