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Each of the authors of this article has served in a leadership capacity at EPA with responsibility for implementing the Toxic Substances Control Act. They see an opportunity to enact legislation reinvigorating the U.S. chemicals regulatory program and examine how a new legislative approach can strengthen environmental protection. The authors set forth key elements that should be reflected in new legislation, including information development and dissemination, management of chemical risks, and fundamental policy objectives. They say a fundamental reform of TSCA will allow EPA to regain domestic and international leadership in chemical risk evaluation and management.

Fundamental Changes Could Be in Store for Regulation of Commercial Chemicals

BY CHARLES M. AUER, BLAKE A. BILES, AND LAWRENCE E. CULLEEN

A number of converging developments point to the likely overhaul of the Toxic Substances Control Act[1] during the coming 12-24 months, one-third century after the law was enacted in 1976: (1) the Democrats' control of the presidency and both houses of Congress; (2) the European Union's new REACH program[2] (perceived in some quarters as a new benchmark for a regulatory regime for chemicals); and (3) domestic developments, including state green chemistry laws[3] and what some see as an overreliance on voluntary initiatives. Many stakeholders consider TSCA to be

[1] The core provisions of TSCA are codified in Title I of the Act at 15 U.S.C. §§ 2601 - 2629.

[2] ''Registration, Evaluation, Authorisation and Restriction of Chemicals''; Regulation (EC) No. 1907/2006.

[3] *See, e.g.*, the California ''Green Chemistry Initiative'' which is comprised of two pieces of legislation: California Assembly Bill AB 1879 (Chapter 599, Statutes of 2008), and California Senate Bill SB 509 (Chapter 560, Statutes of 2008);

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an ineffective, out-of-date instrument for addressing health and environmental risks associated with the thousands of chemicals in commerce.

Several bills introduced during the past two years in both the House and Senate,[4] a 2008 Congressional Research Service Report on TSCA,[5] and the January 2009 Government Accountability Office update (listing TSCA on GAO's ''High Risk'' list),[6] signal that new legislation dealing with risks from commercial chemicals is all but inevitable.

As if to demonstrate that there is across-the-spectrum interest and enthusiasm for ''TSCA Reform'', chemical and consumer product trade associations have released statements supporting the movement.[7] Nongovernmental organizations have not missed the opportunity to encourage the momentum either.[8] Sen. Frank R. Lautenberg (D-N.J.) and Rep. Henry A. Waxman (D-Calif.) are expected to re-introduce the ''Kids Safe Chemicals Act''. During a speech recently in California by EPA Administrator Lisa P. Jackson, the Obama administration announced its own ''Essential Principles for Reform of Chemicals Management Legislation''.[9]

This unique opportunity to enact legislation reinvigorating the U.S. chemicals regulatory program must not be squandered. To that end, this discussion examines how a new legislative approach can constructively strengthen environmental protection by enabling periodic information gathering that takes account of scientific and technical developments, and by creating expectations for chemical assessment and management which apply evolving regulatory paradigms and reflect political and commercial realities. We set forth key elements that should be reflected in the new legislation, dealing with: (a) information development and dissemination; (b) management of chemical risks; and (c) fundamental policy objectives.

A. Information Development, Dissemination

1. Data generation is a fundamental responsibility of companies that produce and use chemicals and chemical products. Revisions to TSCA should embody the principle that chemical manufacturers, importers, processors, and, as appropriate, downstream businesses should be required to develop information and data that are needed in order to assess the risks that chemicals present to health and the environment, and to provide the basis for actions that will control chemical risks. We support retention in the new legislation of a provision based on current TSCA § 8(e), which requires prompt reporting by industry of ''substantial risk'' information.

2. Seeking new information and data, and keeping EPA's knowledge base contemporary, must be core components of the agency's mission. The new legislation should enable EPA to better assess and manage chemical risks by requiring that the agency periodically obtain information addressing hazard endpoints (e.g., health, ecotoxicology), environmental fate endpoints (e.g., persistence, bioaccumulation), and exposure (e.g., workplace, consumer, general population). This information is necessary for responsible risk assessment, which in turn informs effective risk management.

The chemicals which are produced or imported for commercial use, and their volumes, shift to a surprising degree over time. It is essential that hazard and exposure information be updated to allow EPA to stay current with marketplace realities. Thus, EPA should be tasked with periodically gathering information and test data that go beyond what the agency has sought by regulation under the current legislation. EPA's authority under TSCA § 8(a) to require reporting of existing information from manufacturers and processors should be broadened to include certain downstream businesses, such as distributors and users. A case can be made that Congress should consider narrowing or eliminating the current exemption from TSCA § 8(a) reporting enjoyed by small businesses.

EPA should be made responsible for establishing requirements, using production volume reporting triggers, for industry to submit tiered sets of hazard/fate test data and exposure information to the agency. The hazard/fate test menu found in the Organization for Economic Cooperation and Development Screening Information Data Set[10] and the exposure/use reporting elements required in the TSCA Inventory Update Rule for chemicals manufactured/imported in quantities in excess of 300,000 pounds/year,[11] represent useful starting points. The information sets should be required for existing chemicals at appropriate, commercially viable intervals and for new chemicals (and significant new uses of existing chemicals) both prior to and during their initial commercial phases. Such a periodic reporting scheme will provide opportunities for EPA to update its assessments and make adjustments to chemical regulatory priorities.

EPA should be given appropriate statutory flexibility to modify testing and information reporting requirements for particular types or uses of chemicals (e.g., nanoscale materials; chemicals that combine properties of persistence, bioaccumulation, and toxicity; chemicals that are components of products intended for use by children or other vulnerable sub-populations); to exempt certain chemicals altogether (e.g., polymers); and to use administrative orders in addition to rulemaking. Further, the agency should be encouraged to accept

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Washington State, House Bill 2647 (2008), http://www.ecy.wa.gov/programs/swfa/cspa/.

[4] *See, e.g.*, the ''Kid-Safe Chemicals Act'' (H.R.6100/S.3040).

[5] CRS RL34118; http://opencrs.com/document/RL34118/2008-09-18.

[6] GAO-09-271; http://www.gao.gov/new.items/d09271.pdf.

[7] *See, e.g.*, the American Chemistry Council statement at http://www.americanchemistry.com/s_acc/sec_mediakits.asp?CID=2178&DID=9938; the Chemical Specialty Products Association letter at http://www.cspa.org/public/media/press/tsca_2.html; and the Soap and Detergent Association statement at http://www.cleaning101.com/newsroom/08-04-09.cfm.

[8] *See e.g.*, the Natural Resources Defense Council position statement at http://www.nrdc.org/legislation/files/tsca_090512.pdf; the Environmental Defense Fund article at http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf; and the ''Safer Chemicals, Healthy Families'' coalition ''Platform'' at http://www.edf.org/pressrelease.cfm?contentID=10289.

[9] http://yosemite.epa.gov/opa/admpress.nsf/8d49f7ad4bbcf4ef852573590040b7f6/fc4e2a8c05343b3285257640007081c5!OpenDocument; http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.

[10] *See* Manual for Investigation of HPV Chemicals, Chapter 2, pg. 2, http://www.oecd.org/dataoecd/13/18/36045056.pdf.

[11] 40 C.F.R. Part 710, Subpart C; esp. § 710.52(c)(4). *See also*, http://www.epa.gov/iur/pubs/guidance/changes.htm.

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''read-across'' (or ''bridging'') data, category information, and the results of Structure-Activity Relationships analysis, where scientifically justified.

Currently, new chemicals are subject to *premanufacture* notification under TSCA § 5(a)(1) 90 days prior to the first production of a chemical—unless production occurs during limited, exempt research and development activities. This notification scheme differs from other national regulatory regimes in which notification is provided on a *premarket* basis. Although there are advantages to this approach, in practice only about 50 percent of the new chemicals for which a premanufacture notification is submitted to EPA actually commence manufacture. To lessen the reporting burden on industry and to save EPA resources and eliminate the needless review of hundreds of such chemicals that never are commercialized, reform legislation should move the United States in the direction of premarket notification.

Congress should find mechanisms to revise TSCA to enhance data submission requirements for new chemicals and to do this in a way that enhances the capacity for the United States to keep innovation and market incentives within the U.S. economy. One way to meet these goals is to make the new chemical requirements generally consistent with the reporting and testing requirements to be imposed on existing chemicals. This can be achieved by:

- requiring premarket notifications for new chemicals to include basic production, exposure, and use information plus any available hazard and environmental fate information that the company has generated for the substance worldwide, with EPA having the ability to require early development of test data when the agency identifies any concerns; and
- requiring the notifier to undertake and complete the same data set that would be required for existing chemicals when the chemical reaches certain production volumes, in accordance with the same time period allowed for an initial report on existing chemicals that EPA establishes (three years might be a workable initial reporting period for submittal of such test data on chemicals newly entering the market).

Following premarket notification and meeting such an initial data submission requirement, a ''formerly-new'' chemical would need to meet any regular periodic testing and reporting requirements that are established for existing chemicals.

Congress also may wish to amend the current TSCA § 3 definition of ''manufacture'' to include ''produced by recycling'', and to require reporting which distinguishes such production from importation or *de novo* manufacture. Such a metric, which would require development of clear reporting guidance, would be of great value in setting goals and measuring progress towards more sustainable production.

3. Strategies for developing test data must evolve, applying scientific advances and responding to societal concerns. EPA should be responsible for regularly updating test requirements to meet contemporary scientific standards. This should include efforts to achieve by 2020 the testing vision set forth in the 2007 report by the National Research Council of the National Academy of Sciences, ''Toxicity Testing in the 21st Century: A Vision and A Strategy.''[12] Realizing this vision can provide broad coverage of chemical classes, endpoints and life stages, decrease the cost and time of testing, reduce the use and minimize the suffering of animals, and develop a more robust scientific basis for assessing chemical toxicities. Congress should encourage these developments by directing EPA to achieve the National Academy of Sciences vision while broadening the scope to include environmental effects testing. Realizing this long-term goal will require sustained funding.

4. The public should be given access to information concerning chemical risks, while EPA continues to encourage innovation by protecting trade secrets. The new legislation should ensure that hazard and risk information is made available to the general public, including business entities throughout the commercial value chain, and should foster information sharing between federal and state officials and within the international community. Doing so will ensure transparency, minimize redundancies in chemical testing and risk assessment, enhance risk management efforts, and enable stakeholders throughout the stream of commerce to make more informed choices in their purchasing and use practices.

Recognizing the capabilities and efforts of other federal agencies, state programs, and major trading partners (e.g., Canada, the European Union, other OECD countries), EPA also should be directed to work as appropriate with both domestic and foreign officials to further the new legislation's purposes and to avoid duplication of effort and unnecessary testing. This will require that Congress enable EPA to share confidential business information (CBI) with, and receive CBI from, states and foreign governments that satisfy legal requirements and provide practical assurances of their ability to prevent disclosure of CBI. This will encourage cooperation and contribute to greater efficiencies and more consistent assessments—key objectives, given the large number of chemicals that are common to multiple jurisdictions.

To be effective in these regards, EPA will need to (1) assure businesses that the agency, and its regulatory counterparts in state and foreign governments, can and will protect such CBI from unauthorized disclosure and (2) demonstrate to the public that the agency will require companies to appropriately limit and substantiate their CBI claims. Congress should direct EPA to require periodic re-substantiation of CBI claims, assess up-front fees for CBI claims (this also will help to defray EPA's costs in protecting CBI), and take actions that minimize inappropriate claims, such as conducting random audits of CBI claims.

B. Management of Chemical Risks

1. New legislation should provide a range of actions that EPA may take to control risks. To ensure that all chemicals in commerce are subject to comparable standards for health and environmental safety, EPA should be directed to periodically reassess the risks from existing chemicals, publicly communicate scientifically-sound information about those risks, and take prompt action to control such risks to ensure the safety of chemicals and products in the marketplace.

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[12] Toxicity Testing in the 21st Century: A Vision and A Strategy is available at http://www.nap.edu/catalog.php?record_id=11970.

EPA's risk management authority should be materially broadened from its current overwhelming attention on upstream chemical manufacturers and processors, to enhance EPA's ability to reach downstream entities such as distributors, users, and retailers. Congress also should make clear that prevention-based approaches (including green chemistry) are to be encouraged and recognized as an equal to command-and-control approaches for risk reduction.

The statute's emphasis upon chemical substances and mixtures must be modernized to provide EPA additional authority for regulation of chemicals in products and articles when that is the most appropriate way to address risks. Applying this more comprehensive and integrated approach will inform and influence responsible handling and use of chemicals and products throughout the value chain (which can help strengthen industry's own product stewardship programs) and is wholly in line with a life-cycle strategy to chemical risk assessment and management.

EPA should continue to have the authority to act in a preventative manner when the agency determines that new chemicals might present risks that should be mitigated. Thus, Congress must preserve some form of prior review of new chemicals during which EPA can determine whether initial control actions are needed, based upon an assessment of potential risks and benefits. As discussed above, the shift from premanufacture to premarket review of new chemicals is warranted as a significant resources savings device for the agency and provides an opportunity to focus data development requirements on those substances that are the most likely to be commercialized.

Moreover, Congress should take steps to eliminate the current law's ''new chemical bias''. For example, EPA should be required to subsequently review any restrictions imposed upon new chemicals after they have completed an initial (perhaps three to five years) commercialization period. For this subsequent review, the standards applicable to existing chemicals should apply. This will ensure all chemicals in the marketplace are subject to the same data development and risk management standards.

The chemical control requirements set out in TSCA § 6(a) must be updated to provide EPA with other authorities to mitigate or prevent risks. These could include broadened authority to issue administrative orders, the ability to require development of enforceable pollution prevention or green chemistry plans, and a hazard communication/labeling requirement for environmental information (structured so as to complement existing requirements under the Occupational Safety and Health Act and the Federal Hazardous Substances Act). The new legislation should direct EPA to play a driving role in forging and implementing transparent and, in certain circumstances, enforceable agreements with companies to address risks that do not merit formal rulemaking.

2. Congress should make clear that EPA's reviews of, and responses to, chemical risks must be open, measured, and timely. In developing new statutory provisions, Congress should consider the merits of incorporating a staged public process wherein EPA initially screens chemicals to identify priorities for further assessment, develops and releases its risk assessments, and, when unacceptable risks are found, proceeds to consider the need for control action. The process also should include a public dialogue in which stakeholders can participate, but require closure to occur after reasonable debate has been heard.

3. EPA's authority to impose specific risk management requirements should be based upon a standard of reasonableness. Congress should make clear that EPA's chemical control actions must be based upon: (1) a scientifically sound assessment of a chemical's foreseeable risk(s); (2) the identification of one or more measures for minimizing or eliminating the risk; and (3) a determination that it is reasonable to require such measure(s) based upon a documented consideration of certain relevant factors.

The current requirements in TSCA § 6(a) for a finding of ''will present an unreasonable risk'' and the need to apply the ''least burdensome'' measures, as predicates to EPA adopting risk management requirements, must be replaced because they amount to unreasonable and unworkable standards. A more straightforward and sensible approach would be to condition the imposition of particular risk management actions upon EPA's having determined that it is reasonable to impose such actions after the agency has documented its evaluation of certain statutory factors. Moreover, the scope and extent of such EPA actions should be reasonably commensurate with the level of knowledge (e.g., screening versus confirmatory) and significance of the hazards, bioaccumulation and persistence, exposures, and foreseeable risks presented.

Following are the types of factors that should be considered in the agency's reasoned determination whether to impose specific risk management measures:

a. the measures' anticipated risk-reduction benefits;
b. the feasibility and reasonably predictable costs of the planned measures;
c. the viability, and anticipated benefits and costs, of alternative measures;
d. the essentiality of the chemical for particular uses/applications; and
e. the foreseeable availability and feasibility of less-risky substitutes.

4. EPA should be directed and encouraged to collaborate with state, federal, and foreign governments' science-based regulatory bodies. Many states, federal agencies, and foreign governments have developed expertise in chemical risk assessment and management that can be of value to EPA and, recognizing this, Congress should encourage EPA collaboration. Other federal environmental statutes contemplate the states' partnership with EPA in implementing and enforcing those laws, and new legislation concerning commercial chemicals likewise should include a role for state involvement.

As generally interpreted, TSCA (in contrast to other environmental statutes) draws a sharp line between the respective jurisdictions of EPA under TSCA, and FDA under the Federal Food, Drug, and Cosmetic Act, with the key legal question being whether FDA has jurisdiction over a particular activity (e.g., manufacture) and application/use (e.g., a drug or drug intermediate). Given emerging issues such as the presence of pharmaceuticals in the environment, this bright-line deferral to FDA no longer makes sense. EPA should receive new authority to assess and take actions that control or prevent risks presented by environmental releases of human and animal drugs (including drug metabolites) and

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cosmetics from industrial activities, consumer uses, and disposal of unused products. This authority should be exercised following consultation as appropriate with FDA. Carefully crafted legislation can provide EPA the authority to take appropriate actions (including green chemistry approaches) to prevent or control such releases, without adversely affecting FDA's well-established authority and ability to otherwise regulate drugs and cosmetics.

5. Compliance must be strengthened by a visible enforcement effort. There appears to be minimal need to modify the current TSCA enforcement provisions. However, Congress should direct EPA to reinvigorate its chemicals enforcement program by focusing upon noncompliance involving substantial risks to health or the environment, violations evidencing knowing or grossly negligent behavior, and violators whose actions warrant penalties or injunctive relief for purposes of general deterrence. Also, Congress should ensure that chemical regulatory enforcement receives needed resources and Agency attention.

C. Policy Directions to Inform Implementation

To enhance legislative mandates and authorities while guiding EPA's implementation, the new legislation should include congressional policy objectives that convey key overarching considerations and provide a sense of purpose to EPA and relevant stakeholders.

1. Establish an industry canon of duty to the public and the environment. A responsible business model includes the concept of ''product stewardship''. Companies throughout the chemicals value chain should have a responsibility to ensure that information about foreseeable risks from their products is developed, appropriate actions are taken to mitigate risks, and information is conveyed downstream to guide responsible decisionmaking by those throughout the value chain.

2. Make clear that both EPA and industry must strive to develop and use the best available scientific data in risk assessment and risk management decisions. Informed decisionmaking requires use of the best available scientific data and information. Scientific data and methods need to be refined through ongoing and transparent efforts which take into account, *inter alia*, data validity and reliability, peer review, and international harmonization and acceptance.

3. Emphasize that EPA's mission requires having a life-cycle awareness of risks, including consideration of vulnerable subpopulations. Life-cycle approaches can open up new insights and understanding regarding solutions and needs, and should be encouraged generally—and specifically in the analysis of chemical substitutes. In implementing new legislation, EPA should take action to prevent or control risks from chemicals throughout the value chain, particularly in products and articles involving exposures to children and other vulnerable subpopulations.

4. Establish environmental protection as a priority that is equal in importance to protecting human health. New legislation should focus the agency's attention upon significant environmental (non-human) endpoints and populations at risk.

5. Encourage innovation in the development of new chemicals, processes, and technologies. Innovation is critical to future U.S. competitiveness and improved environmental performance. The new law should recognize the importance of continued U.S. leadership in chemical research and development and the role of innovation in the development and commercialization of sustainable products and technologies and should enable EPA to apply an appropriate mix of incentives to encourage such innovation.

6. Provide the necessary resources for governance. Congress should ensure that the resources available to EPA are sufficient to meet the agency's responsibilities under new legislation. In addition to appropriating funds for implementation, Congress should adopt a fee-based approach whereby commercial enterprises throughout the value chain have a reasonable level of shared responsibility for providing the resources needed by EPA to implement the law.

Conclusion

When enacted in 1976, TSCA was widely viewed as granting EPA both the authority and discretion to undertake regulatory actions necessary to ensure that risks from a broad range of commercial chemicals would be properly assessed and managed. With perhaps the exception of the agency's new chemicals review program, such expectations have not been met. Hence, the United States has arrived at a time when Congress appears both interested and willing to take on a major rewrite of the law.

We strongly support fundamental reform of TSCA in a manner which incorporates the principles and measures set out above. The new legislation, which should also rename TSCA,[13] must provide a mandate for EPA to implement a reinvigorated regulatory program that is grounded in sound science; appropriately balances health and environmental protection with important economic factors; and addresses risks from commercial chemicals in a responsible, efficient, and timely manner that ensures the safety of chemicals and products in commerce. In so doing, EPA will regain domestic and international leadership in chemical risk evaluation and management.

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[13] Renaming TSCA might allow any stigma to be shed and provide all interested parties a fresh start. We consider the ''Chemical Assessment and Risk Management Act'' as an alternative title worth considering.