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Congress Introduces Significant New U.S. Toxic Substances Control Act Reform Legislation

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On April 15, 2010, both Houses of Congress introduced legislation aimed at revamping the Toxic Substances Control Act of 1976 (TSCA). As explained in more detail below, if adopted as written, this legislation could impose significant new requirements and constraints on businesses that manufacture or import chemicals (including as constituents of imported products).

Senator Frank Lautenberg, D-NJ, introduced the Safe Chemicals Act of 2010, and Representatives Bobby Rush, D-IL, and Henry A. Waxman, D-CA, presented a discussion draft of the Toxic Chemicals Safety Act of 2010. While this is not the first time Congress has attempted to overhaul American policy on the regulation and import of toxic substances, these bills are particularly significant, as they have been introduced at a time when both the chemical industry and public health and environmental organizations are both calling for TSCA reform.

Proponents of the newly introduced TSCA reform bills say that they are aimed at achieving stronger public health and safety regulation, greater access to information, and a safer and more sustainable market for chemical products. Lisa Jackson, the Obama-appointed Administrator of the U.S. Environmental Protection Agency (EPA), has also recently called for a revision of the agency's chemical management and risk assessment programs, and advocates the enactment of a strong safety standard for chemicals. In fact, the TSCA reform bills, as introduced in Congress, would greatly expand the EPA's authority to require manufacturers and importers to provide any data needed to determine a chemical's safety and to take action beyond what TSCA currently permits to restrict chemicals that may pose a high risk to the public. Both newly introduced TSCA reform bills would also place the burden on industry to demonstrate that such substances are safe in order to remain in the market.

Below is a brief summary of the main aspects of TSCA, its results, and a description of changes proposed in both TSCA Reform bills.

OVERVIEW OF CURRENT U.S. FEDERAL LEGAL SCHEME REGULATING TOXIC SUBSTANCES

TSCA, enacted in 1976, was aimed at developing safety and use information, and regulating the production and use of industrial chemicals deemed a risk to public health and the environment. In 1979, there were 61,000 chemicals identified in TSCA's inventory of chemicals; today, the inventory comprises more than 84,000 substances and the exact number of chemicals currently in commerce is uncertain.

Chemicals identified in the TSCA inventory are currently subject to EPA testing requirements and controls only if they are found to pose an "unreasonable risk" to human health or the environment. This determination is, in part, based on a cost-benefit analysis. As a result, chemicals with beneficial commercial applications have often not been comprehensively regulated under TSCA, and only five chemicals – PBCs, CFCs, dioxin, asbestos, and hexavalent chromium – have been banned in the past 30 years.

Client Alert.

For new chemicals not already identified in the inventory, TSCA requires businesses to provide a pre-manufacturing notification and to undergo a 90-day review process. To date, EPA has reviewed more than 35,000 notifications, but submissions have relied largely on anticipated uses, with only a small percentage containing actual test data. Barring further action by EPA, such chemicals are allowed to enter commerce without further assessment.

Finally, existing law limits disclosure of confidential proprietary business information submitted pursuant to TSCA. As a result, EPA has limited authority to provide the public and other levels of government with certain information on production and risk from chemicals that have been made subject to a confidentiality claim by a manufacturer or importer.

THE PROPOSED TSCA REFORM BILLS

The proposed TSCA reform bills seek to overhaul the current federal framework regulating toxic substances in ways that may create significant new burdens for businesses:

- **Businesses would bear the burden of proving that new and existing chemicals are “safe.”** Manufacturers would be required to submit information proving the safety of every existing chemical in production, and to provide a minimum set of data for every new chemical before it enters the stream of commerce.
- **Chemicals would be evaluated under a stringent new standard that may be impossible to meet.** To find a chemical “safe,” EPA must determine that there is a “reasonable certainty of no harm.” Provisions in the draft House bill would require application of this standard to account for “aggregate and cumulative exposure to a chemical substance or mixture and that provides a reasonable certainty of no harm, including to vulnerable populations” and to “protect[] the public welfare from adverse effects, including effects on the environment.”
- **Chemicals that do not meet this stringent new standard *cannot remain on the market.*** New chemicals may be kept from the market until EPA makes the required findings.
- **Information submitted under TSCA would be subject to public disclosures.** The bills grant EPA authority to make information on new and existing chemicals available to the public and to other levels of government. Claims of confidentiality would be subject to review and approval by EPA, and would eventually expire.

While many aspects of the TSCA reform bills introduced in the U.S. Senate and House of Representatives are substantially similar, there are also some key differences. For example, the House bill includes a list of specific chemicals – like bisphenol-A and formaldehyde – requiring expedited review and further risk assessment by EPA within one year, while the Senate bill gives EPA general authority and more discretion to manage chemicals of concern to the agency without specifying particular substances for expedited action.

CRITICAL ISSUES AND TIMELINE FOR TSCA REFORM

Businesses should be concerned with these new requirements. It is unclear, for example, how EPA is to determine “cumulative” or “aggregate” exposures to a chemical from all possible sources, as the bills currently appear to require. Such a stringent (and vague) standard may result in blocking the use of essential chemicals used in a diverse number of applications. The legislation may also hinder the development of new chemical substances if minimum data showing “no harm” must be provided from the outset.

Several environmental organizations, most notably the Environmental Defense Fund, and the Safer Chemicals – Healthier Families Coalition, are advocating for the amendments and are also seeking changes to address what they characterize as certain “loopholes” in the bills concerning the entry of new chemicals to the market. Interestingly, the Environmental Defense Fund sought – and failed – to introduce similar requirements into a comprehensive new consumer protection

Client Alert.

statute that was enacted by the Canadian Parliament last summer. Those amendments would have resulted in an outright ban of chemicals that could not meet an aggregate exposure analysis.

Better defining the proposed standard that EPA will apply under a revised federal statutory framework for regulating toxic substances appears to be the main challenge lawmakers will have to address before TSCA Reform becomes law. Since only about 60 legislative days in this session of Congress remain, upcoming stakeholders' discussions of the bills could delay passage of the legislation until at least next year. On April 15, the day both bills were introduced, EPA Administrator Lisa Jackson stated that the agency still needed to fully analyze them. However, House Democrats have proposed an aggressive schedule to vote on the Rush-Waxman bill, and are planning to hold hearings and move it through committees in June or July. The Senate has not announced plans for hearings and will likely consider the legislation along a longer timetable.

Notwithstanding disagreement between the industry and environmentalists on these items, due in part from pressures for harmonization created by the implementation of the European Union's REACH program for regulating toxic substances and state-led efforts such as the California's Green Chemistry Initiative, TSCA Reform is coming forward fast and stands a good chance of being enacted by the Congress and signed into law by President Obama within the next year. Businesses are well advised to follow its development and may elect to begin adjusting their product development and compliance programs in anticipation of enactment.

Morrison & Foerster attorneys have regularly advised and represented clients and trade associations on TSCA, REACH, and state-level toxic substances issues since TSCA's enactment and continue to do so today.

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