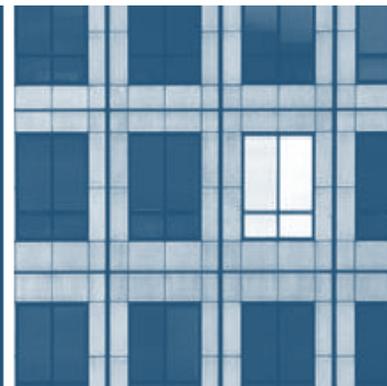


On the Subject



Safety, Health & Environment Advisory

August 2, 2010

On July 22, 2010, Representatives Rush (D-IL), Waxman (D-CA), Castor (D-FL), DeGette (D-CO), Schakowsky (D-IL) and Sarbanes (D-MD) introduced the Toxic Chemicals Safety Act of 2010 (TSCA). This bill is similar in many respects to one entitled Safe Chemicals Act of 2010 filed by Senator Lautenberg (D-NJ) on April 15, 2010. Both of these proposals to amend TSCA could have far-reaching effects on the chemical industry and on manufacturers, processors and importers of a wide range of materials, potentially subjecting them to requirements like those under the REACH program instituted in the European Union.

TSCA Reform In The House & Senate: Extending EPA's REACH

The Toxic Substances Control Act (TSCA), which authorizes U.S. Environmental Protection Agency (EPA) to regulate the safety of chemicals distributed in commerce, is the only major environmental statute that has not been reauthorized since original enactment in 1976 – but change may be coming. Bills recently introduced in Congress to amend TSCA could have far-reaching effects on the chemical industry, potentially subjecting a broad range of substances manufactured or processed in or imported into, the United States to a program like REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), instituted in the European Union.

On July 22, 2010, Representatives Rush (D-IL), Waxman (D-CA), Castor (D-FL), DeGette (D-CO), Schakowsky (D-IL) and Sarbanes (D-MD) introduced the Toxic Chemicals Safety Act of 2010. In many respects it resembles the bill introduced by Senator Lautenberg (D-NJ) as the Safe Chemicals Act of 2010 on April 15, 2010. Both bills would significantly change chemical regulation in the United States.

Regulators and certain members of industry appear to agree that amendment of the statute may be desirable, given the evolution of

both the chemical industry and public awareness of health and safety issues, over the last 30+ years. Under the Obama administration, EPA has identified assuring the safety of chemicals as one of its top four priorities. Federal legislation appears possible in 2011 or 2012.

The Proposed Reforms

Safety Determinations

The centerpiece of the proposed legislation in both houses of Congress is an EPA determination that every chemical substance (possibly including those in mixtures and articles) allowed in commerce meets an established safety standard. TSCA broadly defines “chemical substance” as any “organic or inorganic substance of a particular molecular identity.” Thus substances such as metals and metal alloys can be viewed as “chemical substances” under its provisions. In what would be a significant shift in the law, the bills place the burden on industry to show that the chemical substances they manufacture, process and / or import meet such a safety standard. Under this approach, the manufacturing, processing and importation of chemicals that do not meet the safety standard would be prohibited.

While the parameters of the final “safety standard” are not clearly identified, EPA would appear to have broad authority in formulating the standard. Both bills suggest that the regulated industry would have to establish a reasonable certainty that no harm will result to the general population or to vulnerable populations such as children, pregnant women, the elderly and those who work with chemical substances, as a result of aggregate exposures to the substance in question.

The bills treat safety determinations for “existing” chemicals (e.g. chemicals that are on the TSCA inventory already) and “new” chemicals (and new uses of existing chemicals) differently. For existing chemicals, EPA would establish a priority list of 300 “existing” chemical substances for which safety determinations must be made. EPA must supplement the list with additional existing chemicals as others are removed until all chemical substances in commerce have been subject to a safety determination.

Under the Senate bill, this list must be established within 18 months of enactment. The House bill establishes a priority list of 19 chemicals including Bisphenol A, formaldehyde, n-hexane, hexavalent chromium, methylene chloride, trichloroethylene and vinyl chloride, among others, and would require EPA to establish a complete list of 300 within 12 months.>

The Senate bill generally would require manufacturers to make an initial safety determination submission within 30 months after a chemical is placed on the priority list, and for EPA to make a safety determination within 180 days of that submission. The House bill generally would require EPA to make a safety determination within 30 months of a chemical's placement on the list. However, it would require a safety determination for those substances on the list at the time of enactment within 18 months thereafter.

Exceptions to Safety Standard Requirement

Both bills would prohibit manufacture or processing of a new chemical unless a pre-manufacture notice and other supporting information, including certain health and safety data, is submitted. With certain exceptions, it would also be necessary for EPA to determine that the substance has met the safety standard. The Senate bill generally would require EPA to make a safety determination within 180 days of submittal of the pre-manufacture notice, whereas the House bill would give EPA up to nine months to make such a determination.

Both bills contain EPA authority to grant exceptions to the pre-manufacturing notice procedure, and to manufacturing prohibitions or conditions that have been placed on production as described below. Potential bases for granting exceptions include, among others, specific exceptions based on national security interests, the potential that a substance's unavailability would significantly disrupt the national economy, and critical or essential uses.

Conditions on Manufacture or Processing>

The bills would provide EPA with broad authority to impose conditions through its safety determination on manufacturing and processing in order to ensure a chemical meets the safety standard. The bills would expressly authorize EPA to impose the following:

- Limits on quantity manufactured, processed, or distributed in commerce;
- Limits on concentration for a particular use;
- Limits on quantity distributed in commerce for particular use;

- Warning requirements;
- Recordkeeping requirements;
- Conditions on manner of commercial use;
- Requirements regulating disposal; and
- Mandate to develop risk reduction plan
- Broad Data Gathering Authority

Both bills would require the submittal of significant information to EPA and provide EPA with additional data gathering authority and responsibility. They provide that:

- EPA must define a "minimum data set" that industry has to submit for each chemical, including a broad range of information on substance characteristics, hazard, exposure and use of chemical substances and mixtures.
- EPA has broader authority to require, by rule or order, additional testing of chemicals necessary to implement the law.
- Manufacturers must identify the chemicals that they manufacture or process, as well as their manufacturing facilities, known health and safety studies associated with each chemical, and other information relating to health and safety effects.
- Availability of Administrative and Judicial Review

The bills provide broad opportunities for seeking review of EPA safety determinations and other EPA decisions. Any person can petition the EPA for a redetermination of whether a chemical meets the safety standard. If new information raises a credible question as to whether the chemical substance continues to meet the safety standard, EPA will have to make a redetermination of compliance.

The Senate bill would also limit the opportunity for judicial review of some EPA decisions. The bill specifically precludes judicial review of (1) EPA decisions to place a chemical substance on the priority list; and (2) an EPA determination that a manufacturer or processor has not met the burden of proof that a chemical substance meets the safety standard.

Public Availability of Information/Protection of Confidential Business Information

Under the proposed bills, health and safety information submitted to EPA will be made available on the internet. EPA must

establish an electronic database and make available “significant information” that it receives. Industry will still be able to claim protection for Confidential Business Information (CBI). Although health and safety information is not necessarily protected from disclosure under the current law, the bills shift the emphasis of the law’s data disclosure provisions to make more clear the preference to make health and safety studies available to the public. Furthermore, the House bill gives EPA the authority to impose penalties on manufacturers who improperly designate information as CBI.

Open Issues

The end product of these TSCA reform efforts remains uncertain. It is clear, however, that the House and Senate bills raise important issues that could have significant consequences for industry if the legislation ultimately passes. Such issues include:

- What is the appropriate safety standard;
- Who should have the burden of proving a chemical is safe or unsafe;
- To what extent do obligations imposed under the safety standard extend down the manufacturing and processing chain;
- To what extent should EPA be able to regulate the manufacture and processing of chemical substances through a safety determination;
- Which EPA decisions will be subject to judicial or administrative review;

- To what extent can manufacturers/processors work together to develop data, share data or use the data of others, and to what extent would shared efforts raise anti-trust concerns;
- Will trade secrets and confidential information be compromised; and,
- How will the program will be funded.

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