TSCA-Reform Legislation: Lessons from 2010 for the Next Congress

Following the 2008 presidential election, and US EPA Administrator Jackson's subsequent announcement of the Administration's Principles for Chemical Regulatory Reform, hearings were held in 2009 and 2010 in both houses of Congress concerning the central statute in the US chemical-regulatory framework—the 34-year-old Toxic Substances Control Act (TSCA). Earlier this year, Senator Lautenberg introduced TSCA-reform legislation, while Congressman Waxman almost simultaneously circulated a discussion draft of a similar bill. In late July 2010, after a series of stakeholders discussions, Representative Waxman introduced a TSCA-reform bill, co-sponsored with representative Bobby Rush and others. Although differing in certain respects, both the House and Senate bills clearly reflect frustrations that Democrats on the Hill have had with EPA in general, and Republican administrations in particular, for failing to act more rigorously to regulate the chemical industry. The proposed legislation demonstrates determination on the part of some of the more liberal legislators to see that TSCA is amended in order to ensure that the legislation itself is not to blame for regulatory inaction.

If enacted, these pieces of legislation would grant significant new authority to EPA, and would have a sweeping impact on the chemical manufacturing and importing industry. Moreover, the amendments would allow EPA to reach well beyond the chemical manufacturing sector and regulate the day-to-day activities of processors and formulators of end-use products (including household consumer-use formulations) that contain chemical substances. However, with the two bills positioned so far to the left, and with the midterm election likely to have an impact on the composition of the Congress, this style of TSCA-reform legislation will not pass in the current Congress. Nonetheless, understanding the key provisions of these bills is important because they likely will become reference points for action in the next (2011-12) Congress.

TSCA Reform Legislation Pending in Congress

During the nearly two-year period following the 2008 presidential election, and the year since the Administration published its own principles for TSCA-reform, Democrats did not take advantage of their ample voting majorities to introduce a centrist TSCA-reform bill. Instead, TSCA-reform bills pending in the House and Senate set forth proposals to make

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fundamental and dramatic changes in the way in which chemicals are regulated in the United States and, in so doing, undermined the opportunities for bi-partisan approval of more moderate TSCA-reform legislation.

The Senate Bill

In April 2010, Senator Lautenberg introduced S. 3209, The Safe Chemicals Act of 2010.[1] Highlights of the bill include:

1. A requirement that manufacturers develop and submit a "minimum data set" (MDS) for virtually all chemicals which they produce, while authorizing EPA to request additional information by issuing immediately-effective administrative orders without having to undertake notice-and-comment rulemaking.

2. Significant expansion of the new-chemical notification program to require reporting to EPA before any new manufacturer or processor of a chemical enters the market, and before any *new uses* are commenced by any entity that manufactures or processes an existing chemical.

3. Amendments imposing a new "safety standard" on all chemicals (both new and existing), and regulatory review processes intended to place the burden of proving that a substance meets that standard on the shoulders of manufacturers and processors, rather than EPA. Thus, the proponent of a substance would need to demonstrate that any new substance, and any new use of an existing chemical, will conform to a safety standard that provides a "reasonable certainty of no harm"—taking into account both aggregate and cumulative exposures to the chemical from all uses, and considering potential effects on any vulnerable sub-population (e.g., children, the elderly, workers).

4. Provisions under which EPA would categorize and prioritize chemicals for regulatory actions based on risk, and focus the EPA's resources on evaluating those chemicals that are most likely to cause harm.

5. Significant changes to the way in which EPA manages information and protects trade secrets. The Senate bill would make it more difficult for companies submitting information to EPA to claim it to be confidential: EPA would be required to provide public access to health and safety studies and certain chemical-use information which the Agency obtains on regulated chemicals. EPA also would have to establish a public, web-accessible database for the information submitted by chemical manufacturers and the technical analyses contained in EPA's own safety determinations.

6. New programs to promote the development of "green chemistry" by providing for grants and research centers that encourage "safer" alternatives to existing chemicals.

The House Bill

The "discussion draft", released by House Democrats in April 2010, appeared to indicate an intent to "up the ante" on Senator Lautenberg's version of TSCA reform, prompting some to say that this was a clear indication that environmental groups continue to have significant involvement in Congressmen Waxman's and Rush's drafting process.

A series of stakeholder discussions hosted by House staff were part of a pledge to allow leadership to learn about possible stakeholders' concerns with the discussion draft, and to make revisions before a TSCA-reform bill would be officially introduced in the House. However, notwithstanding certain changes in the as-introduced bill when compared to the draft, the Waxman/Rush Toxic Chemicals Safety Act of 2010 would, like the Lautenberg bill, impose dramatic new requirements not only upon the basic producers of chemical substances and mixtures, but also upon the formulators of commercial and consumer use products. The changes which the House bill would make to TSCA are countless. Thus, the modifications to TSCA's core provisions alone would stifle innovation and significantly slow the market entry of new products (especially those which make use of new chemicals or represent new uses of existing chemicals), and would result in the public disclosure (including to

1 http://lautenberg.senate.gov/newsroom/record.cfm?id=323863&.

competitors) of confidential business information concerning chemicals and formulated products.

Following are key aspects of the Waxman/Rush legislation (in addition to terms concerning the protection of confidential business information, dicussed below).

1. The current TSCA Section 5 new-chemical (i.e., premanufacture) notification requirements would be significantly expanded to require the submission of notifications both by manufacturers/importers and processors, for new chemical substances and certain new mixtures (in addition to new uses of existing substances). This would convert the new-chemicals program into a registration regime. The current 90-day review period for new chemicals would be expanded by an additional nine months, to commence following an initial 90-day screening by EPA. EPA would make its safety determinations during these additional nine months.
2. Substantial new reporting obligations would be imposed. For example, within one year following enactment of the new law, an initial declaration would be required from manufacturers and processors reporting on each chemical substance and mixture they distribute in commerce. The declaration would include information on uses, production volumes, sites of manufacture and processing, and available health and safety data. Moreover, a MDS would be required with any new-substance or new-use notification for a chemical substance or mixture. Existing substances and mixtures also must have a MDS, prepared at phased intervals. Further, EPA would be authorized to issue orders requiring the submittal of data and information in addition to the MDS.
3. All substances, new and existing, would undergo an assessment, following which EPA must issue a safety determination based upon a standard that (as with the Senate bill) provides a "reasonable certainty of no harm". Such determinations would define which uses are permitted, which uses will require regulatory controls, and which uses (and increases in production volumes) will be considered "new" and therefore subject to Agency review before they may be commenced. EPA would be required to prioritize substances for making such safety determinations, and to maintain a list of no fewer than 300 chemicals (and, potentially, mixtures) for review. EPA could remove a substance from the prioritization list only when the Agency has issued the safety determination for that chemical.
4. The public and "downstream" information-disclosure requirements (imposed in an amended Section 8 of TSCA) would require producers of substances and formulated products to reveal certain information that many companies consider to be trade secrets (in particular, chemical identity information) directly to their customers, many of whom are their competitors—thereby making it possible for new and innovative products to be copied.
5. Similar to the Lautenberg legislation, the House bill would grant EPA vast powers that it currently lacks. For example, safety determinations would be issued summarily, without any process specified in the bill (thereby, e.g., authorizing EPA to prohibit on-going uses of an existing substance or mixture). Similarly, the House bill would permit EPA to impose information-reporting requirements pursuant to orders, rather than through rulemaking. Moreover, EPA could respond to violations of core requirements of the law (e.g., a failure to timely submit an MDS) by issuing an order that prohibits the manufacture or processing of the substance in question.

Adverse Impacts of TSCA-Reform Legislation on Confidentiality

The House bill's proposed amendments to TSCA Section 14, "Disclosure of Data", would add certain provisions, to TSCA's requirements concerning confidential business information, that would be onerous to innovators in the chemical manufacturing and end-product formulating sectors. Specifically:

1. EPA would be authorized to establish the criteria that the Agency uses in determining whether specific

information even constitutes confidential business information (CBI). This would enable EPA to develop its own criteria that could contradict well-established criteria concerning the "CBI exemption" in the Freedom of Information Act (FOIA, *see* 5 USC 552(b)(4)).

2. The bill would direct EPA to disclose to the public (among other information) the specific identities of chemical substances, and the specific components of mixtures, when they are: (i) included in health and safety studies; (ii) included in EPA's own safety determinations; or (iii) indicate the presence of the substance/mixture in a consumer article reasonably expected to be used by or exposed to children.

3. Companies would be required to pay fees and provide "up-front" substantiation for all CBI claims. CBI claims would be time-limited, subject to possible renewals. Moreover, EPA would be required to actively police compliance with CBI claims requirements and limitations, and the Agency would be required to disclose CBI to states, municipalities, and tribes upon their request in accordance with certain conditions regarding information security.

Conclusion

The proposed TSCA-reform bills in the House and Senate would not simply overhaul TSCA—they would replace the Act as it is currently known in favor of a profoundly more aggressive approach to the regulation of chemicals and products that contain chemicals. Proponents and detractors of the bills alike agree that the two pieces of legislation would confer enormous new authority upon EPA and new obligations upon regulated entities, including significant reporting and regulatory burdens upon companies that merely formulate chemicals into end-use products for distribution at the consumer retail level. Most notably, both bills would require manufacturers and processors (including formulators of consumer products) to generate, collate, and report a substantial amount of data and other information to EPA throughout the life-cycles of both new and existing chemical substances and mixtures. This would be followed by EPA's ongoing imposition of new conditions for the companies' continued production and use of those chemicals. And while greatly expanding EPA's powers, the bills would remove opportunities for those who may be affected by EPA's actions to participate in, and influence, the Agency's determinations and regulatory actions.

Ultimately, both pieces of TSCA-reform legislation would stifle innovation, slow new-product entry to the market, and force both EPA and businesses to reveal trade secrets and other confidential business information to competitors and the public alike. Consequently, with the prospects that a significant number of seats soon will change hands in both houses of Congress, it is most likely that compromise and movement toward a workable TSCA-reform bill will occur in the next Congress.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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