

ALERTS**Environmental Law Alert - Congress Passes
Landmark Chemical Regulations Reform**

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This week, the Senate approved by voice vote a sweeping bipartisan amendment to the federal law regulating chemical manufacturing and use, the Toxic Substances Control Act of 1976 (TSCA). The Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576), also called the Lautenberg Act, passed the U.S. House of Representatives with broad bipartisan majorities before the Memorial Day congressional recess. President Obama is expected to sign the legislation into law in the coming days. This marks the first significant revision to TSCA since its original passage in 1976, and in part seeks to reconcile U.S. practices with similar international programs, like REACH.

Provisions in the Lautenberg Act have been lauded as making long-necessary updates to TSCA, including: changing evaluation of new and existing chemicals in terms of risk evaluation and risk management; testing of new and existing chemicals; pre-emption of state and local regulations; the treatment of "Confidential Business Information;" and restrictions on the regulation of finished manufactured goods (or articles), among other changes. Final provisions of the legislation represent a compromise between environmental public interest groups seeking stricter oversight of chemicals and industry groups representing regulated manufacturers and importers. Below is a summary of the more significant changes to TSCA presented in the Lautenberg Act.

Evaluation of New and Existing Chemicals

The Lautenberg Act changes the way new and existing chemicals are regulated under TSCA. With regard to new chemicals, revisions to Section 5 of TSCA will provide EPA more flexibility in evaluating the safety of new chemicals in commerce. Under the existing statutory language, after a "pre-manufacture notice" (PMN) is submitted for a new chemical, the PMN is deemed approved within 90-days unless EPA concludes the chemical may present an unreasonable risk. Under the new provision of the Lautenberg Act, EPA is required to make one of three conclusions regarding the chemical: 1. the new chemical presents an unreasonable risk; 2. the new chemical may pose an unreasonable risk, or there is insufficient information to evaluate, or the chemical is made in substantial quantities; or 3. the new chemical is not likely to present an unreasonable risk. Under the first two conclusions, EPA must issue a Significant New Use Rule (SNUR) regulating use to ensure safety precautions are likely to be met, or explain why a SNUR is not necessary. The updated TSCA language broadens EPA's power to regulate a chemical in absence of information.

With regard to the regulation of existing chemicals, the Lautenberg Act removes from TSCA Section 6 the problematic language specifying that

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existing chemicals be regulated by the “least burdensome requirement” and, instead, splits consideration of risk into two steps: 1. risk evaluation in which costs are not considered; and 2. risk management in which cost and benefits are considered. Under the existing language in TSCA, cost could be considered in the initial risk evaluation. Reforms also eliminate certain steps which often inhibited EPA regulation of existing chemicals including certain complicated rulemaking requirements. Additionally, the Lautenberg Act requires that EPA develop a prioritized list of chemicals of concern to be addressed under the act’s risk evaluation and risk management provisions. Overall, the Lautenberg Act will provide more flexibility and broader authority for EPA to regulate existing chemicals.

Preemption of State and Local Regulations

The Lautenberg Act includes a number of key differences from TSCA’s prior approach, including preemption of state laws, which was very controversial due in large part to California’s “Proposition 65” program. Specifically, the amendments prohibit states from implementing restrictions on the use of: (i) chemicals EPA has determined do not pose an unreasonable risk of injury to health or the environment, or (ii) existing chemicals for which EPA has issued a SNUR. Simply put, if EPA determines a chemical neither presents an unreasonable risk nor requires regulatory action, that decision preempts state laws that would contradict that determination (subject to some exclusions). The preemption is chemical specific and applies only when and to the extent EPA acts on a specific chemical.

All state TSCA provisions taken before April 22, 2016, are preserved (excluded from preemption), as are past and future actions taken under laws in effect on August 31, 2003. This carve out protects California’s Proposition 65 and Massachusetts’ Toxics Use Reduction Act.

These new TSCA provisions preempt both past state action - unless grandfathered - and future state action, unless the state action is:

- identical to the federal requirement;
- adopted under a federal law; or
- adopted under a state air or water quality or waste treatment or disposal law.

The Lautenberg Act thus expands substantially EPA’s preemption of state chemical safety laws by introducing a High Priority Pause to the review of chemical safety, during which time states cannot regulate a chemical already under EPA’s consideration. Previously, TSCA preempted state laws only after EPA adopted a final rule or regulated the same chemical. Changes to TSCA’s preemption provisions were thought to be an important piece of compromise between industry and environmental public interest groups as industry sought to avoid conflicting regulation at state and local levels.

Confidential Business Information

The Lautenberg Act makes substantial changes to eligibility for protection of information as Confidential Business Information (CBI). Under the act, EPA must resolve by reviewing and approving or denying all past claims of CBI that hid the identities of chemicals on the TSCA Inventory. Most

CBI claims must be substantiated when made and reviewed by EPA. CBI claims also must be renewed by this same process every 10 years or they will expire.

EPA must document and review all CBI claims for chemicals that do not meet the safety standard. Most CBI claims for uses of chemicals that EPA bans or phases out no longer apply. The amended TSCA also identifies categories of information, including health and safety data, not eligible for CBI protection.

At the same time, the act specifies certain types of proprietary information that merit treatment as CBI without substantiation, review, or renewal. For the first time, TSCA now provides that CBI is to be shared with state governments, health and environmental professionals and first responders, subject to nondisclosure agreements.

Restrictions on the Regulations of Finished Goods (Articles)

In another reform touted by the regulated community, the Lautenberg Act also tightens requirements for EPA's use of SNURs to trigger notifications for importing or processing chemicals in articles (finished goods). Under the Act, EPA must find a reasonable potential for exposure through the article justifies a Significant New Use Notice (SNUN). Additionally, the legislation provides exemptions for certain critical articles, if restriction of a chemical used in the article would disrupt the economy, national security or critical infrastructure, or where the chemical provides a substantial benefit to health, safety, or the environment.

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In addition to industry's drive to understand and comply with the new requirements, EPA will be challenged to implement the Lautenberg Act. EPA must develop policies, procedures, guidance and regulations, as well as begin the work newly required under the Act: develop lists of existing chemicals for prioritization and risk evaluation; collect data on chemicals; initiate risk evaluations; scrutinize Pre-Manufacture Notices for all new chemicals and SNUNs for new uses of existing chemicals. It will also be important whether Congress funds EPA to implement these new mandates. B&T will continue to monitor the development and implementation of the Lautenberg Act.

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