Testimony: The Udalls Sound Off on Today's Challenges

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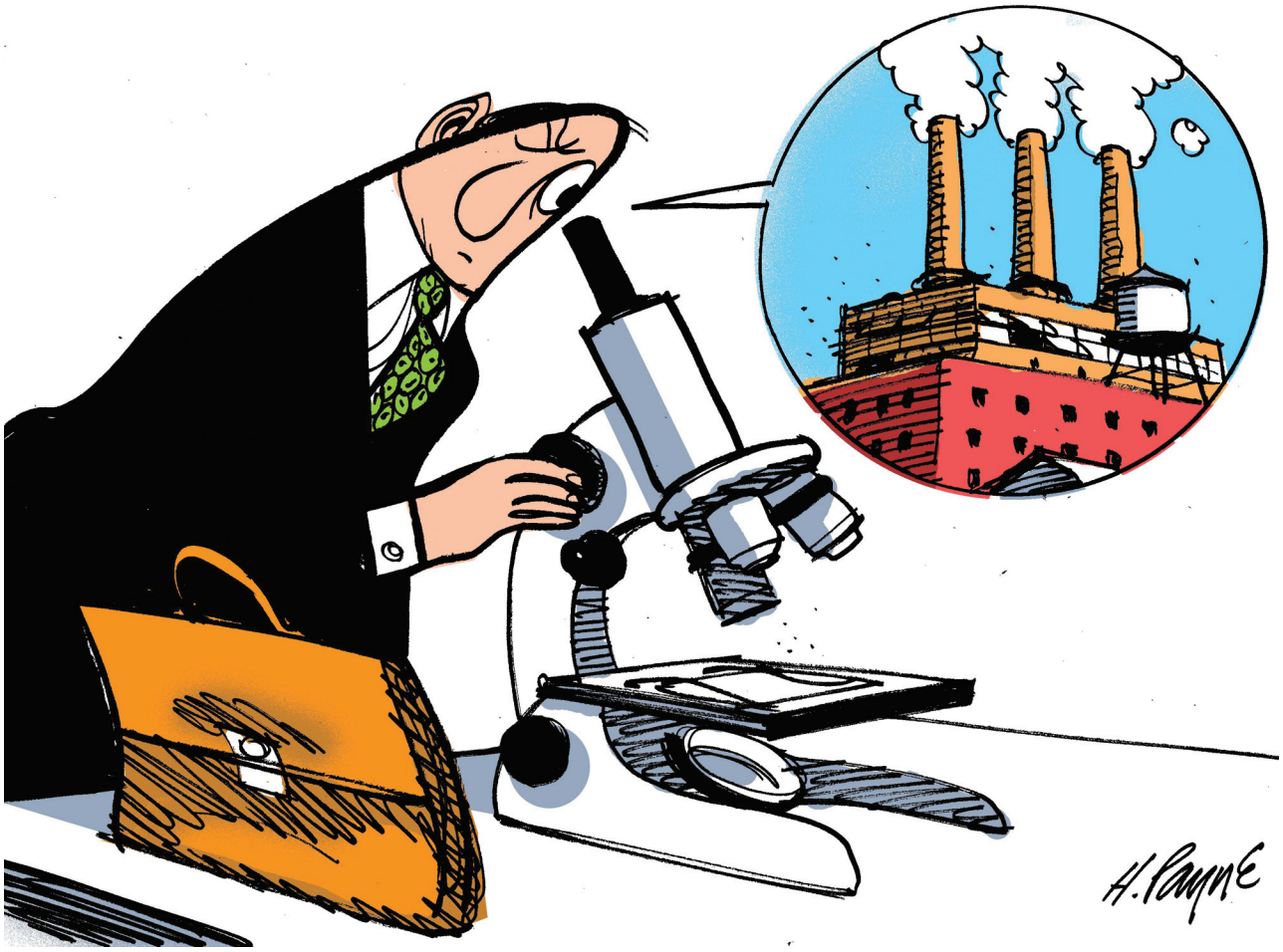

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TSCA, Redux

The Toxic Substances Control Act has been interpreted by agency and court decisions over the course of three decades. It is time for Congress to take the law into its own hands

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Since the Toxic Substances Control Act was passed in 1976, the Environmental Protection Agency's implementation of the law has never lived up to Congress's statements of policy. The legislators intended that producers of chemicals, on the one hand, should develop adequate risk assessment data, and on the other that the agency should assure that chemicals do not present an unreasonable risk of injury to health or the environment. Suffice it to say that Congress was ambitious. Unlike laws governing products that intend toxicological effects — think pesticides and pharmaceuticals — TSCA's jurisdiction encompasses virtually all other chemicals in commerce irrespective of their hazard, exposure, or risk profiles. Also in contrast to other environmental laws, TSCA contains almost no terms giving direction to EPA or setting priorities for the agency in implementing and enforcing the act. And whereas other EPA-administered laws have been the subject of regular congressional review and amendment, there has been no effective legislative ownership or oversight of TSCA during its one-third century of existence.

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(Indeed, its two sponsors exited Congress within a few years.)

Moreover, practically from the start EPA found it difficult to implement many of TSCA's authorities pertaining to risk assessment and risk management. The bright spot has been the premanufacture notification program for new chemicals — which Congress required the agency to begin implementing within a year of the law's enactment. Otherwise, since TSCA's inception EPA has issued requirements for industry-sponsored and -funded testing that apply to only a fraction of the estimated 80,000 chemicals that the agency considers to be in the marketplace. And notwithstanding Congress's clear expectation that EPA would adopt a range of strong measures to regulate human exposures to chemicals having significant chronic toxicities, the agency's single noteworthy regulation has addressed risks from polychlorinated biphenyls, in accordance with the law's prescriptive mandate for a national PCB phaseout.

This paucity of TSCA regulatory actions, plus a number of other legal, technical, and political factors, have materially contributed both to EPA's support of "voluntary" industry data-gathering and risk-management measures, and to the adoption of a patchwork of state and local regulatory initiatives. At the same time, the European Union's REACH program has established a chemical regulatory framework that either directly or indirectly affects the activities of many U.S. companies. REACH is joined by a number of non-U.S. national requirements aimed at banning or substantially limiting the marketing, distribution, and use of particular substances. The prospect for clear signals on chemicals policy for producers and users has never been foggier.

But in recent months it has become apparent that the stars — i.e., key stakeholders — are aligned in a fashion that should finally result in major congressional modifications to TSCA, probably during the 2011–12 timeframe. Such statutory amendments will give EPA both greater direction concerning priorities and a more expansive and flexible range of authorities. Further, such authorities probably will apply throughout the chemicals value chain — both upstream through manufacturing and processing, and downstream through distribution, use (whether by industry or consumers), and end-of-life disposition.

The Responsibilities of Business

In reauthorizing TSCA, Congress should incorporate provisions premised upon the business community's responsibilities and opportunities as producers and users of chemical products. The law should foster the fundamental responsibility of companies throughout the value chain to ensure that data about foreseeable risks are developed, mitigating actions are taken, and information is conveyed downstream in order to guide responsible lifecycle decisionmaking.

The current law focuses almost exclusively upon manufacturers and processors of chemicals as being responsible for the development of health- and environmental-effects data and for implementing measures that control exposures. There was a consensus in 1976 that this emphasis presented the most efficient and effective manner by which to require the industry to characterize and limit risks. In the ensuing years, the larger chemical companies articulated various codes and standards of practice for the production and management of their products. Most notably, in 1988 the largest industry group, the Chemical Manufacturers Association (now the American Chemistry Council), announced its mandatory Responsible Care initiative, addressing management systems and certification, metrics reporting, and other elements to foster best practices. Over the past 20 years, numerous similar actions, including the adoption of formal product stewardship programs, have been instituted by the business community.

During this same period, attention increasingly has focused on controlling chemical risks by dealing directly with finished products (both industrial and consumer), either in addition to or in place of controls imposed upon feedstocks and producers. In addition, lifecycle perspectives (and developing standards of legal liability) concerning chemical risks have legitimized the concept that downstream users and other beneficiaries of chemicals should bear both financial and management responsibility for health and environmental risks associated with their products.

Mirroring this evolving perspective on the business community's responsibility for chemical assessment and management of foreseeable risks, and reflecting EPA's ineffectiveness in using its TSCA authorities, the agency over the years has undertaken a number of informal, voluntary programs with various industry groups in order to develop effects and exposure data and to implement risk-management actions. Examples include the HPV (for High Production Volume) toxicology testing program, certain Design for the Environment measures, and agreements with industry sectors concerning testing and exposure controls on high-profile chemicals of concern (e.g., polybrominated diphenyl ethers, or PBDEs; perfluourinated compounds, or PFCs). In some instances these programs have been incorporated into enforceable agreements — albeit limited to and binding only upon the particular companies that have negotiated and signed such agreements. The agency also has employed other non-rulemaking, and non-enforceable, means to achieve a measure of data development and chemical-control outcomes. These have included publication of EPA-sanctioned hazard and risk data and evaluations via the agency's Integrated Risk Information System. They have also included convening meetings with specific chemicals' stakeholders in an effort to disseminate information about risks and substitutes and thereby lead users away from hazardous substances without the need for more direct (and formal) regulatory action.

Many of these non-regulatory approaches to data development and risk management have been effective in achieving desired goals and efficient in terms of resources spent and timeframes for accomplishment. However, EPA's failure to invoke meaningful, targeted, and enforceable regulatory actions has perpetuated significant data gaps for important toxicology endpoints and exposure scenarios, including chemical fate and transport. And the dearth of enforceable TSCA risk-management actions has left absent what should be a key element of the country's overall system for minimizing reasonably foreseeable health and environmental risks.

To help ensure that EPA receives timely infor-

mation and data needed for chemical assessments, and that companies throughout the value chain take appropriate measures to mitigate risks, better product stewardship and best practices should be established in TSCA as an industry canon of duty to the public and the environment. As a corollary, EPA should be given clear authority to regulate both the activities of downstream users and chemicals contained in products and articles, particularly when such an approach is the most appropriate way to address risks to non-workplace populations or the environment. This is wholly in line with a lifecycle strategy for chemical risk assessment and management, and will bring more certainty and, where necessary, enforceability to companies' stewardship commitments.

A modified TSCA also should enable EPA to apply an appropriate mix of incentives that encourage innovation in the development and commercialization of safer and sustainable alternatives to risky products and technologies. Congress's statement of TSCA policy objectives in 1976 included the admonition that EPA should exercise its regulatory authority over chemicals without unduly impeding innovation. That policy remains important today. However, it should be supplemented by statutory provisions which, in the broader context of TSCA data development and chemical-control measures, facilitate green chemistry, other prevention-based approaches for risk reduction, and sustainable production. Although such practices should continue to evolve primarily through market forces, the agency should be authorized to implement and, if necessary, modify information-development, reporting, and risk-management requirements in a fashion that supports these types of innovation.

The agency's actions under TSCA have focused almost exclusively upon new chemicals that are the subject of Premanufacture Notifications, called PMNs, which companies must submit 90 days prior to commercial production. Firms must include the toxicological and exposure information they possess, but there is no obligation for any data development as a prerequisite. Thus, although EPA has published a list of chemical classes of concern that typically incur increased scrutiny from reviewers, companies have broad discretion to determine their data development and assessment.

In reviewing a PMN, the agency may impose certain testing requirements, plus production, marketing, and use restrictions, via consent orders that are negotiated with producers and, in some instances, with downstream processors, distributors, or users. The agency also may issue Significant New Use Rules, which typically extend the terms of negotiated orders to other manufacturers and downstream entities that are not already the subject of restrictions imposed via the original PMN submitters.

Since the PMN requirements took effect in 1979, the agency has reviewed more than 32,500 notices (plus another 10,000 or so PMN-exemption submittals). Approximately 10 percent of the PMNed chemicals thereafter have been subject to consent orders, voluntary testing, or PMN withdrawals. Further, there is little doubt that, over the years, numerous companies have decided to withhold certain new chemicals from further development in anticipation of agency requests for additional data or restrictions on production and use. (However, we have no ability to gauge the extent of "voluntary" restrictions upon firms' launching of new chemicals.)

Going forward, the PMN requirements should be modified in certain key respects that would necessitate congressional action. Most significantly, TSCA should be amended to require both that PMNs include a core set of physical/chemical, toxicological and exposure-related data and that chemicals which subsequently enter the market must meet periodic testing and reporting requirements that apply as well to existing (i.e., non-PMNed) chemicals. In addition, Congress should move from the current *premanufacture* regime to a *premarket* notice system — one that requires that the 90-day advance notification be tied to the marketing of new chemicals or products. This would give manufacturers the discretion to submit their notices closer to the time when the substances have prospects for market acceptance and, hence, a return on investment. It is estimated that up to half of the chemicals for which PMNs have been submitted over the years never were introduced into commerce, often for reasons unrelated to the submittal. Thus a premarket review program should result in fewer notices and, therefore, considerable savings from the reduced resources spent in PMN preparation (by industry) and review (by EPA), without abrogating TSCA's core responsibilities.

New Measures Needed

In sharp contrast to the procedures for new chemicals, the lack of virtually any risk-management actions for existing chemicals is the best, most telling evidence that major changes are needed if TSCA is to provide a meaningful framework for the control of risks associated with substances already in commerce. Our recommendation above, that EPA be given clear author-

ity to impose risk-management requirements upon downstream businesses and upon chemicals in products and articles, will plug a significant gap in EPA's authority. However, other amendments are needed for the agency to be able to require companies to protect health and the environment.

First, EPA should be authorized to take a range of actions in order to control chemical risks, choosing from among a variety of risk-management approaches the ones that best fit particular situations. Thus, the agency should be able to forgo conventional command-and-control actions when other measures are more appropriate for protecting particular populations (whether human or environmental) from foreseeable exposures. Such measures could include minimizing exposure or phasing out production and use, negotiated with stakeholders and codified in enforceable orders or rules that apply to all similar businesses. In other situations, EPA could facilitate dialogues with companies throughout a chemical's value chain (possibly complementing industry product stewardship activities). These could address hazard, exposure, and risk profiles of possible substitutes. And in limited circumstances, the agency might be able to play a role in judging the hazard and risk profiles of emerging products and technologies.

EPA's authority to use risk communication merits particular attention, because the agency already does so outside the scope of legislative mandates. Particularly in light of EPA Administrator Lisa Jackson's announcement of reforms to the agency's process for obtaining, assessing, and communicating information about health risks from chronic exposures to chemicals — the Integrated Risk Information System — it is appropriate to consider whether and how the risk-management aspects

A Tool in Need of Updating

When the Toxic Substances Control Act was passed by Congress 34 years ago, it represented an important step forward in how the United States would address the risks from hazardous industrial compounds. But over the years, TSCA has proven an inadequate tool for protecting against chemical risks. Our toxics law is the only major environmental statute that has not been reauthorized. Its problems are so significant that the Government Accountability Office has put the statute on its "high risk" list of items needing legislative attention.

When TSCA was enacted, it grandfathered in, without any evaluation, the roughly 60,000 chemicals that existed in 1976. The statute never provided adequate authority for EPA to reevaluate these existing chemicals as new concerns arose or science was updated, and it failed to grant adequate authority to require companies to provide toxicity data. As a result, in the more than three decades since TSCA was passed, EPA has only been able to require testing on approximately 200 of the 80,000 chemicals produced and used in the United States today.


Steve Owens

Even if the agency has substantial data and wants to protect the public against known risks, TSCA creates obstacles to quick and effective regulatory action. For example, in 1989, after years of study and nearly unanimous scientific opinion, EPA issued a rule phasing out most uses of asbestos. Yet, a federal court overturned most of this action because the rule had failed to comply with the law's requirements.

Because of these weaknesses, TSCA reform is a high priority for the agency. Reform is necessary to ensure chemical safety in a rapidly changing world and restore public confidence that EPA is protecting the American people. Administrator Lisa Jackson recently announced a set of principles developed by the administration to fix the statute and give EPA the tools it needs.

These principles include the idea that chemicals should be reviewed against safety standards that reflect risk-based criteria, while the responsibility for providing adequate health and safety data must rest on industry. The agency should have clear authority to take risk management actions when chemicals do not meet the safety standard. EPA should also have clear authority to set priorities for conducting safety reviews. In all cases, the agency and producers must act on priority chemicals in a timely manner, with firm deadlines to maintain accountability.

We also must encourage innovation in green chemistry and support activities that will lead to safer and more sustainable chemicals and processes. Finally, implementation should be adequately and consistently funded, with manufacturers supporting the costs of implementation.

Congress is giving attention to TSCA reform, and many key industry and NGO stakeholders, as well as states, also believe now is the time for reform. EPA looks forward to working with Congress and all interested parties to bring TSCA into the 21st century and ensure an effective chemicals management system that will protect children and families in this country.

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of such processes should be authorized within a statutory framework. The IRIS program is housed within EPA's Office of Research and Development because IRIS focuses on risk assessment (vs. risk management), and because it provides a focal point for hazard and risk evaluations that may be used by program offices throughout EPA (as well as by persons and entities outside the agency). However, communications from the IRIS program in fact often amount to significant EPA risk-management actions, outside the boundaries of any legislative construct. Consideration should be given to whether such risk communication should be required to be taken pursuant to specific legislative authority and direction, distinct from other EPA exposure control measures that might be based upon IRIS findings and are taken pursuant to existing pollution-control laws.

To be sure, there are a number of thorny issues involved in incorporating these and similar legal authorities into TSCA. However, most such approaches already are being taken outside the statutory context.

Second, the law should empower EPA to impose specific risk-management requirements based upon a standard of reasonableness, rather than the current standard of unreasonableness. TSCA now conditions EPA's imposition of chemical-control requirements upon the agency's having found in a rulemaking that to-be-regulated commercial activities involving a chemical present or will present "an unreasonable risk of injury to health or the environment." Moreover, EPA must use "the least burdensome requirements" to control the risk of concern, and must publish a statement with respect to various factors (e.g., relevant health or environmental effects and exposures; the chemical's benefits for various uses, and substitutes for such uses; reasonably ascertainable economic consequences of the rule) that support the requirements that are to be imposed.

For a variety of reasons, EPA long ago concluded that these provisions present unreasonably burdensome barriers to the regulation of chemicals. Most notably, in a 1991 decision (*Corrosion Proof Fittings*), the U.S. Court of Appeals for the Fifth Circuit largely rejected a 1989 TSCA rule that would have banned the manufacture, importation, processing, and distribution of asbestos in virtually all products within the United States. Although EPA's rulemaking record documented asbestos's well-known health hazards, the court concluded that the agency had not complied with its statutory obligations to consider less-burdensome requirements for controlling the identified risks, to carefully evaluate substitute products, and to adhere to certain procedures. Following that decision EPA abandoned all efforts to impose chemical-control actions based upon the unreasonable-risk authority.

In light of the challenges (both perceived and real) that the current TSCA language presents to future EPA rulemaking, that language should be replaced with a standard predicated on the agency's determination that it is reasonable to require a specific risk-management action. In order for EPA to impose a measure upon particular entities (e.g., producers, distributors, or retailers), the agency should be required to have a scientifically sound assessment of the subject chemical's (or chemical product's) foreseeable health or environmental risks and to determine that it is reasonable to require the measure, based on a documented evaluation of certain relevant factors that are set out in the law. Such factors should be the measure's feasibility, reasonably predicted costs, and anticipated risk-reduction benefits; the viability and anticipated benefits and costs of alternative measures; and the availability of less risky substitutes. Another possible factor could be the chemical's essentiality for particular uses.

If Congress modifies TSCA along these lines, it will take a necessary and significant step in effecting meaningful reform of this severely underused provision of the law.

Conclusion

Congress should take the law into its own hands and bring TSCA into the 21st century. It can do so by amending the statute to reflect the varied and quite significant changes during the past 30-plus years in hazard and risk data, protocols, and assessments; chemical products and technologies; business practices and drivers; and paradigms for controlling chemical risks and otherwise regulating commercial activities. A cross section of stakeholders now are engaged in a process that will play out over many months, during which concepts and proposals like those presented here may be carefully vetted and worked into legislative terms that both push and enable EPA to again be a leader in chemical assessment and risk management. And in the spirit of constructive dialogue and debate that we hope will occur, we suggest that TSCA be renamed the Chemical Assessment and Risk Management Act — good karma being a positive element of efforts to transform and then implement this important law. •