

SAFE CHEMICALS ACT OF 2011

Summary of Proposed Legislative Changes

There is broad agreement that the Toxic Substances Control Act (TSCA) must be modernized to adequately protect Americans from toxic chemicals. To reform TSCA in a risk-based manner that ensures safety and allows the continued competitiveness of the U.S. chemical industry, Senator Lautenberg has introduced the Safe Chemicals Act of 2011. It requires chemical companies to demonstrate the safety of industrial chemicals and directs the Environmental Protection Agency (EPA) to evaluate safety based on the best available science. It also encourages the development of safer alternatives to existing chemicals and reductions in the use of animal-based testing.

Since the bill's introduction, there have been numerous hearings, stakeholder meetings, and analyses of this legislation. Based on extensive input from fellow senators, the regulated community, environmental organizations, public health experts, and state regulators, Senator Lautenberg has developed an amendment to the bill. The proposed new language maintains the essential elements of the introduced bill, but:

- **Better Focuses Resources on Priority Chemicals:** The amendment directs EPA to evaluate chemicals in stages, screen chemicals to limit the number that require a full safety standard determination, and prioritize chemicals in need of safety standard determinations.
 - **Existing Chemicals Evaluated in Batches:** The amendment introduces the concept of batching existing chemicals for evaluation. The language directs EPA to review the chemicals on its inventory in batches of approximately 6,000 chemicals per five-year period. This allows EPA to work through a large backlog of existing chemicals in an orderly and efficient manner.
 - **Chemicals Screened Before Prioritization:** In order to narrow the number of chemicals undergoing safety standard determinations, which require full risk-assessments, EPA will screen out chemicals of very low concern (which receive no further action) and chemicals of very high concern (which receive expedited risk management), and identify chemicals for which additional information is required before a screening decision can be made.
 - **Chemicals Undergo Safety Standard Determinations in Order of Priority:** For chemicals requiring a safety standard determination, the amendment establishes three priority levels to guide the order of the determinations. This is intended to focus efforts first on those chemicals that are most likely to pose unacceptable risk.
 - **Immediate Action on Asbestos.** Asbestos is identified as a substance of very high concern, for which EPA must quickly require exposure reduction measures.
- **Requires New Information and Testing Only When Necessary:** Under the amendment, EPA relies first on existing information before requiring companies to submit new information to the agency. Throughout the new language, EPA is directed to rely on existing information first and require additional testing only to the extent necessary to determine safety.

- **Minimum Information Requirements Targeted:** Different tiers of minimum information sets are tailored to fit the different stages of evaluation. This is intended to minimize the data burden for regulated entities, while still providing EPA with the necessary information to make decisions.
- **Use Reporting Narrowed:** EPA is given authority to require use reporting every four years, similar to the current Chemical Data Reporting (CDR) rule requirements, for both manufacturers and processors. Information required in use reporting is limited to what is already available to companies.
- **Better Balances Protection of Confidential Business Information (CBI) and Public Disclosure:** The bill assigns various types of information submitted to EPA into different categories. Information like trade secrets and precise production information is always eligible for CBI protection. Other types of information are eligible for CBI protection on a case-by-case basis, including the identity of chemicals, which can be protected for a specified period of time based on market conditions; and certain information is never eligible for CBI protection, including health and safety information, agency decisions, and general market information.
- **Encourages Innovation By Improving the New Chemicals Process:** Companies are able to bring new chemicals quickly into commerce through a process that is similar to existing TSCA requirements, but with enhanced data and safety requirements.

SUMMARY OF CHEMICAL EVALUATION PROCESS

The process established by the amendment would begin by updating the TSCA inventory, so that EPA and the public know the universe of chemicals currently in commerce (Sec. 8). The chemicals on the updated inventory would then be assessed over an extended period of time (Sec. 6). This would be accomplished by creating batches of about 6,000 chemicals for EPA to review, each over a five-year period. Within each batch, EPA would identify chemicals that are either of very high concern (which require expedited risk management) or very low concern (which require no further action). EPA would also identify chemicals that require additional safety information and those that require a safety standard determination. For the category of chemicals requiring a safety standard determination, EPA would focus its resources first on the highest priority chemicals. Risk management, such as use restrictions or labeling, would be required where necessary to ensure a chemical meets the safety standard. If a chemical cannot meet the safety standard, only critical uses of that chemical may be permitted.

For new chemicals (Sec. 5), the process would be similar to the process under existing TSCA. Manufacturers would submit a pre-manufacture notice (PMN), along with a set of basic information on the chemical. EPA would then perform an initial screening of the chemical based on that information set and other existing information. Chemicals of very low concern would be included on the active inventory without further review. Chemicals likely to meet the safety standard would also be placed on the inventory and await further evaluation in the next batch of chemicals. If a new chemical substance was found to be a substance of very high concern or unlikely to meet the safety standard, it would generally be prohibited from entering commerce except for critical uses.