

On December 17, 2015 the US Senate passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Senate's version of legislation to overhaul the Toxic Substances Control Act (TSCA). The bipartisan bill was introduced on March 10, 2015 by Senators Tom Udall (D-NM) and David Vitter (R-LA) and was approved by the Senate Environment & Public Works (EPW) Committee nearly eight months ago on April 28.

The Senate bill was designated as S.697. The full Senate passed the bill, however, as a substitute for H.R. 2576, the TSCA reform legislation that had been approved by the US House of Representatives on June 23, 2015. As such, the bill passed by the Senate is now designated as H.R. 2576, but its text is that of the Senate EPW bill (with some changes).

Among many significant changes to the current TSCA law, the Senate-passed bill would:

- Require EPA to evaluate chemicals (both new and existing chemicals) based on a safety standard and determine whether they present an unreasonable risk of injury "under the conditions of use."
- Prohibit consideration of costs or other non-risks factors in chemical evaluations.
- Require EPA to consider vulnerable subpopulations in evaluating chemicals.
- Allow companies to ask EPA to review a chemical.
- Give EPA authority to issue administrative orders to require testing of chemicals.
- Eliminate the "least burdensome" requirement for chemical regulations, making it easier for EPA to restrict – or ban – chemicals.
- Preempt state chemical regulations under certain conditions.
- Put limits on confidential business information (CBI) claims and allow EPA to share CBI with states.
- Allow EPA to charge higher fees for chemical reviews.

### Review of New Chemicals

Under the Senate-passed bill, EPA would have to make an affirmative determination that a new chemical (or significant new use of a chemical) is "likely to meet the safety standard" before it can be manufactured, imported or processed in the US. The safety standard is defined to mean that "no unreasonable risk of injury to health or the environment" will result from exposure to the chemical "under the conditions of use." "Conditions of use" are defined as "the intended, known, or reasonably foreseeable circumstances" regarding the manufacture, processing, distribution, use or disposal of a chemical as determined by EPA.

In determining whether a chemical is likely to meet the safety standard EPA must consider vulnerable populations and is prohibited from considering costs or "other non-risk factors." If EPA has insufficient information to make a determination about a chemical, it can suspend the review pending receipt of the information, or impose restrictions sufficient for it to make the "likely safe" determination even in the absence of the information. EPA can enter into a consent decree or order to prohibit or restrict the manufacture, processing, use, distribution or disposal of a chemical that is "not likely to meet the safety standard." EPA can require testing of new chemicals, including by issuing administrative orders.

### Characterization of Existing Chemicals as Active or Inactive

The Senate bill requires that, within one year after enactment, EPA must issue a rule under TSCA section 8 requiring all manufacturers and processors to tell the agency which chemicals on the TSCA Inventory they have manufactured or processed within the 10-year period preceding the date of enactment. Based on the information provided by these notifications, EPA will develop a list of "active" chemicals and a list of "inactive" chemicals. Chemicals on the "active" list will be prioritized for purposes of safety assessments. If a chemical is designated as "inactive," a company must notify EPA before it can manufacture or process the chemical. Once a chemical is moved from the "inactive" list to the "active" list, it is subject to prioritization

### Prioritization of Active Chemicals

The Senate bill requires EPA to designate existing "active" chemicals as "high" or "low" priority through a risk-based prioritization process and then conduct safety assessments of, and make safety determinations about, the high-priority chemicals. EPA may designate a chemical as high priority if it has either "significant" hazard or "significant" exposure. All listing decisions (high- and low-priority) are subject to 90 days public comment, and a decision by EPA to designate a chemical as a low-priority is subject to judicial review. The bill requires EPA to include at least 10 chemicals on the initial high-priority list and at least 10 on the initial low-priority list. Within three years, the list must have at least 20 high-priority and 20 low-priority chemicals, and it must have at least 25 high-priority and 25 low-priority chemicals within five years. At least half of all high-priority chemicals must come from EPA's list of Work Plan chemicals until all of the Work Plan chemicals have been designated.

Additionally, when setting the initial list of high priority chemicals, EPA must give preference to the chemicals among EPA's list of Work Plan chemicals that are persistent, bioaccumulative and toxic (PBTs). EPA also must consider PBTs when making prioritization determinations.

## Safety Assessments and Safety Determinations for Existing Chemicals

Under the Senate bill, EPA must conduct a safety assessment and make a safety determination for each existing chemical on the high-priority list. Through the safety assessment, EPA must evaluate “the risk posed by a chemical substance under the conditions of use, integrating hazard, use and exposure information.” When making the safety determination, EPA must determine “whether a chemical substance meets the safety standard under the conditions of use.” EPA must consider vulnerable populations and cannot consider costs or other “non-risk” factors in assessing a chemical.

EPA must define the scope of the safety assessment and safety determination for a chemical no later than six months after the chemical is designated as a high priority. The scope must include the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that EPA expects to consider. EPA must complete the safety assessment and safety determination within three years after designating the chemical as a high priority. EPA may extend the deadline for up to one year if required information is not yet available or was submitted very late. When performing the safety assessment, EPA may require additional information to be submitted and require testing to be conducting.

## Administrative Order Authority to Require Testing

The Senate bill gives EPA general authority to require testing on a chemical by issuing an administrative order (as opposed to promulgating a formal rule) and without having to make the difficult findings required under current TSCA section 4. EPA may exercise this authority not only to collect information needed for safety assessments and determinations, but broadly for other purposes as well.

## Company Requests for Safety Assessments and Safety Determinations on Existing Chemicals

The Senate bill provides that a manufacturer or processor can ask EPA to conduct a safety assessment and make a safety determination on a chemical if EPA has not yet prioritized it, subject to certain limits on the number of company-requested assessments/determinations compared to ones initiated by EPA. The company must pay the cost of the safety assessment and safety determination, however, and EPA cannot give company-requested assessments preference over ones for chemicals designated as high priority. Initiation of a company-requested assessment by EPA generally would not trigger preemption of state regulation of the chemical, but preemption would occur if the chemical is a Work Plan chemical that has not yet been designated for assessment.

## Regulatory Action on Chemicals

Under the Senate bill, if EPA determines that an existing chemical does not meet the safety standard, it must issue a rule under TSCA section 6 to restrict, ban or phase out the chemical. Significantly, the Senate bill eliminates the current TSCA requirement that EPA must select the “least burdensome” regulatory option when regulating an existing chemical. When considering a section 6 action, however, EPA must take into account “the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action” and any “primary” alternative actions considered. A determination by EPA that a chemical meets the safety standard is subject to judicial review, as is any final rule issued by EPA for a chemical determined not to meet the safety standard.

The Senate bill contains certain special requirements relating to restrictions on replacement parts and articles. Replacement parts manufactured prior to the effective date of the legislation are exempt from regulation under section 6 unless they “contribute significantly to the identified risk.” Articles may be restricted “only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.”

## Preemption of State Chemical Regulations

Under the Senate bill, a state would be preempted from imposing any new regulatory restrictions on a high priority chemical from the time that EPA defines the scope of the chemical’s uses for purposes of the safety assessment until EPA makes a safety determination about the chemical.

However, the bill does not preempt state requirements for reporting, monitoring or disclosure relating to a chemical or any restrictions imposed under a state air quality, water quality, or waste treatment or disposal law. The bill also would not preempt any state chemical regulation taken on a chemical prior to August 1, 2015, or taken under a law in effect on August 31, 2003.

The bill provides that states can seek a waiver from preemption under certain conditions, and EPA’s decision on a waiver is subject to judicial review. Additionally, the prohibition on new state action on a chemical is lifted if EPA misses the deadline for making the safety determination for the chemical. The bill also would allow states to “co-enforce” regulations on chemicals, including seeking penalties, but the combined total penalty obtained by EPA and a state cannot exceed the TSCA statutory amount.

## Confidential Business Information

The Senate bill requires that new “confidential business information” (CBI) claims must be substantiated and reviewed and approved by EPA, and it imposes certain requirements for CBI claims for chemical identity (for substances not already on the confidential portion of the TSCA Inventory). The bill further provides that all CBI claims will expire after 10 years unless they are renewed and re-substantiated.

The bill also directs EPA to review all active chemicals on the confidential portion of the TSCA Inventory within five years after compiling the initial active list, and it requires that the CBI claims for the chemical identities of these chemicals must be re-substantiated. If EPA determines that the CBI claims are valid and the identities of these chemicals should remain confidential, the CBI claims nevertheless would be subject to the 10-year time limit and would expire at the end of that period unless renewed and re-substantiated.

Under the bill, EPA may review and require re-substantiation of any CBI claim for high-priority priority chemicals or inactive chemicals at any time. CBI claims made before enactment that are reviewed by EPA would be subject to the 10-year time limit, unless renewed and re-substantiated at the end of that period.

Finally, the bill permits EPA to share CBI with state and local governments and health professionals under certain conditions.

## Fees

The Senate bill removes the specific fee set in the current TSCA law (which has stayed the same since 1976) and gives EPA the authority to establish “reasonable” fees, subject to an initial total limit of \$25 million or 25% of the costs for the activities covered by the fees, whichever is lower. EPA would be permitted to adjust fees in the future, however, to account for inflation and ensure that they are sufficient to defray 25% of the relevant costs, even if they exceed \$25 million.

## Rulemakings

The Senate bill requires EPA to develop formal rules to implement a number of processes and requirements established by the bill, such as establishing a risk-based screening process and “explicit” criteria for prioritizing chemicals; policies and procedures for safety assessments and safety determinations; reporting requirements relating to active and inactive chemicals; a plan for reviewing CBI claims for chemical identities of active chemicals on the confidential portion of the TSCA Inventory; and fees (in addition to any rulemakings currently required under TSCA). The bill sets various deadlines for the rulemakings.

## Development of Policies, Procedures and Guidance

The bill requires EPA to develop any policies, procedures and guidance documents within two years of enactment.

## Next Steps

Because there are significant differences between the Senate and House bills, the two bodies must agree on a compromise measure before any TSCA reform legislation becomes law. Senate and House leaders are discussing whether a formal conference committee process will be needed or whether the differences between the bills can be reconciled in a more expeditious fashion. Our lawyers will continue to closely monitor developments with this legislation.

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