Client Advisory

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Increasing Prospects for Chemical Regulatory Reform in the 111th Congress

The growing movement to reform the nation's chemical regulatory system gained additional momentum last week with the first of what may be numerous Congressional hearings on the subject. On February 26th, the Commerce, Trade and Consumer Protection Subcommittee of the House Energy & Commerce ("E&C") Committee held a hearing, chaired by Rep. Bobby Rush (D-IL), to discuss the perceived shortcomings of the three decade old Toxic Substances Control Act ("TSCA"). Chairman Rush noted at the hearing that TSCA has "never been reauthorized or reformed, and very little oversight has been conducted on the statute's effectiveness. Today, I hope to start a deliberative process that reverses this Congressional inaction of the past." TSCA reform is also a priority of new E&C Chairman Henry Waxman (D-CA), who in previous Congresses has co-sponsored TSCA reform legislation in the House (the "Kid-Safe Chemicals Act," sponsored in the Senate primarily by Sen. Frank Lautenberg (D-NJ)).

The hearing follows numerous federal, state, and international developments that suggest that the 111th Congress is likely to reevaluate TSCA and the federal structure for regulating the manufacture, distribution, and use of chemicals (including chemicals in products) in the United States. The launch of the European Union's Registration, Evaluation, and Authorization of Chemicals, or "REACH," legislation, which dramatically shifts to industry the burden of proving chemical safety and managing chemical risks, has spurred calls for similar reforms in the U.S. Last year's 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 the federal level in order to prevent a patchwork of differing state requirements. Further, the environmental community has renewed calls for chemical regulatory reform after the release of a January 2009 report in which the Government Accountability Office ("GAO") added TSCA to a list of federal programs that are at a high risk for waste, fraud, abuse, and mismanagement.

This advisory provides a brief overview of these developments and discusses the potential for legislation during the 2009-2010 session of Congress.

Perceived Limits of the Existing TSCA Framework

Under the current TSCA regime, the U.S. Environmental Protection Agency ("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 report[1] released concurrently with the February 26th hearing 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.*
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> *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 62,000 chemicals in commerce and banned or limited the production of only five substances.

This theme was echoed in comments at the February 26th 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."

As a means of addressing these concerns and reinvigorating the chemical assessment process, and to fulfill obligations arising out of an August 2007 summit of North American leaders in Montebello, Canada, EPA instituted the voluntary Chemicals Assessment and Management Program ("ChAMP"). Under ChAMP, EPA is seeking data from industry (generated largely through the High Production Volume (HPV) Challenge program) to develop risk characterizations for 6,750 chemicals by 2012. However, ChAMP has been slow to develop and even some industry observers have recently conceded that a voluntary program may be inadequate. In addition, it appears unlikely that the Obama Administration will continue with the same vigor as the Bush Administration's emphasis on voluntary programs.

REACH and "Precautionary" U.S. Legislative Proposals

The EU's recently enacted REACH program is an obvious starting point in considering TSCA reform. REACH is based upon the "precautionary principle" concept that a manufacturer must demonstrate safety and submit comprehensive toxicity and risk management data before introducing a chemical into the market. Under REACH, as part of a data-intensive registration process, EU-based manufacturers and importers must generate and submit to EU authorities extensive toxicity and safe use information regarding the substances they produce or import.

The February 26th GAO report noted that:

> *[A] key aspect of REACH is that it places the burden on manufacturers, importers, and downstream users to ensure that they manufacture, place on the market, or use such substances that do not adversely affect human health or the environment.*
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[1] GAO, *Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act* (Feb. 26, 2009) ("the February 26th GAO report").

REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place in the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use. In addition, under REACH, chemical companies must obtain authorization to continue to use a chemical of very high concern, such as a chemical for which there is scientific evidence of probable serious health or environmental effects.

Many companies based or operating in the United States are subject to REACH and are currently incurring substantial costs to comply. Given that REACH will require many companies to generate substantial toxicity and risk information about their chemicals, there is an increasing feeling within some segments of industry and the regulatory community that a REACH-like system in the U.S. – which seemed improbable until recently – may make sense. Indeed, at the February 26th hearing, Rep. Kathy Castor (D-FL) asked several industry witnesses whether they would be supportive of "shifting the burden of proof" to manufacturers to demonstrate the safety of their chemicals. Without endorsing the REACH model, all indicated that the burden of proof should be shared between industry and EPA.

Legislation passed last year banning the use of certain phthalates above threshold concentrations in children's products and discussions of a similar ban on bisphenol A demonstrate a growing trend towards a "precautionary" legislative approach in the current Democratically-controlled Congress. While Congress may continue the chemical-by-chemical approach utilized with the phthalate "ban," legislative attention instead appears to be turning towards a wholesale overhaul of TSCA. Most prominently, Sen. Lautenberg's and Rep. Waxman's Kid-Safe Chemicals Act (S. 3040, H.R. 6100 in the 110th Congress), modeled after REACH, would require manufacturers to provide comprehensive health and safety data before a chemical, or product containing that chemical, could be sold in the U.S. market. The key provisions of the Kid-Safe Chemicals Act include:

- ***Safety Certification:*** Requires each manufacturer of a chemical substance distributed in commerce to submit to EPA, within one year of the legislation's enactment, a statement certifying that the substance meets required safety standards or that there is insufficient data to make such determination.
- ***Information Submission:*** Requires manufacturers to submit to EPA (within one year) all reasonably available information concerning the substance not previously submitted and to provide chemical safety information upon EPA's request.
- ***Potential Ban:*** Prohibits 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.
- ***Use Regulation:*** Authorizes EPA to prohibit a specified use of a chemical substance in consumer products if the use of the product in the home results in human exposure that does not meet the safety standard.
- ***New Safety Standard:*** Establishes "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 exposure of a fetus, infant, child, worker, or member of other sensitive subgroup to the chemical substance. The standard would be interpreted as requiring (a) that exposure pose no more than a risk of 1 in 1 million for substances with "non-threshold" adverse effects; and (b) application of a 10-fold margin of safety for substances with threshold effects (to account for potential vulnerability associated with *in utero*, infant or childhood exposures).
- ***Priority List:*** 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.

- ***Safer Alternatives:*** Requires EPA to create market incentives for the development of safer alternatives to existing chemical substances.
- ***Database:*** Requires 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.

While the legislation contains many controversial provisions – particularly the certification provision – it is likely to set the stage for the TSCA reform debate in 2009 and, most likely, into 2010.

The prospects for meaningful action on TSCA reform, either through the Kid-Safe Chemicals Act or another legislative vehicle, increased significantly after California Rep. Waxman's ascension to the chairmanship of the House E&C Committee at the start of the 111th Congress. While former Chairman John Dingell signaled last summer that TSCA reform was not a top priority, Rep. Waxman has long been a proponent of TSCA reform and introduced the Kid-Safe Chemicals Act in the House. The Kid-Safe Chemicals Act has not yet been introduced in the 111th Congress, but both Sen. Lautenberg and Chairman Waxman have vowed to introduce a new version this year and the theme of Rep. Rush's first Commerce, Trade & Consumer Protection Subcommittee hearing indicates that reexamination and reform of TSCA is a priority.

State Chemical Regulations

States are increasingly seeking to fill the perceived void in chemical regulation, and, in doing so, acting as another driver for TSCA reform. After leading the nation in banning certain phthalates, in 2008 California enacted two pieces of "green chemistry" legislation. The first creates an on-line Toxic Information Clearinghouse with the goal of increasing consumer knowledge about the toxicity and hazards of chemicals. The second vests the Department of Toxic Substances Control with authority to identify and prioritize chemicals of concern and to create methods for analyzing alternatives to existing hazardous chemicals. The legislation builds on a broader Green Chemistry Initiative, adopted in 2007, aimed at filling gaps in chemical safety information and promoting alternatives to toxic chemicals currently in use.

More limited, yet still significant, toxic chemical legislation also has been adopted recently in Maine, Massachusetts, Washington, and Michigan, among other states. As a consequence, there is concern within industry circles about the growing diversity of regulatory requirements across the 50 states and the associated costs and need for compliance monitoring. From this perspective, one potential virtue of TSCA reform is that it offers a more uniform and stream-lined approach to chemical management.

Outlook

With the potential risks of toxic substances, particularly in children's products, filling the headlines, the call for more stringent regulatory control of chemicals is increasing. Europe and a variety of U.S. states already have taken significant actions in this regard. The U.S. Congress is starting to address the issue and may follow with legislation that could shift to manufacturers, to some degree, the burden of demonstrating chemical and product safety or at least the absence of significant risk.

While climate change legislation should dominate the attention of the Senate Environment & Public Works and House Energy & Commerce Committees in 2009, TSCA reform legislation appears to be a strong second priority. At a minimum, hearings in Congress can be expected and the contours of the debate will unfold during the current legislative session. If climate legislation falters, it is even possible that TSCA reform legislation could come to a vote this year. Most likely, however, debate during 2009 will set the stage for consideration of legislation in 2010.

Kelley Drye & Warren LLP

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Kelley Drye's team of environmental lawyers and government relations professionals are closely tracking and providing advice to clients on chemical regulatory matters at the federal and state levels. If you have any questions regarding TSCA reform or would like information on this issue or other matters, please contact us.

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