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The Modernization of the Toxic Substances Control Act ("Tsca") and the Tox21 Program

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TSCA was enacted in 1976 as a means to ensure the safe manufacture, usage and disposal of chemicals. It has not been amended since its passage. Meanwhile, the creation, development, use and understanding of chemicals has increased far beyond the regulatory ability of TSCA. One criticism of TSCA is that many toxic chemicals have not been regulated under TSCA because TSCA employs an unreasonable risk cost-benefit standard. In particular, one group – the Natural Resources Defense Council singled out trichloroethylene (TCE) as a chemical with known human health effects that has not been effectively regulated by TSCA.

In response to the concerns, Congress has initiated action to modernize and reform TSCA. On April 15, 2010 Frank Lautenberg (D-NJ) introduced the Safe Chemicals Act of 2010 in the Senate to protect the health of families and the environment. Senator Lautenberg's basis for the bill was that TSCA was an "antiquated law that in its current state leaves Americans at risk of exposure to toxic chemicals." The bill was crafted after a series of hearings with business leaders, public officials and scientists, non profits and other interested parties. Highlights of the Safe Chemicals Act of 2010 include:

- Requires manufacturers to develop and submit a minimum data set for each chemical they produce – thus providing the EPA with sufficient information to judge a chemical's safety,
- Requires EPA to use this information to categorize and prioritize chemicals based on risk,
- Requires EPA to take immediate action to reduce the risk from chemicals that have already proven to be dangerous,
- Creates open access to reliable chemical information and narrows the conditions under which data can be claimed as confidential business information,
- Promotes innovation and development of green chemistry and safer alternatives to chemicals of concern.

The House of Representatives followed up and recently introduced in the House on July 22, 2010 the Toxic Chemicals Safety Act of 2010. The legislation was introduced by Bobby Rush (D-IL) and Henry Waxman (D-CA). A hearing was held on the Act on July 29, 2010. Several key provisions of the House bill are:

- Establishes a framework to ensure all chemicals to which the American public are exposed will be reviewed for safety and be restricted as necessary,
- Requires the chemical industry to develop and provide the Environmental Protection Agency ("EPA") with essential data and improves EPA's authority to compel testing,
- Requires EPA to engage in intervention efforts to control dangerous chemicals,
- Ensures nonconfidential information is shared with the public and that confidential information is shared among regulators, with states and with workers in the chemical industry,
- Establishes an expedited process for EPA to reduce exposure to chemical substances that are known to be persistent, bioaccumutive and toxic.

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Modernization of the Toxic Substances Control Act

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One key difference between the current TSCA and the two proposed bills is the designated responsible party for assuring chemicals are safe. Under current TSCA, it is the government that is responsible for determining when a chemical is dangerous. This process has proven to be ineffective – only about 200 of the more than 80,000 chemicals currently registered in the United States have been subject to required testing under TSCA. Under the proposed bills, the burden will shift to industry who would now have to prove that a chemical is safe.

There are many potential implications to enacting the proposed legislation. For example, only those chemicals that meet a health based standard of safety would be allowed on the market. On one hand, this could help American exports comply with the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH") passed in December 2006. However, the information needed to comply with the proposed legislation and with REACH could lessen protections for trade secrets and cause unfair trade competition. Additionally the requirements in the two proposed U.S. bills may be more strict than laws followed by other foreign producers which may pose a burden to U.S. companies in international competition.

The Senate bill, when it was introduced, would subject certain new chemicals to less stringent requirements – if they were made in volumes of one million pounds or less. This could pose an issue for nanomanufactured chemicals that may have chemical safety issues but are produced below that production level. There is also the issue of how EPA will manage all the information they receive from companies regarding their chemicals. Industry has expressed concerns that the amount of data that is required will discourage the introduction of new chemicals.

All parties, including government, industry, academics agree that TSCA should be overhauled. However, the specifics of that overhaul need to be worked out. Although the provisions of the Senate and House bills have many similarities, there are differences including the time frame that would be imposed upon companies for making information available on chemicals. The House bill would require health and safety data on chemicals to be developed and made public by EPA within five years. The Senate version would require companies to submit information on chemicals that are then put on a priority list; however, the information on other chemicals could be delayed much longer. These differences and those with industry will need to be resolved before the passage of final legislation.

GOVERNMENT'S TOX21 PROGRAM

On the flip side of the proposed toxic chemical reform bills discussed above is the government run Tox21 collaboration. The Tox21 collaboration merges federal agency resources to develop ways to more effectively predict how chemicals will affect human health and the environment. The Tox21 collaboration consists of the EPA, the National Institute of Environmental Health Sciences National Toxicology Program, the National Institute of Health Chemicals Genomics Center and the U.S. Food and Drug Administration ("FDA"). The FDA recently joined the collaboration.

The Tox21 collaboration was established in 2008 to develop models that will be able to better predict how chemicals will affect humans. Through the Tox21 collaboration 2,000 chemicals have already been screened against dozens of biological targets. EPA's objective is to increase the number of screened chemicals under the Tox21 collaboration to 10,000 chemicals by the end of the year.

Overall the Tox21 collaboration has several specific objectives, including: conducts research and develops, validates and translates innovative chemical testing methods that characterize toxicity pathways; prioritizes which chemicals need more extensive toxological evaluation; develops models that can be used to more effectively predict how chemicals will affect biological responses; and conducts ToxCast™ screening assays. ToxCast™ is a program begun by EPA in 2007 to develop a cost effective approach for effectively prioritizing the toxicity testing of thousands of chemicals.

Besides the passing of toxic chemical safety legislation, another development to watch is how the proposed legislation and data derived from the Tox21 collaboration interact and are used by both industry and the government. We will continue to monitor developments in this area and provide updates as needed.

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