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PRODUCT LIABILITY UPDATE**Senator Introduces Latest Attempt to Overhaul TSCA**

Sen. Frank Lautenberg (D-New Jersey) recently introduced the Safe Chemicals Act of 2011 (the Bill) in an attempt to overhaul the 35-year-old Toxic Substances Control Act (TSCA). The Bill is a revised version of a similar bill Lautenberg introduced last year that failed to gain significant congressional support. TSCA, which authorizes the U.S. Environmental Protection Agency (EPA) to regulate chemicals and chemical manufacturing, has not been amended since its adoption in 1976 despite advances in scientific knowledge concerning the toxicity of numerous chemicals and industry-led improvements in chemical manufacturing and environmental processes. While it is unclear at this stage whether Congress will act on the Bill, it merits close monitoring.

The new legislation would give EPA an unprecedented level of authority to regulate the use of chemicals and would require manufacturers to submit information attesting to the safety of every chemical in production and of any new chemical prior to its introduction to the market. Currently, EPA is authorized to review the safety of new chemicals before they are introduced to the marketplace, but it does not mandate reviews of existing chemicals. The Bill would require manufacturers to ensure that all chemicals meet a risk-based safety standard styled after the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH). It would also require companies to disclose sufficient health and environmental information about the chemicals they manufacture, process, or import as a condition for being allowed to distribute them in commerce.

THE SAFE CHEMICALS ACT OF 2011

The Bill would require chemical companies to develop and submit a minimum dataset for each chemical they produce within one year after the date of its enactment. It would mandate that EPA establish the data that constitute minimum datasets for chemical substances, including information on the characteristics, toxicological properties, exposure, and use of a chemical substance.

Under the Bill, chemical manufacturers would be required to prove the safety of their products before marketing. Current regulations require EPA to review the safety of new chemicals prior to marketing, but it can only call for investigation of an existing chemical after being presented with evidence that the chemical is dangerous. As with REACH, the Bill is based on the “precautionary principle,” which holds that industry should manufacture, import, use or place substances on the market with a level of responsibility and care that would ensure, under reasonably foreseeable conditions, that human health and the environment are not adversely affected. In adopting the precautionary principle, the Bill, like REACH, imposes on manufacturers and importers of



chemicals the burden to provide detailed information regarding the health and safety of the substances they manufacture, export, or import in the United States.

This affirmative duty would require that manufacturers or processors of a chemical substance, in addition to supplying minimum datasets, provide declarations including:

- Details regarding the properties of the chemical substance
- Production data including manufacturing data
- Processing, distribution, and customer information
- Lists of known health and safety studies involving the chemical substance
- Exposure information regarding the chemical substance

Companies will be required to maintain files supporting their declarations and submit to random inspections of these files by EPA.

User fee provisions will be paid by “declaration submission” fees from chemical manufacturers, combined with penalties for violations that have been increased by \$12,500 to \$25,000, depending on the nature of the violation. Additionally, the Bill would direct EPA to require testing of any chemical substance and submission of test results by a specified date as necessary to enable EPA to make any determination or carry out any provision of the Bill.

After receiving a minimum dataset for a particular chemical, the Bill would require EPA to assign it one of the following classifications, based on a risk determination:

- Priority Class 1 (requiring immediate risk management based on toxicity and widespread exposure to humans)
- Priority Class 2 (requiring further safety standard determinations)
- Priority Class 3 (requiring no immediate action)

Classification would be accomplished with the assistance of an interagency committee consisting of appointees from:

- EPA
- Department of Labor
- Department of Occupational Safety and Health
- Council on Environmental Quality
- National Institute for Occupational Safety and Health



- National Institute of Environmental Health Sciences
- National Cancer Institute
- National Science Foundation
- Secretary of Commerce

Priority classifications and submissions from chemical manufacturers and processors would be made public on an EPA website.

Further, the Bill would require EPA to expedite action to reduce risks posed by the chemicals of highest concern as determined through its data collection process. These actions may include:

- Monitoring any chemical substance that EPA determines has an adverse effect on early childhood development and creating an Interagency Science Advisory Board on Children's Health Research
- Creating an Interagency Science Advisory Board on Alternative Testing Methods
- Implementing various green chemistry initiatives including creation of four federally funded "green chemistry and engineering centers"
- Conducting annual random inspections of laboratories that test chemicals under the Bill
- Identifying "hot spots" with disproportionate residential exposure to toxic chemical substances

The Bill would pose many ramifications for chemical manufacturers and processors in addition to the burden of proving the safety of their products. Among other issues, reporting, record-keeping, and inspection procedures could require **each manufacturer** of a particular substance to submit information to EPA, as opposed to the joint industry submission process contemplated by REACH.

In addition, companies submitting information to EPA could risk inadvertent disclosure of trade secrets and other confidential information. Although the Bill expressly seeks to protect confidential business information (CBI) by allowing a company to classify portions of its submissions as such, EPA has unlimited authority to determine whether that CBI is still entitled to such treatment following its disclosure. EPA also may disclose CBI without notice to the company if it determines the release of the information is necessary to protect against an "imminent and substantial endangerment to health or the environment." Moreover, chemical manufacturers and processors who attest to the safety of products once labeled safe but since found to be unsafe could face litigation arising from claims based on submissions made years, or even decades, prior to any known potential for harm.



FOR MORE INFORMATION

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