

# Congress Sends Chemical Safety Reform Legislation to Be Signed into Law

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**The historic reform of the Toxic Substances Control Act overhauls the United States' primary chemical safety law for the first time in 40 years.**

Following months of closed-door negotiations, the US House of Representatives and Senate have approved the first major overhaul of the country's primary chemical safety law, the Toxic Substances Control Act of 1976 (TSCA), marking one of the final steps in a multiyear reform effort. After initial reports that congressional Republicans and Democrats had reached a deal to revise the outdated TSCA, the final text of the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (H.R. 2576, the Lautenberg Act) was released in late May (as amended by a manager's amendment sponsored by Representative John Shimkus [R-IL]). Shortly thereafter, on May 24, the House took action by overwhelmingly passing the legislation by a vote of 403 to 12. Although initially delayed because of a hold placed on the legislation by Senator Rand Paul (R-KY.), the Senate passed the legislation by unanimous consent on June 7, sending the bill to President Barack Obama's desk to be signed into law. This legislation constitutes a bicameral, bipartisan compromise that reconciles both of the House and Senate's reform bills passed last year by merging the policy priorities of each.

## Background

The TSCA was enacted to regulate certain chemical substances present in commercial goods in the United States to protect human health and the environment by requiring testing and necessary use restrictions. In the 40 years since TSCA's enactment, it is largely viewed as one of the least effective federal environmental laws, resulting in the US Environmental Protection Agency (EPA) taking minimal action under the law. At the time of TSCA's enactment, nearly 65,000 chemicals on the market were grandfathered in and did not require EPA to review them for safety. Since TSCA's inception, EPA has also been restricted to promulgating regulations that are the least burdensome option for the industry with the agency's authority to promulgate regulation also limited to instances where another EPA statute or regulation could not adequately address any perceived risks. Until now, the law's core provisions have not been significantly changed since the legislation's initial passage.

Although TSCA reform has been a focus of congressional leaders for much of the last year, with both

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sides of the aisle largely in agreement that an overhaul of the country's chemical safety law was needed, the breadth and reach of proposed reforms, however, led to delays in passage of a comprehensive reform bill. Nonetheless, a number of drivers of this reform legislation, including an increased understanding of the interplay between health and chemicals, market demand, effective policy reforms in other countries, state regulatory regimes, and EPA prioritizing TSCA reform have all resulted in a frenzied run up to the first significant reform of TSCA since the law's enactment. The deal, first announced in May, was reached by Senate Environment and Public Works Committee Chairman Jim Inhofe (R-OK) and Ranking Member Barbara Boxer (D-CA) and effectively cleared a path forward. House Republicans, after securing several key changes to policy positions, moved the chamber to support the deal. Ultimately, the bill passed the House with overwhelming bipartisan support. The Senate shortly thereafter followed suit and passed H.R. 2576 unanimously. President Obama, who issued a Statement of Administration Policy in support of the reform legislation on May 23, is expected to sign H.R. 2576 into law in the near future. The final legislation, although a compromise, is predominantly being touted as a vast improvement of the current law.

## **Key Provisions of TSCA Reform Compromise Bill**

The newly reconciled Lautenberg Act implements a number of changes to the United States' primary chemical regulatory scheme and will likely have far-reaching effects throughout the marketplace. The most considerable changes between TSCA's current form and the new law include the following.

### **Testing and Safety Standards**

Under TSCA's prior form, EPA was mandated to manage existing chemicals using the "least burdensome" regulatory option in most instances. The reformed law significantly revises the criteria evaluated by EPA when reviewing chemical substances and adopts a new safety standard of an "unreasonable risk of injury to health or the environment." EPA must now make all decisions based on the best scientific information, technical procedures, measures, methods, protocols, methodologies, or models available when conducting test, reviews, or risk evaluations. EPA must also consider whether a chemical's conditions of use would conform to the bill's safety standard while also explicitly requiring that that EPA consider potentially exposed or susceptible populations when evaluating the chemical's risk. Such populations include infants, children, pregnant women, workers, and the elderly. Under the reform bill, EPA is also prohibited from considering costs or other non-risk factors when evaluating a chemical's risk; however, such non-risk factors may be considered when determining how a chemical that does not meet the health-based safety criterion is regulated (i.e., risk management determinations).

### **Evaluation and Regulation of Existing Chemicals**

Rather than operate from the presumption that every chemical is safe, EPA will now be required to implement a screening process for existing chemicals to evaluate any associated risks. EPA will also now be required to affirmatively undertake risk assessments to determine which chemicals require further evaluation for risk and designate chemicals as either low or high priority. High-priority chemicals or substances include those that EPA concluded may present an unreasonable risk of injury to human health or the environment (via application of the new testing and safety standards outlined above). EPA will subsequently be required to undertake a risk assessment of any high-priority chemical as well as publish the scope of the risk assessment that it will undertake.

Under TSCA's new form, EPA must initiate risk evaluations of at least 20 high-priority chemicals and

designate at least 20 chemicals as low priority within three and a half years after the bill's enactment. Additionally, manufacturers and processors could request EPA to prioritize specific chemicals for evaluation pursuant to the payment of certain fees, limited to 25–50% of the risk assessments of high-priority chemicals to those identified by manufacturers. If EPA determines that a chemical or substance does not present an unreasonable risk of injury to health or the environment, EPA must then issue an order to that effect. Similarly, for any chemicals that EPA determines present an unreasonable risk, it must propose regulations to reduce any perceived risks within one year of publishing its final risk evaluation and finalize said regulation within two years. This is marked change from TSCA's prior requirements, which did not include similar deadlines for regulating chemicals.

## **Evaluation and Regulation of New Chemicals**

The reform law modifies EPA's process of evaluating and dealing with new chemicals and the approval process of a chemical for a significant new use. Under the new law, new chemical substances will not be able to enter commerce until EPA makes an affirmative determination concerning the level of risk posed by the new chemical under the new standards outlined above and without regard of cost. A chemical may not be commercially produced until EPA makes a determination of its risk and the manufacturer or processor subsequently complies with EPA's restrictions (if any). Under the new review procedure, EPA must make one of three determinations concerning the new chemical's risk (without considering other non-risk factors or cost). These three determinations include determinations that the new chemicals or proposed new uses (i) will present an unreasonable risk (which would require immediate EPA regulatory action to address); (ii) may present an unreasonable risk, are produced in sufficient quantities, or involve a lack of information to make an appropriate determination (which would require EPA action under subsection (e) while also allowing the manufacturer or processor the opportunity to submit additional information); or (iii) are "not likely to present an unreasonable risk" (under such circumstances, manufacturing may begin).

## **EPA's Expanded Authority**

In addition to EPA's current rulemaking authority and consent agreement process, the agency gains the authority to issue administrative orders directing that testing be undertaken to review manufacturer notices or significant new use notices. This new authority to simply order testing rather than having to undertake and partake in the longer and more cumbersome rulemaking or consent agreement process will likely expedite the assessment process while also greatly increasing EPA's authority under the Lautenberg Act. The TSCA reform law also expands EPA's authority to charge fees and at higher rates.

## **Preemption of State Laws**

TSCA previously provided for preemption of state laws once EPA adopted a final rule or regulated the same chemical. Provided EPA's limited activity in this regard, however, states had generally been responsible for regulating and implementing their own chemical safety regimes. Although this does not change under the reformed Lautenberg Act, § 13 includes a number of key differences from TSCA's prior form, including a prohibition on states from implementing restrictions on the use of chemicals that EPA has determined to not pose an unreasonable risk of injury to health or the environment or existing chemicals that EPA has issued a Significant New Use Rule for. Thus, if EPA determines that a chemical does not present an unreasonable risk and does not require regulatory action, such a decision would preempt state laws that would contradict that conclusion (subject to some exclusions). Additionally, states will be prohibited from regulating chemicals that EPA has

designated as “high priority” while EPA is conducting its risk evaluation (i.e., a “high-priority pause”). The reform law also includes a grandfathering provision for existing state laws and regulations enacted before April 22, 2016, and actions taken by states pursuant to laws that were in effect on or before August 31, 2003. The new law also dictates that nothing in the Lautenberg Act will preempt any state or federal common law rights or state or federal statute that creates a remedy for civil relief.

## **Trade Secrets and Confidential Business Information (CBI)**

Under TSCA’s prior form, once information was claimed as CBI, the designation remained in place indefinitely and the information remained protected until EPA affirmatively found that it did not meet legal requirements for protection. Under the new law, however, EPA must develop a retroactive review plan for evaluating whether chemicals on the current CBI § 14 database list actually require CBI protection or whether they can be designated as nonconfidential. CBI protections will also be limited to 10 years, after which time a party claiming the CBI designation will be required to resubstantiate its claims of confidentiality. The bill also establishes new standards for claiming confidentiality, mandating that any party seeking confidential treatment must substantiate that (i) it has taken reasonable measures to keep the information confidential, (ii) the information is not required to be disclosed under any other federal law, (iii) disclosure would likely cause substantial harm to the manufacturer’s competitive position, and (iv) the information is not readily available via reverse engineering. EPA will also be authorized to disclose CBI if the information is determined to be needed for the protection of health and the environment, is needed by a state or local government for law enforcement, or must be disclosed under any other federal law.

## **Path Ahead**

With the first significant overhaul of TSCA a reality, it is incumbent on businesses to begin to take certain steps to understand and deal with the reauthorization and changes associated with an entirely revamped and revitalized TSCA regulatory scheme. To be better positioned for TSCA reform, manufacturers and processors can take a number of preliminary steps, including making efforts to better understand and review supply chains, engage suppliers regarding TSCA inventory lists, protect and justify any confidentiality claims, review existing confidentiality claims of information in EPA’s authority, and understand the new requirements associated with new chemicals and new use notifications, including new fees and testing requirements.

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