

The Toxic Substance Control Act (TSCA) Targeted for Overhaul: Proposed Amendments to TSCA

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Abstract

On April 15, 2010, Senator Frank Lautenberg (NJ) introduced legislation S.3209 - Safe Chemicals Act of 2010 to amend the Toxic Substances Control Act (TSCA) Title I. On July 22, 2010 Representatives Bobby Rush (IL) and Henry Waxman (CA) also introduced legislation to amend TSCA, H.R. 5820 - the "Toxic Chemicals Safety Act of 2010."

Although the bills both seek to amend the 35-year-old law, the proposals differ in a number of aspects. This presentation addresses some of the key provisions of S.3209 - Safe Chemicals Act of 2010, and H.R.5820 - the "Toxic Chemicals Safety Act of 2010," and the current law, TSCA (15 U.S.C. § 2601 et seq.).

Introduction

In July 2010, three months after oil began leaking into the Gulf of Mexico; it was hard to imagine any promise emerging from such an unprecedented ecological disaster. Then the United States Environmental Protection Agency (EPA) began facing a number of challenges regarding the environmental and human health impacts of the dispersants being used to break up the oil. It was also discovered that very few tests had ever been performed on these dispersants, and Federal law protecting business interests (confidential business information (CBI) claims) made it difficult for the EPA to reveal the chemicals they contained. Environmentalists, legislators and other advocates immediately demanded answers; why didn't the EPA know more about these dispersants, and why couldn't it inform the public of the chemical constituents contained in the dispersants? The dispersants challenge provided the impetus for the reform of a flawed and outdated environmental law - the Toxic Substances Control Act.

The Toxic Substance Control Act (TSCA) – Background

Signed into law in 1976, the Toxic Substances Control Act (TSCA) established a framework for the regulation of toxic substances by the United States Environmental Protection Agency (EPA). While some modifications have been made to the law and regulations over the years, it has been over 30 years since TSCA regulations took effect. In addition, other jurisdictions, most notably the European Union, have

since passed more comprehensive toxic substance regulations, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). Most government and policy experts, environmental advocates, and even many in regulated industries agree that toxic substance regulations in the United States (US) are antiquated and due for a major overhaul.

TSCA, as written, places a very high burden on the EPA to demonstrate that a substance may cause harm to the environment or human health. The EPA's authority to regulate substances, or even to require companies to provide additional safety data on substances, is severely limited. As a result, the EPA has been able to require testing on only 200 of over 80,000 chemical substances in commerce regulated under TSCA. This means that approximately 99% of the chemicals currently being manufactured, processed, or imported into the US (by weight) and ultimately used in commerce have not been subject to environmental or human health impact reviews.

In the meantime, environmental and public health studies conducted in the decades since TSCA was passed have raised concerns about classes of chemicals previously thought to be benign. The potentially substantial impacts of these chemicals on the environment and human health have prompted calls for a review of at least some of the materials on the list of grandfathered substances.

Current Situation

Currently, companies developing or importing a chemical not already on the TSCA Inventory must go through a notification process to the EPA prior to producing or importing the chemical. The EPA has 90 days to determine whether the material may represent an environmental or human health hazard; if the agency has sufficient reason for concern, it must respond back to the company and request additional data. However, the EPA has the burden of explaining why the agency believes that additional testing should be done, based on the data provided by the company. If, within the 90-day window, the EPA does not respond to the notifying company, it may begin manufacturing, processing, or importing the chemical product for use in commerce.

The EPA has identified **five main principles** that should form the foundation of reform:

1. Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment;
2. Manufacturers should provide the EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment;
3. Risk-management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations;
4. Manufacturers and the EPA should assess and act on priority chemicals, both existing and new, in a timely manner; and
5. Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.

Bills introduced in 2010 (summarized below) in both the United States House of Representatives and Senate incorporate these principles into the overhaul of TSCA.

In addition, the EPA has stated its intention to move aggressively under the current TSCA regulatory framework to help ensure that chemicals currently on the market, as well as new chemical

substances and chemicals involved in a Significant New Use are swiftly evaluated. The EPA is also seeking to increase transparency in the TSCA program, taking a more restrictive view of Confidential Business Information claims that companies often use to limit the amount of information that must be published on the chemicals they manufacture, process, or import.

Summary of Proposed Changes to TSCA Regulatory Framework

In 2010, two different bills were proposed in Congress to modernize TSCA. The Safe Chemicals Act of 2010 was introduced by Senator Frank Lautenberg (D-NJ) in April, 2010. And in the House of Representatives, the Toxic Chemicals Safety Act of 2010 was introduced in July 2010 by Congressmen Bobby Rush (D-IL) and Henry Waxman (D-CA). Both bills contain proposals that would make important changes to the way toxic substances are regulated.

In broad terms, these proposals would:

- *Shift the burden of determining whether a chemical is “safe”, from the EPA, to the company seeking to manufacture, process, or import a substance not already on the TSCA Inventory*
 - ✓ *A company seeking to manufacture, process, or import a substance would be required to provide data sufficient for the EPA to make a determination that the substance meets the environmental and human health safety requirements established by law before being allowed to place the material into commerce*
 - ✓ *The EPA would have increased authority to regulate chemical substances*
- Require the EPA to review the existing TSCA inventory and develop, within 12 to 18 months of enactment (House and Senate versions differ), a list of 300 chemicals of highest priority for review.
 - ✓ *Based on use activities, volumes, persistent bioaccumulation toxicity (PBT) status, etc.*
 - ✓ *Require the EPA to expedite the development of new requirements to reduce use and exposure of chemicals on this list*
 - ✓ *Manufacturers or processors of chemicals on this priority list would be required to submit a minimum data set (MDS) for each chemical within 30 months.*
 - ✓ *Manufacturers or processors of chemicals on the TSCA Inventory but NOT on this priority list would have up to 14 years (House and Senate versions differ) to submit a minimum data set (MDS) for each chemical that they manufacture or process.*
- Increase fines from \$25,000 per incident to \$37,500 per incident.
- Create a public database of industry submissions within 5 years.
- Increase the regulatory requirements for making confidential business information (CBI) claims for chemical substance reporting.
- Require companies to submit a Declaration of Manufacturing or Processing for each TSCA Inventory chemical they are using within one year of the bill’s passage (this is over and above any new substances that the company would be manufacturing, processing, distributing or using from the Bill’s passage forward)
- Revise the definition of a “Chemical Substance” to include “...contained in or formed into an article” (could have a large impact on companies that produce materials from various chemicals)
- Define “aggregate exposure” as including
 - ✓ *All exposures from the manufacture, processing, distribution, use, and disposal of chemical substances or mixtures as defined by the regulations.*
 - ✓ *Includes amounts used in foods, food additives, drugs, devices, and cosmetics (significant change!)*
 - ✓ *All exposures from other routes, including air pollution, soil contamination, food, dust (e.g., house dust), and environmental media, as well as accidental releases, permitted sources, non-permitted sources, and documented background levels*

- Define “cumulative exposure” as the sum of all aggregate exposures to chemical substances (including mixtures) “known or suspected to contribute appreciably to the risk of the same or similar adverse effect.”
- NOT pre-empt State and local laws; therefore, if a State such as California, New York, or New Jersey has more stringent requirements, companies must still meet those requirements, in addition to the Federal requirements.
- Change the declarations required of companies
 - ✓ *Generally more detailed requirements around declarations*
 - ✓ *Would apply to all chemicals on the TSCA Inventory that the company manufactures, distributes, processes, uses, imports, etc.*
 - ✓ *Declarations would have to be updated at least every three years*
 - ✓ *Companies not submitting required declarations could be prohibited from importing, manufacturing, processing, etc. the chemicals for which the declarations are lacking*
- Include Nanomaterials in the regulations; the EPA would be allowed to make the determination that a “variant of a chemical” is a new chemical substance, based on “special substance characteristics” other than the molecular identity (e.g., size or size distribution, shape or shape distribution, reactivity, other properties as defined).
 - ✓ *Thus, even if a chemical substance is already on the TSCA Inventory, if it were produced in such a way that nano particles with “special substance characteristics” might result in potential environmental or human health hazards, it is reasonable to expect that these materials would fall under these regulations.*
- Propose several other exemptions, both new and similar to those already in existence, such as those effecting:
 - ✓ *materials used only for test marketing purposes (with some new restrictions)*
 - ✓ *materials used in small quantities for R&D purposes (unchanged)*
 - ✓ *use of the new chemical that is deemed a “critical use” (new)*
 - ✓ *new chemical approval by EPA as a “safer alternative”(new)*
 - ✓ *EPA finds that “intrinsic properties” render the new chemical “harmless”(new)*

However, industry’s new responsibility to generate significantly more health and safety information will require an update of the scientific methods used.

Most information currently comes from toxicity tests performed on animals, which presents several obstacles to generating data that will protect the public. Effects observed in animals don’t necessarily apply to humans due to differences in physiology and anatomy. This information may delay chemical regulation, while more testing is conducted to determine whether the animal data is relevant to people or not. Another problem is the expense of animal tests. Because they remain so costly, exhaustive testing is not done.

Cell-based methods and computer models are promising new approaches that are much quicker and more affordable, not to mention potentially more reliable and predictive. These new approaches will allow us to assess chemical mixtures much more readily. Both Bills contain a section devoted to the reduction of animal testing, including the use of in-vitro studies and computational toxicology. However, Congressional funding will be necessary in order for the EPA to meet the requirement to fund the development of modern, non-animal methods.

Likelihood of Passage of TSCA Overhaul Bill

The TSCA reform Bills described above were introduced in the Spring of 2010. However, the 2010

November elections resulted in a change of control of the House of Representatives from the Democratic Party to the Republican Party. While the Democrats retained control of the Senate, they did lose some seats, further weakening the party's ability to advance its agenda. Political pundits generally agree that the results of the 2010 elections indicated a reduction in popular support for President Obama and for many items on the Democratic Party agenda.

Given these results, the political and economic environment, and the fact that the lame duck Congress did not act on the TSCA reform bills, it is unlikely that there will be a resurrection of increased chemical legislation in 2011. However, the EPA possesses renewed support from the current Administration, so companies should expect greater involvement from the EPA under its existing authority with regard to TSCA. Furthermore, the widespread agreement about the need to revamp TSCA amongst industry and policy players suggests that legislative action could occur in 2012.

As Congress debates the Bills, some major points of controversy may include:

- The ways and extent to which chemical regulation under TSCA reform will be funded;
- Questions of what constitutes an appropriate safety standard;
- Whether and how the EPA's decisions can be challenged; and
- The extent to which obligation imposed under the safety standard extend down the processing chain to second- and third-hand users.

Most stakeholders believe that passage of the bills in their current form is unlikely. Several factors, however, may coerce Congress to take action. In particular, the blend of State and local requirements may result in confusion, uncertainty, inefficiency, and increased cost to industry. With a sympathetic ear in Congress, industry will likely seek the preemption of these State and local regulations. In the Senate, Environment and Public Works Committee Chairman Barbara Boxer (CA) has indicated previously that TSCA is a priority. Moreover, Senator Boxer has made protection of children a personal cause, and with California recognized as a leader among the States in chemical reform, Senator Boxer may use California's recent chemical reform law as the model for TSCA reform.

Implications for Companies

A company producing chemically-intensive products would see significant changes in the regulatory requirements it faces regarding its manufacture, processing, or importation of chemicals. Most significantly, the company may be required to provide minimum data sets (MDSs) on the environmental and human health impacts of chemicals it uses in the production of articles, which would be covered by these reforms.

Summary

How will the most significant piece of environmental legislation in years affect you?

Enacted in 1976, the law gave the newly created Environmental Protection Agency authority to regulate chemical manufacturers and importers through reporting, record-keeping and testing requirements and through restrictions on chemical substances and mixtures in commerce. A progressive statute at the time, TSCA is today universally deemed overdue for an overhaul; it is, in fact, the only major environmental statute that has not been reauthorized. Among the most prominent criticisms are that the law: does not require comprehensive environmental and human health effects testing on each chemical; relies on outmoded forms of chemical testing; does not provide the public with enough information on the contents of chemical formulations; and does not give EPA adequate authority to restrict chemicals that were already in commerce in 1976 (its authority over "new" chemicals is somewhat greater).

The oil release in the Gulf of Mexico in 2010 and the weaknesses in TSCA it revealed was eerily timely: on April 15, just two months before the oil leak, Sen. Frank Lautenberg (D-NJ) had introduced The Safe Chemicals Act (S. 3209).

The House version, the Toxic Chemicals Safety Act of 2010 (H.R. 5820), was introduced by Representatives Henry Waxman (D-CA) and Bobby Rush (D-IL) on July 22, 2010 just seven days after the oil flow was staunched. The implications of the bills' passage for the public are considerable.

Both bills would, among other things:

- Require every chemical substance allowed in commerce to meet a safety standard that will be established by the EPA. Whereas currently the EPA is required to prove harm before it can regulate a chemical, and no minimum health or environmental data set is required, the reauthorization legislation would shift to industry the legal burden of proving that chemicals are safe, and those that did not meet the safety standard could not be manufactured, processed, or imported.
- Require industry, through the EPA's safety standard, to establish a reasonable certainty that no harm will result to the general population or to vulnerable populations (such as children, pregnant women, the elderly and those who work with chemical substances) as a result of aggregate exposures to the chemical being regulated. Currently, there is no requirement on industry to assess all sources of exposure to a chemical or to assess risk to vulnerable populations.
- Require the EPA to establish a priority list of 300 "existing" chemical substances, including those already in commerce, for review to ensure they meet the safety standard (the House version says this list must include bisphenol A, formaldehyde, n-hexane, hexavalent chromium, methylene chloride, trichloroethylene and vinyl chloride). The EPA would then add to the list until all substances in commerce had been evaluated for safety. The EPA would also be required to prioritize chemicals based on both exposure and hazard characteristics. The bill would instruct EPA to take quick action on those chemicals that clearly demonstrate high risk, and manufacturers would have to prove that a chemical is safe to keep it on the market.
- Instruct the EPA to create a public database containing information about each chemical and the EPA actions on that chemical, and the legislation would require the EPA to review and approve all industry claims that information on their chemicals constitutes "confidential business information" (CBI), and therefore must be kept secret, before commercialization, and any approved CBI claims would expire after a period of time. Currently, companies are free to claim that most information they submit to the agency is CBI. EPA is not required to review the claims, and they never expire.
- Give EPA authority to require, through an order, additional testing of chemicals. Currently, EPA must promulgate regulations over the course of many years to require testing.
- Seek to promote green chemistry by establishing a program to develop incentives for companies to make and use safer alternatives to some chemicals.

The reauthorization bills represent a sea of change in U.S. chemicals regulation, most notably in the paradigm shift that would force industry to prove that chemicals are safe as opposed to requiring the EPA to show they're unsafe.

Bibliography

1. (D-IL), Congressmen Bobby Rush. "Toxic Chemicals Safety Act of 2010 (TCSA) - Summary & Analysis | EHS-World.net." EHS-World.net | Applied environmental, health, & safety information for corporate managers. N.p., n.d. Web. 3 Mar. 2011. <<http://www.ehs-world.net/TCSA-draft>>.
2. "08/11/2010: EPA Proposes Improvements to Chemical Reporting." Environmental Protection Agency. N.p., n.d. Web. 3 Mar. 2011. <<http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/8069e2d1bcea368d8525777c005227b8%21OpenDocument>>.
3. "Congressional Outlook for 2011 | Government & Policy | Chemical & Engineering News." ACS Publications - Cookie absent. N.p., n.d. Web. 3 Mar. 2011. <<http://pubs.acs.org/cen/government/89/8903gov5.html>>.
4. "Enhancing Existing Chemical Management Under TSCA | Existing Chemicals | OPPT | US EPA." US Environmental Protection Agency. N.p., n.d. Web. 3 Mar. 2011. <<http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html>>.
5. "Essential Principles for Reform of Chemicals Management Legislation | Existing Chemicals | OPPT | US EPA." US Environmental Protection Agency. N.p., n.d. Web. 3 Mar. 2011. <<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>>.
6. MELOY, MICHAEL. "Client Alert Forecast 2010 - Reauthorization of TSCA and Proposed Regulatory Changes - Manko, Gold, Katcher & Fox LLP, An Environmental and Energy Law Practice." Manko, Gold, Katcher & Fox LLP, An Environmental and Energy Law Practice. N.p., n.d. Web. 3 Mar. 2011. <<http://www.mgkflaw.com/ca-201003/ca-201003-20.html>>.
7. "SCJ's Semrau Talks TSCA in Washington - HAPPI." HAPPI - Household and Personal Products Industry. N.p., n.d. Web. 3 Mar. 2011. <http://www.happi.com/news/2011/02/04/scj%27s_semrau_talks_tsca_in_washington>.
8. "Safe Chemicals Act of 2010 - Summary & Analysis | EHS-World.net." EHS-World.net | Applied environmental, health, & safety information for corporate managers. N.p., n.d. Web. 3 Mar. 2011. <<http://www.ehs-world.net/safe-chemicals-act>>.
9. "Senate Subcommittee Holds Hearing on Assessing the Effectiveness of U.S. Chemical Safety Laws | Bergeson & Campbell, P.C..." Listed as One of the Best Environmental Law Firms in Washington -- Bergeson & Campbell, P.C... N.p., n.d. Web. 3 Mar. 2011. <<http://www.lawbc.com/news/2011/02/senate-subcommittee-holds-hearing-on-assessing-the-effectiveness-of-u-s-chemical-safety-laws/>>.
10. "Senator Frank R. Lautenberg." Senator Frank R. Lautenberg. N.p., n.d. Web. 3 Mar. 2011. <<http://lautenberg.senate.gov/newsroom/record.cfm?id=323863&>>.
11. "Summary of the Toxic Substances Control Act | Laws and Regulations | US EPA." US Environmental Protection Agency. N.p., n.d. Web. 3 Mar. 2011. <<http://www.epa.gov/lawsregs/laws/tsca.html>>.
12. "U.S. GAO - Chemical Regulation: Observations on Improving the Toxic Substances Control Act." U.S. Government Accountability Office (U.S. GAO). N.p., n.d. Web. 3 Mar. 2011. <<http://www.gao.gov/products/GAO-10-292T>>.
13. "US Environmental Protection Agency." US Environmental Protection Agency. N.p., n.d. Web. 3 Mar. 2011. <<http://www.epa.gov>>.
14. "Widespread Reform to TSCA Regulations Anticipated "TSG News." TSG State, Federal, Global Regulatory Support, EPA Pesticide Registration, Human Health & Environmental Risk Assessment. N.p., n.d. Web. 3 Mar. 2011. <http://www.tsgusa.com/tsgnewsW_tsicareform.htm>.
15. Understanding of S.3209 - Safe Chemicals Act of 2010 and H.R. 5820 the "Toxic Chemicals Safety Act of 2010", as introduced.

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