Recent Congressional approval of amendments to the Toxic Substances Control Act ("TSCA") will soon impact chemical regulation in the United States. The new legislation, the "Frank R. Launtenberg Chemical Safety for the 21st Century Act" ("H.R. 2576"), requires the United States Environmental Protection Agency ("EPA") to further limit the risk of injury to human health and the environment caused by the importation, production, distribution, use, and disposal of chemical substances. The law is a compromise between two separate bills introduced in the House and Senate in 2015. The passage of the law is the first time since TSCA’s enactment in 1976 that Congress has substantively reformed TSCA, which was widely considered ineffective and outdated. It is important that government entities and companies engaged in commerce in the United States recognize how the new law will impact their existing operations.

Background of TSCA Reform

The primary objective of TSCA is to regulate chemical substances that present an “unreasonable” risk of injury to human health or the environment. But in the years following the 1976 Act, as few chemicals were actually tested and fewer still banned as “dangerous,”¹ individual states implemented tighter restrictions on certain chemicals, creating a patchwork of chemical regulation standards across the United States. In 2015, Senators David Vitter (R-La.) and Tom Udall (D-N.M.) introduced S.697 to address the need for stronger EPA regulations and national unity in chemical regulation standards. Early critics of the bill included Senator Barbara Boxer (D-Calif.), a Ranking Member of the Senate Environment and Public Works Committee, who opposed early versions of the bill because of the limiting effect the legislation’s preemption provisions would have had on the ability of state agencies to implement their own chemical regulations. In California, the bill would have stifled the state’s aggressive push towards safer chemicals in everyday consumer products, such as the state’s Green Chemistry Initiative². But after months of negotiation and an alternative draft bill introduced by Senators Boxer and Ed Markey (D-Mass.), a compromise bill passed the House and Senate.

Major Changes to TSCA

Government entities and companies doing business in the United States should take notice of several key changes to TSCA in the new legislation. The following outlines some of these important changes.
**Preemption of State Regulatory Actions**

As part of the compromise reached on the key issue of federal preemption of state regulatory actions, the new law grandfathers in any state statutory or regulatory action taken prior to April 22, 2016 (Earth Day), as well as new actions taken under an existing state law in effect prior to August 31, 2003. Notably, these dates ensure the survival of California’s Green Chemistry Initiative. States, however, are prohibited from enforcing statutes or administrative actions that would require the development of information about a chemical that would produce the same information required under EPA’s testing, prioritization, and risk evaluation programs; or restrict or prohibit a chemical after EPA has made a decision or issued a final rule regarding a particular chemical; or require notification of use for a chemical for which EPA has already required notification pursuant to a significant new use rule.

Notwithstanding these exceptions, any existing or future state law that conflicts with a final EPA decision with respect to the safety or regulation of a particular chemical is preempted. Additionally, during the risk evaluation process itself, the new legislation also preempts for a limited duration—specifically, between EPA announcement of the scope of the risk evaluation for a particular chemical and the conclusion of the risk evaluation process or the expiration of the deadline for the risk evaluation, whichever is sooner—new state statutes or regulations that would fall within the scope of an announced EPA risk evaluation for a particular chemical.

Despite the law’s preemption provisions, there is still considerable room for a state to impose or expand legislative efforts against potentially harmful chemicals. First, if a state enacts a new regulatory requirement that is identical to an EPA regulation, the state regulation is not preempted. Provided that the EPA and state regulations are identical, and that EPA has not previously issued a penalty for a violation, a state may also issue an independently assessed penalty for a violation of the state regulation. Second, states may seek waivers for federal preemption, including a waiver for the temporary preemption phase during EPA risk evaluation. Third, states have up to 18 months after EPA has initiated the prioritization process for a chemical substance or published the scope of the risk evaluation for a chemical substance, whichever is sooner, to (a) enact a statute or (b) propose or finalize an administrative action intended to restrict manufacture, processing, distribution, or use of the chemical without triggering preemption while EPA evaluates the chemical. Fourth, a state may impose information-gathering requirements—e.g. reporting and monitoring—that are not otherwise required by TSCA. Finally, a state may initiate actions not subject to preemption pursuant to state air pollution, water, and waste management laws.

*Greater EPA Authority*
One of the biggest changes in the new legislation is the expansion of EPA authority under Section 5 of the Act to order testing to review pre-manufacture or “significant new use” notices. Although the agency can still obtain testing by rule or consent agreement, EPA's new, expanded ability to directly order testing may become EPA's preferred method.

**Expanded Chemical Regulation Process**

Under the new legislation, EPA will conduct a risk evaluation of all chemicals already existing in commerce using the best-available science and prioritize review for those chemicals deemed to have the highest level of risk to human health or the environment. While the agency already had a similar ability to conduct this type of review, EPA under the preceding iteration of TSCA would have first needed to make certain legal findings before it could do so.

For new chemicals, EPA must make an affirmative determination whether the chemical may present an unreasonable risk of injury to human health or the environment before the chemical can enter commerce. If EPA does not make a timely decision on a new chemical, the agency is required to refund all applicable fees to the submitter.

**Limited Cost-Benefit Analysis**

The new law also modifies the standard EPA must use when conducting a risk evaluation: if a chemical presents an unreasonable risk of injury to human health or the environment, including risks to subgroups of the population that may be uniquely susceptible to the hazard, EPA must regulate the chemical without regard to costs or benefits. The preceding iteration of TSCA required EPA to determine if a particular chemical presents an unreasonable risk by balancing consideration of costs and other non-risk factors against possible injury to human health or the environment. Under the new legislation, only in the context of deciding how to manage an identified chemical’s risk and choosing among particular approaches to regulation does EPA utilize a cost-benefit analysis. In addition, the new law eliminates language that required EPA to impose the “least burdensome” restrictions available when addressing an identified risk.

**New Deadlines**

The new legislation also implements a number of important deadlines for the evaluation process. EPA has one year after enactment of the amendments to establish by rule the risk evaluation process. Within six months of the legislation’s enactment, EPA must also identify ten “high priority” chemical substances for risk evaluations. Three and a half years after enactment, this number must expand to at least 20, and EPA must also by this time identify at least 20 “low priority” chemical substances. Half of the prioritized chemicals will come from EPA's 2014 Work Plan for Chemical Assessments. Chemical manufacturers may petition EPA to review a chemical out of turn, but the
manufacturer must generally fund the cost of the evaluation. After initiation, all risk evaluations must be completed within three years. If after evaluation EPA determines a chemical presents an unreasonable risk, EPA must propose a risk management rule within one year.

Mercury Restrictions

Commerce and storage of mercury in the United States will see tighter restrictions. By April 1, 2017, EPA will need to publish an inventory of mercury supply, use, and trade and update the inventory every three years thereafter. EPA is likewise responsible for developing guidance that establishes procedures for the short-term storage of mercury. The legislation also bans the export of a number of mercury compounds and empowers EPA to add to the list within 90 days of the law’s enactment.

Disclosure of Confidential Business Information

The new legislation also allows EPA to share confidential business information (“CBI”) with state and tribal governments for purposes of administration or enforcement of a law; federal, state, and tribal health or environmental professionals; and treating physicians or nurses. In addition, EPA will review all CBI claims for nondisclosure of identities of chemical substances and 25 percent of all other CBI claims. Substantiated claims will earn additional protection from disclosure for a period of ten years, with extensions available for additional ten-year terms.

Harmonization with Europe’s REACH

The new law represents a step toward harmonizing chemical regulation in the United States and the European Union, the latter of which is governed by the Registration, Evaluation, Authorization, and Restriction of Chemicals (“REACH”) program, the more recent European counterpart to TSCA. REACH, which took effect on June 1, 2007, has been praised for its comprehensive approach to evaluating and regulating chemicals, including placing the burden of proof that a chemical does not adversely affect human health or the environment on chemical manufacturers, importers, and downstream users. Similar to European chemical manufacturers under REACH, manufacturers under the revamped TSCA will now face stricter regulations and bans. Chemical manufacturers under TSCA will also face increased fees anticipated to cover up to 25 percent of EPA’s costs of implementing the risk evaluation process, confidential information review, and the new chemical notification program, often through the kind of consortia set up in the European Union.
In Conclusion

Once signed by President Obama, the amendments to TSCA will change the way government entities and companies dealing in the importation, production, distribution, use, and disposal of chemicals operate in the United States. Recognizing these key upcoming changes will help government entities and companies better navigate the new chemical regulation landscape and prepare for their new responsibilities and obligations.

1See Dale Kemery & Enesta Jones, EPA Announces Actions to Address Chemicals of Concern, Including Phthalates: Agency Continues Efforts to Work for Comprehensive Reform of Toxic Substance Laws, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (Dec. 30, 2009), https://yosemite.epa.gov/

2The Green Chemistry Initiative is comprised of Assembly Bill 1879 and Senate Bill 509.

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