Key issues in reform of the Toxic Substances Control Act of 1976

By Daniel E. Uyesato

The Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq*., enacted in 1976, gave the U.S. Environmental Protection Agency (EPA) authority to regulate chemicals manufactured or imported in the United States. Recently, concerns over TSCA's adequacy have arisen. The three primary concerns have been that (1) TSCA's burdensome regulatory framework for obtaining hazard and exposure information has impeded EPA's ability to conduct adequate safety assessments on the vast majority of chemicals, (2) TSCA's threshold for EPA to ban or otherwise regulate chemicals is too stringent, and (3) TSCA's prohibitions on the disclosure of confidential business information submitted by industry have interfered with the public's right to know. These concerns are driving TSCA reform, but amending a complex, thirty-year old statute raises other issues, notably, how to do so while maximizing innovation and maintaining the competitiveness of American industry.

Increased calls for reform

In 2009, the U.S. Government Accountability Office identified EPA's assessment and control of toxic chemicals to its list of "high-risk" areas for waste, fraud, abuse, and mismanagement or in need of broad-based transformation (High Risk Series: An Update. GAO-09-271. Washington, D.C.: Jan. 22, 2009). These issues were also taken up by the House Energy and Commerce Committee's Subcommittee on Commerce, Trade and Consumer Protection, the House subcommittee with TSCA oversight, which held hearings on Feb. 26 and Nov. 19, 2009, and the Senate Environment and Public Works Committee, which held hearings on Dec. 2, 2009. These hearings included representatives from various stakeholder groups, including the chemical and insurance industries, consumer protection groups, labor, and government. While participants generally agreed that (1) EPA lacked adequate information on potential health and environmental risks of chemicals, (2) TSCA's regulatory framework made it unduly difficult for EPA to control such risks, and (3) there needed to be greater transparency respecting chemical risk information, there was a wide diversity of opinions on how such issues should be addressed.

Widespread bipartisan support for TSCA reform at the grass-roots level was indicated by a poll conducted in August 2009 by the opinion research firm Lake Research Partners for Safer Chemicals Healthy Families, a coalition of over 100 activist groups advocating greater chemicals regulation. In a press release dated Nov. 10, 2009, the organization announced that its nationwide phone survey of 1,000 registered voters indicated that 71 percent supported TSCA reform, when given a brief description, with 53 percent expressing strong support. While Democrats expressed the greatest support for TSCA reform (81 percent), strong majorities of Independents (63 percent) and Republicans (66 percent) also supported TSCA reform.

On Sept. 29, EPA Administrator Lisa Jackson weighed in with the Obama administration's position, identifying EPA's "Essential Principles for Reform of Chemicals Management Legislation" (Principles). The Principles are not a legislative roadmap, but a set of legislative goals comprising the following: (1) chemicals should be reviewed against standards based on science reflecting risk-based criteria protective of human health and the environment; (2) manufacturers should be required to provide hazard, use, and exposure data sufficient for EPA to conduct a chemical assessment against the standard; (3) EPA should have authority to take risk management actions for chemicals not meeting the standard, with flexibility to take into account sensitive subpopulations, cost, availability of substitutes, and other relevant considerations; (4) manufacturers and EPA should timely assess and act on priority chemicals (existing and new), with EPA authorized to set priorities on existing chemicals; (5) Green Chemistry should be encouraged and transparency and public access to information strengthened by requiring manufacturers to substantiate confidentiality claims and by not considering data relevant to health and safety to be confidential; and (6) EPA should be given a sustained source of funding.

Addressing the three major TSCA areas of reform

While there has been consensus at the 50,000-foot level on certain points, e.g., that chemicals in commerce should be safe, that chemicals are not adequately regulated under TSCA, and that TSCA needs to be "modernized," there continues to be a diversity of opinion on specifics. TSCA reform raises many issues, not the least of which includes the scope of its exclusions and exemptions. TSCA excludes articles, impurities, and substances regulated elsewhere, such as, among others, radioactive materials, tobacco, food, drugs, cosmetics, and pesticides. In addition, TSCA contains

a number of exemptions, such as test marketing, low volume, low release/low exposure, polymers, intermediates, research and development, and export-only substances. The purpose of this article, however, is to address three key higher-level TSCA reform issues: (1) obligations of industry to provide relevant information to EPA, (2) the standards for EPA to ban or otherwise regulate chemicals, and (3) treatment of confidential business information submitted by industry to EPA. These basic issues must be resolved before addressing questions of what exemptions or exclusions might apply.

The first key issue concerns modification of industry obligations to provide EPA with hazard, use, and exposure information required to make a safety determination. TSCA Section 4 authorizes EPA to require such information from manufacturers/importers of an "existing" chemical—meaning a chemical on the TSCA Inventory—upon finding that (1) such chemical may present an unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities and that either (a) there may be substantial human exposure or (b) the chemical enters the environment in substantial quantities, and (2) there is insufficient data, and testing is necessary to obtain such data.

Respecting "new" chemicals, i.e., those not on the TSCA Inventory, TSCA Section 5 requires chemical manufacturers/importers to notify EPA of an intent to manufacture/import new chemicals by filing a premanufacture notice (PMN), which includes the chemical's identity/molecular structure, anticipated uses, production volume, exposure levels, release estimates, and available test data. EPA relies on available data, and where there is none EPA uses modeling to compare the new chemical with chemicals with similar molecular structures for which test data on health and environmental effects is available.

Some nongovernmental organizations (NGOs) have advocated for similar requirements to the European Union's REACH Regulation (Regulation (EC) 1907/2006, 30.12.2006 J.O. (396)) by requiring as a condition of market access that manufacturers, importers, and downstream users provide comprehensive hazard information on chemicals and robust data on uses and exposures for existing and new chemicals. Industry groups, while accepting EPA's need to obtain information on chemicals to conduct safe use determinations, have advocated an approach where EPA would prioritize chemicals for safe use determinations, similar to Environment Canada's and Health Canada's role under Canada's Chemical Management Program. Prioritization would be based on considerations such as volume in commerce, uses (including whether contained in children's products), detection in biomonitoring programs, persistent or bioaccumulative properties, and adequacy of available information.

The second key issue centers on the standard for EPA to take regulatory action. There has been widespread criticism of TSCA Section 6, which authorizes EPA's regulation (including ban) of chemicals, upon EPA's finding of "unreasonable risk of injury to health or the environment." Critics note that EPA has acted to restrict only five existing chemicals and for one of them, asbestos, the Fifth Circuit Court of Appeals vacated most of EPA's 1989 regulation phasing out asbestos, because the ban on most uses was found to be not based on substantial evidence, i.e., sufficient cost-benefit analyses. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The standard used in the Food Quality Protection Act of 1996 of "reasonable certainty of no harm" has been discussed, but with no consensus. Some within industry have indicated, however, that despite a lack of agreement on the specific standard, they understand that the "unreasonable risk of injury" standard is too restrictive and EPA's safe use determination should not include a cost-benefit analysis (such analysis would be part of a separate EPA risk management decision). See *10 Principles for Modernizing TSCA*, American Chemistry Council, (www.americanchemistry.com/s_acc/sec_article_acc.asp?CID=2178&DID=9939).

The third key (and most problematic) point concerns treatment of confidential business information (CBI) submitted by industry under TSCA. EPA and NGOs have identified as top priorities increasing transparency and public access to confidential information submitted by industry under TSCA. They assert that (1) better access to CBI will cause markets to migrate away from risky chemicals, (2) to rely on industry-generated data, such data must be credible and have the public's confidence, which can only occur if it is made public, and (3) TSCA prohibitions on disclosure of CBI to other governments interfere with such governments' respective roles in controlling chemical risks. While industry is unlikely to object to disclosure of CBI to other governments, subject to appropriate protections, industry will hotly contest other aspects due to their potential to damage business. For example, with the knowledge of the chemical identity, a competitor could use reverse engineering to obtain formula and other key manufacturing information, which could be very problematic to the manufacturer.

Public disclosure of use information also potentially compromises trade secret information of both the manufacturer/importer and downstream user. Making testing and other data public would result in the loss of trade secret protection for such data and the loss of proprietary rights for companies that have likely expended substantial resources in the studies generating such data. This is especially problematic in the context of new chemicals: the obligation to provide testing data prior to market access would be a substantial barrier to entry; to promote innovation, provisions would be needed analogous to those governing pesticide and drug registrations respecting data exclusivity (where EPA may not rely on such data to approve the same substance for a competitor for an appropriate period) and data compensation (where subsequent applicants must compensate prior submitters for the use of their data).

One final note: key elements missing from the debate have been estimates of the cost and economic impact of reform, which are significant issues given the current economic crisis. Representatives and others have expressed concerns in Subcommittee hearings over any changes to TSCA that would significantly damage small and medium-sized businesses and drive companies and jobs to other countries. Those concerns will depend largely on the cost and other economic impacts of reform, which in any case will need to be balanced against the health and environmental benefits of such reform.

Daniel E. Uyesato *is an attorney with Hunton & Williams LLP in Raleigh, North Carolina, practicing in its Environmental Law Group.*