

The Safe Chemicals Act 2.0

Finding Common Ground

Senator Lautenberg has substantially revised his Safe Chemicals Act in preparation for action in the Senate Environment and Public Works Committee. The revisions reflect input from various companies and trade associations through a bi-partisan stakeholder process he convened with Senator Inhofe. They also reflect input from multiple formal and informal dialogues between Safer Chemicals, Healthy Families and chemical and consumer product companies. The result is legislation that maintains strong protections for public health and the environment, while substantially reducing the burdens on regulated industry and making the best use of EPA resources. The major revisions include:

A New "Architecture" that Responds to Industry Concerns about REACH

A major concern expressed by regulated industry about the earlier legislation was the fear that the new program would require industry to develop too much health and safety information too soon in the process, and that EPA would not be able to manage and act on the information in a timely manner. This concern was based partly in industry's perspective on the European Union's REACH law.

The Safe Chemicals Act 2.0 responds to these concerns by delineating a new "architecture" for the program in Section 6 and more carefully tailored information requirements in Sections 4 and 8. EPA will review and act on chemicals in "batches," starting with roughly 6,000 chemicals, based on those manufactured above the reporting threshold for TSCA's current Chemical Data Reporting program. It will categorize those chemicals as follows:

- Chemicals of very low concern will effectively be set aside, with no further action.
- Chemicals of very high concern will be promptly subject to measures to maximally reduce exposure to them. This category is limited to toxic chemicals that persist and build up in the environment and in people, or chemicals that are highly toxic, and to which there is widespread exposure.
- Chemicals lacking sufficient information to judge their safety will be subject to a requirement that their manufacturers provide a basic set of data adequate to re-categorize them.
- The remaining chemicals will be prioritized for safety determinations to be conducted by EPA. The information needed will be greatest for chemicals in this category.

The chemicals in each batch will be subject to appropriate actions within 5 years: set aside, expedited exposure reduction, minimum information requirements (carefully tiered), or safety determinations and needed risk management. At the end of 5 years, the EPA would then begin the process again with the next "batch" of 6000 chemicals.

New Chemicals Allowed on the Market Prior to a Safety Determination

Under the current program, industry is not required to demonstrate the safety of new chemicals – nor is EPA required to assure safety – before they are allowed on the market. Industry files a "pre-manufacture notice" that in the great majority of cases contains no health and safety information.

Health and environmental leaders, as well as the general public, uniformly believe new chemicals should be proven safe before they are allowed on the market. However, the chemical industry has argued strongly that *any additional requirement* prior to market introduction would unduly impede their ability to bring a product to market.

The Safe Chemicals Act 2.0 allows most new chemicals on the market after a preliminary EPA review, with modest enhancements in the information required. Unless EPA found in its review that the chemical was unlikely to meet the safety standard, the chemical would be allowed to enter the market. The chemical would then follow the process for existing chemicals and be added to the current or next batch for categorization and further evaluation as described above.

The provisions for new chemicals represent a major concession to the chemical industry by allowing chemicals on the market quickly and relatively little information, but they also better safeguard public health and the environment than existing law by ensuring that more substantial review and action are undertaken relatively soon after market entry.

Confidential Business Information Protection Assured

Confidential Business Information (CBI) has been a flashpoint in the debate over chemical management. On the one hand, health advocates point to the public's Right to Know about chemicals to which they may be exposed and the strong health and safety improvements that have come from disclosure of chemical information under other laws. On the other hand, businesses that invest significant time and money in developing a new product don't want to lose that investment. There is a clash of legitimate interests.

Currently, there is broad agreement among health advocates, industry and EPA that CBI is widely over-claimed. However, within industry, and particularly the formulated products industry, there was concern that the original Safe Chemicals Act would allow too much information to be revealed.

The Consumer Specialty Products Association and Safer Chemicals Healthy Families pursued a compromise on CBI, which the new section 14 reflects. It provides clear direction for making and reviewing CBI claims by establishing three categories of information: 1) always eligible for CBI protection, 2) never eligible, and 3) eligible if substantiated. This last category will now include the identity of new chemicals for a time after their market entry, which means manufacturers do not have to disclose that information to their competitors immediately upon entering the market. While this would generally apply even in the context of health and safety studies, disclosure would be mandated for any chemical that is a known or probable toxicant, a PBT or that does not meet the safety standard in the bill. The section also requires that submitters of CBI be notified of the sharing of that information with State governments.