Reforming TSCA
Progressive Principles for Toxic Risk Regulation

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Executive Summary

Despite 40 years of regulatory effort, chemical regulation in the United States has been a dismal failure, and our current law – the Toxic Substances Control Act (TSCA) – deserves much of the blame for this regulatory dysfunction. ¹ When Congress enacted TSCA, the final legislation reflected a deal under which chemicals then on the market were “grandfathered” in, while new chemicals would be subject to a quick review by the Environmental Protection Agency (EPA). But experience shows that a vast majority of those reviews are based on inadequate data.

Moreover, under TSCA, chemicals are subject to regulation only if the EPA can prove that they present an unreasonable risk of harm to human health or the environment. That “unreasonable risk” standard has proven to be a great barrier to EPA’s ability to regulate toxic chemicals. While more than 80,000 chemicals can be found in the TSCA inventory (including the pre-1979 “existing chemicals” and the post-1979 “new” chemicals), EPA has only been able to ban the use of a handful of chemicals after they went on the market. A weak TSCA leaves the public and the environment vulnerable.

The influx of engineered nanomaterials into the marketplace provides a prime example of a loophole that needs to be closed. Many engineered nanomaterials are, in a sense, just existing chemicals that have been manipulated at a small scale to act in new ways and provide different benefits to product manufacturers and consumers. But from a toxicological standpoint and from an environmental standpoint, these engineered nanomaterials may have very different effects than they would have before they were manipulated. Carbon nanotubes, for instance, are being developed for use in everything from new drugs to solar cells to aircraft. Long carbon nanotubes resemble asbestos fibers in physical structure, and evidence from animal studies suggests that the nanotubes may have health effects more like asbestos than other carbon molecules.² EPA is debating with stakeholders whether nanomaterials should be treated as “new” chemicals or “existing” chemicals under TSCA, but this tired debate misses the real issue: TSCA needs to be amended to expand EPA’s authority to order testing and, if necessary, to regulate these materials.

The Senate has two vastly different proposals on the table for dealing with the broken law. This Issue Alert focuses on the principles for TSCA reform that CPR Member Scholars and staff have identified as most important. It is by no means an exhaustive list, but it underscores the different approaches to TSCA reform that the two bills take. Numerous experts will testify on the details of the S.1009, the Chemical Safety Improvement Act (CSIA), and S.696, and the Safer Chemicals Act (SCA) on July 31, 2013, before the Senate Committee on Environment and Public Works. The purpose of this document is to put that testimony in context.

The most fundamental requirement, of course, is that the cure for TSCA needs to be better than the original legislation. If deal-making and compromises render a new bill weaker than the old, no constructive purpose is served. More specifically, the new TSCA should set health protection as its primary goal, eliminate overly complex cost-benefit analysis, enable EPA to gather
information easily, establish a standard for reviewing chemicals that ensures only the best chemicals — from an environmental and public health perspective — are on the market, and encourage state regulatory and civil justice systems that fill holes in federal regulation.

This Issue Alert addresses four elements of TSCA reform:

- **Testing:** TSCA creates a “Catch 22” for EPA, requiring that the agency show a chemical may present an unreasonable risk of harm to human health or the environment before it can demand new test data that would help the agency determine whether it can make that case. The provision should be scrapped and replaced with language that gives EPA broad authority to demand test data for any reason related to implementation of the Act.

- **Standard of review:** The federal courts’ crabbed reading of TSCA has left Americans vulnerable to a regulatory system in which chemicals are assumed safe until proven hazardous, and EPA’s efforts to make a case to the contrary are stymied by insufficient information and limited authority to regulate. A novel, competition-based standard of review would transform the TSCA framework from “anything goes” to “the best of what science can offer.”

- **Deadlines:** Time and again, Congress has gone back to rewrite public health statutes to demand that regulatory agencies take specific actions according to specific schedules. TSCA has never undergone comprehensive revisions along those lines, which is why the safety of thousands of chemicals has never been reviewed by EPA. It is high time Congress set a schedule for review.

- **Preemption:** State legislatures, regulatory agencies, and courts play valuable roles in preventing toxic exposures and ensuring compensation for people who are adversely affected by dangerous chemicals. TSCA must encourage vibrant state action to protect people and the environment by preemptsion only those laws that make compliance with federal standards impossible.

Congress deserves approbation for attempting to fix TSCA. If it worked properly, the statute would fill the interstices between protections afforded by other regulatory programs that address chemical hazards in the air, water, and land, in consumer products, and in the workplace. It is critical that changes to the statute embody the progressive principles that will transform our regulation of chemicals from “anything goes” to “the best of what science can offer.”
What We Don’t Know Certainly Hurts Us

In order to properly manage the risks posed by toxic chemicals, EPA first needs sufficient information to act. Under the current law, that need has not been fulfilled. One oft-cited assessment found that comprehensive health and safety information is available for only seven percent of high production volume chemicals produced in the United States (i.e., chemicals produced in quantities greater than one million pounds per year). Indeed, it is this dearth of health and safety information that drove the Government Accountability Office (GAO) to place EPA’s chemical management program on its “High Risk List” – a biennial list of federal government programs that GAO has found are “most in need of transformation.”

Under TSCA § 4, EPA must first make a regulatory finding that the chemical “may present an unreasonable risk of injury to health or the environment” as a prerequisite to requiring testing. This has been interpreted to mean a “more-than-theoretical” possibility of an unreasonable risk. The TSCA § 4 testing scheme is often described as a “Catch-22” because it is difficult to make the determination that a chemical “may present an unreasonable risk” without the very health and safety data that is being sought. EPA has used its authority under § 4 and other parts of TSCA to mandate testing requirements for a few hundred chemicals, but that coverage is a far cry from what should be considered the norm – a basic suite of toxicity screening tests for nearly every chemical on the market, with further testing requirements based on the results of the screening tests.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), provides a useful model for improving EPA’s ability to gather information about toxic chemicals. Under FIFRA § 3(c)(2)(B), the “data call-in” provision, EPA has broad authority to demand additional information from pesticide registrants after a pesticide is on the market. The information that EPA demands must be information that is “required to maintain in effect an existing registration” – a much lower barrier to action than the finding required under TSCA § 4.

The SCA proposes a somewhat analogous approach. It would give EPA the authority to mandate testing for a particular chemical “as appropriate for making any determination or carrying out any provision of the Act.” The CSIA, on the other hand, would not fix the problems with TSCA and instead would add seven more pages of procedural findings and requirements to existing EPA requirements. These new provisions risk adding still further delay and ossification to EPA’s effort to require basic testing on untested chemicals.

EPA’s priorities for gathering chemical information are nearly as important as the standard the agency must meet to exercise that power. Congress should indicate national priorities for chemical risk assessment by including a list of high-priority chemicals in any TSCA reform legislation. Numerous sources of information for identifying high-priority chemicals exist, but some key factors must be:

- High production volume chemicals;
- Chemicals on the Candidate List for Authorization under REACH;
- Chemicals restricted under REACH;
- Chemicals listed under the Stockholm Convention on Persistent Organic Pollutants; and,
• Chemicals listed as hazardous substances under the Superfund law and other federal statutes.

Both the SCA and the CSIA rely on EPA to set priorities. While that approach has the benefit of putting EPA experts in charge of determining the agency’s own priorities, it is an unnecessary step in the short term, when Congress could consult with academics, federal and state officials, and stakeholder experts to develop a workable list of a few hundred chemicals of highest concern for public health and the environment. For the medium- to long-term, though, it is appropriate to let the agency’s experts set priorities for reviewing chemicals of lower concern.
Paralysis by Analysis

TSCA, under the federal courts’ crabbed reading of the statute, creates a regulatory system in which chemicals are assumed safe until proven hazardous, and EPA’s efforts to make that case are stymied by insufficient information and limited authority to regulate. The agency’s one effort to ban a chemical under TSCA § 6 was a proposed ban on most uses of asbestos in the late 1980’s. Despite overwhelming evidence of health damage linked to asbestos exposure, this important regulatory effort failed to pass muster in litigation.

The U.S. Court of Appeals for the Fifth Circuit held that EPA produced insufficient evidence to justify the proposed regulation under the court’s narrow interpretation of TSCA’s “unreasonable risk” standard. The court held that EPA not only had the burden of establishing the scientific case that a chemical poses an unreasonable risk of harm to human health or the environment, but also the burden of proving that the proposed § 6 restrictions are the least burdensome option available to the agency. In the court’s view, the “least burdensome” analysis was an information-intensive exercise of incredible complexity, involving a cost-benefit analysis not just on the proposed restrictions, but also on other possible alternative measures (in the case of asbestos, anything short of a ban).

It is also important to note that under TSCA, courts review EPA determinations using the “substantial evidence” standard of review, which is harder for the agency to meet than the “arbitrary and capricious” standard more often employed when reviewing regulatory agencies’ actions. Given the hurdles to regulating, EPA has only used § 6 to establish limited restrictions on only a handful of toxic chemicals.

Contrast the TSCA approach with two key principles of progressive regulatory policy: (1) that the company proposing to manufacture a potentially harmful substance should have the burden of establishing its safety, and (2) that precautionary regulation – acting as soon as potential hazards are identified – is preferable to retroactive regulation.

Chemical risk assessment is inherently uncertain – individual variations in exposure pathways, durations, physiological responses, and myriad other factors prevent researchers from establishing a precise estimation of chemical risks. Uncertainty should thus cut in favor of protective regulation, rather than against it. That is, regulatory agencies have a responsibility to act in a precautionary manner, setting risk-management rules that are stringent enough to protect against many potential health and environmental effects, even if proactive regulation means restricting production or uses that are not guaranteed to cause significant harm. This “better safe than sorry” approach to regulation means that agencies focus on preventing harm rather than waiting for harm to be visited upon people or the environment and then reacting to it.

The precautionary approach to chemical regulation is inextricably linked to the principle that risk creators bear the responsibility of assessing and, if possible, eliminating the risks that they impose on society. Chemical manufacturers have the greatest ability to test their products before putting them into the stream of commerce. They should have the burden of proving that the human health and environmental risks under foreseeable exposure scenarios meet a particular safety standard using a basic analytical framework designed by EPA. To ensure that a
manufacturer’s review is not too narrow, the analysis and all underlying health and safety information should be shared with EPA, which can review the information and determine that (a) the chemical meets the safety standard and should be allowed on the market; (b) the chemical does not meet the safety standard; or (c) more information is necessary before making a determination.

The CSIA and SCA define EPA’s burdens in very different ways:

- Under the CSIA, the basic standard for agency action – unreasonable risk – would be the same as it is under TSCA today. The burden of proof would remain on EPA and courts would still subject EPA’s analysis to a high “substantial evidence” review. Moreover, the CSIA would require EPA to make findings to support an “unreasonable risk” determination that are largely identical to those required under TSCA as it stands, and the bill also appears to add to the demands on the agency to provide elaborate scientific research.

- Under the SCA, the standard for EPA action would be altered to ensure that there is a “reasonable certainty that no harm will result to human health or the environment from the aggregate exposure to the chemical.” This is a standard similar to the one used when EPA reviews pesticide tolerances and the Food and Drug Administration approves food additives under the relevant laws. A chemical’s sponsor would bear the burden of submitting to EPA sufficient information for EPA to determine whether the chemical meets the safety standard, and EPA’s analysis would be based on the best available science according to recommendations of the National Academy of Sciences. The SCA states that EPA safety determinations would not be subject to judicial review. The combined effect of these proposed changes would be a great improvement over the status quo, transforming TSCA into a statute that promotes safety, rather than one that allows marketing of most chemicals without any review of risk.
A Novel Standard Designed to Promote Innovation

A truly progressive standard for toxic chemical regulation would do away with analytical frameworks keyed to static dividing lines between what is “safe” or “unsafe,” “unreasonably risky” or not. Instead, chemicals would be reviewed according to a standard that aims for constant improvement upon the status quo. Building on the principles of “green chemistry,” which seek to ensure all new chemicals are less toxic to organisms and ecosystems, are not persistent or bioaccumulative, and are inherently safer with respect to handling and use, a competition-based standard would query whether any particular use of a chemical is at least as good – from a public health and environmental standpoint – as its competitors.

TSCA inadvertently reinforces adverse selection for under-tested chemicals. Without regulatory certifications or rewards for extensive testing, there is no market recognition or other trustworthy validation of a manufacturer’s conscientious research investment. Cost-cutting manufacturers can out-compete rival manufacturers who invest heavily in testing to ensure the safe and efficacious use of their chemicals. In fact, “good” manufacturers, who invest in researching the effectiveness and safety of their products, may not only lose the money spent on testing, but they could inadvertently trigger interest from litigators and regulators since there will be some toxicity information available flagging their products. In such a regime, testing can become a negative attribute and the chemicals for which little is known have competitive advantages over chemicals subjected to extensive research or “green” innovations.

A better approach would force manufacturers to show that their chemicals are at least as good as some of the safest or best on the market. This basic showing should be easier for EPA to administer than the complex, multi-layered showing of unreasonable risk that entails establishing a particular product’s aggregate costs exceed its benefits. Equally important, by tethering the regulatory ideal of “safe” chemicals to what is available on the market, and readjusting that standard as manufacturers innovate, a “do your best” chemical standard would provide a much-needed reward for those producers who do make safer, greener, chemicals. For example, if a highly toxic chemical used for asphalt sealant can be replaced, with no added cost or loss of function, with a competitor chemical that is one-hundred times less hazardous, then EPA should not be required to do a full safety assessment before restricting the highly toxic chemical. The safer, more effective chemical should be rewarded; the highly toxic chemical restricted simply through a showing of their relative merits. This simple, common sense principle of substitution provides incentives for greater chemical innovation.
A Streamlined Process for Reviewing Chemicals

Under a competition-based “green chemistry” standard or any other system for reviewing chemicals, legislation must ensure that EPA has predefined deadlines. The lack of deadlines has been a problem in TSCA’s current iteration. TSCA has deadlines for EPA review of new chemicals (generally, 90 days), but no deadlines for review of existing chemicals. Hundreds of new chemicals get reviewed every year, but only a handful of existing chemicals are reviewed. In fact, EPA test rules under TSCA can take from two to ten years from development to receipt of the data. Statutory deadlines help define staffing levels and priorities. An absence of deadlines creates an incentive vacuum, leading to long delays and regulatory inaction.

Congress has successfully added deadlines to EPA regulatory programs in the past, notably to the 1996 Food Quality Protection Act (FQPA) amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In the FQPA, Congress set specific dates by which EPA was to review a certain number of pesticide tolerances (33% of all existing tolerances by Aug. 3, 1999; 66% by Aug. 3, 2002; and 100% by Aug. 3, 2006). Though EPA was unable to meet the final deadline, it was able to complete all required tolerance reassessments by late 2007. EPA’s decisions in those reassessments were, of course, subject to criticism from stakeholders, but the completion of nearly 10,000 reassessments in the course of 11 years is remarkable.

The TSCA reform proposals before Congress again diverge on the issue of deadlines. The CSIA does not include statutory deadlines for reviewing all chemicals. The SCA, on the other hand, mandates specific timeframes for review based on the priority level that EPA has assigned to a particular chemical. The lesson learned from the FQPA (as well as amendments to the Clean Air Act and Clean Water Act) is that deadlines are the best way to ensure an agency acts in a timely manner.
States as Laboratories for Democracy

With tens of thousands of chemicals already on the market and hundreds more being introduced each year, one of the most important features of TSCA is that the statute encourages state agencies and legislatures to develop their own rules to protect people and the environment from toxic chemical hazards. Congress recognized that toxic chemical regulation must be a shared responsibility among various levels of government and that alternative models for regulation based at the state or local level might complement EPA’s work. TSCA also leaves the courts to their own devices, allowing the civil justice system to weigh the competing interests that come forward in toxic tort suits and other cases that may affect the use and distribution of chemicals. The fact that TSCA has limited preemptive effect over state or local regulation is one of the few success stories of the existing law.

California has two programs that underscore the benefit of state-based toxic chemical regulation: Proposition 65 and the soon-to-be-implemented Green Chemistry Program. Under Proposition 65, the Governor of California publishes a list of chemicals known to the State to cause cancer or reproductive toxicity. Once a chemical is listed, discharge of the chemical into a source of drinking water is prohibited and businesses must warn people about exposures to the chemical, including warnings about the presence of chemicals in consumer products. The law has been immensely successful, protecting children from arsenic in playground equipment and lead in “moon bounce” equipment, reducing hair stylists’ exposure to formaldehyde, and ensuring greater public knowledge of diesel fume emissions from port facilities. The new Green Chemistry Program will identify a list of “chemicals of concern” (due to their toxicity and presence in consumer products), a list of “priority products” (containing “chemicals of concern” and posing significant potential adverse effects), and establish a framework for performing “alternatives analysis” in which manufacturers will search for ways to formulate those products with less toxic ingredients. The program holds the potential to drastically reshape the way consumer products are “conceived, formulated, and distributed.”

Other states, too, have established toxic chemical regulatory programs of the sort that should continue under an amendment to TSCA.

- Maine, Minnesota, and Washington all have programs for identifying “Chemicals of High Concern” and prioritizing those chemicals for study and regulation in the respective states.
- In Massachusetts, the Toxic Use Reduction Act requires certain businesses to track and report the amount of toxic chemicals they use, as well as engage in biennial toxics use reduction planning. These simple steps have prompted drastic reductions in toxic chemical use in the Commonwealth.
- Numerous states have passed laws restricting the use of individual chemicals or particular uses of chemicals (e.g., BPA, MTBE). These actions can create market incentives for chemical manufacturers to develop “greener” substitutes or non-toxic alternatives.

State tort law systems also play an important role in protecting the public and environment from toxic chemicals. One need look no further than the notorious history of asbestos regulation. When the U.S. Court of Appeals for the Fifth Circuit invalidated EPA’s asbestos ban, the tort
system acted as a backstop. Asbestos use has declined sharply,\textsuperscript{24} notwithstanding EPA’s inability to enforce its proposed ban, in large part due to the threat of tort liability. The gasoline additive MTBE provides a more modern example. The chemical was added to gasoline to improve engine performance and reduce air pollution, but it was found to be leaking out of storage tanks and contaminating public water systems. EPA took initial steps toward regulating MTBE through TSCA, but did not finalize the rule because petroleum refiners decided to take MTBE out of gasoline, largely out of concern for liability.

As Congress considers reforming TSCA, it is essential that the roles of state and local governments, as well as the courts, are preserved, if not strengthened. The CSIA and SCA take strikingly different approaches to the issue.

- The CSIA would establish EPA safety determinations as regulatory “ceilings,” that is, standards that state agencies, legislatures, and even courts may not bolster with additional protections for the public or the environment.\textsuperscript{25} The CSIA would even prevent state bans and restrictions on chemicals that EPA has scheduled for future review.\textsuperscript{26} Under the CSIA, states have the opportunity to apply for waivers from preemption restrictions, as they do under TSCA’s existing preemption clause, but the waiver process is subject to judicial review in federal courts, creating unpredictability for state regulators and legislators.\textsuperscript{27}

- The CSIA would also put unprecedented restrictions on state courts, making EPA safety determinations automatically admissible in any private litigation and declaring them “determinative of whether the [chemical at issue] meets the safety standard under the conditions of use addressed in the safety determination.”\textsuperscript{28} It is unclear how the CSIA safety standard (“no unreasonable risk of harm”) correlates with judges’ and juries’ various standards for allocating liability in civil cases, but Congress does not typically venture into this territory.

- The SCA would create a simplified approach to preemption, allowing state and local governments – and courts – to establish regulatory standards and standards of civil liability as they see fit, unless compliance with both the federal and the state or local standard is impossible.\textsuperscript{29}
Conclusion

Chemicals are integral to virtually every facet of our society, yet in performing these functions chemicals are sometimes highly toxic. At the very least, our regulatory system should demand from manufacturers the best in terms of the combined safety and efficacy of chemicals. Such a shift in focus—demanding the best chemicals and culling out the unsafe and worthless—would indeed be a giant step forward in public health protection. More pragmatically, this approach to regulation—insisting on the “best” chemicals on the market for functional uses— is also much more cost-effective in drawing on the agency’s scarce resources than the elaborate analytical artifice of TSCA or the even more ornate and unrealistic CSIA, which involves dozens of analytical requirements and is vastly more information-intensive than a “best” chemical finding. In a regulatory system and market where the best chemicals cannot be distinguished from the worst, and the agency’s hands in protecting the public are tied with onerous analytical requirements, the path forward to better chemical safety seems clear.
Endnotes


2 See, e.g., Poland et al., Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study, 3 NATURE NANOTECH. 423 (2008). See also, DEP’T OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL INST. OF OCC. SAFETY AND HEALTH, Current Intelligence Bulletin 65: Occupational exposure to Carbon Nanotubes and Nanofibers (Apr. 2013).  


7 Chemical Safety Improvement Act, S.1009, 113th Cong. § 4(4) (2013) (proposing new TSCA §§ 4(f), (g)). The “improvement” bill even appears to remove the modest TSCA requirement that manufacturers of new chemicals must provide EPA with all relevant existing research on a chemical as a condition to their application for market clearance. See id. § 5(3) (2013) (striking from TSCA § 5 the subsection that pertains to the submission of test data).  

8 Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).  


11 Chemical Safety Improvement Act, S.1009, 113th Cong. § 16 (2013). Safety determinations are also judicially reviewable and hence can be subjected to litigation. Id. §6(1) (proposed new TSCA § 6(c)(11)).  

12 See, e.g., Chemical Safety Improvement Act, S.1009, 113th Cong. §6(1) (2013) (proposing new TSCA § 6(b)(4)(A), which does not reference the need for default judgments in the course of the evaluation).  


14 Id. (proposed new TSCA §§ 6(d)(1)(B), 6(d)(2)(D)(ii)).  

15 Id. (proposed new TSCA § 6(c)).  

Endnotes (cont’d)

23 Rachel I. Massey, Program assessment at the 20 year mark: experiences of Massachusetts companies and communities with the Toxics Use Reduction Act (TURA) program, 19 J. CLEANER PRODUCTION 505 (Mar. 2011).
26 Id. (proposed new TSCA § 18(b)(1)).
27 Id. (proposed new TSCA § 18(d)(5)).
28 Id. (proposed new TSCA § 18(e)(2)).
About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information.

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