Reforming the Nation's Chemical Regulatory System: A Legislative Overview

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The growing movement to reform the nation's chemical regulatory system gained additional momentum last month when legislation to reform the Toxic Substances Control Act (TSCA) was introduced in the U.S. Senate and House of Representatives. TSCA, which was signed into law in 1976, remains the only federal environmental law that has never been amended or updated.

Introduction of TSCA reform legislation was long-expected. Senator Frank Lautenberg (D-NJ), Chairman of the Senate Environment and Public Works Committee's Subcommittee on Superfund, Toxics, and Environmental Health, is the lead sponsor of S. 3209, the "Safe Chemicals Act of 2010" (Senate bill). He has been an outspoken advocate for TSCA reform and has sponsored similar TSCA overhaul legislation (the "Kid Safe Chemicals Act") in previous Congresses. House Energy and Commerce Committee Chairman Henry Waxman (D-CA) and Subcommittee on Commerce, Trade, and Consumer Protection Chairman Bobby Rush (D-IL) are authors of the "Toxic Chemicals Safety Act of 2010" (the House discussion draft). Both have also been outspoken TSCA reform advocates and have introduced the House version of the "Kid Safe Chemicals Act" in previous years. Throughout this 111th Congress, Senator Lautenberg and Congressmen Waxman and Rush have convened a number of hearings focused on the need for TSCA reform.

This advisory provides a brief overview of the House and Senate proposals and discusses in more detail the prospects for passage of TSCA reform legislation.

The Pressure For Legislative Action

The Obama Administration is pushing aggressively for TSCA reform. U.S. Environmental Protection Agency (EPA) Administrator Lisa P. Jackson has indicated that revising and strengthening the Act to better manage chemical risks is a top priority. Last September, Administrator Jackson—who holds a master's degree in chemical engineering—outlined six "Essential Principles for Reform of Chemicals Management Legislation" to inform the legislative process and to ensure that EPA has "the mechanisms and authorities to expeditiously target chemicals of concern and promptly address and regulate new and existing chemicals."

Calls to reform our nation's chemical laws were further bolstered by the President's Cancer Panel's (PCP) May 6 report titled, "Reducing Cancer Risk: What We Can Do Now." The report offered a scathing analysis of TSCA, stating that it "may be the most egregious example of ineffective regulation of environmental contaminants." The PCP went on to say that, "because of TSCA's constraints and weakness, EPA … has been unable to substantially restrict or eliminate the use of … known carcinogens" and concluded that existing regulations for environmental contaminants need to

be updated, strengthened and enforced. Specifically, the report's recommendation section stated:

A precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action is taken to reduce or eliminate exposure. Though not applicable in every instance, this approach should be the cornerstone of a new national cancer prevention strategy. … Optimally, [legislation] should shift the burden of proving safety to manufacturers prior to new chemical approval, in mandatory post-market studies for new and existing agents, and in renewal applications for chemical approval.

The incorporation of that "precautionary principle" in the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) legislation has no doubt further spurred calls for similar reforms in the U.S. A recent federal ban on certain phthalates and limits on lead in children's products, as well as California's Green Chemistry Initiative, also have set the stage for action by Congress. In fact, the proliferation of state chemical regulations even has generated interest from some regulated parties in enacting comprehensive TSCA reform at a federal level to prevent a patchwork of differing state requirements. The environmental community also has been loudly calling for TSCA reform and citing a 2009 Government Accountability Office (GAO) report, which found that the TSCA program created a high risk for waste, fraud, abuse and mismanagement.

Perceived Limits of the Existing TSCA Framework

Under the current TSCA regime, EPA faces a significant burden of proof before it can regulate, or even request companies to conduct additional testing for, a chemical. EPA must find that a chemical presents or will present an "unreasonable risk" to human health or the environment (or that the substance is produced in substantial quantities and there is or may be substantial human or environmental exposure) before the agency can take action to require testing to evaluate the chemical's potential toxicity or to place limits on the manufacture, distribution or processing of the substance. Conversely, TSCA does not require chemical companies to test new chemicals for toxicity or potential exposures before placing a chemical on the market (i.e., before submitting a pre-manufacture notice to EPA).

The GAO concluded in a 2009 report[1] (released concurrently with a February 26, 2009 hearing held by Chairman Rush's Subcommittee) that:

TSCA generally places the burden of obtaining data on existing chemicals on EPA, rather than on the companies that produce the chemicals. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce annually for their toxicity, and companies generally do not voluntarily perform such testing. Further, the procedures EPA must follow in obtaining test data from companies can take years to complete. While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet present a legal threshold that has proven difficult for EPA and discourages the agency from using these authorities.

Consequently, since 1979, EPA has used its authority to require testing for fewer than 200 of the thousands of chemicals in commerce and banned or limited the production of only five substances.

This theme was echoed in comments at the 2009 subcommittee hearing. Subcommittee Chairman Rush stated, "TSCA is meant to provide adequate data on the potential health and environmental

risks of all chemical substances and mixtures in the United States. Furthermore, the statute is supposed to provide EPA with adequate regulatory tools to protect the public from unreasonable risk of injury to health or the environment. Unfortunately, the statute has seemingly been a failure on both of these basic policy goals." Full Committee Chairman Waxman indicated that reform efforts were long overdue as "for years, it has been clear that TSCA is not living up to its intent."

The TSCA Reform Bills

Both the Senate bill and the House discussion draft are modeled after REACH and reflect the Administration's core principles—namely, they would require manufacturers – and, in some cases, "processors" – of chemicals to provide comprehensive health and safety data before a chemical, or product containing that chemical, could be sold in the U.S. The key provisions of these bills include:

- **Information Submission**: Require manufacturer submission of a minimum dataset for all chemical substances and mixtures, including information on substance characteristics, hazard, exposure pathways and uses. The precise "minimum data set" requirements are to be established by the Administrator. The Administrator has the authority to require testing or information in excess of the established "minimum data set."
- **Risk Prioritization**: Requires EPA to: (1) publish a priority list that categorizes all chemical substances distributed in commerce; (2) develop a priority list for making safety determinations for at least 300 chemical substances; and, (3) determine whether a manufacturer has established that priority-list substances meet applicable safety standards.
- **Potential Ban**: Prohibit the manufacture, import, or distribution in commerce of a chemical substance if EPA determines that the manufacturer has failed to comply with this Act or that the substance does not meet applicable safety standards. The House discussion draft identifies specific chemicals of concern for expedited review and potential prohibition (e.g., BPA and formaldehyde). The Senate bill provides EPA the same authority to deal with unspecified chemicals of concern.
- **New Safety Standard**: Establish "a reasonable certainty of no harm" as the new "safety standard," replacing the existing "unreasonable risk" standard described above. To meet the standard, there must be a reasonable certainty that no harm will be caused by aggregate or cumulative exposure of a fetus, infant, child, worker or member of other sensitive subgroup to the chemical substance or mixture.
- **Safer Alternatives ("Green Chemistry")**: Require EPA to create market incentives and research grants for the development of safer alternatives to existing chemical substances.
- **Database**: Require EPA to create a database to share information on the toxicity and use of, and exposure to, chemical substances and provide public access to such data. Manufacturers would be required to provide information on chemical identities of mixtures, as well as data about manufacture, processing, and distribution locations, health and safety studies, production, volume, use, and exposure data, and all available information about the physical, chemical or toxicological properties of chemical substances or mixtures. Both proposals also narrow the conditions under which confidential business information could be claimed or granted.

Outlook

While TSCA reform, at a conceptual level, draws broad bipartisan support, as well as the support of industry and activists, it is unclear whether legislation can be passed in this legislative session. Logistically, there are less than 60 legislative days left in the 111th Congress and both Chambers face a substantial number of other priorities.

Indeed, despite near universal calls for TSCA reform, early reaction to the House and Senate bills suggests that support will fracture under traditional lines. Industry is particularly concerned with the "reasonable certainty of no harm" standard – that the standard is difficult to define and impossible to meet, would make it difficult to bring new chemicals to market, and would dampen domestic innovation. Industry is further concerned with timing issues and fear that sensitive proprietary information would be required to be disclosed.

Environmentalists, on the other hand, are concerned with relaxed phase-in requirements and various mitigating provisions that provide regulatory relief for smaller-batch productions. They are also seeking to grant EPA clearer authority to restrict production of dangerous chemicals.

To be sure, the distance between the emerging factions is not insurmountable and, already, House Energy and Commerce Committee Chairman Waxman has laid out an aggressive timetable for his Committee's consideration of the legislation. Regardless of whether the overhaul can be finalized in the waning days of the 111th Congress, these legislative proposals and pressures from the Administration will no doubt lay the groundwork for consideration early in the next Congress.

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[1] Currently, EPA has authority under TSCA to request toxicity and other data from "manufacturers or processors" of a chemical (processors include companies that use chemicals to create products). In practice, EPA rarely pursues data from processors. Under the draft legislation, however, EPA would be directed to seek such information from "manufacturers and processors," thereby significantly expanding the scope of companies likely to be affected by such data requests.