Ten Essential Elements in TSCA Reform

by Richard A. Denison

Richard Denison is a Senior Scientist with Environmental Defense Fund in Washington, D.C.

Editors' Summary:

Congress enacted TSCA in 1976 to control risks from chemicals in commerce. It requires the government to review most new chemicals while they are being developed and it gives government the power to regulate chemicals already in or entering commerce if they create an "unreasonable risk" to health or to the environment. Yet current policy hinders government's ability to generate information and to act on such information when it indicates significant risk. This Article identifies 10 elements that can facilitate a shift toward knowledge-driven policies that motivate and reward, rather than impede and penalize, the development of information sufficient to provide a reasonable assurance of chemical safety. Adopting a more comprehensive approach that seeks to develop good information on most or all chemicals would allow us to select safer chemicals with confidence.

For the last several decades, government policy has granted the tens of thousands of industrial chemicals already in commerce a strong "presumption of innocence." In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals as they've seen fit. This policy contrasts sharply with the "presumed guilty until proven innocent" approach adopted for pharmaceuticals and pesticides. For these substances, producers have the burden of providing to the government information demonstrating their safety, at least when used as intended.

Yet for industrial chemicals, the opposite is true: Government—and, hence, the public—shoulders the burden of proof. In what amounts to a classic Catch-22, *government must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require the development of information sufficient to determine whether there is actual risk*. This burden is so high that in the 32 years since the Toxic Substances Control Act (TSCA)[1] was enacted, the U.S. Environmental Protection Agency (EPA) has required testing for only about 200 chemicals.[2]

Current policy essentially says: "We'll consider developing a better understanding only of those chemicals that we already have good reason to believe pose a risk." This is rather like the old adage about looking for lost car keys at night only under the streetlight because the light is better there. So when it comes to choosing among several available options to provide a desired chemical function, or to replacing a problematic chemical, we are often in the dark and run the risk of simply "replacing the devil we know with the devil we don't." Society remains largely ignorant about the risks of the great majority of chemicals because we only investigate those about which we already know something. That means we fail to learn not only which chemicals pose risks, but also which chemicals pose little or no risk. Adopting a more comprehensive approach that seeks to develop good information on most or all chemicals would allow us to select safer chemicals with confidence.

TSCA places an even higher—some would say impossibly high—burden on EPA before it can act to control a chemical. Government must effectively prove beyond all reasonable doubt that a chemical poses a risk in order to take any regulatory action to restrict its production or use. Since adoption of

1. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
2. Since 1979, EPA has used its test rule authority under TSCA §4, 15 U.S.C. §2603, to require testing of about 200 chemicals. For about 60 of these chemicals, the data were obtained through §4 Enforceable Consent Agreements (ECAs), which EPA uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing. Office of Pollution Prevention & Toxics (OPPT), U.S. EPA, Overview: Office of Pollution Prevention and Toxics Programs 4, 15 (2007), *available at* http://www.epa.gov/oppt/pubs/oppt101c2.pdf [hereinafter OPPT Overview, 2007].

TSCA in 1976, EPA has succeeded in mandating restrictions on the production or use of only five substances.[3]

By allowing action only once there is clear evidence of harm, current policy does not reward, and may well provide a sizeable disincentive against, the gathering of better information about chemicals. A company is likely to view undertaking this activity as only increasing the likelihood that evidence of harm will be uncovered. And where the default in the face of any uncertainty is no action, industry has an incentive to seek to perpetuate rather than resolve the uncertainty.

As recognition of these problems has increased, calls for reforming TSCA have become more urgent. This Article lays out 10 essential elements in any such reform.

I. Establish a Policy and Develop and Apply Criteria to Identify and Act to Control All Chemicals of Concern

Outside the vague and undefined concept of "unreasonable risk,"[4] TSCA provides no basis on which to identify what attributes of chemicals should trigger action. Establishing such a policy framework is critical to direct and drive further needed efforts: developing information about chemicals focused on those attributes; efficiently prioritizing and assessing chemicals against the relevant criteria; and undertaking appropriate actions to reduce production, use, and release of chemicals of concern and to replace them with alternatives known to be of lesser or no concern.

Attributes and their associated criteria can be hazard-based or exposure-based. Such criteria-driven policies have become core elements and drivers in other countries' recent reforms of chemicals policies. For example, the Canadian Environmental Protection Act (CEPA), as amended in 1999, required health and environmental agencies to use available information to categorize each of the roughly 23,000 previously unassessed chemicals on its domestic substances list to identify chemicals that are persistent, bioaccumulative, inherently toxic to humans or nonhuman organisms, or of greatest potential for exposure to humans.[5]

REACH (Registration, Evaluation, Authorisation, and Restriction of CHemicals),[6] the European Union's recently adopted chemicals regulation, is also attribute- and criteria-driven. It uses hazard-based criteria, surrogates for exposure and use attributes, to drive the processes it puts in motion of registering, evaluating, and authorizing use of an estimated 30,000 chemicals.[7]

In the United States, some states have adopted policies that focus on particular chemical classes or uses to identify and drive action on chemicals of concern. Maine, for example, has prioritized the elimination of mercury-containing products.[8] In Washington, priority has been placed on identifying and restricting use of PBT chemicals, focusing initially on mercury and brominated flame retardants.[9] More recently, both states as well as California have passed broader bills that establish policies and set in motion processes to identify and act to control chemicals of concern.[10]

Recommendation: TSCA should rest on clear policy objectives and criteria for identifying and acting to control chemicals of concern. These criteria should be used to determine information requirements, prioritize chemicals for assessment, and decide whether and what risk management is needed.

The policy should allow chemicals of concern to be identified based on their hazard or exposure characteristics, not just on risk; hence, hazard- and exposure-specific, as well as risk-based, criteria should be articulated. EPA should be authorized and required to assess and impose risk management measures on chemicals that meet such criteria.

II. Separate Scientific Decisions as to Whether a Chemical Is of Significant Concern From Policy Decisions as to How Best to Address Such Concerns

TSCA's only articulation of a safety standard, that of "unreasonable risk," demands that EPA answer much more than the scientific question of whether a chemical may or will harm people or the environment. It must also consider the economic and social costs of imposing controls on the chemical, including the benefits of the chemical, the availability of alternatives, and the impact of regulation on the economy, small businesses, and innovation.[11] EPA must also demonstrate that any proposed control is the least burdensome it could have

3. The five substances are: polychlorinated biphenyls (PCBs), by virtue of a mandate from Congress; fully halogenated chlorofluoroalkanes used as aerosol propellants; dioxin in certain wastes; asbestos (limited to products no longer in commerce); and hexavalent chromium used in water treatment chemicals in comfort cooling towers. *See* U.S. Government Accountability Office, Chemical Regulation—Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program 58 (2005) (GAO-05-458), *available at* http://www.gao.gov/new.items/d05458.pdf [hereinafter GAO, 2005].
4. 15 U.S.C. §§2601(b)(2) & 2604(a).
5. *See* Canadian Environmental Protection Act, 1999, R.S.C. ch. 33, §73 (1999) (Can.), *available at* http://www.ec.gc.ca/CEPARegistry/the_act/Contents.cfm [hereinafter CEPA].
6. Regulation (EC) 1907/2006, 30.12.2006 J.O. (396) 1, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF [hereinafter REACH].
7. *See id.* art. 57.
8. *See* Maine Department of Environmental Protection, *Mercury Products*, http://www.maine.gov/dep/mercury/products.htm.
9. *See* Washington Department of Ecology, *PBT Initia*tive, http://www.ecy.wa.gov/programs/swfa/pbt/.
10. In 2008, Maine adopted the Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products, which calls for the state eventually to identify 100 chemicals of high priority and for producers or manufacturers of such chemicals to register their use with the state. *See* janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280027552&LD=2048&Type=1&SessionID=7. Also in 2008, Washington passed the Children's Safe Products Act of 2008, which calls for the virtual elimination of phthalates, lead, and cadmium in children's products and requires the state to develop an inventory of potentially harmful chemicals. *See* apps.leg.wa.gov/documents/billdocs/2007-08/Pdf/Amendments/Senate/2647-S2.E%20AMS%20ENGR%20S5756.E.pdf. In September 2008, California passed AB 1879, which calls for the development of regulations to establish processes to identify, prioritize and evaluate chemicals of concern and their potential alternatives. *See* http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_bill_20080929_chaptered.html.
11. 15 U.S.C. §2605(c)(1).

proposed.[12] Finally, it must demonstrate that no other statute could address the concern.[13]

The result is a blurring together of what should be two distinct questions: Does a chemical pose a significant risk? If so, what should be done about it? In effect, TSCA precludes EPA from identifying a chemical that poses a significant risk unless it can also demonstrate that the risk could be or is *unreasonable*. While both questions are appropriate for government to answer, precluding government from providing a clear answer to the first question effectively denies both the public (citizens and consumers) and private entities their right to act on their own to reduce risks even in the absence of government action.

This policy again stands in contrast to those of Canada and the EU. Under CEPA, the determination of whether a chemical is "CEPA-toxic" and requires some type of regulatory or other risk management action is separate from the determination of how risk should be managed.[14] The former decision does not entail consideration of economic and social factors, the benefits of the chemical, or the availability of alternatives, although these types of factors do influence the subsequent decision about what risk management measures to impose.

Similarly, under REACH, the activity of identifying "substances of very high concern" based on application of objective criteria is wholly separate from both industry's and government's subsequent decisions relating to managing and regulating such chemicals. Economic and social factors, the costs and benefits of the chemical, and the availability of alternatives are all considered in determining whether to grant such substances use-specific authorizations[15] (although the burden of analyzing these factors as well as the burden of proof rest with the industry applicant for authorization rather than with government).

Recommendation: The determination as to whether an existing chemical is of sufficient concern to require the imposition of controls should be based *solely* on its hazard, exposure, or risk characteristics. Socioeconomic factors may play a role in determining what measures should be mandated, but they should not influence the decision about whether a chemical warrants control.

III. Eliminate the All-or-Nothing Approach to Regulation Under TSCA

The range of regulatory measures that EPA can impose on a chemical under TSCA §6 is very broad. On one end of the spectrum, EPA can merely require recordkeeping or monitoring, or communication or labeling of potential risks. On the other end, it can ban all production and use of a chemical. Yet to exercise any of these authorities, EPA must meet the same standard of proof: It must demonstrate that the chemical "*presents or will present* an unreasonable risk." If EPA cannot meet its burden, it cannot impose even the most innocuous of measures, even those such as monitoring for releases or exposures that could help to clarify both the certainty and magnitude of risk.

In contrast, CEPA §64 allows designation of a chemical as CEPA-toxic—and hence eligible for regulation[16]—based on a showing of *potential* harm. This showing can be based on evidence of significant hazard *or* exposure, not necessarily both, and applies to substances that enter or *may* enter the environment.[17] A substance may be "suspected" of being toxic if either its hazards or exposure potential are of concern.[18]

REACH is underpinned by the precautionary principle, which the European Commission indicates applies "where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."[19]

While the principle's implied allowance for government to act even in the face of scientific uncertainty is typically highlighted (and often criticized by U.S. government and industry representatives), another of its core elements is far less frequently acknowledged or understood: its reliance on the so-called proportionality principle.[20] Measures taken to address potential or uncertain risk are to be in proportion to the appropriate level of protection to be achieved and should reflect the associated uncertainty and magnitude, e.g., severity, reversibility, etc., of the potential harm.

Recommendation: Reforms to TSCA should provide a calibrated approach that would provide for application of specific risk management measures in proportion to the strength of evidence of risk as well as the magnitude of risk. Further, EPA should be allowed to initiate action in response to less than absolute evidence of harm. And the Agency should be able to impose controls that address potential harm as well as uncertain, but potentially significant, harm.

IV. Shift the Burden of Proof From Government to Demonstrate Harm to Industry to Demonstrate Safety

Under TSCA, the government must demonstrate that a chemical is or could be harmful before any action can be taken. Those who produce and use chemicals bear no burden of

12. *Id.* §2605(a).
13. *Id.* §§2605(c) & 2608.
14. *See* U.S. General Accounting Office, Toxic Substances Control Act—Legislative Changes Could Make the Act More Effective 26 (1994) (GAO/RCED-94-103), *available at* http://archive.gao.gov/t2pbat2/152799.pdf.
15. *See* REACH, *supra* note 6, tit. VII.
16. Once a substance is found to be CEPA toxic and placed on the List of Toxic Substances, the government has two years to develop and propose a management strategy and an additional 18 months to finalize the strategy. *See A Guide to Understanding the Canadian Environmental Protection Act, 1999* 11-13 (Dec. 10, 2004), *available at* http://www.ec.gc.ca/CEPARegistry/the_act/guide04/toc.cfm.
17. CEPA, *supra* note 5, §64.
18. Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers 97-98 (Environment Canada & Health Canada 2005), *available at* http://www.ec.gc.ca/substances/nsb/pdf/cpguidem688.pdf.
19. *See* Commission of the European Communities, Communication From the Commission on the Precautionary Principle 8 (2000), *available at* http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf.
20. *See id*. at 18.

demonstrating, or even being routinely required to provide the information necessary to determine whether, their chemicals are safe.

This policy stands in marked contrast to those affecting other classes of chemicals, most notably pharmaceuticals and pesticides, which are regulated under other statutes. Producers must generate extensive data demonstrating the safety of these chemicals, and government review and approval are required as conditions for their entering or remaining on the market. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticides are subject to extensive testing and government approval processes before they can be registered[21]:

> EPA must first ensure that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants.[22]

FIFRA also requires pesticides already in use to be reregistered and reassessed for safety.[23]

It may have been reasonable not to expect most industrial chemicals to pose health or environmental risk based on the science available at the time TSCA was enacted, given that many or most of them were not intentionally designed to be biologically active. But recent advances have deepened our understanding of the myriad ways by which chemicals can enter and accumulate in the environment, lead to exposure of people or other organisms, and exert adverse effects.

Chemicals widely used in consumer products—including phthalates used as plasticizers, polybrominated diphenyl ethers (PBDEs) used as flame retardants, and several families of perfluorinated chemicals used in coatings for textiles, cookware, and food packaging—were thought to be safely embedded in polymers or other matrices and, hence, to pose no risk of exposure. Yet they are present in the bodies of virtually all people on earth.

Recommendation: Chemical manufacturers should be required to demonstrate the safety of their products as a condition for entering or remaining on the market, using a standard that establishes a reasonable certainty of no harm. Where government bears the burden of demonstrating harm in order to act, the default in the face of inadequate data or high uncertainty is to implicitly assume safety and take no action. Shifting the burden of proof to industry would help create incentives to expedite information development and assessment and to reach closure and agreement, rather than perpetuate uncertainty.

Manufacturers should also be responsible for developing information sufficient to demonstrate safety. They are best able to maximize the efficiency of producing the information and to allocate those costs to all users of the chemicals. They are also best able to internalize such costs and information and use them to minimize risk from their products.

EPA should be required to determine whether manufactures have met their burden of proof of safety.

V. Require Comprehensive Hazard Information as a Condition for Existing Chemicals to Remain On, and for New Chemicals to Enter, the Market

TSCA's Preamble states:

> It is the policy of the United States that . . . adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[24]

This statement applies to all chemicals and places the burden of data generation squarely on chemical producers and processors. Yet the reality under TSCA has been far different.

For the great majority of chemicals already in commerce, few data are available to the public or to EPA to characterize their hazards. EPA's authority to require testing of chemicals is highly constrained. First, it must have enough information about a chemical to demonstrate that it "may present an unreasonable risk" or that it is produced in large quantities and results in significant environmental releases or human exposures. EPA must also demonstrate that insufficient information exists to determine the effects of the chemical on health or the environment, and that testing is necessary to develop such information.[25] Finally, EPA must, on a case-by-case basis, promulgate a regulation, which typically takes many years and substantial agency resources.[26] In contrast, Canadian officials need only promulgate a Ministerial notice to require testing,[27] while REACH mandates that a minimum data set be developed for all chemicals produced annually above one metric ton per producer (applicable immediately for new chemicals and phased in over time for chemicals already in commerce).[28]

Large data gaps and limited regulatory authority to fill them have led EPA to rely on voluntary efforts to obtain more information on existing chemicals. The most notable of them is the U.S. High Production Volume (HPV) Chemicals Challenge[29] under which producers of HPV chemicals were asked voluntarily to develop and make public a "base set" of screening-level hazard information on their chemicals.[30] Because it

21. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-34.
22. *See* Office of Pesticides, U.S. EPA, *Regulating Pesticides*, http://www.epa.gov/pesticides/regulating/index.htm#eval.
23. *See* Office of Pesticides, U.S. EPA, *Pesticide Reregistration Facts*, http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm.
24. 15 U.S.C. §2601(b)(1).
25. 15 U.S.C. §2603(a)(1)(A)(ii) and (iii), ELR STAT. TSCA, §4(a)(1)(A)(ii) and (iii).
26. A TSCA §4 rule can take between 2-10 years to promulgate and requires significant resources. GAO, 2005, *supra* note 3, at 26.
27. *See* CEPA, *supra* note 5, §71(c).
28. REACH, *supra* note 6, art. 23.
29. *See* U.S. EPA, *High Production Volume Challenge*, *at* http://www.epa.gov/chemrtk/index.htm.
30. The base set is based on the Screening Information Data Set developed by the Chemicals Committee of the Organization for Economic Cooperation and Development. For a list of the data elements, see U.S. EPA, *Determining the Adequacy of Existing Data*, app. A, http://www.epa.gov/chemrtk/pubs/general/datadfin.htm.

is voluntary, it sidesteps the "unreasonable risk" and other findings EPA must make to compel data development and submission. However, for the same reason, EPA has had limited recourse to ensure full participation by manufacturers or the timely submission of complete and high-quality hazard data sets for HPV chemicals, and the program has fallen well short of its goals.[31]

For new chemicals, TSCA provides EPA with premanufacturing review authority. Two major constraints apply, however. First, TSCA precludes EPA from requiring upfront development and submission of a minimum set of data on a chemical's hazards.[32] As a result, the majority of new chemical notifications EPA receives actually contain no hazard data.[33] Second, TSCA grants EPA typically only one bite at the apple—a one-time, 90-day review opportunity. Once that review is completed and manufacture commences, the chemical is placed on the TSCA Inventory, becomes an "existing" chemical, and any company can manufacture and use it without even having to notify EPA it is doing so. Any conditions EPA imposes apply only to the original notifier, unless EPA also promulgates a significant new use rule (SNUR) specific to that chemical.[34]

These limitations—little if any hazard data and one-time review at the premanufacturing stage, well before the full picture of the actual production, use and exposure, and lifecycle impacts of a chemical has emerged—are in contrast to practices in Canada and the EU. Both of those systems employ multi-tiered notification and assessment systems, and both mandate submission of minimum data sets, the scope of which increases as production and use expand.[35]

Recommendation: Reform of TSCA needs to provide EPA with broad authority, without having to demonstrate potential or actual risk, to require industry to generate and submit any data or other information necessary to gain a thorough understanding of the potential risks of any chemical of interest or concern. Submission of minimum data sets should be required of all chemicals, both new and existing.

Companies should be required to notify EPA whenever significant changes occur in a chemical's production volume or use pattern. Government should be authorized and required to request any additional information needed for a re-review of such chemicals to assess the effects of such changes.

For new chemicals, a tiered scheme should be used, with increasing information required as production increases and the extent or diversity of uses expands. While there is merit in retaining the first notification at the premanufacturing stage, even in the absence of a significant data requirement, such an approach needs to be coupled with subsequent notifications accompanied by sufficient data.

VI. Require Robust Data on Chemical Uses and Exposures

For industrial chemicals already in commerce, EPA requires reporting of only limited information on how chemicals are used and the extent to which environmental releases or exposures to workers, consumers, or the environment may occur, and it does so infrequently. TSCA requires such reporting only from chemical manufacturers (and in some cases, processors), but not from the companies that use the chemicals, whether directly or as ingredients in products.

Because of recent amendments, EPA's Inventory Update Rule (IUR) now requires limited reporting on use and exposure.[36] Beginning in the 2006 reporting cycle, all manufacturers of non-exempt[37] chemicals in amounts of 25,000 pounds or more per year per site must report "known or reasonably ascertainable" information pertaining to:

- the number of workers reasonably likely to be exposed to the chemical substance at the site;
- physical form(s) of the chemical substance as it leaves the submitter's possession, along with the associated percent of total production volume; and

31. For a full description of the HPV Challenge and what it has and has not accomplished, see RICHARD A. DENISON, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE (Environmental Defense Fund 2007), *available at* http://www.edf.org/documents/6653_HighHopesLowMarks.pdf.
32. Any requirement for submitting hazard data for a new chemical under TSCA §5 is limited to existing test data already "in the possession and control" of the notifier of the new chemical (§5(d)(1)(B)) and to descriptions of any other relevant information that is already known or "reasonably ascertainable" to the notifier (§5(d)(1)(C)). The lack of an upfront minimum data requirement may in part reflect the fact that notification takes place *premanufacture*, when it may not be realistic to expect a company to have conducted much testing. EPA's intervention at this stage has the advantage of flagging potential concerns before manufacturing has commenced and before significant financial investment has been made by the producer. It also may allow redesign of the manufacturing process or the chemical itself to eliminate or reduce any concern in advance of commercialization. However, the lack of data on a chemical's hazards and other properties, and the more speculative nature of information on its potential uses, releases, and exposures can severely limit the robustness of any risk evaluation conducted at this stage. *See* GAO, 2005, *supra* note 3, at 10-16.
33. According to EPA, 67% of PMNs contain no test data and 85% of PMNs contain no health data. OPPT OVERVIEW, 2007, *supra* note 2, at 8. More than 95% of PMNs contain no ecotoxicity data. OPPT, U.S. EPA, DRAFT Q&A FOR THE NEW CHEMICALS PROGRAM 1-55 (answer to question 118-5) (undated), http://www.epa.gov/opptintr/newchems/pubs/qanda-newchems.pdf. EPA can, and, for a small fraction of new chemicals, does, require some testing or data development on a case-by-case basis where it is able to meet the statutory burdens for requiring testing. A requirement for such data may be included in a TSCA §4 Enforceable Consent Agreements (ECAs), which EPA uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing. EPA has issued such orders for about 60 chemicals. *See* OPPT OVERVIEW, 2007, *supra* note 2, at 15. Alternatively, EPA may negotiate with the notifier a voluntary agreement to conduct testing, which is known as a Voluntary Testing Action. Through the end of September 2005, EPA had negotiated about 300 Voluntary Testing Actions. *See* OPPT OVERVIEW, 2007, *supra* note 2, at 11.
34. SNURs, which EPA has issued for about 7% of new chemicals, typically extend the same conditions imposed on the original notifier to any other manufacturer and require that anyone else who begins producing or using the chemical outside of such conditions first notify EPA. *See* OPPT OVERVIEW, 2007, *supra* note 2, 9-11.
35. *See* RICHARD A. DENISON, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS III-4 to III-6 (2007), *available at* http://www.edf.org/chempolicyreport.
36. *See* U.S. EPA, TSCA Inventory Update Rule Amendments, 68 Fed. Reg. 847 (Jan. 7, 2003), *available at* http://www.epa.gov/fedrgstr/EPA-TOX/2003/January/Day-07/t32909.htm.
37. Certain chemicals on the TSCA Inventory are fully or partially exempted from IUR reporting. *See* OPPT, U.S. EPA, QUESTIONS AND ANSWERS FOR REPORTING FOR THE 2006 PARTIAL UPDATING OF THE TSCA CHEMICAL INVENTORY DATABASE 7-10 (2006), *available at* http://www.epa.gov/opptintr/iur/pubs/guidance_qanda.pdf (answers to questions 30-37).

- the maximum concentration of the chemical substance as it leaves the submitter's possession.

For chemicals manufactured in amounts of 300,000 pounds or more per year per site, additional information is required, including the number of downstream processing and use sites, the number of workers reasonably likely to be exposed, and the types of commercial and consumer uses. Manufacturers, however, only need to report this additional information to the extent it is "readily obtainable." While EPA has yet to release any data from the 2006 IUR reporting cycle, early indications are that significant amounts of the requested information were not submitted because they were deemed by submitters to be "not readily obtainable."[38] This result is not surprising, as manufacturers frequently have only limited access to information about downstream uses.[39]

Reporting requirements now cover fewer than 8,000 chemicals. At most, a few thousand of these are subject to the more extensive reporting that extends to downstream processing and use information. Reporting is required only once every five years and then only for a single reporting year. Infrequent reporting yields a highly inaccurate picture of actual manufacturing levels and use patterns over time,[40] and this inaccuracy is likely to extend to the use and exposure information EPA is now beginning to collect.

EPA may require manufacturers and processors of specified chemicals to report basic manufacture and use information under TSCA §8(a).[41] But each request requires a case-by-case rulemaking and provides for only one-time reporting, although a single rule can cover multiple chemicals. EPA has standardized this type of regulation in the form of a Preliminary Assessment Information Reporting rule, a few dozen of which have been issued for about 1,200 chemicals.[42]

For new chemicals, Premanufacture Notifications (PMNs) must include basic information on anticipated use, production volume, exposure, and release—but only to the extent it is known or reasonably foreseeable by the submitter at the premanufacture stage. The only other circumstances under TSCA requiring reporting of changes in manufacture or use are the rare cases where a new chemical is subject to such a condition during PMN review or when a chemical is subject to a SNUR that includes such a requirement (called a "volume SNUR"[43]).

REACH offers two major innovations in this regard. First, REACH compels the bidirectional flow of information along the chain that links chemical producers, processors, distributors and users.[44] Suppliers typically have limited knowledge of how or by whom their chemicals are used, and users have limited knowledge of the characteristics of the substances they receive or appropriate risk management measures recommended by the producers. REACH requires suppliers to inform their customers about the hazards and risks of their chemicals and about risk management measures that need to be applied. In turn, it requires downstream users to give their suppliers sufficient information on their use(s) of a substance so the supplier can evaluate exposure and identify risk management measures that are then communicated back to the users.[45]

Second, while REACH has no direct counterpart to the TSCA IUR periodic reporting requirement, information is updated as new and existing chemicals move along the program's multitiered registration scheme. In addition, REACH requires registrants to update and resubmit "without undue delay" their registrations whenever there is any significant change in status, including any new use, as well as any new knowledge of risks.[46]

In addition to chemical usage, directly measuring chemicals in human (or other organisms') tissues or fluids can be a powerful means of gauging the actual extent of exposure, and has the further advantage of effectively integrating all exposure sources. Since 1999, the Centers for Disease Control's National Health and Nutrition Examination Survey has measured the levels of a limited number of chemicals and their metabolites in samples of human blood and urine every two years.[47] Biomonitoring to date has focused on chemicals already known to be hazardous and on chemicals that are known to bioaccumulate, which are only a subset of chemicals of potential health concern. Government has yet to conduct broader, more exploratory biomonitoring—aimed at identifying the full range of xenobiotics to which humans are exposed, as one means of identifying chemicals that are priorities for further scrutiny with respect to both hazard and exposure. In addition, the extent of sampling conducted to date is too limited to provide the degree of geospatial "resolution" that

38. Such cases are so common that EPA has coined an acronym for use as shorthand: "NRO." *See* Richard A. Denison, *Environmental Defense Fund's Comments on ChAMP: EPA's Recent Commitments and Possible New Initiatives for Existing Chemicals*, May 2, 2008, *available at* http://www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.
39. *See* references in note 44, *infra*.
40. *See* U.S. EPA, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, Initial Thought-Starter: How Can EPA More Efficiently Identify Potential Risks and Facilitate Risk Reduction Decisions for Non-HPV Existing Chemicals? 3-4 (Draft Oct. 6, 2005), *available at* http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf. *See also* Comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (Feb. 18, 2005), *available at* http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064800ae9de&disposition=attachment&contentType=pdf.
41. *See* U.S. EPA, EPA Authorities Under TSCA 23 (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/tscaauthorities71105.pdf.
42. OPPT Overview, 2007, *supra* note 2, at 16.
43. U.S. EPA, *supra* note 41, at 16.
44. For more discussion of information flow in the context of improved chemicals assessment and management, see Richard A. Denison, Improving Information Flows—In Supply Chains and Beyond, paper presented at the North American Dialog on "Framing a Future Chemicals Policy," Boston, Mass., Apr. 2005, *available at* http://www.chemicalspolicy.org/downloads/W3-Informationflow.doc; and Rachel Massey, *Sharing Knowledge about Chemicals: Policy Options for Facilitating Information Flow, in* Options for State Chemicals Policy Reform: A Resource Guide 69-96 (Lowell Center for Sustainable Production, University of Massachusetts at Lowell 2008), *available at* http://www.chemicalspolicy.org/downloads/OptionsforStateChemicalsPolicyReform.pdf.
45. Two entire titles of REACH are devoted to these tasks: Title IV covers Information in the Supply Chain and Title V covers Downstream Users.
46. REACH, *supra* note 6, art. 22.
47. The latest survey was published in 2005 and tested samples collected in 2001 and 2002 for 148 chemicals. While many of the chemicals included are either "historical" or unintentionally produced substances, human biomonitoring for substances still in commerce has increased in the more recent survey. *See* Centers for Disease Control & Prevention, Third National Report on Human Exposure to Environmental Chemicals (2005), *available at* http://www.cdc.gov/exposurereport/report.htm.

is needed to begin to elucidate exposure routes for chemicals found in human tissues.

Recommendation: As with hazard data, EPA should have broad authority to require industry—both chemical manufacturers and downstream users of chemicals—to generate and submit any use, release, or exposure data or other information necessary to gain a thorough understanding of the potential risks of any chemical of interest or concern. Submission of minimum sets of such data should be required of all chemicals, both new and existing.

Companies should be required to notify EPA whenever significant changes occur in a chemical's production volume or use pattern. Government should have authority and be required to request any additional information needed for a re-review of such chemicals to assess the effects of such changes.

In addition, biomonitoring should be required for any chemical for which there is any reason to suspect human exposure. To avoid conflicts of interest, the government should conduct biomonitoring at manufacturers' expense.

VII. Improve Integrity and Credibility of Industry-Generated Data

Essentially all policies affecting chemicals worldwide—whether industrial chemicals or drugs, cosmetics ingredients, pesticides, or food additives—rely on data chemical manufacturers generate. It is critical, therefore, that every effort be made to ensure that industry-generated data used to formulate and support public policy are—and are seen as—credible. This need is even more pronounced when one considers the obvious financial incentives industry has in minimizing testing costs and being able to state that its products are safe.

Recommendation: To ensure a high degree of public trust in the government's assessment and management of chemicals, sound policy should[48]:

- Establish a registry of health- and safety-related studies to ensure that all study results, along with details of the method used in each study, are reported and made available to the public. This is similar to what already occurs in pharmaceuticals regulation.
- Provide government access to all records of privately sponsored research used in setting or implementing public policy. Such a requirement already exists for publicly funded research.
- Require privately funded researchers whose research is used in public policy settings to disclose the source of their funding and the extent of sponsor review or approval, as well as potential financial conflicts of interest. A growing number of scientific journals and organizations require such disclosures.
- Require independent peer review or certification of studies submitted for use in public policy contexts, along with transparency safeguards to ensure disclosure of the identity of reviewers and any potential conflicts of interest, as well balanced representation of the scientific community among reviewers.
- Provide unfettered authority and requirements for government to conduct random inspections of laboratories used to develop data submitted by industry and audits of the data submissions.

VIII. Broaden Public Access to Chemical Data

Independent of the extent to which government itself acts on chemical information to identify and reduce or manage risks, providing broad public access to such information can empower a host of other actors to make better decisions about the chemicals. Such actors include companies and institutions that make, purchase, or sell chemicals or chemical products, as well as citizens and end consumers.

Better access to information may also drive markets to demand more information and to migrate away from chemicals known or suspected of being risky. Indeed, a field of specialization within economics known as information economics has demonstrated that access to information is a critical need if markets are to operate properly, and, conversely, that the lack of robust information can adversely affect market economies."[49]

One of REACH's main strengths is the extent to which the government intends to make public a large amount of the information it receives, including the identification of substances of very high concern that are to be subject to authorization and information about potential substitutes. In contrast to TSCA, REACH includes numerous provisions calling for public access to non-confidential information—including government decisions and the basis for them—and it mandates that most such information be made available on the internet, free of charge.

Recommendation: Chemical policy reform should include explicit requirements that government make readily and publicly available, in a timely manner, as much information as possible about chemicals as well as documentation of government decisions and the basis for them.

48. Many of these proposals are liberally adapted from RENA STEINZOR ET AL., SAVING SCIENCE FROM POLITICS: NINE ESSENTIAL REFORMS OF THE LEGAL SYSTEM (Center for Progressive Reform 2008), summary available at http://www.progressivereform.org/scienceRescue.cfm.

49. *See, e.g.*, Joseph E. Stiglitz, *Information and the Change in the Paradigm in Economics, Part 1*, 47 AM. ECON. 6-26 (2003); Joseph E. Stiglitz, *Information and the Change in the Paradigm in Economics, Part 2*, 48 AM. ECON. 17-49 (2004); and JOSEPH E. STIGLITZ, GLOBALIZATION AND ITS DISCONTENTS 73-74, 261 n.2 (W.W. Norton & Co. 2003), all cited in Joseph H. Guth et al., *Require Comprehensive Safety Data for all Chemicals*, 17 NEW SOLUTIONS: J. ENVTL. & OCCUPATIONAL HEALTH POL'Y 233-58 (2005), *available at* http://www.louisvillecharter.org/paper.safetydata.shtml.

IX. Tighten Conditions Under Which Industry Can Claim Its Submissions as Confidential Business Information

TSCA §14 provides that "manufacturers, processors or distributors" submitting information may designate any such information as confidential and submit it separately. It further states that, with limited exceptions, information considered to be "trade secrets and commercial or financial information obtained from a person and privileged or confidential" that is reported to or otherwise obtained by EPA "shall not be disclosed" except to federal government employees or their designated contractors, or to law enforcement officials.[50] This prohibits EPA from disclosing any information designated by a submitter as confidential business information (CBI) not only to the general public but also to foreign governments, U.S. states, tribes, and local governments.[51]

Although health and safety studies and associated data are not eligible for CBI protection, chemical and company identity can be eligible.[52] This allowance can lead to perverse outcomes, such as that a chemical's adverse effects on mammalian reproduction must be disclosed, but identification of which chemical causes the effect may be kept a secret.[53]

CBI designations are common; for example, about 95% of PMNs for new chemicals contain information, including chemical identity, designated by the submitter as CBI.[54] There is typically no requirement to reassert such claims even after these chemicals enter commerce.[55] A 1992 EPA study identified extensive problems with respect to the extent of inappropriate CBI claims.[56]

EPA does not always require submitters to provide a justification for such designations at the time they are made.[57] Nor does it require that these claims be reviewed and approved in order to be retained. In addition, such designations are generally not time-limited and, hence, do not expire unless the submitter so designates. EPA may challenge CBI designations on a case-by-case basis, but it rarely does so because of the extensive resources required.[58] In the absence of a successful challenge by EPA, the information must be held as confidential.

The net result of all of these provisions and practices is a system that effectively denies access by the public and even other levels of government to much more chemical information than is legitimately to be claimed CBI.

Recommendations: Submitters advancing CBI claims should be required to: specify precisely what information is requested to be kept confidential; make such a request at the time of submission and provide a full justification and documentation in writing; and specify and justify a time period for which the request is made.

EPA should be required to: specify acceptable and unacceptable justifications for, and documentation that must accompany, any confidentiality request; review, in a timely manner, all confidentiality requests and determine whether to accept or deny the requests; and where a request is accepted, set a time period after which disclosure may occur unless a new request is submitted and accepted.

EPA should be able to disclose submitted information for which it has rejected a confidentiality request, after providing a reasonable opportunity for the submitter to rectify the request.

Health and safety information should never be eligible for CBI protection. As a rule, the identity of the associated chemical and of the submitter of the information should also be ineligible; government should explicitly state the basis for any exceptions.

Workers should have access to all available information, whether or not CBI protected, concerning chemical identity, properties, hazards and workplace exposures for any substance with which they work or to which they could be exposed during work.

Other governments, whether those of domestic states, provinces, municipalities, tribes or foreign countries, should be given access to CBI for the purpose of administration or enforcement of a law, under appropriate agreements and where the recipient takes appropriate steps to keep the information confidential.

50. 15 U.S.C. §2613 (citing 5 U.S.C. §552(b)(4) of the Administrative Procedure Act).
51. *See* OPPT OVERVIEW, 2007, *supra* note 2, at 21.
52. See, for example, such allowance in EPA's PMN regulations, 40 CFR §720.85(a). Elsewhere, EPA regulations state that EPA considers chemical identity to be part of the underlying data to a health and safety study. *See, e.g.*, 40 CFR §§716.3 and 720.3(k).
53. An example of where this frequently occurs is in EPA's public listings of submissions received under TSCA §8(e), which requires the submission of information indicative of substantial risk. Whereas a generic name for the substance must be supplied, its specific name and other identifiers such as Chemical Abstract Service (CAS) number are often listed as "confidential"—as are the names of the submitters themselves. For a recent example, see EPA's compilation of §8(e) submissions received in July 200, at http://www.epa.gov/opptintr/tsca8e/pubs/8emonthlyreports/2008/8ejul2008.htm. Oddly, EPA's guidance for §8(e) submissions states that "EPA considers chemical identity to be part of, the underlying data to, a health and safety study," citing 40 CFR §§716.3 and 720.3(k). EPA goes on to state: "Consequently, the confidential identity of a chemical substance will not be protected by EPA unless otherwise provided for under section 14 of TSCA and the interpreting regulations in 40 CFR part 2." See http://www.epa.gov/fedrgstr/EPA-TOX/2003/June/Day-03/t13888.htm. Either EPA has not been able or willing to challenge such claims made in §8(e) submissions or the claims have been found to comport with TSCA §14 and the interpreting regulations in 40 CFR pt. 2.
54. GAO, 2005, *supra* note 3, at 5, 32; OPPT OVERVIEW, 2007, *supra,* note 2, at 10. The fraction of submitters making CBI claims for chemical identity drops to about 65% for chemicals actually entering commerce, those chemicals for which Notices of Commencement (of manufacture) are filed.
55. An exception is that a claim to keep chemical identity—but not other information—in a PMN confidential expires once manufacture of the chemical commences, unless in filing the required Notice of Commencement the notifier again asserts that the chemical identity is CBI. In this latter case, in contrast to the case when filing a PMN, a justification for the CBI claim must be provided. *See* 40 CFR §720.85(b).
56. *Cited in* GAO, 2005, *supra* note 3, at 32-33.
57. Examples of cases where an up-front justification is explicitly required include CBI claims for chemical identity and facility identification under EPA's TSCA Inventory Update Rule (see http://www.epa.gov/oppt/iur/pubs/guidance/confidentiality.htm) and for "substantial risk" information required to be submitted under TSCA §8(e) (see http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.htm).
58. GAO, 2005, *supra* note 3, at 5, 33.

X. Allow State Governments to Undertake More Protective Actions

Given the very limited level of activity at the federal level in advancing policy reforms to better identify and address chemicals of concern, many states have stepped in to fill the void.[59] States have a critical role to play in chemicals policy development and implementation, not only in affecting practice within their borders, but also in innovating new policy approaches and driving national policy forward.

A chemical's use pattern and human or environmental exposure to it is often specific to a geographic region and may change over time. For this reason, such information may be more appropriately developed at the state level. It is reasonable for states to take steps to understand the flow of chemicals within and across their boundaries. States can and do differ with respect to their policy priorities, both from each other and from national priorities. These priorities may be of cultural or historic origins, signify economic conditions, or reflect geospatial distinctions, such as the extent of reliance on groundwater, features of the natural landscape, or the presence of subpopulations dependent on subsistence lifestyles. Given these distinctions, it makes sense that states will pursue approaches that may differ from and in some cases go beyond those of the federal government or other states.

Recommendation: While some measures needed to establish effective chemicals policies are best undertaken at the federal level, maintaining a vibrant level of state activity is important both in its own right and in driving the evolution of federal policy. Federal policy reform should establish floors, not ceilings, for state government action and should only preclude state actions that are less protective of health or the environment.

XI. Conclusion

Implementation of the elements identified in this Article can facilitate a shift toward *knowledge-driven* policies that motivate and reward, rather than impede and penalize, the development of information sufficient to provide a reasonable assurance of safety for chemicals. Such policies would also place more of the burden of providing and acting on that information on those who stand to profit financially from the production and use of chemicals, as they are arguably in the best position to internalize such information and use it to design out risk from their products from the outset.

59. *See* Massey, *supra* note 44.