BETTER LIVING THROUGH CHEMICALS (REGULATION)? THE CHEMICAL SAFETY IMPROVEMENT ACT OF 2013 THROUGH AN ENVIRONMENTAL PUBLIC HEALTH LAW LENS

*By Tracy Bach**

INTRODUCTION

"Better Things for Better Living . . . Through Chemistry."
—DuPont advertising slogan, 1935–82[1]

The Chemical Safety Improvement Act of 2013 ("CSIA")[2] was introduced at the end of May, 2013 as a bipartisan effort to remedy the well-documented deficiencies in regulating chemicals used in U.S. commerce. The current law in force, the Toxic Substances Control Act of 1976 ("TSCA"),[3] barely scratches the surface of researching and setting limits on the thousands of synthetic chemicals available to manufacturers: among the approximately 85,000 commercial chemicals registered for use in the United States, only 200 have been tested by the Environmental Protection Agency ("EPA"), and fewer than a dozen have been restricted.[4] Notably, TSCA is the sole statute dating from the recognized heyday of federal environmental law making[5] that has escaped significant updating in the last four decades.[6]

Starting in 2005, Senator Frank Lautenberg, a Democrat from New Jersey, regularly offered bills to address TSCA's anemic regulatory reach.[7] In 2013, after gaining little traction with his solo effort, he teamed up with Senator David Vitter, a Republican from Louisiana, girded by an almost

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* Professor of Law, Vermont Law School. I am indebted to Caitlin Stanton, VLS'14, whose background in public health and passion for environmental health law provided both needed research assistance and welcomed companionship. I also thank Matthew Bach-Lombardo, my last writing student, who kept me company on the final lap of this article's journey to print, and Brian Lombardo, who nourished us both en route.

1. *See Innovation Starts Here*, DUPONT, http://www2.dupont.com/Phoenix_Heritage/en_US/1939_b_detail.html (last visited Jan. 28, 2014) (discussing the history of DuPont's advertising department).

2. Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013).

3. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2697 (1976).

4. John M. Broder, *New Alliance Emerges to Tighten Chemical Rules*, N.Y. TIMES (May 24, 2013), http://www.nytimes.com/2013/05/25/us/politics/lautenbergs-chemical-safety-bill-gains-momentum.html?smid=pl-share&_r=0.

5. David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 334 (2010) (noting this "most active phase" began with The National Environmental Policy Act ("NEPA") in 1969 and culminated with the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") in 2006, and includes the Clean Air Act in 1970, Clean Water Act in 1972, and both the Resource Conservation and Recovery Act ("RCRA") and TSCA in 1976).

6. Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1818, 1818 (2008) (characterizing chemical regulation as a "lapdog" because it is among the weakest and least amended of federal environmental statutes).

7. *See, e.g.*, Kid Safe Chemicals Act, S. 1391, 109th Cong. (2007); Kid-Safe Chemicals Act of 2008, S. 3040, 110th Cong. (2008); Safe Chemicals Act of 2010, S. 3209, 111th Cong. (2010); Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011); Safe Chemicals Act of 2013, S. 696, 113th Cong. (2013).

equal number of Republican and Democratic co-sponsors.[8] Fundamentally, their bipartisan bill seeks to remedy TSCA's weaknesses and bolster public confidence in federal safety regulation[9] while recognizing the important place of synthetic chemicals in our everyday lives.[10]

The chemicals industry's reaction to the bill was swift and uniform, hailing it as a breakthrough. Manufacturers and processors understood well that paying for increased testing and regulatory requirements at the federal level was cost-effective.[11] During the last two decades, states have acted to fill TSCA's regulatory vacuum, with California leading the way.[12] National exposés about the flame retardant chemicals used on crib mattresses[13] and bisphenol A ("BPA") in baby bottles[14] have galvanized a focused cohort of consumers and voters. Between 2003 and 2011 alone, eighteen states passed seventy-one chemical safety bills.[15] This bottom-up regulatory approach within the United States has occurred at the same time that our major trading partners, Canada and the European Union ("EU"), have more actively regulated commercial chemicals[16] and thus indirectly put a top-down crimp on U.S. manufacturers seeking to sell their products in those

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8. *Bill Summary & Status, 113th Congress (2013–2014) S.1009 Cosponsors,* LIBRARY OF CONG., http://thomas.loc.gov/cgi-bin/bdquery/z?d113:SN01009:@@@P (last visited Jan. 22, 2014) (noting that there are currently 12 Democrats and 13 Republicans, including Lamar Alexander [R-TN]; Mark Begich [D-AK]; John Boozman [R-AR]; Richard Burr [R-NC]; Saxby Chambliss [R-GA]; Susan Collins [R-ME]; Michael Crapo [R-ID]; Richard Durbin [D-IL]; Kirsten Gillibrand [D-NY]; Kay Hagan [D-NC]; Tom Harkin [D-IA]; John Hoeven [R-ND]; James Inhofe [R-OK]; Johnny Isakson [R-GA]; Mary Landrieu [D-LA]; Joe Manchin [D-WV]; Robert Menéndez [D-NJ]; Lisa Murkowski [R-AK]; Patty Murray [D-WA]; Mark Pryor [D-AR]; Marco Rubio [R-FL]; Charles Schumer [D-NY]; Pat Toomey [R-NY]; Tom Udall [D-NM]; David Vitter [R-LA]).

9. S. 1009 § 2(a)(3),(5).

10. *Id.* § 2b.

11. Rebecca Coons, *Lautenberg, Vitter Announce Bipartisan Bill for TSCA Modernization,* IHS CHEMICAL WEEK (May 23, 2013), http://www.chemweek.com/lab/Lautenberg-Vitter-announce-bipartisan-bill-for-TSCA-modernization_52239.html. (pointing out, Ernie Rosenberg, President and CEO of the American Cleaning Institute, observed, it "was a better alternative to 50 state-level regulations").

12. *Election Results Signal More State Level Chemical Regulation*, ENVT'L LEADER (Nov. 20, 2012), http://www.environmentalleader.com/2012/11/20/election-results-signal-more-state-level-chemical-regulation/.

13. *Tribune Watchdog, Playing With Fire,* CHI. TRIB. (2012), http://media.apps.chicagotribune.com/flames.index.html.

14. David Case, *The Real Story Behind Bisphenol A*, FAST COMPANY (Feb. 2009), http://www.fastcompany.com/1139298/real-story-behind-bisphenol.

15. *See* Michael E. Belliveau, *The Drive For A Safer Chemicals Policy In The United States,* 21 NEW SOLUTIONS 359–86 (2011), *available at* http://www.chemicalspolicy.org/Publications.Reports.NewSolutions.php (last visited Jan. 26, 2014) (including Delaware, Hawaii, Rhode Island, Wisconsin, Michigan, Vermont, Maryland, Missouri, Connecticut, New York, Illinois, Maine, Oregon, Minnesota, Washington, California, Nevada and Iowa).

16. *See* Richard A. Denison, *Ten Essential Elements in TSCA Reform,* 39 ENVTL. L. REP. 10020 (2009). (contrasting TSCA chemicals review with that of the EU and Canada).

markets.[17] Together they combine to make federal regulation more attractive to industry.

But while industry has responded to the CSIA in unison, environmental and public health groups have reacted in discordant tones. Richard Denison of the Environmental Defense Fund ("EDF") sums up the position of those who support the CSIA: "This bill embodies a hard-fought compromise, [and] . . . opens a bipartisan path forward to fix our badly outmoded system to ensure the safety of chemicals in everyday use."[18] Two former officials in EPA's Office of Chemical Safety and Pollution Prevention ("OCSPP"), Steve Owens and Charlie Auer, support this view.[19] In contrast, environmental health groups like the Environmental Working Group ("EWG") see the compromise bill as giving up too much ground to the chemical industry while gaining only small improvements to the status quo. Ken Cook, EWG's president, compares the CSIA to previous Lautenberg bills and concludes, "I don't know if this is a retreat or a rout, but it's somewhere in that range."[20] In other words, the Chemical Safety Improvement Act cannot be as good as the Chemical Safety Act when bringing the Toxic Substances Control Act into the twenty-first century. "What's in a name? That which we call a rose by any other name would smell as sweet."[21] Or does it?

This Article asks whether the CSIA represents the best way forward for U.S. commercial chemicals regulation and environmental public health law practice overall. Environmental public health law sits at the confluence of environmental and public health laws. Public health law traditionally collected data, conducted research, investigated sources of human illness, and educated the public by disseminating best practices. The signature U.S. environmental laws of the 1970s and 80s defined pollution limits in terms of baseline public health impacts and sought to enforce them via EPA administrative actions and private enforcement suits in the courts. Now, almost forty years after the first wave of these laws, we see a growing body of research on environmental public health out of the National Institute for

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17. *See* Sachs, *supra* note 6, at 1819 (explaining the transnational effects of EU chemical regulation).

18. Sharyn Stein & Richard Denison, *A Bipartisan Path Forward to Reform U.S. Chemical Safety Law,* ENVTL. DEFENSE FUND (May 22, 2013), http://www.edf.org/news/bipartisan-path-forawrd-reform-us-chemical-safety-law.

19. Press Release, U.S. Senate Comm. on Env't and Pub. Works, Top EPA Toxics Officials Under Obama & Bush Admins Hail Lautenberg-Vitter Bill to Reform Nation's Chemical Laws (May 23, 2013), http://www.epw.senate.gov/public/index.cfm?FuseAction=Minority.PressRelease&ContentRecord_id=d2553c0f-beb5-e270-2971-ff2b84a06e88.

20. Broder, *supra* note 4.

21. WILLIAM SHAKESPEARE, ROMEO AND JULIET act 2, sc. 2 (Burton Raffel, ed. 2004).

Environmental Health Sciences ("NIEHS") and the National Center for Environmental Health ("NCEH"), and awareness of it via non-governmental organizations like EWG and EDF.[22]

As the environmental health research agenda has matured,[23] the gaps between federal environmental laws, public health laws, and the environmental pollution increasingly associated with adverse human health outcomes have become more apparent. These spaces in the environmental public health regulatory joints regularly center on the 1) scope of agency authority, 2) precision of risk assessment methodologies, safety standards, and risk management measures, 3) existence of legislatively imposed deadlines for agency action, 4) public transparency via reporting and disclosure requirements, and 5) the states' role in national regulation. Hovering in the background is the identification of, and approach to, scientific uncertainty and the role of social and economic analysis when facing it.

The CSIA gives us the opportunity to review these critical environmental public health regulatory pivot points and analyze how new norms of environmental public health can be translated into law on point. To do so, this Article first examines the weak points in TSCA that have led to the current anemic approach. Second, it draws on commercial chemicals law made during the last forty years at the state and international levels, which has nudged[24] Congress to structure the bipartisan bill as drafted. Third, it scrutinizes the CSIA as introduced in May, 2013 and debated throughout the remainder of the year, to assess how it addresses TSCA's weaknesses in a manner that promotes environmental public health law norms. In this way, we can determine whether better chemicals regulation

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22. Other NGOs play an important role in the dissemination of environmental health research, including the Natural Resources Defense Council ("NRDC"), Center for Environmental Health, Safer Chemicals Healthy Families, Pew Charitable Trust, and EarthJustice. Their work has been essential to the current, popular understanding of phthalates and bisphenol A ("BPA") in children's products, atrazine from pesticide runoff in groundwater, and a family of flame retardant chemicals applied to crib mattresses, and their associations with specific illnesses ranging from endocrine disruption to cancer.

23. *See* Tracy Bach, *Protecting Human Health and Stewarding the Environment: An Essay Exploring Values in U.S. Environmental Protection Law*, 3 MICH. J. ENVTL & ADMIN. L 19–30 (2014) (providing a brief explanation of this progression). *See also*, *e.g.*, Linda Birnbaum and Paul Jung, *From Endocrine Disruptors To Nanomaterials: Advancing Our Understanding Of Environmental Health To Protect Public Health*, 30 HEALTH AFFAIRS 814 (May 2011) (providing a good array of this increasingly sophisticated body of research); Philip Landrigan and Lynn Goldman, *Children's Vulnerability To Toxic Chemicals: A Challenge And Opportunity To Strengthen Health And Environmental Policy*, 30 HEALTH AFFAIRS 842 (May 2011); Rachel Morello-Frosch et al., *Understanding The Cumulative Impacts Of Inequalities In Environmental Health: Implications For Policy*, 30 HEALTH AFFAIRS 879 (May 2011).

24. *See generally* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH (2008) (analyzing choice behavior and arguing that "choice architecture" can "nudge people toward the best decision without restricting their freedom of choice").

leads to better living and how environmental laws are evolving to improve public health.

This Article concludes that the CSIA, as written, represents measured progress toward recalibrating the balance between protecting health and the environment and promoting the U.S. chemicals industry. It suggests that this major overhaul of U.S. commercial chemicals policy be viewed through a public health law lens, as TSCA's original language tells us was Congress's intent. Through it, we can see out over the long latency periods between chemical exposure and health impact, and over the evolution and separation of risk assessment and risk management standards and methods. Through this lens, we can also see the regulatory paradigm shift from acute, large, and single chemical exposure to managing risk in an era of chronic, small, and multiple exposures from gestation till death. Ultimately, it provides us a close view of how to handle uncertainty when legislating for preventive medicine. By creating a regulatory framework that prioritizes chemical regulation based on scientific understanding of these substances' impacts on human health, then managing the risks posed by the high priority chemicals through policy tools that reflect our tolerance for taking precaution, the CSIA offers better living through chemistry and chemistry regulation. It's not perfect. But it's better. And it sets us on the path of making wiser environmental public health law in the twenty-first century.

I. TSCA'S ENACTMENT, POOR TRACK RECORD, AND REGULAR ATTEMPTS TO AMEND

History of TSCA's Promise

In 1971, President Nixon's Council on Environmental Quality ("CEQ") proposed a federal law to control toxic substances.[25] Since World War II, growth in high-volume chemicals manufacturing exploded: from 1930 to 2001, annual production increased from one million to four hundred million tons.[26] Many of these synthetic chemicals had been developed for war-time purposes and little was known about their health impacts; nonetheless, use of them in the post-war manufacturing boom proceeded without further research or regulation.[27] Senator Tunney pointed

25. LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL31905, TOXIC SUBSTANCES CONTROL ACT (TSCA): A SUMMARY OF THE ACT AND ITS MAJOR REQUIREMENTS 2 (2013), *available at* http://www.fas.org/sgp/crs/misc/RL31905.pdf.

26. David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxic Regulation*, 32 WASH. U. J. L. & POL'Y 377, 383 (2010).

27. SANDRA STEINGRABER, LIVING DOWNSTREAM 88–89 (1998) (noting that Rachel Carson originally made these observations in her seminal work, *Silent Spring*).

to the National Cancer Institute's estimate that sixty to ninety percent of U.S. cancer cases result from environmental contaminants, and to a 60-Minute television special and Newsweek cover story on the "impact of environmental cancer on society."[28] The CEQ's report, Toxic Substances, declared the need for a comprehensive statute that would identify and control chemicals that were 1) manufactured, processed, used, and distributed commercially; 2) potentially dangerous; and 3) inadequately regulated under other federal environmental statutes.[29]

Four years later, Deputy EPA Administrator John Quarles testified before a House committee that preventing the proliferation of dangerous chemicals throughout the environment "is one of our most urgently needed environmental laws."[30] He highlighted vinyl chloride as a chemical compound that should have been tested for its effects on human health and the environment before entering commercial production: by 1975, it was prevalent in the plastics industry, yet had been found to cause a rare form of liver cancer that had already killed fifteen workers.[31] Quarles also cited the fluorocarbons used in refrigeration and aerosols, which had recently been linked to ozone depletion in the atmosphere,[32] and the polychlorinated biphenyls ("PCBs") used as electrical coolants and considered a likely carcinogen, as other examples of toxic chemicals present in the environment that made TSCA's passage a priority.[33]

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28. Markell, *supra* note 5, at 342 (noting that the fear of cancer in the early 1970s—a virtually untreatable disease at the time—was high, and arguably led to President Nixon's declaration of a "war on cancer" with the enactment of the National Cancer Act in 1971).

29. *Id.* at 338–39 (citing U.S. COUNCIL ON ENVTL. QUALITY, TOXIC SUBSTANCES 759–60 (1971) (noting that this last point on coordination with other federal statutes is important, for all policymakers intended this new law to complement how existing law regulated commercials, namely those used in pharmaceuticals and food governed by Federal Food, Drug, and Cosmetics Act ("FDCA"), and those used in pesticides governed by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). These two federal statutes also took a primary prevention route, as compared to the secondary approach of most extant environmental statutes, like the Clean Air Act (42 U.S.C. § 7401) and Clean Water Act (33 U.S.C. §§ 1251–1387)).

30. Press Release, U.S. Envtl. Prot. Agency, Quarles Testifies on the Need for Toxic Substances Act (July 10, 1975), *available at* http://www2.epa.gov/aboutepa/quarles-testifies-need-toxic-substances-act [hereinafter *Quarles*].

31. *Id.*

32. *See generally* Mario J. Molina & F.S. Rowland, *Stratospheric Sink for Cholofluoromethanes: Chlorine Atom-Catalysed Destruction of the Ozone,* 249 NATURE 810–12 (1974), *available at* http://ozone.unep.org/pdf/stratopheric.pdf (establishing in the link between CFCs and ozone depletion); Press Release, Royal Swedish Acad. of Scis. Nobel Prize in Chemistry (Oct. 11, 1995), *available at* http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1995/press.html.

33. *Quarles*, *supra* note 30. Notably, PCBs played an important role keeping congressional debate of TSCA on track. While the House and Senate had passed separate bills by 1973, debate over chemical screening and its potential to impede commercial production stalled passage. The well-documented PCB contamination of the Hudson River is credited with helping to push Congress to enactment in 1976. SCHIEROW, *supra* note 25.

Importantly, TSCA's proponents wanted Congress to understand that primary prevention was needed. While two federal laws regulated toxic substances used in pesticides, drugs, and food additives before those products reached consumers,[34] most environmental laws, like the Clean Air Act, Water Pollution Control Act, and Safe Drinking Water Act, merely set safety standards for emissions and effluents already in the environment.[35] As Quarles underscored, this post hoc approach "deals with the problem at a point where the contaminants are very difficult to control."[36] In addition, these media-focused laws fail to protect humans from their aggregate exposures to substances in the air and water that surround them:

> The multiplicity of ways by which man can be exposed to these substances makes it difficult . . . to consider the total exposure of an individual to any given substance, a consideration necessary for the establishment of adequate environmental standards.[37]

The EPA envisioned TSCA getting ahead of the pollution curve by requiring premarketing notification for all chemicals to be used in commerce and then testing some of them to determine the risks posed to human health and the environment.[38] This was no small task, for by the early 1970s, about 600 new chemical compounds were being introduced into U.S. commerce each year.[39]

This preventive approach would not only benefit human health and the environment, but also industry's profits, Quarles asserted in his House testimony. "By examining the potential dangers associated with the production and use of a product before investing considerable capital, the chemical industry can avoid the serious disruption and losses attendant to remedial action after the fact."[40] A preliminary EPA estimate showed that compliance costs would be $80 to $140 million annually, a "relatively modest" sum when compared to the commercial chemical industry's 1974

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34. Quarles, *supra* note 30. Consequently, TSCA's jurisdiction does not include chemicals already regulated under the FDCA and FIFRA.

35. Robert Glicksman & Christopher H. Schroeder, *EPA and the Courts: Twenty Years of Law and Politics*, 54 LAW & CONTEMP. PROBS. 249, 252 (1991). In these environmental laws, Congress focused on "end-of- pipe" controls rather than trying to regulate the inputs into industrial processes, in part because they presented the most obvious and expedient approaches to the pollution problems of the time. *Id.*

36. Quarles, *supra* note 30.

37. Markell, *supra* note 5, at 346 (quoting U.S. COUNCIL ON ENVTL. QUALITY, TOXIC SUBSTANCES 760 (1971)).

38. Quarles, *supra* note 30.

39. *Id.*

40. *Id.*

sales of $72 billion, research and development costs of about $2 billion, and profits after taxes of more than $5.5 billion.[41]

In his first public comment about TSCA after President Ford signed the bill into law on October 11, 1976, EPA Administrator Russell Train called the statute "preventive medicine legislation" because it gives public health "far more of the weight that it deserves in the decisions by which chemicals are commercially made and marketed, by which they enter and spread throughout the human environment."[42] In a speech to the American Public Health Association, he continued the analogy to good public health practice:

> Preventive medicine, of the kind the new law entails, brings together a broad and diverse mixture of actors and actions in a concerted and coordinated effort to reduce the health risks that individuals and society are exposed to. The legislation represents a major step toward an increasingly effective preventive approach toward the 'environmental disease' that has been called the 'disease of the century.'[43]

Train envisioned TSCA working for both the consumer and the producer by creating an "orderly, open and inclusive process" that fostered collaboration, not litigation, and considered "all important views and values" from "all affected and interested parties," along with "relevant evidence and expertise."[44]

In a hauntingly contemporaneous refrain, Administrator Train worried out loud to his public health colleagues on this last point, given how "abysmally little" regulators knew about the commercial chemicals currently in use. "We know little about their health effects, especially over the long term at low levels of exposure. We know little about how many humans are exposed, and how and to what degree. We do not even know precisely how many—much less precisely which—new chemical compounds are made and marketed every year.[45] That is why TSCA's

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41. *Id.*

42. Press Release, U.S. Envtl. Prot. Agency, Train Sees New Toxic Substances Law as "Preventative Medicine" (Oct. 21, 1976), *available at* http://www2.epa.gov/aboutepa/train-sees-new-toxic-substances-law-preventive-medicine.

43. *Id.* Given the contemporaneous concern about PCBs and HFCs, Administrator Train specifically pointed out EPA's authority to tackle both: "The first is one of the most frustrating and long-standing chemical problems we have faced—the problem of PCBs. The second is what I have called the first truly global environmental problem—the destruction of fluorocarbons of the ozone which screens the surface of the earth from harmful ultraviolet radiation." *Id.*

44. *Id.*

45. *Id.*

preventive approach, via premarketing notification to EPA, independent scientific analysis of the substances, and long term study of their impacts, was fundamental to remedying the situation.[46] The first step in solving the problem is gathering the data.

TSCA as Written

As enacted,[47] TSCA differed from other contemporaneous federal environmental statutes by regulating all phases of chemical manufacturing, not just controlling pollution via emissions and effluent limits[48] or after-the-fact cleanup.[49] To do this, Congress tasked the EPA with first identifying, then regulating all toxic substances used in U.S. commerce. To identify them, TSCA laid out EPA's authority to screen commercial chemicals by requiring manufacturers and processors to provide information on the ones they use. Based on this data, EPA would then apply a range of regulatory tools—from an outright ban to warning labels and record keeping requirements.

Given the magnitude of the task of gathering data on chemicals used in commerce, the identification process was congressionally divided into two, distinct tracks: one for chemicals used in commerce at the time of the 1976 enactment and another for new ones.[50] For existing chemicals, TSCA mandates that EPA require testing if it "finds"[51] that a substance falls into one of two categories—it "may present an unreasonable risk of injury to health or the environment"[52] or be "produced in substantial quantities"[53] that have the potential to enter the environment[54] or cause "significant or

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46. *Id.* He went on to connect this paucity of data with why a robust stakeholder process was so important: "It is precisely because we know so little about all these things, because we must balance risks against benefits as well as costs against benefits, and because we must draw upon as much outside expertise and advice as we can, that the [sic] kind of 'political' process I have described is essential in any successful effort to reduce chemical risks while preserving their benefits." *Id.*

47. Since 1976, several new titles have been added to TSCA, with the original law redesignated as Title I. Title II was added in 1986 to regulate asbestos; Title III, in 1988, to address radon; Title IV, in 1992, concerning lead; and Title V, in 2007, about environmental and energy issues in schools. *See generally* SCHIEROW, *supra* note 25 (providing a straight-forward description of TSCA's provisions).

48. *See generally* Glicksman & Schroeder, *supra* note 35, at 253 (discussing the metamorphosis of environmental statues to cover problems previously overlooked).

49. *See, e.g.,* CERCLA, 42 U.S.C. § 9601 *et seq.* (2006); RCRA, 42 U.S.C.A. § 6901 *et seq* (2006).

50. *See* TSCA 15 U.S.C. § 2604(a)(2) (2006) (clarifying that regulation of "new ones" applies to both new chemical compounds, as well as new uses of existing ones).

51. *Id.* § 2603(a).

52. *Id.* § 2603(a)(1)(A)(i).

53. *Id.* § 2603(a)(1)(B)(i).

54. *Id.* § 2603(a)(1)(B)(i)(I).

substantial" human exposure[55]—and lack sufficient data to "reasonably determine" these effects;[56] thus testing "is necessary to develop such data."[57] Because there was such a backlog of untested chemicals in 1976, Congress created the Interagency Testing Committee ("ITC") to help EPA set priorities and coordinate with other government agencies.[58] Taking into account such factors as the quantity manufactured[59] and found in the environment,[60] number of people exposed in[61] and outside of their workplaces,[62] and the existence of toxicological data[63] and potential for developing more,[64] the ITC recommends chemicals to the EPA for designation on a priority list, in rolling batches of fifty, paying specific attention to those substances suspected to play a role in cancer, gene mutations, or birth defects.[65]

TSCA's separate track for gathering data prospectively requires manufacturers to notify EPA at least ninety days before they intend to introduce a new chemical[66] or use an existing chemical in a significantly new way.[67] These notices should contain any testing data that the company has at the time.[68] EPA must then evaluate and act on these pre-manufacture notices ("PMNs") using the same standards as for existing chemicals, determining whether or not it has a "reasonable basis" for concluding that a substance may present an unreasonable risk. If it finds such risk, then the EPA must promulgate requirements to protect humans and the environment from it.[69] If it doesn't find a risk, then EPA may permit the chemical to be used commercially.[70] If unsure because of insufficient data and an unreasonable risk appears possible or the chemical is a high volume one, then EPA may issue a proposed order prohibiting use until more data is provided.[71]

Once having made these determinations for existing and new chemicals, and a finding that no other federal law can reduce a commercial

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55. *Id.* § 2603(a)(1)(B)(i)(II).
56. *Id.* § 2603(a)(1)(A)(ii).
57. *Id.* § 2603(a)(1)(A)(iii).
58. *Id.* § 2603(e)(2)(A).
59. *Id.* § 2603(e)(1)(A)(i).
60. *Id.* § 2603(e)(1)(A)(ii).
61. *Id.* § 2603(e)(1)(A)(iii).
62. *Id.* § 2603(e)(1)(A)(iv).
63. *Id.* § 2603(e)(1)(A)(vi).
64. *Id.* § 2603(e)(1)(A)(vii).
65. *Id.* § 2603(e)(1)(A).
66. *Id.* § 2604(a)(1)(B).
67. *Id.* § 2604(a)(2).
68. *Id.* § 2604(b).
69. *Id.*
70. *Id.* § 2604(g).
71. *Id.* § 2604(e).

chemical's risk, TSCA puts a broad range of specific control measures at EPA's disposal. These include bans or limits on the amount,[72] use,[73] and concentration[74] of specific chemicals; "clear and adequate" warnings;[75] record-keeping requirements;[76] disposal bans or limits;[77] and required post hoc public notification of a product's "unreasonable risk" due to its chemical composition and the offer to replace or repurchase it.[78] But Congress also limited the agency's discretion when exercising these options, for TSCA requires that EPA have "a reasonable basis to conclude that the manufacture . . . of a chemical substance . . . presents or will present an unreasonable risk of injury to health or the environment" and act only to "the extent necessary to protect adequately against such risk *using the least burdensome requirements*."[79]

TSCA requires EPA to publish a statement, when issuing a rule, about the chemical's effects on health and the environment, and the magnitude of exposure to both;[80] its benefits and the availability of substitutes to achieve those same benefits;[81] and the "reasonably ascertainable economic consequences of the rule, after considering the effect on the national economy, small business, technological innovation, the environment, and public health."[82] It also charges EPA with considering all other federal environmental laws when determining how to regulate a manufacturer of a risky chemical substance. The agency can only issue a section 6(a) regulation if it considers "all relevant aspects of the risk," compares the estimated costs of complying with TSCA versus other federal laws, and determines the "relative efficiency" of taking action under TSCA versus another law.[83] When these requirements are added to the public hearing requirements, a full picture emerges of the difficulty of regulating commercial chemicals against the backdrop of how "so abysmally little" EPA knows about these chemicals.

Two other provisions in TSCA are worth noting, in light of Congress's "preventive approach" toward this "environmental disease" and the importance of information gathering to succeeding at it.[84] First, TSCA

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72. *Id.* § 2604(a)(2)(A).
73. *Id.* § 2604(a)(2)(B).
74. *Id.* § 2605(b)(2)(A).
75. *Id.* § 2605(a)(3).
76. *Id.* § 2605(b)(2)(B).
77. *Id.* § 2605(a)(1)(B).
78. *Id.* § 2605(a)(7)(C)
79. *Id.* § 2605(a)(emphasis added).
80. *Id.* § 2605(c)(1)(A),(B).
81. *Id.* § 2605(c)(1)(C).
82. *Id.* § 2605(c)(1)(D).
83. CAROLYNE R. HATHAWAY ET AL., TSCA DESKBOOK 83 (Envtl. Law Inst. 2d ed. 2012).

requires EPA to create and maintain an inventory of all commercial chemicals used in the United States, beginning with those in use at the time of enactment and updated to include all new ones approved under Section 5.[85] To that end, EPA was granted authority to collect a wide array of information from industry, including chemical identity and molecular structure, quantities, environmental and health studies, number of human exposures, and disposal methods.[86] Industry, in turn, must maintain and share records of adverse effects.[87] But simultaneously, TSCA protects confidential business information ("CBI") that limits the federal government's use of it[88] and permits companies complying with the information requirements to designate data as entitled to confidential treatment and to submit it separately.[89]

Finally, in terms of how state and federal governments work with one another under TSCA, it bears mentioning that Section 18 contains unequivocal language of state law preemption. While the provision begins by stating that "nothing in this Act shall affect the authority of any State . . . to establish or continue in effect regulation of any chemical substance,"[90] it goes on to define more specifically that where state law is similar to federal rules or orders on testing and restrictions, it will be preempted unless it is identical, made under other federal law authority, or applies only to in-state use.[91] Section 18 then "saves" preempted state law by exempting that which does not engender conflicting compliance requirements for industry and does not "unduly burden interstate commerce."[92] Arguing this TSCA preemption clause would permit states to exceed federal regulation "floors," as in the case of many federal environmental statutes of the period.[93] But given the dearth of EPA regulation of specific chemicals under TSCA, the Agency has not applied the preemption provision nor have the courts interpreted it.

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85. 15 U.S.C. § 2609(b) (2006).
86. *Id.* § 2607(a)(2)(A).
87. *Id.* § 2607(a)(3)(A)(ii)(II).
88. *Id.* § 2613(a)–(c).
89. *Id.* § 2613(c).
90. *Id.* § 2617(a)(1).
91. *Id.* § 2617(a)(2)(B).
92. *Id.* § 2617(b)(2).
93. *See, e.g.*, Clean Air Act, 42 U.S.C. § 7416 (2006); Clean Water Act, 13 U.S.C. § 1370 (2006). For one state official's interpretation, s*ee* Jim Florio, *Federalism Issues Related to the Probable Emergence of the Toxic Substances Control Act*, 54 MD. L. REV. 1354, 1371–72 (1995) (noting that, while Congress has generally preempted states in all phases of TSCA except disposal, state are allowed to enact additional testing requirements if they don't unduly burden commerce and may ban chemical uses within state borders).

From High Hopes to Low Sights

TSCA showed its inherent flaws from the start. As the CEQ frankly observed two years after its passage, "bringing toxic substances under control is more easily said than done."[94] The tens of thousands of chemicals already in commerce, as well as the thousands of companies that produced and distributed them, combined to show the "astonishing dependence of modern life on chemicals" and the "staggering task that faces industry and government" to regulate them.[95] As Charles Auer, former OCSPP director, put it, despite "high hopes . . . that TSCA would establish an effective program to identify and regulate potentially dangerous chemicals, the nearly four decades since have shown that the current law is not up to the task."[96] The law provided broad authority but vague priorities to guide the EPA's work.[97]

This powerful combination of large task and unclear strategy to attack it manifested itself when creating the inventory, an important first step in achieving TSCA's goal of identifying substances. As a group of former EPA administrators recently wrote, one of TSCA's signature accomplishments in 1976 was the very creation of this federal list, given that up until then, no information had been publicly gathered on the kinds, numbers, and quantities of chemicals used commercially in the United States.[98] But TSCA initially populated the inventory with some 62,000 "grandfathered" chemicals.[99] By directly placing on the Section 8 inventory all chemicals manufactured in or imported to the United States before December 1976, EPA presumed them not to present an unreasonable risk—simply because they were in use.

When adding new chemicals to the inventory via Section 5's PMN, the glass is again both full and empty in terms of prospective identification and regulation, the very foundation for TSCA's "preventive medicine."

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94. Markell, *supra* note 5, at 350.

95. *Id.*

96. Charles M. Auer, *Lautenberg-Vitter Is a Breakthrough for Flawed Toxics Law, Commentary,* ROLL CALL (Sept. 17, 2013), http://www.rollcall.com/news/lautenberg_vitter_is_a_breakthrough_for_flawed_toxics_law_commentary-227658-1.html.

97. *Id.*

98. James V. Aidala, Jr. et al., *Practical Advice for TSCA Reform: An Insider Perspective*, 2010 A.B.A. SEC. ENV'T, ENERGY, & RES. 7, *available at* http://www.americanbar.org/content/dam/aba/administrative/nr/projects/tsca_reform/whitepapers/practical_advice_for_tsca_reform.authcheckdam.pdf.

99. Steve Owens, *Congress Must Do More to Ensure Chemical Safety*, REAL CLEAR POLICY (Aug. 24, 2013), http://www.realclearpolicy.com/articles/2013/08/24/congress_must_do_more_to_ensure_chemical_safety.html (arguing for state preemption under a more robust federal act).

While all companies must notify the EPA of their intent to manufacture a new chemical by submitting a PMN that includes basic data like chemical identity, volumes, and uses, in fact the data collected was "nominal."[100] Seventy percent of all PMNs do not include chemical testing data and eighty-five percent lack health study data.[101] EPA instead uses computer modeling to determine whether the new chemical "may present an unreasonable risk;" if the Agency does not take further action on the new chemical within ninety days, it enters the inventory.[102] EPA estimates that approximately ninety percent of PMNs are not "restricted or regulated in any way" as a result of the 90-day review.[103] It is in this way that the Section 8 inventory has grown to include some 86,000 chemical substances today.

Furthermore, testing of old chemicals grandfathered into the inventory requires EPA to first make a finding that testing is needed per Section 4's multi-part criteria and then promulgate a "test" rule to compel it. Because little was known about these chemicals when they entered the inventory, EPA faces an uphill battle gathering the data to make the findings for rulemaking. The General Accounting Office ("GAO") testified to Congress in 2005 that a test rule could take between two to ten years to finalize and cost EPA as much as $234,000.[104] Consequently, EPA has issued rules or entered into consent agreements with manufacturers to require testing for only 200 or so chemicals and reviewed only two percent of chemicals on the inventory.[105] The GAO concluded that TSCA "places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe."[106] When the old and new screening programs are taken together, it is readily apparent why TSCA's critics have concluded that "limited regulatory oversight has permitted production of health and safety data to stagnate."[107]

Finally, TSCA imposes significant procedural barriers on EPA's broad authority to regulate a chemical under Section 6 once the Agency has, under its information-gathering requirements under Sections 4 and 5,

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100. Adelman, *supra* note 26, at 388–89 (noting pre-market *testing* was dropped by the Senate as part of the political compromise to get TSCA passed in 1976).

101. Aidala, *supra* note 99, at 7.

102. Markell, *supra* note 5, at 361–62; Adelman, *supra* note 26, at 389 (characterizing EPA's review as "perfunctory" because of the short timeframe and the "nominal data" provided in the notices).

103. *Possible Outcomes of a PMN Review,* U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/oppt/newchems/pubs/possible.htm (last updated Apr. 3, 2013).

104. Markell, *supra* note 5, at 354; Adelman, *supra* note 26, at 390.

105. Markell, *supra* note 5 at 355.

106. *Id.*

107. Adelman, *supra* note 26, at 384.

found a new or old chemical to pose a risk. First, it must show a "reasonable basis" for its conclusion that a chemical "presents or will present an unreasonable risk of injury to health or the environment."[108] To do so, EPA must show in its Section 6 rulemaking the health effects or environmental impact and the magnitude of exposure, the chemical's uses and benefits, availability of alternative substances, and the "reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health."[109] Finally, when EPA chooses its regulatory action, TSCA requires that the "least burdensome" option be used.[110]

Judicial interpretation of TSCA's Section 6 language has further limited EPA's discretion. Asbestos, which is well proven to cause the fatal illness, asbestosis, provides the case in point. Despite the fact that the U.S. Surgeon General, EPA, and the World Health Organization had all declared asbestos to be unsafe at any exposure level, EPA's ban of it was judicially invalidated. In *Corrosion Proof Fittings v. E.P.A.*, the Fifth Circuit held that EPA had failed to sufficiently consider other, less burdensome alternatives when choosing to ban asbestos.[111] The court of appeals concluded that TSCA's "substantial evidence" standard required a reasoned explanation supported by substantial evidence in the rulemaking record for why EPA chose a ban over other kinds of regulation.[112] A total ban therefore required EPA to demonstrate not only that the ban adequately reduces risk, but also that a less burdensome action would either fail to reduce risk or would be ineffective in reducing risk.[113] It was not sufficient for EPA to show that a ban might reduce harm; it must also show that there is not some immediate state of regulation that would be superior to both the current regulation and a complete ban.[114] Since this decision, EPA has not completed any rules to ban or limit a chemical.[115]

In a 2010 report, EPA's Office of the Inspector General ("OIG") used strong language to characterize where TSCA stands today—"inconsistent

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108. 15 U.S.C. § 2605(a) (2006).

109. *Id.* § 2605(c)(1)(A)–(D).

110. *Id.* § 2605(a).

111. Corrosion Proof Fittings v. Envtl. Prot. Agency, 947 F.2d 1201, 1229 (5th Cir. 1991)(using a standard of review that is more rigorous than the APA's arbitrary and capricious test, and generally begins with the court questioning whether EPA considered each regulatory option and ends with the court questioning whether EPA provided a reasonable basis for the rulemaking).

112. *Id.* at 1217 (citing 15 U.S.C. §§ 2605(a), 2618(c)(1)(B)(i)).

113. *Id.* at 1217 (noting the court thus required the agency to review all options in a hierarchical fashion, from least burdensome to most burdensome).

114. *Id.*

115. Markell, *supra* note 5, at 368.

and presents a minimal presence."[116] The OIG specifically criticized how EPA handles new chemicals regulation and confidential business information claims, stating that it is "predisposed to protect industry information rather than to provide public access to health and safety studies."[117] It specifically acknowledged that trade secrets prevent effective testing, for sometimes EPA does not even know what chemical the TSCA application refers to, and cannot report any problems because "health and safety data are of limited value if the chemical the data pertain to is unknown."[118]

While some of this poor performance is due to the structure and language of TSCA, chronic underfunding of screening research and PMN review activities has also undermined the EPA's ability to keep up with the workload. Both private and public reviews have come to the same conclusion: "OPPT [now called OCSPP], the implementer of the TSCA program, is one of the most underfunded programs in all of EPA."[119] In doing the "numbers game" to first determine labor costs before estimating a reasonable TSCA review budget, several experienced former EPA officials compared staffing under the Agency's pesticides program to provide a sense of scale and context: EPA employs a staff of 900 to evaluate around 500–600 pesticide chemicals.[120] At the time of this number crunching, EPA employed only 350 people in its toxic chemicals program.[121]

Lautenberg's Attempted Updates

Senator Lautenberg introduced bills in 2007,[122] 2008,[123] 2010,[124] 2011,[125] and 2013[126] to remedy TSCA's documented failures.[127] Each year,

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116. U.S. ENVTL. PROT. AGENCY, OFFICE OF INSPECTOR GEN., EVALUATION REPORT, EPA NEEDS A COORDINATED PLAN TO OVERSEE ITS TOXIC SUBSTANCES CONTROL ACT RESPONSIBILITIES 7 (2010), http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.

117. *Id.* at 6.

118. *Id.* at 11.

119. Mark A. Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ENVTL. L. REP. 10034, 10036 (2009).

120. *See* Aidala, *supra* note 99, at 6 (describing staff shortages on the TSCA task force).

121. *See id.* (noting that while the evaluation of pesticides is "more intense," the review under TSCA is arguably "far more challenging" because of the wider variety of chemical types and possible exposure pathways).

122. Kid Safe Chemicals Act, S. 1391, 109th Cong. (2007).

123. Kid Safe Chemicals Act, S. 3040, 110th Cong. (2008).

124. Safe Chemicals Act of 2010, S. 3209, 111th Cong. (2010).

125. Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011).

126. Safe Chemicals Act of 2013, S. 696, 113th Cong. (2013); Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013).

127. *See* BEVERIDGE & DIAMOND P.C., UPDATES ON TSCA DEVELOPMENTS IN CONGRESS AND AT EPA 1–2 (2013), http://www.bdlaw.com/assets/attachments/BD%20Client%20Alert%20-%20Update%20on%20TSCA%20Developments%20in%20Congress%20and%20at%20EPA.pdf

as he revised per his political experience and the evolving body of scientific studies, the bills grew more specific and longer.[128] But over the eight years of rolling this Sisyphean rock back up Capitol Hill, his bills maintained a consistent focus: requiring industry to create "safe chemicals," not safer ones; paying particular attention to aggregate exposures from multiple chemicals; protecting vulnerable populations, like the young and old; and getting it all done under legislated deadlines for chemical categorization, prioritization, and safety determinations.

Fundamentally, all the of Lautenberg bills sought to eliminate exposure by identifying the highest priority chemical substances for review, making safety determinations for them, and restricting use if they did not meet safety standards.[129] The safety standard was a "reasonable certainty that no harm will be caused by aggregate exposure."[130] "Reasonable certainty," as defined in the 2008 bill, limited aggregate exposure to a no more than 1 in 1,000,000 risk of adverse effects in the population of concern.[131] The later bills articulated a risk-based safety standard to protect vulnerable populations,[132] requiring that aggregate and cumulative exposures present a "negligible risk of any adverse effect on the general population or a vulnerable population."[133] The 2007 and 2008 bills' name, "Kid Safe Chemicals Act," clearly showed the population at the center of these safeguards, while the subsequent bills focused more generally on the health of "children, workers, consumers, and the public," as well as the environment.[134]

To prioritize the work of assessing so many chemicals, earlier Lautenberg bills required EPA first to divide its active inventory into "batches" for categorization, based on review of available use, hazard, and exposure data, and then determine whether the chemical required further

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(focusing exclusively on activity in the Senate, although the House of Representatives has also made attempts to "modernize" TSCA. For example, the Endocrine Disrupting Chemicals Exposure Elimination Act (H.R. 2521) would ban chemicals that NIEHS considers to be of "highest concern," and the Cleaning Product Right to Know Act (H.R. 3457) would require labels on U.S. cleaning products that list all ingredients).

128. *See* S. 1391; S. 3040; S. 3209; S. 847; S. 696; S. 1009 (noting the 2007 bill numbered thirty-five pages and the 2013 more than doubled in size, to eighty-nine pages).

129. *See,* S. 1391 § 2(c); S. 3040 § 2(c); S. 3209 § 2(c); S. 847 § 3; S. 696 § 3; S. 1009 §§ 4(e), 2(b)(2)(A), 5(c)(4)(B), 2(b)(2)(A), 5(c)(4)(B).

130. *See* S. 1391 § 3; S. 3040 § 3(5)(A).

131. *See* S. 3040 § 3.

132. *See* S. 847 § 4; S. 696 § 4; S. 1009 § 6 (noting differences in metabolism and physiology at certain stages of development can make infants and children more vulnerable than adults to the effects of chemical exposure, especially exposure that occurs in utero, during infancy, and during other critical periods of development).

133. *See* S. 3209 § 4 (ensuring a reasonable certainty of no harm to specific populations).

134. *Compare* S. 1391 *and* S. 3040, *with* S. 3209, S. 847, S. 696 *and* S. 1009.

risk management to protect health and the environment.[135] The 2013 Safe Chemicals Act created the following categories: substance of very high concern ("SVHC"), substance of very low concern, substance to undergo safety standard determination, and substance for which there is insufficient information to make an informed categorization.[136] SVHCs are chemicals that are toxic, persistent in the environment, and bioaccumulative, or chemicals that are highly hazardous.[137] The bills prohibit manufacturers from using these substances until they submit additional information necessary to conduct an expedited assessment of the known uses of, and exposures to, the chemical.[138] The Chemical Safety Act relies on a health-based standard and does not allow for cost-benefit analysis.[139] It also directs EPA to use "the best available science" as recommended by the National Academy of Sciences.[140]

All of Lautenberg's bills sought to minimize exposure to toxic substances by promoting the use of safer alternatives, and by requiring manufacturers to provide health and environmental data. The 2011 and 2013 bills required EPA to establish a network of no less than four green chemistry and engineering centers to support the development and adoption of safer alternatives; provide grants to promote and support the research, development, and adoption of alternatives; create market incentives for the development of safer alternatives; and develop a common protocol or electronic database relating to safer alternatives.[141] Interestingly, recent studies have suggested that U.S. consumers have flocked to "green products," many of which are produced outside the U.S., because they no longer trust the chemicals used in "regular" products nor the government's ability to regulate them for their safety.[142] The 2011 and 2013 bills also created the Children's Environmental Health Research Program, which would provide grants to increase understanding of children's vulnerability

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135. *See* S. 696 § 7.

136. S. 696 § 5.

137. *See* S. 3209 § 26 (mandating that expedient action be taken on those chemicals with the highest risk to human and environmental health); S. 847 § 6; S. 696 § 6; S. 1009 § 4.

138. S. 1391 § 3; s*ee also* S. 3040 § 3; S. 3209 § 5; S. 847 § 26; S. 696 § 6; S. 1009 § 6.

139. *See* S. 696 § 7 (assigning human health as the "sole" consideration).

140. *Id.*

141. S. 847 §§ 31, 32; S. 696 §§ 31, 32. EPA defines "green chemistry" as the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. S*ee Green Chemistry*, U.S. ENVTL. PROT. AGENCY, http://www2.epa.gov/green-chemistry (last updated Dec. 12, 2013).

142. *See, e.g.*, *Consumers Don't Trust Green Product Claims, Survey Says*, ENVTL. LEADER (Mar. 28, 2012), http://www.environmentalleader.com/2012/03/28/consumers-dont-trust-green-product-claims-survey-says/ (reporting that consumers believe producers of "regular" products are not addressing the environmental impacts).

to chemical substances,[143] and an interagency Science Advisory Board on Children's Health and Toxic Substances.[144]

Lautenberg's proposed bills contained other provisions that show attentiveness to concerns beyond just amending TSCA. For example, several bills sought to establish alternatives to animal testing, cooperation with international efforts to monitor chemicals, and a public database to share information on the toxicity and use of chemicals.[145] The 2008 bill made provisions for a biomonitoring study to determine the presence of chemicals in human cord blood[146] and included a user fee to finance it.[147] The 2010 bill required EPA to publish a list categorizing all chemicals distributed in commerce, and to develop and publish action plans to reduce disproportionate exposure to toxic chemicals.[148] It also provided for a general fee to help implement the Act.[149]

Lautenberg's bills, while intended to enhance EPA's authority, did not displace state regulation and instead envisioned a working relationship between both levels of government. Early bills contained the same state preemption language, that "[n]othing in this Act affects the authority of a State or political subdivision of a State to establish or continue in effect any regulation of a chemical substance, mixture, or article containing a chemical substance or mixture."[150] The 2010 bill was more specific, clarifying that nothing in the statute or any rule, regulation, or order promulgated pursuant to it "shall be construed, interpreted, or applied to preempt, displace, or supplant any provision of any law, including common

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143. S. 3209 § 26; S. 847 § 26; S. 696 § 29.

144. S. 3040 § 3; S. 1391 § 3.

145. S. 1391 § 3; S. 3040 § 3; S. 3209 § 3; S. 847 § 9; S. 696 § 9.

146. S. 3040 § 2 (a)(5). Biomonitoring is the process of measuring levels of chemicals, chemical metabolites, or elements of a biological substance in an individual's blood or urine. S*ee, e.g.*, *Pollution in Minority Newborns: Executive Summary*, ENVTL. WORKING GRP. (Nov. 23, 2009), *available at* http://www.ewg.org/research/minority-cord-blood-report/executive-summary. In 2005, in response to TSCA's failure to mandate safety studies, the Environmental Working Group ("EWG") conducted a study of umbilical cord blood from ten babies born in August and September of 2004 in U.S. hospitals, finding an average of 200 industrial chemicals and pollutants in the samples, including pesticides, consumer product ingredients, and eight perfluorochemicals—including the Teflon chemical PFOA, recently characterized as a likely human carcinogen by the EPA's Science Advisory Board—dozens of widely used brominated flame retardants and their toxic by-products. *Body Burden: The Pollution in Newborns*, ENVTL. WORKING GRP. (July 14, 2005), *available at* http://www.ewg.org/research/body-burden-pollution-newborns. Of the 287 chemicals detected in the cord blood, 180 are known carcinogens, 217 are neurotoxins, and 208 cause birth or developmental defects. *Id.*

147. S. 3040 § 3.

148. S. 3209 § 7.

149. S. 3209 § 23; S. 847 § 23; S. 696 § 23.

150. S. 1391 § 18; S. 3040 § 18.

law, of any state," if that law is more stringent than the act itself.[151] The 2011 and 2013 bills contained revised preemption language:

> [n]othing in this Act affects the right of a State . . . to adopt or enforce any regulation . . . that is different from, or in addition to, a regulation . . . established pursuant to this Act unless compliance with both . . . is impossible, in which case the applicable provisions of this Act shall control.[152]

This language continues a trend begun in the 2010 bill's preemption language of encouraging cooperative federalism by setting a federal regulatory floor that states may exceed but not fall below.

Given TSCA's clear problem with confidential business information exemptions, Lautenberg's bills addressed them head on. While the earlier bills provided a general exemption for confidential business information,[153] the later bills more specifically limited it to precise information describing the manufacture, processing, or distribution of a chemical substance or mixture; marketing and sales information; information identifying specific customers; details of the full composition of a specific mixture; precise information about the use, function, or application of a chemical substance; and precise production or import volumes of a particular manufacturer, processor, or distributor.[154]

II. REGULATING IN THE FEDERAL VOID

As a result of TSCA's anemic regulatory reach, individual states stepped into the void. Beginning with California in 1986 and ending most recently with Maine, almost all states of various sizes and political stripes now use a range of regulatory tools to protect their respective citizens from commercial chemicals used in products sold to them.[155] Unsurprisingly, this

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151. S. 3209 § 18.

152. S. 847 § 18; S. 696, 7 § 18.

153. *See* S. 3040 § 3; S. 1391 § 3 (relying on the definition of "confidential business information" under 40 CFR § 350.27 and requiring written justification for maintaining confidentiality and certification that the information is not otherwise publicly available).

154. S. 3209 § 14; S. 847 § 14; S. 696 § 14; S. 1009 § 13.

155. *See generally* Daryl W. Ditz, *The States and the World: Twin Levers for Reform of U.S. Federal Law on Toxic Chemicals*, 8 SUSTAINABLE DEV. L. & POL'Y 27, 28 (2007) (discussing the historical overview of state chemical laws). It is estimated that "[a]t least 442 bills involving toxics and chemicals have been filed in 2014, or refiled from previous sessions, covering 39 states, according to an environmental health legislation database maintained by the National Conference of State Legislatures. A year earlier, 399 such bills were filed and the year before that, the database shows, more than 500." Ronnie Greene, The Center for Public Integrity, *States target toxic chemicals as Washington fails to act*, http://www.publicintegrity.org/2014/04/02/14505/states-target-toxic-chemicals-washington-fails-act.

"patchwork" of state regulations has troubled national manufacturers. Through their lobby, the American Chemistry Council, they have worked to limit the impact of them.[156] But U.S. manufacturers and sellers doing business internationally have simultaneously felt the extraterritorial impact of the EU's regulation of chemicals in commerce through REACH. Consequently, combined pressure from the states below and international trade partners above have led the U.S. commercial chemicals industry to accept a federal overhaul of TSCA.[157]

State-by-State

California was the first state to step into the regulatory void, enacting a criteria-based commercial chemicals disclosure system whose influence continues today, with recent, similar legislative attempts by Connecticut and Maine in 2013.[158] California's law, Proposition 65 or the Safe Drinking Water and Toxic Enforcement Act, was enacted by ballot initiative in November, 1986.[159] It focuses on protecting Californians from chemicals known to cause cancer, birth defects, or other reproductive harm by requiring the governor to publish a list of chemicals known to have these impacts[160] and businesses to notify the public about significant amounts of these listed chemicals in the products they purchase.[161] By providing this information, Prop 65 seeks to enable Californians to make informed decisions about protecting themselves from unhealthy exposures.[162]

The Office of Environmental Health Hazard Assessment ("OEHHA"), a division of the California EPA, administers Prop 65 and determines which substances are listed through one of four main ways. One pathway is via a determination by members of OEHHA's Science Advisory Board that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm.[163] A second is when an "authoritative

156. *Id.* at 27 (referring to these as the "twin levers").

157. Sachs, *supra* note 6, at 1819.

158. Ronnie Greene, *In New Battleground Over Toxic Reform, American Chemistry Council Targets the States,* CTR. FOR PUB. INTEGRITY (Sept. 9, 2013), http://www.publicintegrity.org/2013/09/09/13323/new-battleground-over-toxic-reform-american-chemistry-council-targets-states.

159. *Proposition 65*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, http://www.oehha.org/prop65.html (last visited Feb. 12, 2014).

160. CAL. HEALTH & SAFETY CODE § 25249.8 (1986); *see also* OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY (2014), *available at* http://oehha.ca.gov/prop65/prop65_list/files/P65single01032014.pdf.

161. CAL. HEALTH & SAFETY CODE § 25249.6.

162. *Proposition 65 in Plain Language!*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, http://oehha.ca.gov/prop65/background/p65plain.html (last updated Feb. 2013).

163. *Id.* The Science Advisory Board is comprised of two committees called the Carcinogen Identification Committee ("CIC") and the Developmental and Reproductive Toxicant ("DART")

body," like the EPA, FDA, National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer, identifies a chemical as causing cancer or birth defects or other reproductive harm.[164] A third occurs when a state or federal agency requires that it be labeled or identified as causing cancer or birth defects or other reproductive harm.[165] Finally, if a chemical meets certain scientific criteria identified in the California Labor Code as causing cancer or birth defects or other reproductive harm, it may be listed by OEHHA.[166] The Prop 65 list, which must be updated at least once a year, has grown to include approximately 800 chemicals since it was first published in 1987.[167]

Once chemicals are listed, Prop 65 then requires all companies doing business in California to provide a "clear and reasonable" warning before knowingly exposing anyone to them.[168] Notably, businesses have the burden of proving that a warning is not required.[169] This warning requirement can be met by labeling a consumer product, posting signs at workplaces, distributing notices at housing complexes, or publishing notices in newspapers.[170] Businesses have twelve months to comply with warning requirements and twenty months to comply with the prohibition on knowingly discharging them into drinking water sources.[171] However, businesses do not have to report the warnings they have issued to OEHHA,

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Identification Committee. Committee members are appointed by the Governor and are designated as the "State's Qualified Experts" for evaluating chemicals under Proposition 65. When determining whether a chemical should be placed on the list, the committees base their decisions on the most current scientific information available. OEHHA staff scientists compile all relevant scientific evidence on various chemicals for the committees to review. The committees also consider comments from the public before making their decisions. *Id.*

164. *Id.*

165. *Id.* Most chemicals listed in this manner are prescription drugs required by the FDA to contain such warnings. *Id.*

166. *Id.* This method established the initial chemical list following adoption of Proposition 65 in 1986 and continues to be used today. *Id.*

167. *Id.*

168. CAL. HEALTH & SAFETY CODE § 25249.6 (1986); *see also* 27 CAL. CODE REG. § 25601 (discussing "clear and reasonable" warnings).

169. CAL. HEALTH & SAFETY CODE § 25249.10(c) (1986).

170. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, *supra* note 160.

171. *Id.* Also, "[b]usinesses with less than 10 employees and government agencies are exempt from Proposition 65's warning requirements and prohibition on discharges into drinking water sources. Businesses are also exempt from the warning requirement and discharge prohibition if the exposures they cause are so low as to create no significant risk of cancer or birth defects or other reproductive harm." For a cancer warning, "the 'no significant risk level' is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime." "For birth defects or reproductive harm warning, the 'no observable effect level' is determined by identifying the level of exposure that has been shown to not pose any harm to humans or laboratory animals. Proposition 65 then requires this 'no observable effect level' to be divided by 1,000 in order to provide an ample margin of safety. Businesses subject to Proposition 65 are required to provide a warning if they cause exposures to chemicals listed as causing birth defects or reproductive harm that exceed 1/1000th of the 'no observable effect level.' " *Id.*

and so the agency does not collect specific information about any particular warning, such as what chemicals are present, at what levels, and how exposure to them may occur.[172] The law is enforced by a combination of the California Attorney General's Office, district attorneys and city attorneys, and citizen suits by individuals acting in the public interest filed against a business alleged to have violated the law.[173] Penalties for failing to provide notices can be as high as $2,500 per violation per day.[174]

As a result of Prop 65's warning requirement, California has seen manufacturers remove listed chemicals from their products. For example, the known carcinogens trichloroethylene and methylene chloride "are no longer used in most correction fluids and reformulated paint strippers, respectively, and toluene, which causes birth defects or other reproductive harm, has been removed from many nail care products."[175] In addition, a Prop 65 enforcement action prompted manufacturers to decrease the lead content in ceramic tableware and wineries to eliminate the use of lead-containing foil caps on wine bottles.[176] Given that California is regularly ranked as the ninth largest economy in the world[177] and the largest one within the United States,[178] its approach to regulating commercial chemicals influences industry practice outside, as well as inside, its boundaries. California effectively shut down the national market for certain bromated flame retardants ("BFRs") when it unilaterally chose to ban them, given that it is the largest U.S consumer of products containing BFRs.[179]

Looking beyond California's trend-setting start to the majority of other states that have passed some form of chemicals regulation, one can readily appreciate the chemical industry's view that a patchwork of laws currently exists. Nonetheless patterns appear when looking at the specific state regulatory tools used, including an early tendency toward single chemical restrictions; creation of state government purchasing programs;

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172. *Id.*

173. *Id.* (indicating that, thus far, lawsuits have been filed by the Attorney General's Office, district attorneys, consumer advocacy groups, and private citizens and law firms).

174. CAL. HEALTH & SAFETY CODE § 25249.7(b) (1986).

175. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, *supra* note 160.

176. *Id.*

177. *2013 Cal Facts,* LEGISLATIVE ANALYST'S OFFICE (Jan. 2, 2013), http://www.lao.ca.gov/reports/2013/calfacts/calfacts_010213.aspx.

178. News Release, U.S. Dept. of Commerce, Bureau of Econ. Analysis, Widespread Economic Growth Across States in 2011 (June 5, 2012), *available at* http://www.bea.gov/newsreleases/regional/gdp_state/2012/pdf/gsp0612.pdf.

179. Tracy Daub, *California—Rogue State or National Leader in Environmental Regulation?: An Analysis of California's Ban of Bromated Flame Retardants,* 14 S. CAL. INTERDISC. L.J. 345, 346, 349, 351 (2005) (noting the EU also banned these chemicals in 2004, leading to a similar result of one jurisdiction's precautionary approach to chemical regulation affecting broad swaths of the U.S. market).

mandated assessments of alternatives to "chemicals of concern" and application of "green chemistry;" initiation of biomonitoring programs; required prioritization in chemical assessment and restriction; use of life cycles analysis; and increased transparency through right-to-know and other public information laws.[180] Single chemical laws have been frequently used, and range from outright bans to restrictions on use; more states impose restrictions on chemicals that have been most studied and thus present the least uncertainty about their toxicity, like mercury (thirty-one states), lead (seventeen states), and polybrominated diphenyl ethers ("PBDEs")[181] and phthalates (twelve states).[182] Twenty-five states use government purchasing power to reduce chemical exposures,[183] like Connecticut, New Jersey, and New York's executive orders that require state agencies to use "green" cleaning products.[184] The same number of states has enacted various forms of data-gathering laws,[185] like Washington requiring that all children's products manufacturers report their use of chemicals of high concern and Maine mandating facilities to report use of more than 1,000 pounds of a priority toxic chemical per year.[186]

Interestingly, one can see states making progress in a "stepwise" fashion toward more comprehensive chemicals regulation, adding successive tools from initial data reporting and collection, to prioritizing chemicals of concern based on human health harms, then promoting safer alternatives via research on substitutes, and finally restricting these prioritized chemicals via single chemical or product-specific restrictions or incentives to use preferred items.[187] In this manner, some states are making the transition from single chemical to comprehensive chemicals regulation, and a push toward life cycle regulation. In 2013, California's new Safer Consumer Product regulations took effect.[188] They signaled a move beyond

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180. *See generally* ROSS STRATEGIC, NAT'L POLLUTION PREVENTION ROUNDTABLE, STATE CHEMICALS POLICY: TRENDS AND PROFILES 6–9 (Apr. 2013) [hereinafter *NPPR*].

181. Cary G. Coburn, Margarita C. Currás-Collazo & Prasada Rao S. Kodavanti, *Polybrominated Diphenyl Ethers and Ortho-Substituted Polychlorinated Biphenyls as Neuroendocrine Disruptors of Vasopressin Release: Effects during Physiological Activation In Vitro and Structure–Activity Relationships,* 98 TOXICOL. SCI. 178 (Apr. 13, 2007) (showing PBDE's use as flame retardants in an array of consumer products, including building materials, furnishings, and textiles, have been shown to disrupt hormones).

182. NPPR, *supra* note 181, at 8–9. In contrast, a smaller number of states restrict the use of other kinds of flame retardants (6) and BPA (3). *Id.*

183. *Id.*

184. *Id.* at 12.

185. *Id.* at 9.

186. *Id.* at 14.

187. *Id.* at 10.

188. *California's Safer Consumer Products Regulations Now in Force*, ENVIRON (Oct. 1, 2013), http://www.environcorp.com/news/2013/10/california%E2%80%99s-safer-consumer-products-regulations-n.aspx; CAL. HEALTH & SAFETY CODE § 25253 (1986).

Prop 65's notification requirements to mandated identification and prioritization of consumer products containing chemicals of greatest concern; performance of "alternative analyses" by the manufacturers of those high priority product-chemical combinations; and a range of legal tools ranging from outright bans and use restrictions to information disclosure and end-of-life management programs.[189] Both Maine and Washington regulate in a similar, comprehensive manner, but only for children's products.[190] With the life cycle approach, states seek to reduce chemicals of concern in all phases of manufacturing, distributing, use, and disposal. For example, Michigan's state agencies and departments promote green chemistry solutions that reduce the use of hazardous chemicals throughout a product's life cycle from development to disposal,[191] while Minnesota requires manufacturers to collect mercury-containing products and New York and Wisconsin laws require manufacturers to collect and recycle their electronics products.[192]

In sum, activity at the state level since 1986 shows a steady progression toward wider and deeper regulation of commercial chemicals. A variety of techniques have been tried. Some have been adopted by several states, as jurisdictions share their experiences and national advocacy associations seek to extend best practices.[193] Although national companies observe that this plethora of state laws impedes their operations, in fact the states have succeeded in their time-honored role as "laboratories" of social change.[194]

REACHing Across the Pond

The EU's Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH") regulation was adopted in December 2006 and entered into force six months later on June 1, 2007.[195] Its goal is to facilitate assessment of the risks of using both new and existing chemicals in industry

189. NPPR, *supra* note 181, at 19.
190. *Id.* at 11.
191. *Id.* at 13.
192. *Id.* at 14.
193. *Id.* at 6. But interestingly, no systematic and comprehensive studies have yet analyzed how states have implemented these laws nor assessed whether they have been effective at decreasing exposures and health impacts.
194. *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis J., dissenting) (stating that a state "may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country").
195. EUR. COMM'N, *REACH: History and Background—History of the Adoption Process for the New Chemicals Legislation*, (Feb. 13, 2001), http://ec.europa.eu/environment/chemicals/reach/background/index_en.htm.

and commerce.[196] REACH replaced over forty different directives and regulations[197] in place throughout the EU's member countries, with over 140 articles, 17 annexes, and hundreds of pages of guidance.[198] All of these regulations sought to "ensure a high level of protection" of health, safety, and the environment.[199]

REACH's main mechanism of regulation is registration and evaluation of individual chemicals by the European Chemicals Agency ("ECHA"),[200] an independent agency established to evaluate manufacturer-provided data and determine whether chemicals are safe for market.[201] ECHA prioritizes all substances, categorizing substances as approved for use or requiring evaluation. Chemical manufacturers that produce or import more than one ton of existing[202] or new chemicals[203] in a year[204] must first register the substance with ECHA. They must also provide a technical dossier describing the characteristics of each substance posing human health and/or environmental hazards[205] through "literature search, data sharing, and testing" if necessary.[206] The dossier information required depends on the volume of each substance[207] and whether the substance is characterized as "dangerous" or as "persistent, bio-accumulative and toxic."[208] ECHA then uses these dossiers to establish exposure

196. *See* Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 4 November 2004*, G/TBT/M/34, ¶¶ 14–16 (Jan. 5, 2005).

197. *See generally* COMM'N OF THE EUROPEAN CMTYS., WHITE PAPER: STRATEGY FOR A FUTURE CHEMICALS POLICY (2001), *available at* http://www2.unitar.org/cwm/publications/cbl/synergy/pdf/cat3/eu_wp_chemicals/eu_white_paper.pdf (discussing the regulation of chemicals within the European Union).

198. Lynn L. Bergeson, *Chemical Management, North American Style: The Montebello Agreement*, ENVTL. QUALITY MGMT. 89, 91 (Spring 2008).

199 Commission Regulation 1907/2006, art. 1(1), 2006 O.J. (L 396) (EC) [hereinafter *REACH*].

200. *Id.* at arts. 15, 20; EUROPEAN CHEMS. AGENCY, GUIDANCE ON REGISTRATION 3, 112 (2011), http://www.safetyhitech.com/coddocumento/14/Registration%2520EN% 2520.pdf.

201. *About Us*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/about-us (last visited Feb. 27, 2014).

202. *See* REACH, *supra* note 199, at arts. 3(20), 12(1)(a), 23, 26–28 (discussing the reporting requirements for phase-in chemicals in quantities of more than one tonne).

203. *Id.*

204. *See id.* at arts. 6(1), 6(3)(b), 17(1), 18(1), 23(1), 23(3), 28(1), 28(6), 41(d)(b) (stating the threshold quantity is produced per year).

205. *Id.* at arts. 10(a), 12(1)(a)–(b).

206. *See id.* at arts. 13(1)–(2), 25, Annex VI (discussing preferred information-gathering techniques); *see also* Committee on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 21 March 2007*, G/TBT/M/41, ¶ 26 (June 11, 2007) (describing the necessary control information to be demonstrated by applicants).

207. *See REACH*, *supra* note 200, at 12(1), 14(1), Annex XI (stating that new requirements correspond to each increase in tonnage).

208. *Id.* at Annex XIII.

information,[209] assess the risks from identified uses,[210] and make recommendations to ensure the safe use of each substance.[211] The provided information is maintained in a central chemicals database[212] that is available to manufacturers as part of mandatory Substance Information Exchange Forums ("SIEFs") intended to minimize duplicative testing.[213]

Since 2008, REACH has approved 4,938 substances for standard registration[214] and 3,547 under limited registration for intermediate uses.[215] ECHA lists substances suspected of posing a risk to human health or the environment in a Community Rolling Action Plan ("CoRAP")[216] and evaluates them according to risk-based criteria to determine the presence and degree of risk posed.[217] Substances that do not pose an unacceptable risk to human health and the environment are approved; otherwise, they are listed as candidates for restriction. As of September 2013, there are 105 categories of restricted substances, covering more than 1,000 substances including lead and phthalates.[218]

EU member states are chosen to evaluate candidate substances, and may request additional information from the manufacturer or importer if needed to make a risk determination. Member states' evaluations may result in the conclusion that the risks are sufficiently under control with the measures already in place, or that the risks require further management. For

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209. *See id.* at art. 10(a)(x) (applying to "substances in quantities of 1 to 10 tonnes per year").

210. *See id.* at arts. 12(1)(c), 14(1) (applying to substances in quantities of 10 tonnes or more).

211. *Id.* at arts. 77(2)(i), 123. REACH requires evaluation in the context of other EU directives and ECHA will not grant approval of a substance if doing so would violate other environmental statutes. *See generally* Council Directive 2000/60, 2000 O.J. (L. 327) (EC) (providing an example of a European Union environmental law, the violation of which would trigger ECHA denial).

212. *REACH*, *supra* note 200, at art. 16(1).

213. *Id.* at arts. 11(1), 13(5). *See also Substance Information Exchange Fora*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/ja/regulations/reach/substance-registration/substance-information-exchange-fora (last visited Feb. 6, 2014) (stating that a purpose of SIEF is to avoid duplication of studies).

214. *REACH*, *supra* note 200, at art. 10 (indicating what information shall be contained in a chemical registration); *see also Registration Statistics*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/web/guest/information-on-chemicals/registration-statistics/detailed-registrations-statistics (last updated Dec. 23, 2013).

215. *REACH*, *supra* note 200, at art 17, 18 (indicating what information shall be included in registration for intermediates); *see also Registration Statistics*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/web/guest/information-on-chemicals/registration-statistics/detailed-registrations-statistics (last updated Dec. 23, 2013).

216. EUROPEAN CHEMS. AGENCY, COMMUNITY ROLLING ACTION PLAN (CORAP), (2012), *available at* http://echa.europa.eu/documents/10162/13628/corap_2012_en.pdf.

217. *Id.*

218. *See List of Restrictions Table*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions-table (last updated Dec. 23, 2013).

the latter, management can include use restrictions, identification as "substances of very high concern" ("SVHC"), harmonized classification, and bans. As of December 2013, there were 151 substances on the SVHC "Candidate List,"[219] which includes twenty-two candidates for possible inclusion in the "Authorization List."[220]

Substances placed on the "Authorization List" cannot be produced or used in the EU after the date listed without authorization for a specific use. Authorization is granted "if the applicant [is] able to demonstrate adequate control of risks" or "if there [is] no alternative substance or technology (even if the risks [are] not adequately controlled) and socio-economic benefits outweigh[] the risks."[221] The European Commission ("EC") may also place restrictions on the manufacture, use, or placement of a substance on the market or in certain products.[222] There are over fifty-nine categories of restricted substances, covering 102 substances with restrictions, including asbestos, which is prohibited in all substances, and benzene, which should not exceed 5mg/kg in toys or toy parts.[223]

Given that REACH was designed to address the shortcomings of the existing chemical regulation system, ECHA has been overwhelmed with regulatory work. Because REACH requires that ECHA check five percent of all dossiers from each tonnage band for compliance, 1,250 of the 25,000 registration dossiers received by the first registration deadline in November 2010 required review.[224] To lessen this burden, REACH established "Joint Submissions," a legal obligation requiring multiple registrants of the same substance to submit a single dossier. As of September 2013, ECHA had received over 5,706 joint submissions and 2,226 individual submissions.[225]

Despite the workload, the REACH approach is widely viewed as successful. The registration and disclosure requirements reflect a shift that moves the burden of proof from the government to the manufacturer on the

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219. *Candidate List of Substances of Very High Concern for Authorization*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/web/guest/candidate-list-table (last updated Dec. 16, 2013).

220. *Authorization List*, EUROPEAN CHEMS. AGENCY, http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list (last visited Jan. 28, 2014).

221. Comm. on Technical Barriers to Trade, *supra* note 207; *see also* REACH, *supra* note 200, at art. 60(2)–(4) (providing that authorizations shall not be granted for substances meeting the criteria of article 57(a), (b), (c), or (f) for which a threshold cannot be determined; substances meeting the criteria of article 57(d) or (e); and substances identified in article 57(f) which have "persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties").

222. *See generally* REACH, *supra* note 200, at Annex XVII (describing the process by which such restrictions may be put in place).

223. *List of Restrictions Table*, *supra* note 219.

224. *Steps*, EUROPEAN CHEMS. AGENCY, https://echa.europa.eu/regulations/reach/evaluation/steps (last visited Jan. 28, 2014).

225. PWC, FINAL REPORT ON THE REVIEW OF THE EUROPEAN CHEMICALS AGENCY 18 (2012), *available at* http://ec.europa.eu/enterprise/dg/files/evaluation/201203-final-report-echa_en.pdf.

basis of the substance's hazardous properties, separate from the risk the substance poses to human health or the environment. In this way, REACH embodies the precautionary principle.[226] Importantly, for understanding the landscape of the debate about current US chemicals regulation, REACH casts its precautionary net on this side of the Atlantic, affecting the manufacturing practices of U.S. firms who sell or manufacture their products in the EU.[227]

III. THE COMPROMISE BILL OF 2013

The CSIA caught many people by surprise.[228] Although Senator Lautenberg had already introduced his Safe Chemicals Act in April and Senator Vitter was said to be working on his own bill, few appeared to know that they were working together on a compromise bill. Introduced just a few weeks before Senator Lautenberg died, this bipartisan bill was endorsed by an almost equal number of Republicans and Democrats.[229]

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226. As phrased by the February 2, 2000 European Commission Communication on the Precautionary Principle, the precautionary principle 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." COMM. OF THE EUROPEAN CMTYS., COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE 10 (2000), *available at* http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf. This EC formulation of the precautionary principle derived from the foundational statements in the 1992 Rio declaration and the 1998 US-based Wingspread Conference. Principle 15 of the Rio Declaration states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." United Nations Conference on Environment and Development, Rio de Janiero, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/5/Rev. 1 (June 14, 1992), *available at* http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163; *Wingspread Conference on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK (Jan. 26, 1998), http://www.sehn.org/wing.html. The Wingspread Statement on the Precautionary Principle summarizes the principle slightly differently: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." *Id.*

227. The United States is the third largest exporter of manufactured goods. THE MFG. INST., FACTS ABOUT MODERN MANUFACTURING 16 (8th ed. 2009), *available at* http://www.nist.gov/mep/upload/FINAL_NAM_REPORT_PAGES.pdf.

228. *See* BERGESON & CAMPBELL, P.C., *The Chemical Safety Improvement Act: An In-Depth Review and Analysis* (May 29, 2013), http://www.lawbc.com/regulatory-developments/entry/the-chemical-safety-improvement-act-an-in-depth-review-and-analysis/ (analyzing and summarizing key aspects of the 2013 bill).

229. LIBRARY OF CONG., *supra* note 8.

The CSIA now sits in the Senate Environment and Public Works Committee, which Senator Barbara Boxer of California chairs.[230] It has received one hearing, in July, 2013, at which an array of representatives from NGOs, state and federal governments, academia, and industry testified.[231] Four months later, the House Energy and Commerce Committee, which has been holding regular meetings to review ways in which TSCA should be updated, held a hearing to consider the CSIA's provisions.[232] Witnesses at both hearings remarked on ways in which the CSIA improved TSCA's demonstrated weaknesses, including mandating safety reviews of all existing chemicals, requiring new chemicals to be found likely to meet the safety standard before market approval, clarifying that the "unreasonable risk" standard is based solely on health and environmental risks, and permitting EPA to require more testing without going through a rulemaking process.[233] They also sounded several concerns about the bill as drafted, including state law preemption, insufficient limits on the CBI exceptions to information gathering, insufficient attention to vulnerable populations and aggregate exposures when setting safety standards, absence of legislated timelines, lack of explicit support for a green chemistry program and international coordination, and inattention to funding.[234] Although the CSIA builds on the awareness created by Senator Lautenberg's tenacity, it includes many clear compromises and thus differs in both tone and substance from his Safe Chemicals Act of 2013.

Envisioning the Change Needed

The CSIA styles its purpose modestly: to improve consumer safety and to ensure that risks from chemicals are adequately understood and managed.[235] Throughout its 23 sections, the bipartisan bill seeks to strike a compromise between absolute consumer safety and equally unbridled

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230. U.S. SENATE COMM. ON ENV'T AND PUBLIC WORKS, http://www.epw.senate.gov/public/?CFID=103634163&CFTOKEN=14166360 (last visited Jan. 28, 2014).

231. *Strengthening Public Health Protections by Addressing Toxic Chemical Threats: Hearing Before the S. Comm. on Env't & Public Works,* 113th Cong. (2013).

232. *S. 1009 The Chemical Safety Improvement Act: Hearing on S. 1009 Before the H. Comm. on Energy & Commerce*, 113th Cong. (2013), *available at* http://energycommerce.house.gov/hearing/s-1009-chemical-safety-improvement-act. More recently, the chair of the Environment and the Economy Subcommittee (of the House Energy and Commerce Committee), John Shimkus (R-Ill.) floated a draft bill called the Chemicals in Commerce Act in February 2014. Chemicals in Commerce Act Discussion Draft, *available at* https://energycommerce.house.gov/fact-sheet/chemicals-commerce-act-cica.

233. *Id.* (showing Mr. Tonko of New York speaking about the unreasonable risk standard).

234. *Id.*

235. S. 1009§ 2(a).

manufacturing freedom. Among its findings are that chemicals should be safe for their intended uses,[236] that they are used in a variety of ways and have benefitted society, and that "unmanaged risks of chemical substances" may endanger human health.[237] These findings also acknowledge that confidence in federal chemical regulation has diminished, that TSCA must be updated to create a "robust Federal system for assessing and managing chemical risks" that preempts state requirements,[238] and that development of safer chemicals should be encouraged to "reduce risk, provide improved products, stimulate the economy, create jobs, and protect interstate commerce."[239]

The CSIA's policy section builds on these findings, stating that the EPA Administrator should have "the appropriate hazard, use and exposure information" needed to make chemical safety determinations, the authority to share confidential business information with other government officials, and "the resources and tools necessary to implement this Act."[240] It also advises EPA to encourage the use of best laboratory methods, minimize animal testing, and implement the act in a way that "promotes transparency of information and decisionmaking, protects substantiated confidential business information, and promotes innovation."[241] Finally, CSIA policy declares that development of adequate data on a chemical's effects and exposures "should be the primary responsibility" of manufacturers, and explains that the states' "important role" in an updated TSCA lies in recommending priorities and providing safety assessment data to the EPA, along with general consumer protection.[242] As with the findings, the CSIA's policies are more numerous than TSCA's, but are also written in a more specific and less tepid manner.[243]

Fundamentally, Congress encapsulated EPA's balancing act when regulating chemicals in commerce by laying out the CSIA's two goals: maintain human health and foster economic health. The CSIA declares that the Administrator shall "rely on robust scientific evidence to implement this

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236. *Id.* § 2(a)(1).

237. *Id.* § 2(a)(6).

238. *Id.* § 2(a)(5).

239. *Id* § (2)(a)(8). The CSIA's eight new findings replace the three findings currently codified in TSCA.

240. *Id.* § 2(b)(b) (2)(E).

241. *Id.* §§ 2(b)(b)(2)(B–F).

242. *Id.* § 2(b)(b)(3).

243. For example, TSCA's policies seek only "adequate" data collection and EPA authority. *See* 15 U.S.C. § 2601(b)(1)–(2) (2006) (requiring adequate data and authority); s*ee id.* § 2601(b)(3) ("authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.").

Act in a way that balances . . . promoting the safety of American consumers and preventing harm to American innovation, manufacturing, and the economy" and "implement this Act to protect the health of the people . . . and the environment in such a manner as not to unduly impede commerce or create unnecessary economic barriers to technological innovation, including safer chemistry."[244]

Screening and Setting Priorities

The CSIA's biggest change to risk assessment practice under TSCA lies in creating a framework that establishes a priority system for assessing all chemicals currently used in commerce. In doing so, Congress would eliminate almost all of TSCA's Section 4 and put in its place a requirement that EPA assess all Section 8 inventory chemicals in use, with an emphasis on those actively[245] being used in manufacturing, using a risk-based screening process.[246] To determine whether substances are high or low priority, the CSIA directs EPA to consider such criteria as hazard and exposure potential, intended conditions of use, production volume and significant changes to it, and recommendations by state agencies charged with protecting health or the environment.[247] High priority chemicals are those that have the potential for high hazard and high exposure.[248] Low priority chemicals are those that the EPA determines are likely to meet the safety standard.[249] The safety standard is defined as ensuring that "no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance."[250]

CSIA Section 4 focuses primarily on the process of developing this framework, with EPA mandated to develop all policies and procedures for implementing it, including collecting information, evaluating its quality, analyzing the data, determining the need for additional data (including information on specific subpopulation impacts), and providing transparency

244. S. 1009 § 2(c); *see also* 15 U.S.C. § 2601(c) (putting more weight on protecting commerce than public health by stating, "It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter").

245. S. 1009 § 8(b)(6)&(7) (defining active and inactive substances).

246. *Id.* § 4(a)(4)(e)(1)(B).

247. *Id.* § 4(a)(4)(e)(2)(C).

248. *Id.* § 4(a)(4)(e)(3)(E)(i)–(iii). *See id.* § 4(a)(4)(e)(2)(C)(vii) (stipulating that inadequate data on a substance can qualify it for high priority status).

249. *Id.* § 4(a)(4)(e)(3)(F).

250. *Id.* § 3(4)(16) (as critics rightly point out, this standard assumes some level of risk—a reasonable risk—to be tolerated, thereby requiring a reasonableness analysis).

throughout.[251] This process, which is to be developed within one year of enactment,[252] requires industry to provide baseline data to the EPA, complete with the funding sources for this data.[253]

Importantly, the CSIA gives EPA authority to acquire additional data from regulated companies when needed by issuing an order, as well as promulgating a test rule or negotiating a test consent agreement.[254] To issue an order, EPA must explain why "good cause exists," including efforts made to obtain testing voluntarily, the availability of data on structurally related chemicals, and safety assessments on other relevant chemicals.[255] In theory, despite this show cause process, this additional method for gathering information should cut down the screening delay due to multi-year rulemaking. Overall, while the CSIA provides much description of the framework process and sets a timeline for the framework's completion, it only requires EPA to "make every effort to complete prioritization of all active substances in a timely manner."[256]

Safety Determinations and Risk Management

Having determined the chemical priority list, EPA must then conduct a risk-based safety assessment, make a safety determination, and establish risk management requirements for all high-priority substances.[257] In a marked change from TSCA, the CSIA requires that EPA base its risk assessments "solely on considerations of risk to human health and the environment."[258] The cost-benefit analysis required under TSCA is no longer included. When doing the exposure assessment, the CSIA instructs EPA to take into account exposure "duration, intensity, frequency, and number, and the vulnerability of exposed subpopulations."[259] Just as when setting screening standards under new Section 4, EPA has the additional tool of issuing an order when faced with needing more data to assess chemicals under Section 6.[260]

In the penultimate step of managing the risks of commercial chemicals under the CSIA, the EPA must make safety determinations, again based "solely on considerations of risk to human health and the

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251. *Id.* § 4(a)(4)(a)(2)(B)(3).
252. *Id.* § 4(e)(1).
253. *Id.* § 4(a)(4)(e)(1)(B).
254. *Id.* § 4(a)(4)(f)(2).
255. *Id.* § 4(a)(4)(g).
256. *Id.* § 4(a)(4)(e)(1)(C)(i).
257. *Id.* § 6(2)(a).
258. *Id.* § 6(2)(b)(1).
259. *Id.* § 6(2)(b)(4)(D)(ii)(II), (III).
260. *Id.* § 6(2)(b)(5).

environment."[261] These determinations require published statements that explain EPA's decision-making, which are then subject to notice and public comment.[262] When a chemical does not meet the safety standard, the Administrator must promulgate a rule detailing the restrictions placed on it.[263] These restrictions may include warnings, recordkeeping requirements, quantity and use limits, or a ban or phase-out.[264] Notably, in contrast to the current limits placed on the EPA's discretion when choosing the risk management approach under TSCA, only a ban requires consideration of other, non-health and environment factors under the CSIA. Only when banning does the CSIA require EPA to consider the availability of "technically and economically feasible alternatives" and risks posed by them, the "economic and social costs and benefits" of the ban and other options considered, and the "economic and social benefits" of the banned chemical and its alternatives.[265] Having accepted this level of risk taking, the CSIA goes a little further, by exempting certain substances if the "lack of availability of the chemical substance would cause significant disruption in the national economy," if the use "provides a net benefit to human health, the environment, or public safety" compared to alternatives, if the use is "critical or essential" and feasible alternatives are lacking, or if needed for national security.[266] Finally, safety determinations are subject to judicial review because they are final agency actions, while safety assessments are not.[267]

Transparency and Information Gathering

The CSIA appears to take several steps forward in terms of gathering information and sharing it. Section 8 would require reporting of all information on active substances "necessary to carry out sections 4 and 6," including data "known by, or reasonably ascertainable by" the person making the report.[268] This would include processors and not just manufacturers.[269] In addition, all manufacturers must notify the EPA of chemicals currently on the TSCA inventory that have been produced or processed during the five years prior to the CSIA's enactment,[270] as a

261. *Id.* § 6(2)(c)(2).
262. *Id.* § 6(2)(c)(3), (6).
263. *Id.* § 6(2)(c)(9)(A)(i).
264. *Id.* § 6(2)(c)(9)(B)(i), (ii)(I), (iii), (iv).
265. *Id.* § 6(2)(c)(9)(D)(i), (iii), (iv).
266. *Id.* § 6(2)(c)(10)(B), (C), (D).
267. *Id.* § 6(2)(c)(11)(A), (B).
268. *Id.* § 4.
269. *Id.*
270. *Id.* § 7.

means of updating the inventory and thereby enabling EPA to determine which chemicals are active and inactive.[271] Finally, the CSIA requires the EPA to make this list available to the public.[272]

But many of Section 8's mandates are subject to confidential business information ("CBI") exemptions, which are detailed in Section 14's almost twenty pages of description.[273] Although these provisions are explicit and developed, and establish a presumption of protection for specific information about chemical manufacture and sales, mixture formulas, production and import volumes, and chemical identity if claimed and verified when submitted,[274] there are several explicit limitations placed on TSCA's current scope of protection and means of asserting it. First, safety assessments submitted under Section 6 are categorically not subject to the CBI, as well as health and safety data submitted under Sections 4 and 8(e).[275] Second, manufacturing volumes reported as ranges and general descriptions of a chemical's uses and functions are viewed as not revealing confidential information and thus not exempted.[276] Third, in order to assert CBI protection, the CSIA now requires that submitters justify their claims when making them with supporting written documentation, including showing how disclosure is likely to cause substantial harm to their competitive position and the time period necessary for protection.[277] Finally, the CSIA provides for disclosure of CBI to other federal, state, and local officials, as well as to treating medical personnel, subject to their taking appropriate steps to maintain confidentiality.[278]

Federal Versus State Regulation

Finally, the CSIA unequivocally seeks a uniform federal system for regulating chemicals in commerce. This policy is made explicit from the opening lines of Section 2's statement of findings, policy, and intent. Hence Section 18[279] explicitly says that no state may "continue to enforce a requirement for the development of test data or information . . . that is reasonably likely to produce the same data and information required under

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271. *Id.*
272. *Id.*
273. *See id.* § 13 (proposing to amend TSCA § 14 pertaining to confidential information).
274. *Id.*
275. *Id.*
276. *Id.*
277. *Id.*
278. *Id.*
279. Again, a note to the reader to avoid confusion: it is Section 15 of the CSIA that amends Section 18 of TSCA, both of which concern preemption.

section 4, 5, or 6."[280] Likewise, no state may "continue to enforce a prohibition or restriction on the manufacture . . . of a chemical substance after issuance of a completed safety determination . . . under section 6."[281] In addition, states may not enact new restrictions on chemicals that have been prioritized as low priority nor on those designated as high priority yet still pending EPA safety assessment and determination.[282] The CSIA provides three limited exceptions to this broad preemptive sweep, but they are narrowly pegged to actions taken under other federal law, needed to implement some federal obligation, or pertaining to other state environmental laws.[283] States may seek waivers from this preemption provision, which will be reviewed by the EPA for compelling local conditions and the impacts of federal delay.[284] While states are invited to participate in the creation of the prioritization framework, to provide health and safety data during safety assessments, and to receive some confidential business information from the EPA, the CSIA's preemption provision does not delineate a future sovereign lawmaking role for them in commercial chemicals regulation in the United States.

IV. DOES THE CSIA CONTAIN THE ESSENTIAL ELEMENTS FOR REFORM?

As stated at the outset of this Article, there are several key components of a comprehensive commercial chemicals law that illustrate environmental public health's regulatory pivot points, namely the 1) scope of agency authority, 2) precision of risk assessment methodologies, safety standards, and risk management measures, 3) existence of legislatively imposed deadlines for agency action, 4) public transparency via reporting and disclosure requirements, and 5) the states' role in national regulation. The CSIA contains provisions addressing these essential elements for reform, notably those attempting to remedy the clear failure of Sections 4 and 6 to permit adequate risk assessment and management. Interpretation of them by various stakeholders questions their advantages. The following analysis assesses the sufficiency of each.

EPA's New Authority

EPA's starting point for reform principles is having clear authority to base safety standards on sound science reflected in "risk-based criteria that

280. *Id.* § 15.
281. *Id.*
282. *Id.*
283. *Id.*
284. *Id.*

protect human health and the environment," thereby separating the scientific risk assessment phase from policy-based decisions on how to manage risk in the face of uncertainty.[285] With the deletion of the TSCA Section 4 language of "unreasonable risk" and "reasonably certain," CSIA would appear to have met that goal.[286] But testimony at the House committee hearing in November questioned the "good science" rhetoric used throughout the CSIA, most frequently in redrafted Sections 4 and 6. Professor Wendy Wagner testified that the language of "best available science" used to define risk assessment data (what she calls "inputs") and risk management procedural requirements ("procedures") provides "attachment" points that could be exploited as ambiguity ripe for legal challenge: "If history is any guide, entities with the most at stake (e.g., manufacturers of the least effective and least safe chemicals) will use these attachment points to delay EPA's implementation or force EPA into negotiations before, during, or after a rule is published."[287] Others have noted that a "sound science" definition would be most easily achieved by simply referencing National Academy of Sciences ("NAS") recommendations.[288]

Risk Assessment and Management Methods

EPA seeks clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns. In the CSIA, new Sections 4 and 6 grant the EPA authority to create a framework for prioritizing review of chemicals, establishing a system for tackling the backlog of unstudied

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285. *Essential Principles for Reform of Chemicals Management Legislation*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/oppt/existingchemicals/pubs/principles.html (last updated Dec. 20, 2012) (reflecting Principle 1) [hereinafter *EPA Essential Principles*].

286. *Compare* 15 U.S.C. § 2603 (2006) *and* S. 1009 § 4 (amending TSCA § 4).

287. *Testimony on S. 1009: The Chemical Safety Improvement Act Before the House Subcomm. on Env't & the Economy of the H. Comm. On Energy & Commerce* 2–4, 10 (2013), *available at* http://docs.house.gov/meetings/IF/IF18/20131113/101468/HHRG-113-IF18-Wstate-WagnerW-20131113.pdf (testimony of Wendy E. Wager, Joe A Worsham Centennial Professor, University of Texas School of Law). She analyzes at least forty pages of the bill and believes that "[t]his level of detailed legislative prescription is unprecedented" and predicts it will "cause significant delays in implementation." *Id.* at 5. In particular, she expresses concern that it would make EPA more solicitous of industry during the rulemaking process, to avoid litigation around terms, and thereby place the Agency in the position of compromising too early. *Id.* at 14.

288. *See, e.g.*, *Hearing on S. 1009, The Chemical Safety Improvement Act of 2013 Before the House Subcomm. on Env't & the Economy of the H. Comm. on Energy & Commerce*, 113th Cong. 2 (2013) (statement of Richard Denison, Senior Scientist, Environmental Defense Fund), *available at* http://docs.house.gov/meetings/IF/IF18/20131113/101468/HHRG-113-IF18-Wstate-DenisonPhDR-20131113.pdf.

chemicals on the inventory. In this way, EPA retains some flexibility and ability to exercise its discretion without being overwhelmed as it was when faced with the workload post TSCA.[289] Using the prioritization process to organize the scale of review permits EPA to focus its data collection and risk assessment efforts. For example, if the emphasis is on settings where there is more direct human exposures, then EPA can prioritize review of chemicals in children's products, consumer products in general, home products, and those likely to result in worker exposure. In contrast, if the emphasis is more on ecosystems, the Agency could prioritize review of chemicals that contribute to greenhouse gas emissions and bioaccumulation.[290] With this discretion, EPA may also choose not to study certain *de minimis* exposure pathways or study vulnerable subpopulations or aggregate exposures.

Likewise, prioritization in chemical screening—in essence, setting the scale—permits EPA to improve its risk assessment process, as the focused, iterative process leads to results that make a more predictive policymaking tool. As more data is assessed, the stronger its predictive value becomes. And also faster, for the Agency has found that it can perform half as many chemical evaluations in the first years of implementing as it can in subsequent years.[291]

Even though TSCA did not require this prioritized approach in the past, EPA created voluntary programs that used similar devices and thus has experience for implementing these CSIA provisions as proposed. The High Production Volume ("HPV") Challenge Program for new chemicals under Section 5 and the Chemical Assessment and Management Program ("ChAMP") for inventory chemicals under Section 8 are two examples of EPA's voluntary chemical screening initiatives.[292] In this way, both industry and regulator have tested these systems and can improve them in their new form under the CSIA, hopefully leading to faster start-up and a less fraught transition. In addition, U.S. manufacturers who sell in the EU will experience more uniform regulation and have decreased compliance

289. Former EPA leaders believe that maintaining flexibility is important. Exhorting Congress not to "freeze in time" elements that seem contemporaneously reasonable, they point out that the "least burdensome" language may have seemed logical in 1976 but ended up bogging down the regulatory process for thirty-six years. Aidala, *supra* note 99, at 9. "Requirements that are overly specific about how the regulatory science is conducted or evaluated might be seen as outmoded, inefficient, or inappropriate in relatively short order if Congressional appetite for TSCA legislative amendments appears only twice as often as Haley's Comet." *Id.* at 10.

290. *Id.* at 3.

291. *Id.* at 5.

292. *See* Adelman, *supra* note 26, at 391–92 (providing a detailed explanation of these programs). *See also* Markell, *supra* note 5, at 356–59 (discussing these programs).

costs, given the likelihood that the CSIA framework approach will share many similarities with REACH's system.

Externally Imposed Deadlines

The lack of firm deadlines imposed by Congress within the CSIA gives all stakeholders pause. All NGOs have noted them, regardless of whether they support or oppose the bipartisan bill, and seek their addition. In its November House committee testimony, EDF underscored this point by offering a precise timeline of when specific benchmarks could be achieved once Congress passed the CSIA. Per the drafted bill language, EDF calculates that it would take a little over three years for EPA to produce the first prioritized chemicals, a little over seven years to produce the first safety determination, and about eight-and-a-half-years until the first final rule imposing restrictions could be enacted.[293]

Several former EPA officials also mentioned the time involved in phasing in new legislative mandates and the benefits of external deadlines for achieving them, when offering their advice to Congress on how to improve TSCA. They estimated a typical six-to-eighteen-month lag time between a law's passage and the EPA administrator's ability to begin producing results.[294] They also singled out the practical benefit of externally imposed deadlines by helping to establish priorities during budget negotiations within the Agency.[295]

EPA itself notes the importance of deadlines to its work on commercial chemicals regulation. As one of its six essential principles for TSCA reform articulated before the CSIA was proposed, Principle 4 urges manufacturers and the Agency to assess and act on priority chemicals "in a timely manner."[296] It actively encourages Congress to give the EPA authority to set priorities for conducting safety reviews, and then in passive language, states that "[c]lear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of

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293. *Hearing on S. 1009*, *supra* note 289, at Attachment 2.

294. Aidala, *supra* note 99, at 4–5. ("Simply understanding the new requirements organizationally, as well as developing interpretations and policy in line with new legislative mandates, takes time. A transition period of 6–18 months is a minimum amount of time needed to begin to devise new policies and procedures and to engage stakeholders and the scientific community around these efforts. If elements of the new requirements are to be completed through some element of rulemaking, the rule development process takes at least two years minimum and typically longer.").

295. *See id.* at 4 (observing that "[o]ne unseen advantage of missing a deadline and having a court order for EPA to meet certain milestones comes in the internal budget battles within EPA").

296. *EPA Essential Principles*, *supra* note 286, at 2.

chemical reviews."[297] Read in light of past officials' advice, this could readily be understood to show openness to deadlines imposed legislatively.

Transparency and Confidential Business Information

While there is again general agreement that the CSIA improves on several of TSCA's information gathering weaknesses, there is nonetheless a sense of wariness about whether EPA's principles for reform will actually be achieved. Principle 2 places the burden on manufacturers to provide "sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard," including information addressing sensitive subpopulations.[298] When not met, EPA seeks "the necessary authority and tools" to obtain testing or other information relevant to safety determination and to do follow up assessments on listed chemicals when production volumes increase, new uses are developed, or new information on potential hazards or exposures occurs.[299] The Agency also wants to extend its information gathering mandate to downstream processors and users of chemicals.[300] EPA also seeks stricter requirements for confidential business information ("CBI") claims by manufacturers, including initial and ongoing substantiation of claims, health and safety data never treated as CBI, and the ability to share appropriately with other governments (local, state, and foreign) subject to protections, when needed to protect public health and safety.[301] Overall, the CSIA as drafted captures all of these principles. Given the impact that REACH registration has had on many U.S. companies, it would appear that the commercial chemicals industry is ready to embrace them in U.S. law. The bigger challenge will be in implementation, where EPA will need the staffing to change reporting habits forged under TSCA.

The States' Role

One of the biggest topics of debate surrounding the bipartisan attempt to reform TSCA has been whether the CSIA would preempt state law. Senator Barbara Boxer (D-CA), Chair of the Committee on Environment and Public Works ("CEPW"), has expressed her concern that the bill would preempt state laws, including California's Proposition 65. In late July,

297. *Id.*
298. *Id.* at 1.
299. *Id.*
300. *Id.* at 2.
301. *Id.*

2013, at the hearing she organized,[302] much of the discussion focused on whether the CSIA would preempt existing state laws and prevent states from promulgating additional laws regulating toxic chemicals. Competing testimony and reports were introduced, including reports from the Congressional Research Service ("CRS") and the Republican and Democratic staffs, as well a letter from the attorneys general of nine states.

The Republican CEPW minority staff paper began by asserting in bold face that the CSIA "will never preempt the traditional state roles of regulating water quality, air quality, waste treatment, or disposal and does not preempt wholesale state regulatory programs," but follows in regular text that "in some instances" state chemical-specific regulations could be preempted "in a narrowly tailored way."[303] It specifically claims that the CSIA would not entirely preempt the comprehensive programs in California, Maine, Minnesota, and Washington, but only to the degree that their chemical-specific regulations differ.[304] While agreeing that the CSIA would not entirely preempt existing state laws and that determinations would be made on a chemical-specific basis, the Democratic CEPW majority staff paper drew a clearer line between Section 18's impact on existing and new state laws; specifically, new state laws prohibiting or restricting chemicals would be preempted by an EPA prioritization decision, while current state law would remain valid until EPA made a final safety determination.[305] In contrast, the CRS report adheres most closely to the structure of the CSIA's drafted preemption provision, stating that it would preempt existing and new state law that requires information and testing "reasonably likely to produce the same" as the federal act; prohibits or restricts a chemical after a final federal safety determination; and requires a new use notification if also required by TSCA.[306] The CRS interprets new state law preemption by EPA prioritization and the non-

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302. *Strengthening Public Health Protections by Addressing Toxic Chemical Threats: Hearing Before the S. Comm. on Env't & Pub. Works,* 113th Cong. (2013), *available at* http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=15d8775e-f02a-6ab7-1973-8ea6ce1196c7.

303. S. COMM. ON ENV'T & PUB. WORKS, 113TH CONG., MYTH VS. FACT: THE CSIA AND PREEMPTION (Minority Staff Paper), *available at* http://www.lawbc.com/uploads/docs/GOPTSCA.pdf (last visited Feb. 10, 2014).

304. *See id.* (stating EPA has authority under TSCA to preempt state laws that are in conflict with federal regulations).

305. S. COMM. ON ENV'T & PUB. WORKS, 113TH CONG., CLAIMS VS. FACTS ABOUT THE CHEMICAL SAFETY IMPROVEMENT ACT (CSIA) (Majority Staff Paper), *available at* http://www.lawbc.com/uploads/docs/DEMTSCA.pdf (last visited Feb. 10, 2014).

306. LINDA-JO SCHIEROW, CONG. RESEARCH SERV., R43136, PROPOSED REFORM OF THE TOXIC SUBSTANCES CONTROL ACT (TSCA) IN THE 113TH CONGRESS: S. 1009 COMPARED WITH S. 696 AND CURRENT LAW 9 (2013), *available at* http://www.lawbc.com/uploads/docs/R43136.pdf.

preemption of other facets of state laws in the same manner as the majority staff paper.[307]

The Attorneys General ("AG") from California, Connecticut, Delaware, Maryland, Massachusetts, New Mexico, Oregon, Vermont, and Washington expressed "deep concerns about [CSIA's] unduly broad preemption language" that could "seriously jeopardize public health and safety by preventing states from acting to address potential risks of toxic substances and from exercising state enforcement powers."[308] The AGs highlighted their focus on children's health and the historic role that states have played in chemical regulation, ranging from California's ban on certain flame retardants,[309] limits on VOCs in consumer products,[310] Proposition 65,[311] and the Safe Cosmetics Act[312] to Vermont's laws banning lead in consumer products,[313] brominated and chlorinated flame retardants,[314] phthalates,[315] and bisphenol A.[316] Like the CRS and CEPW majority staff, these state AGs read the CSIA's preemption provision as keeping them from enforcing "existing laws or from adopting new laws regulating chemicals that EPA designates as 'high priority' months or even years before *any* federal regulations protecting health and the environment become effective."[317] They argued that displacing state law this way is unwise, because state efforts may complement federal ones, states are in a particularly good position to protect vulnerable populations, and state experience may serve as "templates for national standards,"[318] invoking Justice Brandeis's image of states as laboratories for new laws.

Given the different readings of the scope of the CSIA's preemption provision, the language needs clarification, at a minimum. How broadly existing state law would be displaced has not been clearly interpreted. While only a handful of states have enacted comprehensive chemicals

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307. *Id.* It also agrees with the waiver provision reading. *See id.* at 74 (stating that S. 1009 authorizes states or political subdivisions to apply for exemptions from preemption).

308. Letter from State Att'ys Gen. of Cal., Conn., Del., Haw., Md., Mass., Or., Vt., & Wash. to Chairwoman Boxer & Majority Comm. Members of the S. Comm. on Env't & Pub. Works (July 31, 2013), *available at* http://oag.ca.gov/system/files/attachments/press_releases/TSCA%20Multistate%20Letter%20_FINAL_.pdf? [hereinafter *AG Letters*].

309. CAL. HEALTH & SAFETY CODE § 108922 (2005).

310. CAL. CODE REGS. tit. 17, § 94509(a) (2007).

311. CAL. HEALTH & SAFETY CODE § 25249.5–.13 (2003).

312. *See* CAL. HEALTH & SAFETY CODE § 111791 (2006) (naming the California Safe Cosmetics Act of 2005).

313. *See* VT. STAT. ANN. tit. 9, § 2470f (2006) (prohibiting lead in children's products).

314. *Id.* § 2973–2974.

315. VT. STAT. ANN. tit. 18, § 1511(b), (c) (2012).

316. *Id.* § 1512(b), (c)(1).

317. AG Letters, *supra* note 309, at 1–2.

318. *Id.* at 2.

legislation, many more have passed statutes that regulate individual chemicals. In light of the well-documented breadth of state law currently in force, this ambiguity would have an impact.

More importantly, as the AG letter underscored and Senator Lautenberg's past Chemical Safety Acts spelled out, it is possible for the states to harmonize their commercial chemicals laws under a modernized TSCA, with preemption of state law limited to those that fall below a federal minimum or floor, and state laws that exceed federal minimums permitted to stand. This is a common preemption device in federal law and serves to strengthen both legal standards and enforcement. It also contributes to the dynamic development of law, as state regulatory initiatives are tested out for possible inclusion in amended federal laws. To do this would require changing Section 18 as drafted. Given that Senator Boxer is on the record opposing the current language, this change may be needed in order to move the bill out of committee.

Important Errata

Although they fall outside these analytical pivot points, three important aspects of commercial chemicals regulation are not clearly addressed in the CSIA and bear mentioning. First, on the practical side of implementing legislation, is funding. This division of EPA has been chronically underfunded, according to all observers.[319] TSCA currently enables EPA to charge fees to the regulated entity for activities like PMN review.[320] Senator Lautenberg's bills explicitly updated this authority, yet the CSIA is silent on this point. Arguably fees will be implicitly reauthorized if the CSIA is passed, but being explicit about funding seems the wiser course.

Second, two major substantive oversights leap out from the CSIA: the absence of green chemistry initiatives and coordination with the

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319. Given that environmental health is a subset of public health, and that public health consumes a very small proportion of health care expenditures in the United States, this shouldn't surprise. *See* Greenwood, *supra* note 120 (noting the underfunding of EPA). Government spending on public health activities represents a tiny fraction of U.S. per capita national health expenditures, decreasing from 3.2% to 2.7% from 2002 to 2012. *Historical Spending*, CTR. FOR MEDICARE AND MEDICAID SERVS., http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf (last visited Jan. 9, 2014) (itemizing the "public health activities" spending figures in Table 1).

320. Yet EPA asks for "a sustained source of funding for implementation" in future reform efforts. *EPA Essential Principles*, *supra* note 286, at Principle 6. ("Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.").

international law on toxic substances. As EPA affirmed in one of its essential reform principles, "the design of safer and more sustainable chemicals, processes, and products should be encouraged and supported."[321] Currently EPA operates a number of voluntary programs to increase the design, manufacture, and use of lower risk chemical products and processes, notably the Green Chemistry Challenge.[322] Senator Lautenberg's Safe Chemicals Act specifically supported green chemistry.[323] More could be done within specific provisions of the CSIA to integrate these voluntary programs into the updated TSCA, including mandating industry's consideration of green chemistry approaches when providing review data on specific substances.

Finally, while TSCA does not refer to coordination with international toxics law, given the lack of it in the 1970s, today there is not only useful comparative law from the European Union and Canada,[324] but also several major international treaties on point.[325] Although the United States has not signed these international treaty regimes, and so is not bound to incorporate their provisions into national law, TSCA's modernization attempts via the CSIA could benefit from the collective and individual experiences of the countries which have, just as it has learned from EU and Canadian domestic toxics law.[326]

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321. *Id.* at Principle 5.

322. *Green Chemistry*, U.S. ENVTL. PROT. AGENCY, http://www2.epa.gov/green-chemistry (last updated Dec. 12, 2013).

323. *See* S. 847 § 26 *and* text accompanying note 142; *see also* S. 696 §§ 31–32 *and* text accompanying note 142.

324. *See supra* pages 26 to 30.

325. *See generally* SYNERGIES, http://synergies.pops.int/Home/tabid/813/mctl/ViewDeatails/EventModID/8849/EventID?439?xmid/8753/language/en-US/Default.aspx (last visited Jan. 25, 2014) (including the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade). *See also* BASKUT TUNCAK, CTR. FOR INT'L ENVTL. LAW, DRIVING INNOVATION (2013), *available at* http://www.ceil.org/Publications/Innovation_Chemical_Feb2013.pdf (focusing on both international and comparative law's potential impacts on U.S. law).

326. *See* BEVERIDGE & DIAMOND, P.C., UPDATE ON TSCA DEVELOPMENT IN CONGRESS AND AT EPA (Mar. 22, 2012), *available at* http://www.bdlaw.com/assets/attchments/BD%20Client%20Alert%20-%20Update%20on%20TSCA%20Developments%20in%20Congress%20and%20at%20EPA.pdf (demonstrating that REACH is a potential source of data, whether shared by EU authorities or by U.S. companies who have registered their products with ECHA). Similarly harmonized data request substance and format could be useful for the multinational chemicals corporation, in the spirit of the Global Harmonized System for labeling and chemical classification. Aidala, *supra* note 99, at 8.

CONCLUSION

Modernizing TSCA is important and timely. First, it is woefully out of date with current scientific knowledge. As Professor Adelman has observed, "[t]he past 30 years have demonstrated that toxics regulation is inextricably tied to scientific understanding. Science informs the architecture of regulatory regimes and supplies the factual ground for agency decisions."[327] Second, TSCA lags behind the commercial chemicals laws of our major trading partners, and potentially sets up the United States to become the weak receiving state for products that fail to meet the more rigorous registration and testing requirements in REACH. Third, it is increasingly out of step with public sentiment. Even though TSCA's "unreasonable risk of harm" standard has hamstrung EPA when trying to act on evolving scientific understanding, it has proven largely irrelevant to the growing public debate about the health impacts of commercial chemicals. Fueled by research funded by the NIEHS and NCEH, whose findings are disseminated broadly via NGOs like EWG, an increasingly large segment of the population has been mobilized to change laws at the local level and affect industry practice through consumer preference. Almost forty years after TSCA's enactment, people in the U.S. are coming to understand that the federal government has been slow to protect them,[328] and that while some state governments are more proactive than others, in the end, they have to choose individually how to exercise precaution in the face of scientific uncertainty. As more people do this for themselves, the precautionary principle becomes less abstract as individual understanding of its trade-offs matures.

How we modernize TSCA is equally important. Can the bipartisan CSIA get us closer to TSCA's fundament goal of "preventive medicine"? Now almost forty years on, we have witnessed a new wave of political will to rebalance economic development with protection of health and the environment humans inhabit.[329] Importantly, when it comes to how we recalibrate our approach to the synthetic chemicals that surround us, that political will is supported by a vibrant civil society infrastructure of public health and environmental NGOs. This new wave understands better the

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327. Adelman, *supra* note 26, at 380–81 (arguing that toxicogenomics as a means of solving scientific uncertainty is far off in the future, so sound toxic regulation should instead grant discretion to agencies to manage "unavoidable uncertainty," using quantity sold annually, environmental persistence, and ability to bioaccumulate as proxies for chemical risk).

328. Some have argued that TSCA's ineffectiveness has made the U.S. public wary of chemicals overall. *See* Deborah Blum, *A Chemical (Battle) Cry,* WIRED (May 15, 2011), http://wired.com/wiredscience/2011/05/a-chemical-battle-cry/.

329 *See generally* JAMES GUSTAVE SPETH, THE BRIDGE AT THE EDGE OF THE WORLD: CAPITALISM, THE ENVIRONMENT, AND CROSSING FROM CRISIS TO SUSTAINABILITY (2012).

importance of connecting individual "everyday environmentalism" that seeks to make change from the bottom up with the top-down public health goals of federal legislation like TSCA. In this way, grassroots changes add a layer of awareness to policymaking that not only sharpens the choice and scope of regulatory tools, but potentially makes the resulting lawmaking more durable because it more effectively codifies behavioral norms.

In the early 1970s, the CEQ observed that political support for a cleaner environment (as evidenced in the recently enacted federal environmental statutes) "signaled a fundamental redirecting of our economy and society" and simultaneously opened a Pandora's Box of questions on how to achieve it.[330] "[H]aving decided that environmental quality is a valuable good, we have to decide more precisely how much we want, how we will pay for it, and who will pay for it. These questions often require complicated analyses involving difficult tradeoffs."[331] Speaking this way to the U.S. public through its annual report almost forty years ago, the CEQ reminds us well of the complexities of addressing the "environmental disease" that Train called "the disease of the century."[332]

Commercial chemicals are now better understood in terms of chronic, small, and multiple exposures that disproportionately affect some populations, like the young, old, and immunocompromised. In addition, we have greater knowledge of how these chronic exposures to multiple chemicals can have both cumulative and synergistic effects. With advances in genomic science, many believe that the emerging study of epigenetics will reveal individual genetic reactions to varying quantities, concentrations, and combinations of chemical exposures. We are now poised to grapple with the "environmental disease" of the 21st century equipped with more data connecting the chemicals we use in commerce with a greater variety of illnesses.

The CSIA's proposed changes to TSCA are a solid next step. They create a regulatory framework that prioritizes chemical regulation based solely on scientific understanding of these substances' impacts on human health and the environment. They then manage the risks posed by high priority chemicals through policy tools that balance economic, social, environmental, and health tradeoffs, thereby reflecting our collective tolerance for taking precaution. They permit more transparency and hence

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330. Council on Environmental Quality, ENVIRONMENTAL QUALITY: FOURTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 73 (1973) (*quoted in* Markell, *supra* note 5, at 334).

331. Markell, *supra* note 5, at 334–35.

332. Press Release, Envtl. Prot. Agency, Train Sees New Toxic Substances Law as "Preventative Medicine" (Oct. 21, 1976), *available at* http://www2.epa.gov/aboutepa/train-sees-new-toxic-substances-law-preventive-medicine.

public involvement by individuals, civil society, and subnational public bodies (although more changes will be needed here). These components of the CSIA will help us better manage the scientific uncertainty inherent in regulating commercial chemicals. Through them, we sharpen our focus on public health, as TSCA's language tells us Congress intended, and work to make environmental public health policymaking more preventive. The CSIA offers better living through chemistry and chemistry regulation. It's not perfect. But it's better. And it sets us on the path of making wiser environmental public health law for the twenty-first century.