

Comprehensive TSCA Reform Bill Introduced in Senate

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Senator Frank Lautenberg (D-NJ) last month introduced the Safe Chemicals Act of 2010 (the "SCA"), a bill proposing a complete overhaul of the regulation of chemicals under the Toxic Substances Control Act of 1976 ("TSCA"). The SCA as written represents a major shift in who has the burden of proof in chemical safety showings – currently the EPA has the burden to show that a chemical is unsafe before its use is controlled, whereas the SCA would place the burden on manufacturers and processors to show that a chemical is safe. This new scheme would give federal regulators significant new powers in the regulation of chemicals. Following are some key provisions and requirements of the proposed bill:

Declarations of Current Manufacture or Processing

All manufacturers and processors would be required to submit to EPA a declaration containing certain information for each chemical substance or mixture that they currently manufacture or process. The initial declaration would be due within one year of passage of the SCA, and would require the submittal of the following types of information: production information, information on how the chemical is used, identification of downstream users, readily available health and safety studies, toxicological properties, exposure and fate information, etc. Declarations would be required for all existing chemical substances and mixtures. Follow-up declarations would be required every three years. It is anticipated that EPA would use information from the declarations to create a baseline of chemical usage in the United States and to assist in regulatory prioritization.

Safety Determinations

The essence of the SCA is that all existing and new chemical substances and mixtures, as well as new uses of existing substances and mixtures, that are distributed in commerce would be subject to a requirement to obtain an affirmative safety determination from EPA. To enable EPA to make its determinations, the SCA would require manufacturers and processors to develop and submit a "minimum data set" for each chemical substance or mixture they manufacture or process.

The schedule for when a chemical substance or mixture would require a safety determination would depend on whether it is a new chemical, a new use of an existing chemical, or a new chemical. For new chemicals and new uses of existing chemicals, a minimum data set would be required with submittal of the premanufacture notice ("PMN"). For existing chemicals, the schedule would be based on a priority list to be established by EPA. The priority list would contain no fewer than 300 chemicals at any give time, with new chemicals added to the list as previously listed chemicals are deemed safe and removed from the list.

Minimum data sets would be required to be submitted within 18 months after the date the chemical is placed on the priority list. EPA would have broad authority to require testing of chemicals and submittal of chemical samples as part of minimum data set submittals. Allowances would be made for the establishment of industry consortia for testing and submittal of data to avoid duplication of effort (similar to the HPV Challenge effort for MbOCA).

To obtain a favorable safety determination from EPA, submitters would be required to prove a "reasonable certainty of no harm," which would be shown if "aggregate exposure and cumulative exposure of the general population or of any vulnerable population to the chemical substance or mixture presents a negligible risk of any adverse effect on the general population or a vulnerable population." EPA's safety determinations would specify the allowed uses of the substance, production/use volume limits, and any conditions placed on the specified uses to ensure the safety standard is met.

Other Provisions

- Accelerated review timetables for substances that may present an "imminent and substantial endangerment" to health or the environment
- Submitted data to be made available on the internet
- Incentives for development of safe and "green" chemicals (e.g., expedited review processes, R&D grants, special government designations for marketing purposes (like Energy Star rating for appliances))
- "Environmental justice" issues (e.g., identification of locales with disproportionate exposures to chemicals and development of action plans to reduce those exposures)
- Would allow states to adopt their own regulations, resulting in non-uniform standards

Although companion legislation has not yet been introduced in the House, a "discussion draft" that is substantially similar to the Senate version of the SCA has been issued. It is unknown whether Congress will be taking up the SCA during this legislative session, but it appears that the legislation has a great deal of support from environmental and consumer groups, as well as tentative support from some industry groups. PMA will be closely monitoring the progress of the SCA. As more details emerge, it may be prudent for the Association to provide comment or for individual members to contact their Senators and Representatives with their concerns.