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A New Day in Chemical Regulation

What You Need to Know about the 2016 TSCA Amendments

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On June 7, 2016, the Senate passed a revised version of the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" (S. 697), which the House of Representatives had already approved, to enact sweeping amendments to the Toxic Substances Control Act, 15 U.S.C. § 2601, et seq. (TSCA). The new amendments significantly strengthen and streamline EPA's authority to take action to ban or restrict the manufacturing, processing, or use of chemicals that may pose an unreasonable risk of injury to human health or the environment. By doing so, the amendments remove a longstanding perception that TSCA presents a considerable obstacle to EPA's ability to effectively regulate or phase out potentially harmful chemicals.

At the same time, the new legislation will make it more difficult to introduce new chemical substances into commerce, increase the likelihood of EPA reevaluating the safety profile of existing chemicals, and render confidential business information (CBI) more accessible to the public. To adapt to these new requirements and avoid future enforcement actions for failing to meet them, facilities should reassess their chemical usage and reporting practices, and develop strategies for engaging both the government and public on chemical safety. The key changes to TSCA, which had not been modified in over forty years, are summarized below.

Prioritization and Risk Evaluations of Existing Chemicals

To date, TSCA Section 6(a) has mandated that EPA use "the least burdensome requirements" to restrict the use of harmful chemicals. Furthermore, under Section 6(c), any rulemaking that EPA initiates pursuant to Section 6(a) must include a rigorous cost-benefit analysis of, among other things, the effects of the proposed restriction or ban "on the national economy, small business, technological innovation, the environment, and public health." EPA historically has been reluctant to restrict the use of harmful chemicals given these statutory prerequisites. This reluctance became an engrained practice after EPA unsuccessfully attempted to invoke its authority under Section 6 of the statute 25 years ago in *Corrosion*

Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991), in which the Fifth Circuit overturned EPA's attempt to ban asbestos-containing products under TSCA Section 6.

The TSCA amendments make it easier for EPA to use its authority under Section 6 by eliminating both the "least burdensome" requirement in 6(a) and the duty of EPA to account for costs and other non-risk factors in evaluating harm. Specifically, the amendments require EPA to designate chemical substances as either "high-priority"—that "may present an unreasonable risk of injury to health or the environment"—or "low-priority"—all other substances. EPA must make such designations through scientifically-grounded analysis and procedures established by rulemaking within one year of the bill's enactment. High-priority chemicals will then be subject to further evaluation to determine whether they *actually* present an unreasonable risk of injury under stated conditions of use. Notably, this determination must be made *without regard to cost or other non-risk factors*. If the agency determines that the chemical substance indeed poses an unreasonable risk, then it has two years to issue a final rule under Section 6(a) to restrict the use of the substance.

Because the TSCA Inventory currently lists approximately 84,000 chemical substances, many of which are no longer in commerce, the process of prioritization and evaluation will occur on a rolling basis. To this end, the amendments modify Section 8(b) to enable EPA to identify active chemicals (i.e., chemicals that been used over the last ten years) and require that, within 180 days after enactment, EPA designate as high priority chemicals ten substances from the 2014 list of TSCA Work Plan chemicals—the list of existing chemicals that have been prioritized by the Agency based on persistence, bioaccumulation and toxicity.

TSCA amendments open the door for EPA's reassessment of substances already in commerce and allow for stakeholder input on the prioritization of chemicals and risk evaluations. In practice, this will place the burden on manufacturers and processors of high priority chemicals to gather information and conduct scientific and legal analysis in preparation of possible agency efforts to restrict the use of such substances on the basis of risk evaluations. Companies should familiarize themselves with Section 6(b)(1)(C), which allows stakeholders to submit information to EPA before the agency designates a chemical as high priority; this information may prove vital in efforts to dissuade EPA from issuing such a designation for a given chemical.

Test Rules for Existing Chemicals

EPA's authority to require manufacturers, importers, and processors to test chemical substances and mixtures under TSCA Section 4 constitutes another integral aspect of the Agency's ability to restrict the use of chemicals already in commerce. Under the current provisions of TSCA, the Agency can require companies to perform such testing only through a formal rulemaking, subject to public notice and comment, which can be a lengthy and challenging process from the agency's standpoint. The TSCA amendments facilitate the Agency's ability to require such testing by authorizing the use of unilateral orders and consent agreements to compel action.

Regulation of New Chemicals

With certain exceptions, TSCA Section 5(a) currently requires that manufacturers or importers submit a premanufacture notification (PMN) to EPA at least 90 days prior to the commencement of manufacture or importation. The PMN has to include sufficient information to identify the chemical substance and demonstrate that it does not present an unreasonable risk of injury to human health or the environment. As currently written, however, TSCA does not require EPA to make an affirmative safety determination regarding PMN substances. Therefore, if a company submits a PMN and does not receive a response from EPA, it may begin to manufacture or import the chemical substance, subject to certain recordkeeping provisions.

Under the amendments, EPA must review each PMN and make an affirmative determination as to whether the chemical substance presents an unreasonable risk of injury, or whether insufficient information exists to make a reasoned evaluation. The requirement that EPA make an affirmative determination may place a heavy administrative burden on the Agency, given the need to review information for several hundreds of chemicals per year. Furthermore, the amendments do not place a firm deadline on how long EPA has to make this determination, as the only ramification of the Agency's failure to render a determination within the 90-day timeframe, as may be extended under Sections 5(b) or 5(c), may be to simply refund PMN fees. As a practical matter, this means that it may take significantly greater time for companies to satisfy the PMN requirement. Companies will need to undertake more advance planning for the manufacture or importation of new chemical substances, and they certainly will have to ensure that the health and safety data provided in support of a PMN sufficiently demonstrates chemical safety.

Furthermore, under Section 26, the fees for PMN review may be increased to fund up to 25 percent of EPA's administrative costs for implementing the new chemicals program. It is expected that the costs of submitting a PMN, which currently are capped at $2,500, may be increased by as much as ten times that amount. Together with the new affirmative determination requirements in Section 5(a), this modification significantly increases the "entry-barrier" for obtaining PMN review for new chemical substances. As a result, companies will be well-served to closely assess the applicability of any possible exemption and exclusions from Section 5 requirements, to avoid the PMN process. This applicability analysis is no easy task, as the guidance on the PMN exemptions is limited, leaving the scope and parameters of exemptions still ill-defined.

Confidential Business Information (CBI)

The amendments significantly limit the ability of companies to assert claims of CBI under TSCA Section 14. Specifically, the compromise bill authorizes EPA to reevaluate existing CBI claims and sets a 10-year limit on new CBI claims, at the end of which a company must renew the protections and sufficiently substantiate the continued need for confidentiality. These changes increase the likelihood that information claimed as CBI eventually may be subject to disclosure. Consequently, companies that have made or may make CBI claims under TSCA should be prepared to vigorously substantiate the protected nature of the information. Furthermore, companies should consider crafting policies regarding the management of information and data produced in developing new chemical substances. The policies should also cover the treatment of information shared with third parties, such as testing laboratories, whose reports may be submitted to EPA.

Preemption

A major driver behind TSCA reform was industry's interest in a strong preemption provision that would avoid the problem of compliance with inconsistent state laws, in favor of a uniform federal law. The amendments in Section 18 preserve any state actions taken before April 22, 2016 and any past or future actions taken under laws in effect on August 31, 2003—measures intended to preserve California's Proposition 65 and Massachusetts' Toxics Use Reduction Act.

Besides these grandfathering provisions, however, the amendments introduce a "high-priority pause," under which EPA action will preempt state restrictions between the time that the federal agency commences its risk evaluation and the time that it determines that the chemical presents an unreasonable risk under stated conditions of use. Furthermore, the amendments prevent states from adopting their own laws and regulations restricting chemical use if EPA determines that the safety profile of the chemical does not warrant restrictions.

Increased Penalties

The amendments make significant changes to the penalty provisions in TSCA Section 16. The amendments increase the daily cap on civil penalties from $25,000 to $37,500, to reflect the amount that EPA has been assessing since 2013 under the "Amendments to the Civil Monetary Penalty Inflation Adjustment Rule," 78 Fed. Reg. 66,643 (November 6, 2013). Furthermore, the maximum fine for criminal violations of TSCA is now $50,000. The amendments further add a special criminal provision, consistent with other environmental statutes, which subject anyone who knowingly or willfully commits a violation that creates an imminent danger of death or serious bodily injury to a maximum fine of $250,000 and/or imprisonment for up to 15 years.

Conclusion

While the TSCA amendments streamline EPA's regulatory oversight in several important aspects, they considerably increase EPA's authority to regulate both new and existing chemicals. The amendments create a clear and comparatively easier mechanism by which the Agency can restrict or ban the use of chemicals already in commerce, while they increase the costs and time necessary to introduce new chemicals into the marketplace. To cope with these changes, companies should devise TSCA compliance strategies, bearing in mind the following points:

- Manufacturers, importers, and processors of chemicals that may be classified as "high-priority" should work now to develop strategies for addressing agency attempts to invoke Section 6 authorities to restrict the use of existing chemical substances. Such strategies could entail evaluating the use of alternative chemicals or, instead, developing safety data to rebut potential agency arguments that the chemicals pose an unreasonable risk.

- New chemicals may require increased review time and closer scrutiny of PMNs and other Section 5 submissions, as well as significantly increased administrative costs. Because of the increased entry-barriers for achieving compliance with requirements for new chemicals, companies would be well-advised to reassess the applicability of Section 5 requirements in light of the numerous and complicated exemptions set forth at 40 CFR Parts 720 and 723.

- Companies subject to TSCA regulations should develop strategies for making new CBI claims, as well as for reassessing past claims, which may need to be re-substantiated in light of the new amendments.

Companies should work closely with counsel to familiarize themselves with these and other important new requirements in TSCA, and develop strategies to ensure compliance consistent with their current and future chemical manufacturing, importation and processing plans.

If you have any questions about the content of this Alert, please contact the Pillsbury attorney with whom you regularly work, or the authors below.

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