

## Environmental Alert

June 22, 2016

### Key Points:

- Congress and the Administration have reformed the decades-old Toxic Substances Control Act (TSCA). The new bill broadens the government's authority to regulate chemical substances.
- On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, instructing the Environmental Protection Agency (EPA) to revise and update its regulations governing how existing and new commercial and industrial chemicals are tested, reviewed and used in the United States.
- Companies should act proactively to identify the chemical substances they import, manufacture, use or sell, and to develop strategic plans for ensuring the long-term availability of those substances, protecting trade secrets and proprietary data, and defending their technologies against state and federal regulations.



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### President Obama Signs the Frank R. Lautenberg Chemical Safety for the 21st Century Act

Since its passage in 1976, TSCA has been widely criticized—by industry and environmental groups alike—for its perceived inefficacy. When first passed, TSCA aimed to fill an important gap in the nation's environmental laws, creating a comprehensive, but flexible, system for assessing and managing the risk from the roughly 60,000 substances then in commerce. As funded by Congress, implemented by EPA and interpreted by the courts, however, the legislation made it difficult for the EPA to require testing needed to assess the risk of substances lacking data or to control substances where existing data identified risks.

This gridlock prompted some states to develop their own criteria for restricting chemicals, resulting in ambiguous and contradictory state-level regulations. The Frank R. Lautenberg Chemical Safety for the 21st Century Act aims to address these irregularities by creating a stronger federal regulatory framework, fixing flaws in the prior risk-based standard and reducing the need for (and, in some cases, pre-empting) duplicative, state-by-state action.

## Key Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

**Greater Testing Authority.** The modernized law will strengthen EPA's authority to require additional health and safety testing on new and existing chemicals and uses, and reduce the procedural obstacles that have prevented EPA from requiring such testing in the past.

**Risk-Based Assessment.** The legislation instructs the EPA to (1) develop criteria assessing the "risk" posed by a chemical, especially to the health of vulnerable populations, like children and pregnant women; then (2) develop a plan to manage the chemicals that it finds to present an "unreasonable risk" under conditions of use. It must do so both for new chemicals and for those currently in production, including the tens of thousands that were grandfathered in by the original TSCA in 1976. The retention of a risk-based standard was an important aspect of the final compromise bill, as some stakeholders had argued for **a hazard-based system**.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act grants the EPA broad discretion to determine the risk posed by a particular chemical. However, the subsequent determination to restrict a chemical's production can take place only after an extensive cost-benefit analysis: the EPA must consider the chemical's benefit to society, its effects on the national economy and the availability of a viable substitute. Under the original TSCA, plaintiffs have successfully challenged chemical restrictions on the basis that no viable substitute existed, or because the restrictions were arbitrary and capricious. The Frank R. Lautenberg Chemical Safety for the 21st Century Act preserves companies' ability to challenge regulations on this basis.

**A Reset of TSCA's Existing Chemical Inventory.** The statute directs EPA to update its list of chemicals in active commerce within the United States, creating the potential that some of the roughly 85,000 chemicals and related uses previously grandfathered under the original law could be deemed inactive, placing premarket notice requirements on potential importers and manufacturers.

**More Predictable Administrative Funding.** One of the major flaws in the original 1976 Bill was the **lack of a predictable funding stream** to support the scope and complexity of EPA's mission, the enormous number of chemicals already in commerce, and the continued pipeline of new chemicals and uses resulting from private sector innovation. The updated statute builds in a more predictable source of funding and allows companies to supplement that funding for company-requested reviews.

**Company-Initiated Review.** Companies wishing to avoid uncertainty may petition the EPA to review a particular chemical substance at the company's expense. This could be an important strategic move for organizations that want to highlight the sustainability of specific products; that fear the implementation of restrictive state regulations; or that wish to confirm the product's marketability before undertaking expensive research, development and marketing.

**Confidential Business Information.** The existing TSCA contains provisions for protecting confidential business information (CBI) to prevent the public disclosure of trade secrets. The Frank R. Lautenberg

Chemical Safety for the 21st Century Act imposes stricter substantiation requirements on companies that wish to claim CBI protection and makes certain information available to states, health professionals and environmental professionals.

**Federal Pre-Emption Scheme.** The updated **federal pre-emption scheme** in the modernized law will make it more difficult for states to impose new duplicative testing or risk management requirements on chemicals that the EPA has already regulated or found not to present an unreasonable risk, while reserving to states considerable latitude to implement existing chemical regulatory regimes and to state courts in assessing tort law.

### **Bottom Line—This is Not Your Old TSCA**

The amended TSCA will have significant business implications for companies located in or doing business in the United States, creating opportunities for some, and threats for many others.

From a regulatory perspective, federal regulators will be under tight deadlines to revise their regulatory processes for assessing, prioritizing, and managing the risk from thousands of substances used in industrial, commercial, and consumer applications in virtually every sector of the economy. Companies engaged in the import, manufacture, or use of chemical substances and materials will need to monitor, if not engage directly with federal regulators during the implementation period, to ensure the substantive and procedural validity of the rule and to ensure ongoing compliance with changing requirements.

From a litigation perspective, the transition to a modernized TSCA regime is likely to spur new sources of litigation exposure, including increased tort and regulatory enforcement actions; the need to protect confidential business information and proprietary data from release or theft; and the need to challenge arbitrary and capricious action by regulators during the implementation process.

Finally, from a corporate and transactional perspective, companies will need to factor the new law into future assessments of environmental liability and risk for the purposes of corporate disclosure obligations as well as investment, divestment, and financial restructuring matters.

Akin Gump will be supplementing this initial alert with more detailed analyses of the Frank R. Lautenberg Chemical Safety for the 21st Century Act throughout the summer.

## Contact Information

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