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Congress Passes Sweeping Overhaul of Chemical Safety Law

On June 7, 2016, the U.S. Senate passed without amendment the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the first comprehensive overhaul of the Toxic Substances Control Act (TSCA) since the bill's enactment 40 years ago. The U.S. House of Representatives passed the bill on May 24, 2016, and President Obama is expected to sign the bill into law. The revised TSCA establishes a new regulatory framework for the assessment and regulation of chemicals, including a new chemical safety standard.

Provisions of the Revised Bill

Under the revised TSCA, new and, over time, existing chemicals will be required to undergo a new regulatory screening process to be approved for manufacture or use in the United States. Under the new process, the U.S. Environmental Protection Agency (EPA) must identify substances that are high priorities for risk evaluations, evaluate the health and environmental risks of those substances, decide whether high-priority substances present an unreasonable risk without regard to cost or other non-risk factors, and regulate substances found to present an unreasonable risk under their conditions of use – all under specific deadlines.

The bill allows EPA, for the first time, to issue unilateral orders requiring additional information to reach determinations on prioritization and risk assessment. The bill also includes new requirements relating to the protection of confidential business information and federal pre-emption of conflicting state laws.

Key changes in the bill include:

New Safety Standard

Establishes a new safety standard of “an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation … under the conditions of use.”

Defines “conditions of use” to ensure that EPA focuses on uses of chemical substances that are “intended, known, or reasonably foreseen.”

Testing of Chemical Substances and Mixtures

Authorizes EPA to develop new information by order, as opposed to a notice-and-comment rulemaking, on chemical substances at all stages of the safety evaluation process.

Establishes a tiered screening and testing process under which the results of screening-level tests or assessments of available information inform the decision of whether additional testing is required to reach a safety determination.

Inventory Reset

Within one year of enactment, EPA must require manufacturers and importers to submit reports of those chemicals listed on the TSCA Chemical Substance Inventory that they have manufactured or imported in the previous 10 years.

Chemical processors may also be required to submit these reports.

The chemicals reported will be placed on the TSCA Inventory active list, and a notification will be required to manufacture or import any chemical not on the active list.

New Chemicals and Significant New Uses

Adds a requirement to the new chemical review process that EPA determine – and publish that determination – whether a new substance or significant new use is likely to meet the safety standard before approval for commercial manufacturing or processing. This includes whether the relevant substance or new use presents an unreasonable risk to a potentially exposed or susceptible subpopulation.

Cost or other non-risk factors may not be considered.

Allows EPA to postpone a decision on a new substance until additional information is generated.

Maintains the long-standing exemptions from new chemical notification requirements.

Prioritization Screening for Risk Assessments

Requires EPA to establish a risk-based prioritization screening process for existing chemicals within one year of enactment. Chemicals will be designated as high or low priority, and EPA must publish each prioritization determination.

Prioritization designations must include consideration of the hazard and exposure potential of a chemical, including consideration of persistence and bio-accumulation, and the conditions of use.

Allows manufacturers to request that EPA designate a substance as an additional priority for safety evaluation.

Safety Evaluations and Determinations

Requires EPA to conduct a risk assessment and determination for all high-priority substances over time. Within 180 days after enactment, EPA must conduct initial risk evaluations on at least 10 substances drawn from the TSCA Work Plan. Within 3½ years, EPA must conduct risk evaluations on at least 20 high-priority substances and must designate at least 20 substances as low priority or low hazard.

Risk evaluations will eventually be performed on all high-priority chemicals.

In the risk evaluation process, EPA must determine whether a substance meets or fails to meet the safety standard based on its conditions of use.

If EPA finds that a substance does not meet the safety standard, EPA must decide within 90 days whether to issue a significant new use rule.

If the safety standard cannot be met, EPA is authorized to ban or phase out the substance.

Cost and technical feasibility are to be considered only in the choice of applicable risk management measures.

Safety determinations are considered to be final agency action and are subject to legal challenge.

Confidential Business Information

The bill establishes new procedures for protecting confidential business information (CBI) and adds a requirement for upfront substantiation of all confidentiality claims.

Establishes a presumption of confidentiality protection for a limited set of information generally considered to be proprietary, such as sales information and customer lists.

Permits certain state, local and tribal government officials and healthcare professionals to have access to certain CBI information, with penalties for unauthorized disclosure.

Requires that confidentiality claims be re-evaluated every 10 years.

Provides that current exemptions from CBI protections for health and safety studies do not include the release of data that would disclose formulas, including molecular structures, for chemical substances and mixtures whose confidentiality has been justified to EPA.

Penalties

Establishes a criminal penalty for willful violations where the person knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury.

Pre-emption

Federal pre-emption of new and existing state laws would apply when EPA determines that a high-priority chemical meets the safety standard or when EPA enacts a rule to regulate a chemical found not to meet the safety standard.

Provides for a “high-priority pause” providing limited pre-emption of new state restrictions while EPA conducts risk evaluations on high-priority substances.

States may apply for a waiver of pre-emption provisions.

Exempts from pre-emption any state law or regulation relating to a specific chemical in existence before April 22, 2016, and any past or future action taken pursuant to a state law that was in effect on August 31, 2003.

Prior state laws that do not conflict with TSCA and private rights of action under tort or contract law would be preserved.

What This Means to You

Given EPA’s new mandates and authority under the revised TSCA, industry should expect EPA to review more chemicals more thoroughly and to regulate more chemicals that do not meet the new safety standard. However, while the bill adds many new regulatory provisions with which industry

will have to comply, it also contains provisions generally supported by industry, such as protection of confidential business information, pre-emption provisions and the requirement that EPA use best available science when determining prioritization and risk assessment.

Industry should consider whether to take action well before EPA proposes to regulate a given substance. Actions may include:

Developing additional information on business-critical substances to influence a priority determination.

Voluntarily nominating a substance and paying for an expedited risk assessment review.

Commenting on draft risk evaluations or proposed risk management rules.

Industry should also be prepared for EPA to issue more unilateral orders requiring testing of substances and additional EPA scrutiny of pre-manufacture notices.

Several questions remain with respect to how EPA will implement certain mandates in the bill. For example, within one year, EPA will be required to establish a process for screening chemical substances as high or low priority. While the bill provides some guidelines for this process, there is uncertainty as to what that process will look like. Likewise, EPA will have one year to establish a process for conducting risk assessments to determine if chemicals meet the new safety standard. These are critical provisions, and industry will need to scrutinize the details of those processes when proposed by EPA.

Given the tight time frames for EPA rule promulgation, industry will need to be ready to quickly respond to any proposals. Lastly, the exemptions to the federal pre-emption provisions were included at the insistence of several Democratic senators and are designed to preserve state laws such as California's Proposition 65 warning/labeling law and Massachusetts' Toxics Use Reduction Act. As a result, restrictions on chemical substances under these state laws will be preserved.

Contact Us

For more information about how the new chemical safety bill could affect you or your clients, contact Bob Wilkinson at 314.480.1842 and Amy Wachs at 314.480.1840 of the Environmental & Chemical Regulation practice.