

# Jumping the Pond: Transnational Law and the Future of Chemical Regulation

Noah M. Sachs\*

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\* Associate Professor, University of Richmond School of Law and Director, Robert R. Merhige, Jr. Center for Environmental Studies. Email: nsachs@richmond.edu. Many thanks to the participants at the Environmental Law Workshop at Tel Aviv University, where this paper was presented in December 2008, and to the participants at the Virginia Junior Faculty Forum, where this paper was presented in May 2008. I also want to thank faculty at the University of Richmond for suggestions at a faculty colloquium, as well as faculty and students at Loyola University College of Law in New Orleans, where an early draft of this paper was presented in February 2008. James Salzman, Douglas Kysar, David Wirth, John Applegate, Ninja Reineke, Corinna Lain, Jim Gibson, and Jessica Erickson provided helpful comments on drafts, and Leslie McCall and Elizabeth Bushnell Myers provided invaluable research assistance.

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## INTRODUCTION

Chemical regulation is the lapdog of American environmental law. The primary chemical regulatory statute, the Toxic Substances Control Act of 1976 (“TSCA”),<sup>1</sup> lacks the sharp regulatory bite of most U.S. environmental laws. Virtually every expert panel that has examined the U.S. system of chemical regulation has concluded that it inadequately protects public health and the environment.<sup>2</sup> Yet despite a chorus of criticism<sup>3</sup> and growing concern over the health effects of chemical exposure, TSCA has been remarkably resistant to reform. It is among the weakest, and the least amended, of all of the federal environmental statutes.<sup>4</sup>

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1. 15 U.S.C. §§ 2601–92 (2006).

2. See Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629, 636 n.40 (2008) (listing expert studies that express concern over the lack of information about adverse effects of chemicals); see also David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 ECOLOGY L.Q. 623, 641 n.59 (listing Government Accountability Office reports critical of TSCA).

3. For scholarly critiques of TSCA, see John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 734–40 (2008) [hereinafter Applegate, *Synthesizing TSCA and REACH*]; John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 315–30 (1991) [hereinafter Applegate, *The Perils of Unreasonable Risk*]; Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1822–25 (1989); Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 313–15 (1999); Wendy Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1663–705 (2004) [hereinafter Wagner, *Commons Ignorance*]; Wagner, *supra* note 2, at 631–37.

4. See *Oversight on the Toxic Substances Control Act and the Chemicals Management Program at EPA: Hearing Before S. Comm. Environment & Public Works*, 109th Cong. 2 (2006)

Chemical regulation in the United States is now being transformed, however, through the transnational effects of foreign legislation. In 2006, the European Union (“EU”) enacted ambitious legislation called Registration, Evaluation, and Authorization of Chemicals (“REACH”).<sup>5</sup> REACH is the pit bull of global chemical regulation. It accomplishes, in Europe, reforms in chemical regulation that have long been advocated by American environmental law scholars.<sup>6</sup> REACH is the first major chemical regulatory regime in the world to shift the burden of proof on chemical safety from government to manufacturers, and it requires safety testing for thousands of chemicals on which there is limited or non-existent toxicity data in the United States.<sup>7</sup> This vast new information from Europe will enrich the data-poor environment in which the United States has attempted to regulate chemicals since the mid-1970s. Europe’s internal environmental law is going global, and the implementation of REACH in Europe now significantly increases the likelihood that chemical regulation in the United States will be reformed.

The extraterritorial impact of REACH is just one example of a larger trend in which the EU is increasingly setting de facto global standards through its internal environmental legislation. The EU is the world’s largest economy, and decisions in Brussels, applicable throughout the twenty-seven Member States of the EU, are affecting how products are designed and manufactured from Boston to Beijing. Since 2000, the EU has embarked on ambitious environmental lawmaking in areas such as chemical regulation, energy efficiency, hazardous waste, and climate change. Europe has in many cases supplanted the United States as the leading originator and exporter of

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[hereinafter *Hearing*] (testimony of Lynn R. Goldman, Professor, Environmental Health Science, Johns Hopkins University, Bloomberg School of Public Health) (“TSCA is probably the EPA statute that has seen the least change in the last 30 years.”).

5. Commission Regulation 1907/2006, 2006 O.J. (L396) 1 (EC) [hereinafter REACH].

6. See, e.g., John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365, 1389–90 (2008) (advocating placing the burden of proof of chemical safety on chemical manufacturers); Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J.L. & MED. 119, 128–35, 151–54 (arguing that TSCA’s confidential business information provisions have been abused and need reform).

7. See GOV’T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISK OF TOXIC CHEMICALS 7 (2007), available at <http://www.gao.gov/new.items/d07825.pdf> (“TSCA does not require companies to develop information for either new or existing chemicals, whereas REACH generally requires companies to submit and, in some circumstances, requires companies to develop such information for both kinds of chemicals.”).

environmental law innovation.<sup>8</sup> With the United States' competitiveness and global influence at stake, scholars and policymakers need to understand the mechanisms through which European environmental law is affecting the United States and the globe.<sup>9</sup>

This Article demonstrates how the transnational interactions of the EU and the United States, the two "green giants" of environmental law,<sup>10</sup> are shaping the future of chemical regulation. I bring two distinct literatures into conversation: domestic environmental law scholarship that has focused on problems of data generation and information management in the U.S. regulatory process,<sup>11</sup> and a separate international law and political science literature that has focused on the transnational interaction of

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8. The rise of Europe as a global standard-setter is a reversal of past trends in which U.S. innovations in domestic environmental law influenced European law. See GIANDOMENICO MAJONE, REGULATING EUROPE 53 (Jeremy Richardson ed., 1996) (explaining that Europe has often benefited from the results of U.S. regulatory experiments). Examples of European imports of U.S. innovations include environmental impact review, tradeable emissions permits, pollution taxes, and advocacy of cost-benefit analysis in environmental law. *Id.*

9. The rising European influence in global environmental affairs has been documented in both scholarly literature and the popular media. See, e.g., MARK SCHAPIRO, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS AND WHAT'S AT STAKE FOR AMERICAN POWER 8–10 (2007) (describing the increasing influence of EU environmental regulation in the United States); Ragnar E. Lofstedt & David Vogel, *The Changing Character of Regulation: A Comparison of Europe and the United States*, 21 RISK ANALYSIS: INT'L J. 399, 399–400 (2001) (listing European regulatory methods that have been adopted by the United States); Henrik Selin & Stacy D. VanDeveer, *Raising Global Standards: Hazardous Substances and E-Waste Management in the European Union*, ENVIRONMENT, Dec. 2006, at 6, 7 (stating that the EU has become a "global leader on hazardous substances policy"); David Wirth, *The EU's New Impact on U.S. Environmental Regulation*, FLETCHER F. WORLD AFF., Summer 2007, at 91, 103–04 (arguing that EU policy is increasingly influencing U.S. environmental regulation); Tobias Buck, *Standard Bearer: How the European Union Exports Its Laws*, FIN. TIMES, July 10, 2007, Analysis, at 13 (describing the increasing global adoption of EU environmental innovations and the political and economic mechanisms through which the EU is exerting a global influence); Mark Schapiro, *New Power for 'Old Europe'*, NATION, Dec. 27, 2004, at 11 (discussing the significance of REACH for the U.S. chemical industry).

10. Sheldon Kamieniecki & Michael E. Kraft, *Series Foreword to GREEN GIANTS? ENVIRONMENTAL POLICIES OF THE UNITED STATES AND THE EUROPEAN UNION*, at vii (Norman J. Vig & Michael G. Faure eds., 2004).

11. See, e.g., Applegate, *supra* note 6, at 1377–1406 (discussing the gap between the supply and demand of data on chemical toxicity); Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 197–209 (2004) (arguing that new information technologies will help to close data gaps and improve environmental protection); Douglas A. Kysar & James Salzman, *Foreword: Making Sense of Information for Environmental Protection*, 86 TEX. L. REV. 1347, 1350–61 (2008) (arguing that a central concern of environmental law is the development of information for regulatory decision making); James Salzman, *Beyond the Smokestack: Environmental Protection in the Service Economy*, 47 UCLA L. REV. 411, 480–88 (1999) (advocating a variety of informational tools for environmental protection, with a focus on retailers as a leverage point for environmental improvement); Wagner, *supra* note 2, at 640–46 (advocating using competition within industries to produce information on chemical toxicity).

domestic regulatory regimes.<sup>12</sup> By drawing on both sources, I show how transnational developments in environmental law can help repair the broken chemical regulatory regime in the United States.

This Article proceeds in two main parts. In Part I, I argue that REACH represents a significant advance over TSCA for addressing chemical risks to public health and the environment. TSCA has been crippled by a data gap. It imposes stringent informational demands on regulatory authorities to restrict or ban a chemical, yet the statute provides few incentives for chemical manufacturers to develop the information necessary for effective risk assessment and regulation. Nearly thirty-five years after TSCA's enactment, we still lack detailed toxicity data for the vast majority of the chemicals that have been introduced into commerce in the United States.<sup>13</sup> We are conducting an uncontrolled experiment on the health effects of synthetic chemicals, with humans as the test subjects.

REACH, in contrast to TSCA, frames incentives in favor of research and disclosure by making the provision of toxicity data a condition of access to the €537 billion European chemical market—the largest in the world.<sup>14</sup> REACH also shifts certain burdens of proof from government to industry, makes some hazardous chemicals subject to government authorization, and focuses systematically on identifying and promoting safer substitutes for hazardous chemicals.<sup>15</sup>

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12. See, e.g., DANIEL W. DREZNER, *ALL POLITICS IS GLOBAL: EXPLAINING INTERNATIONAL REGULATORY REGIMES* 43–51 (2007) (discussing global regulatory coordination); Frank Dobbin et al., *The Global Diffusion of Public Policies: Social Construction, Coercion, Competition, or Learning?*, *ANN. REV. SOC.* 449, 450–62 (2007) (reviewing the literature on transnational diffusion of policies); David Lazer, *Regulatory Interdependence and International Governance*, 8 *J. EUR. PUB. POL'Y* 474, 474–82 (2001) (discussing regulatory interdependence of states). For earlier examples of this literature, see RICHARD ROSE, *LESSON-DRAWING IN PUBLIC POLICY: A GUIDE TO LEARNING ACROSS TIME AND SPACE* 103–10 (1993); George Hoberg, *Sleeping with an Elephant: The American Influence on Canadian Environmental Regulation*, 11 *J. PUB. POL'Y* 107, 107–25 (1991); Peter Gourevitch, *The Second Image Reversed: The International Sources of Domestic Politics*, 32 *INT'L ORG.* 881, 892–93 (1978).

13. In 1994, the U.S. General Accounting Office estimated that EPA had reviewed the risks of only 2 percent of the 62,000 “existing” chemicals that had been introduced before 1979. U.S. GEN. ACCOUNTING OFFICE, *TOXIC SUBSTANCES CONTROL ACT: LEGISLATIVE CHANGES COULD MAKE THE ACT MORE EFFECTIVE* 3 (1994), available at <http://archive.gao.gov/t2pbat2/152799.pdf>. Since 1994, additional screening-level data has been developed for approximately two thousand High Production Volume chemicals, *infra* text accompanying notes 65–67, but data is still lacking for the vast majority of chemicals.

14. The sales figures, compiled by the European Chemical Industry Council, are from 2007. See EUROPEAN CHEMICAL INDUSTRY COUNCIL, *PROFILE OF THE CHEMICAL INDUSTRY* (2009), [http://www.cefic.org/factsandfigures/level02/profile\\_index.html](http://www.cefic.org/factsandfigures/level02/profile_index.html).

15. See EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *REACH IN BRIEF* 18 (2007) [hereinafter *REACH IN BRIEF*], available at [http://ec.europa.eu/environment/chemicals/reach/pdf/2007\\_02\\_reach\\_in\\_brief.pdf](http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf) (outlining data submission and authorization procedures of

While REACH still faces significant implementation challenges, this next-generation chemical regulation is likely to increase, at reasonable cost, protections for public health and the environment relative to U.S. law. Recent scholarship has emphasized elements of continuity between TSCA and REACH.<sup>16</sup> I argue, in contrast, that REACH represents a significant departure from the American paradigm of chemical regulation and offers an important model for policy reform in the United States.

Part II examines chemical regulation through the lens of transnational regulatory theory and assesses the likely impacts of REACH on the United States. I show how legal norms, initially embodied in domestic legislation in one jurisdiction, can be transplanted horizontally to other jurisdictions. This process begins with what I call “regulatory turbulence,” or extraterritorial political, commercial, and legal effects from internal legislation. In response to regulatory turbulence, other countries may pursue a path of regulatory coordination with the originating jurisdiction, overtly oppose the external influence (as in a trade conflict), or continue to maintain divergent environmental standards.

The response of the United States to regulatory turbulence from REACH appears to be shifting from conflict to coordination. The United States is unlikely to adopt every component of REACH in the coming years. But REACH-like reforms may be enacted in U.S. law as major U.S. firms comply with REACH’s requirements, industry objections to TSCA reform become weaker, and the toxicity data developed under REACH becomes widely available in the United States.

This last factor—the transnational effect of information disclosure—has not received significant attention in the literature on transnational regulatory interactions, but it is likely to be a major driver of reform in U.S. chemical policy. Part II fills this gap in the literature by analyzing the transnational consequences of information disclosure regimes. With the EU acting as a global chemical information officer, disclosures in the EU are likely to provide needed

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REACH and stating that authorization may be withdrawn if a suitable substitute becomes available).

16. See, e.g., Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 721 (despite some differences, “REACH follows many of TSCA’s fundamental approaches to chemical regulation.”); Ortwin Renn & E. Donald Elliott, *Precautionary Regulation of Chemicals in the U.S. and EU*, in *THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE U.S. AND EUROPE* (Jonathan B. Wiener et al. eds., forthcoming 2009) (finding similarities in the levels of precaution embodied in the European and U.S. systems of chemical regulation).

toxicity data in the United States. They will also alter the political playing field on which U.S. interest groups battle for influence.

TSCA reform is not inevitable, of course. The future of TSCA rests with the Obama Administration and with Congress, which have many competing priorities. Yet even if TSCA is amended only partially, or not at all, REACH could still have a beneficial impact on the \$637 billion U.S. chemical marketplace<sup>17</sup> by prompting firms to reduce the use of hazardous substances, spurring global product innovation, and empowering consumers with health and safety information. REACH may also lead to a reevaluation of the toxic hazards that are regulated under a wide variety of U.S. environmental laws. One thing is clear: in examining the future of chemical regulation, we can no longer rely on a single-jurisdiction analysis.

### I. TSCA AND REACH: STRONGER CHEMICAL REGULATION ACROSS THE POND

Chemical regulation involves collecting data on the physical and toxicological properties of chemicals, conducting risk assessments, and restricting chemicals deemed to pose unacceptable risks to human health or the environment. Chemical regulation governs the “front-end” of the product life cycle, as it applies to chemicals marketed as useful products; it can be distinguished from the variety of environmental laws in the United States and EU regulating “back-end” chemical issues, such as waste disposal or toxic emissions from manufacturing processes. Ideally, chemical regulation should serve as an early-warning system, alerting regulators to a chemical’s risks before it is widely dispersed through use in consumer goods or industrial processes, or through disposal in the environment.<sup>18</sup>

For decades, however, chemical regulation on both sides of the Atlantic has been plagued by a data drought: scientists and regulators lack the risk data that would allow them to assess whether exposure to a particular chemical, or chemicals in combination, is causing harm. More than 82,000 synthetic chemicals have been introduced into commerce in the United States,<sup>19</sup> and we produce or import over 73

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17. Standard and Poor’s Industry Surveys: Chemicals (Jan. 2008), *available at* [homepage.smc.edu/thomas\\_phillip/rpt/Chemicals.pdf](http://homepage.smc.edu/thomas_phillip/rpt/Chemicals.pdf) (2006 sales figures).

18. *See* S. REP. NO. 94-698, at 5 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4495 (“The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest.”).

19. U.S. GOV’T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 2 (2005), *available at* <http://www.gao.gov/new.items/d05458.pdf>.

billion pounds of chemicals *per day*.<sup>20</sup> More than 100,000 chemicals have been introduced in the EU.<sup>21</sup> Human intake of chemicals is widespread. Recent biomonitoring studies, which analyze chemical contaminants in human tissue samples, have confirmed that synthetic chemicals are ubiquitous in the human body.<sup>22</sup> Industrial chemicals have been identified in the umbilical cord blood of developing fetuses<sup>23</sup> and in human breast milk.<sup>24</sup> Chemicals once thought to be safely contained in products, such as perfluorinated compounds used in textiles, cookware, and food packaging, are now present in virtually all people.<sup>25</sup> And while exposure does not equal harm, detailed toxicity data that could connect exposure and harm has been scarce.

In both jurisdictions, toxicity data has long been unavailable—not because scientists are incapable of obtaining it, but because existing laws provide few requirements, or even incentives, to find it. Weak legislation has failed to counteract chemical manufacturers' underlying economic incentive to avoid testing,<sup>26</sup> and after decades of

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20. See U.S. EPA, 2006 INVENTORY UPDATE REPORTING: DATA SUMMARY 15 (2006), available at [http://www.epa.gov/iur/pubs/2006\\_data\\_summary.pdf](http://www.epa.gov/iur/pubs/2006_data_summary.pdf) (reporting approximately twenty-seven trillion pounds of chemicals produced or imported in the United States in 2005). This figure is likely an underestimate of total U.S. chemical production, because low-volume chemical production, below 25,000 pounds per year at one site, did not need to be reported to EPA. *Id.* at 1.

21. REACH IN BRIEF, *supra* note 15, at 3.

22. In a 2003 biomonitoring study, the Environmental Working Group found that of 210 synthetic chemical substances analyzed in a population of volunteers, 167 synthetic chemicals were present in the tissue of at least one person. JANE HOULIHAN ET AL., ENVTL. WORKING GROUP, BODY BURDEN: THE POLLUTION IN PEOPLE 3 (2003), available at [http://archive.ewg.org/reports/bodyburden1/pdf/BBreport\\_final.pdf](http://archive.ewg.org/reports/bodyburden1/pdf/BBreport_final.pdf). On average, participants in the study had fifty-three carcinogens, fifty-eight known endocrine disrupting chemicals, fifty-three immunotoxins, and fifty-five chemicals linked to birth defects or abnormal development in their tissue samples. *Id.* For a detailed study of human exposure to chemicals, see generally NAT'L CTR. FOR ENVTL. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION, THIRD NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS 13–443 (2005).

23. See JANE HOULIHAN ET AL., ENVIRONMENTAL WORKING GROUP, BODY BURDEN: THE POLLUTION IN NEWBORNS 13–15 (2005), available at [http://ewg.org/reports\\_content/bodyburden2/pdf/bodyburden2\\_final-r2.pdf](http://ewg.org/reports_content/bodyburden2/pdf/bodyburden2_final-r2.pdf).

24. Kim Hooper & Thomas A. McDonald, *The PBDEs: An Emerging Environmental Challenge and Another Reason for Breast-Milk Monitoring Programs*, 108 ENVTL. HEALTH PERSP. 387, 387 (2000).

25. RICHARD A. DENISON, ENVTL. DEF. FUND, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION, AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS, at I-3 (2007).

26. Chemical manufacturers have little incentive to conduct toxicity testing voluntarily because toxicity data is a form of informational commons. Wagner, *Commons Ignorance*, *supra* note 3, at 1640–41. The benefits of additional toxicity information inure to society as a whole, while the costs of toxicity testing are privately borne. See *id.* at 1640 n.61 (stating that toxicity information is a public good and that providers “are not capturing the full economic benefit” of their production). No single manufacturer has an incentive to contribute to the informational commons because disclosure of toxicity data can lead to reductions in sales or to potential civil

chemical regulation on both sides of the Atlantic, we are still confronted with a persistent data drought.

This data drought is a central concern of information-and-environment literature, a subfield of environmental law scholarship that addresses the role of information management and disclosure in environmental protection. Scholars such as Wendy Wagner, John Applegate, Douglas Kysar, Jim Salzman, Rena Steinzor, and Mary Lyndon have demonstrated that data gaps are often the result of legislative choices and regulatory ossification, rather than the result of any inherent inability of science to obtain the data.<sup>27</sup> For example, regulators often operate in data-poor environments because of trade secret protections, high statutory barriers to collecting data, stringent judicial review requirements, and endless disputes over data accuracy and quality control.<sup>28</sup> Accordingly, changes to the way environmental information is gathered and managed in the regulatory process could produce breakthroughs in understanding of toxic risks and in protection of public health and the environment.

This Part argues that REACH offers a superior model for developing and managing such information on toxic risks. It begins with a critical examination of TSCA and then assesses the new paradigm of regulation embodied in REACH.

#### A. TSCA's Troubles

Congress enacted TSCA in 1976 to generate “adequate data” on the effects of chemicals and to provide “adequate authority” to EPA to regulate chemicals that “present an unreasonable risk of injury to

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liability. *Id.* at 1636–37. Government regulation therefore becomes necessary to overcome what Wagner has identified as manufacturers’ “strategic ignorance,” their underlying incentive not to find and disclose toxicity information. *Id.* at 1682, 1726.

27. See Applegate, *supra* note 6, at 1395–96 (advocating reducing data demand by lowering the informational predicates for regulatory action); Esty, *supra* note 11, at 142 (arguing that high transaction costs for private parties to collect environmentally-relevant information suggest the need for regulatory agencies to fill the gaps); Kysar & Salzman, *supra* note 11, at 1350 (presenting a model of how information flows through regulatory institutions); Sidney A. Shapiro & Rena Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741, 1769 (2008) (supporting well-publicized informational metrics that would focus the public and oversight authorities on an agency’s core missions); Wagner, *Commons Ignorance*, *supra* note 3, at 1791 (suggesting institutional and legal reforms to cope with the toxicity data gap).

28. See Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEX. L. REV. 1601 (2008) (noting examples of agency misuse of scientific information); Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health, and Safety Law*, 78 U. COLO. L. REV. 465, 491–501 (2007) (trade secret protections); *infra* text accompanying note 39 (statutory barriers); *infra* text accompanying note 45 (judicial review requirements).

health or the environment.”<sup>29</sup> Nearly thirty-five years later, TSCA’s promise has remained unfulfilled. In January 2009, the Government Accountability Office (“GAO”), noting longstanding weaknesses in chemical regulation, put the EPA toxics regulatory program on its biannual list of “High Risk” government programs.<sup>30</sup> These are programs that need “broad based transformation” and priority attention from the new administration and Congress.<sup>31</sup>

The fundamental problem with TSCA is that it both limits information supply and creates a high regulatory demand for information before EPA can restrict a chemical.<sup>32</sup> The result is regulatory paralysis.

### 1. Limited Information Supply

TSCA chokes the supply of information on chemical toxicity through several provisions. Most importantly, TSCA exempts manufacturers of chemicals that were in commerce before 1979 (known as “existing” chemicals in TSCA parlance) from routinely providing information about the toxicity of those chemicals to EPA.<sup>33</sup> This exemption has no basis in toxicology. Instead, it reflects the lobbying strength of the chemical industry, which worked assiduously to obtain this legislative grandfathering of all existing chemicals to avoid the expense (and liability exposure) of testing chemicals already on the market.<sup>34</sup> Congress’s acquiescence in 1976 has severely undermined the effectiveness of the statute. About 64,000 of the 82,000 chemicals (78 percent) that have been introduced in the United States are “existing” chemicals that are grandfathered under the

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29. TSCA § 1, 15 U.S.C. § 2601 (2006).

30. U.S. GOV’T ACCOUNTABILITY OFFICE, REPORT TO THE CONGRESS, HIGH-RISK SERIES: AN UPDATE 22 (2009), available at <http://www.gao.gov/new.items/d09271.pdf>.

31. *Id.* at 9, 21 (“Without greater attention to EPA’s efforts to assess toxic chemicals, the nation lacks assurance that human health and the environment are adequately protected.”).

32. John S. Applegate & Robert L. Fischman, *Missing Information: The Scientific Data Gap in Conservation and Chemical Regulation*, 83 IND. L.J. 399, 402–03 (2008).

33. See TSCA § 5(a) (pre-manufacture notices required only for new chemicals introduced after 1979). EPA can require testing of existing chemicals on a case-by-case basis, but there are numerous hurdles to promulgating and enforcing a test rule. See *infra* text accompanying notes 38–41 (describing statutory and judicial hurdles); TSCA § 4(a) (listing required agency findings before testing).

34. The old-new distinction in TSCA provided a means of reducing political opposition from the chemical industry by regulating new entrants and leaving existing products untouched. Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 732.

Act.<sup>35</sup> By volume, the grandfathered “existing” chemicals represent about 99 percent of chemicals on the U.S. market.<sup>36</sup>

The default presumption of TSCA, therefore, is that the vast majority of chemicals can be freely marketed, even absent any toxicity testing, unless and until EPA can prove that they pose unreasonable risks. This presumption stands in marked contrast to the regulatory regimes the United States has established for the introduction of pesticides and pharmaceuticals, where the applicant has the burden of proving safety.<sup>37</sup> Moreover, by creating sharply divergent regulatory standards for “existing” chemicals and “new” chemicals (those introduced after 1979), TSCA retards innovation and provides continuing incentives for use of older, untested chemicals.<sup>38</sup>

Even under the “new” chemicals program, which is generally seen as more stringent than the program for existing chemicals, TSCA has failed to produce extensive data on health and environmental risks. Under TSCA, new chemicals undergo a premanufacture notice procedure, in which chemical manufacturers submit to EPA data about the physical and chemical properties of the substance and projected uses.<sup>39</sup> Manufacturers must disclose toxicity information about a new chemical only if it is in the manufacturer’s “possession or control” or if it is “known to or reasonably ascertainable by” the

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35. GOV’T ACCOUNTABILITY OFFICE, *supra* note 19, at 2, 4.

36. Joel A. Tickner et al., *The U.S. Experience in Promoting Sustainable Chemistry*, 12 ENVTL. SCI. & POLLUTION RES. 115, 116 (2005).

37. Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 735.

38. Applying new environmental standards only to new entrants is a common feature in U.S. environmental law. Richard B. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CAL. L. REV. 1256, 1270 (1981). Such grandfathering provisions can retard industry innovation and often provide a competitive advantage to existing facilities or practices. Such grandfathering is often justified on the grounds that it would be unreasonably costly to retrofit existing plants to conform to the latest pollution control standards, and on the grounds that existing plants will soon cease operation, due to natural turnover in the capital stock. These assumptions have not proven correct even in the case of major stationary sources of emissions. See Jonathan Remy Nash & Richard L. Revesz, *Grandfathering and Environmental Regulation: The Law and Economics of New Source Review*, 101 NW. U. L. REV. 1677, 1708–09 (2007) (discussing evidence that grandfathering provisions result in delayed plant retirement). And these assumptions clearly do not hold in the context of chemical regulation. Older, “existing” chemicals should be subject to testing because they can continue to be used for decades, they are usually produced in the highest volumes, and they are unlikely to be phased out due to years in use.

39. TSCA § 5(a), 15 U.S.C. § 2604(a) (2006). EPA has ninety days to object or seek more information before the manufacture of new chemicals (or significant new uses of existing chemicals) can commence. TSCA § 5(c). As of June 2005, EPA review of premanufacture notices resulted in some action being taken to reduce risks of over 3,500 of the 32,000 new chemicals that companies have submitted for review since TSCA’s enactment. U.S. GOV’T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION 2 (2005), available at <http://www.gao.gov/new.items/d06217r.pdf>.

submitter.<sup>40</sup> With this “disclose it if you have it” model, a rational firm is incentivized *not* to undertake toxicity research on the products it is bringing to market.<sup>41</sup>

TSCA does authorize regulators to compel testing for any chemical (existing or new), but the regulators carry a heavy burden. EPA can order testing under Section 4 of TSCA if EPA meets a series of regulatory hurdles in which it carries the burden of proof.<sup>42</sup> These hurdles in many cases place the agency in a Catch-22 by requiring a quantitative risk assessment on a chemical before EPA can issue a testing order to obtain more information about that chemical.<sup>43</sup> Finalizing a test rule can take between two and ten years,<sup>44</sup> and EPA’s testing orders are considered rulemakings under the Administrative Procedure Act, subject to “substantial evidence” judicial review.<sup>45</sup> EPA has neither a legislative mandate nor the staff and funding to conduct comprehensive toxicity testing for existing chemicals. The agency has issued formal TSCA testing orders for fewer than 200 of the 62,000 existing chemicals,<sup>46</sup> and these orders have frequently been delayed or withdrawn after litigation.<sup>47</sup>

Because of the hurdles to testing under Section 4 and the weaknesses of other information disclosure provisions of TSCA,<sup>48</sup>

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40. 40 C.F.R. § 720.50(a)–(b) (2009).

41. Not surprisingly, only 15 percent of PMNs contain any health and safety information, and the GAO has reported that only 20 percent of PMNs receive a detailed review by EPA. GOV’T ACCOUNTABILITY OFFICE, *supra* note 19, at 12. In the absence of chemical-specific test data, EPA uses computer models and structure activity relationships (“SARs”) to compare new chemicals with chemicals of similar molecular structure on which toxicity data is available. *Id.* at 11.

42. Specifically, EPA can require additional testing only when the agency finds that the chemical (1) may present an unreasonable risk of injury to health or the environment; or (2) is or will be produced in substantial quantities, and (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities. TSCA § 4(a).

43. See Applegate, *The Perils of Unreasonable Risk*, *supra* note 3, at 319 (noting that in practice, EPA often conducts a quantitative risk assessment on a chemical prior to issuance of a test order); see also Daniel A. Farber, *Five Regulatory Lessons from REACH* 9 (Univ. Cal. Berkeley Pub. Law, Research Paper No. 1,301,306, 2008), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1301306](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1301306) (arguing that TSCA embodies a “reverse precautionary principle” because it allows “information to be gathered only when a risk is already known to exist”).

44. GOV’T ACCOUNTABILITY OFFICE, *supra* note 19, at 9.

45. TSCA § 19(c)(1)(B).

46. GOV’T ACCOUNTABILITY OFFICE, *supra* note 19, at 4.

47. *Id.* at 18.

48. TSCA Section 8, for example, imposes a requirement to “immediately inform” EPA if a manufacturer, processor, or distributor of a chemical obtains studies or data indicating that a chemical poses a “substantial risk” of injury to human health or the environment. TSCA § 8(e). In practice, the intended early warning system of Section 8 has not promoted consistent

chemical regulation in the United States has operated in a data-poor environment that benefits the chemical industry but undermines regulators' ability to understand, let alone respond to, public health and environmental risks from chemicals. Other information disclosure statutes—such as the Freedom of Information Act of 1966,<sup>49</sup> the National Environmental Policy Act of 1969,<sup>50</sup> and the Emergency Planning and Community Right to Know Act of 1986<sup>51</sup>—have become cornerstones of environmental protection in the United States. TSCA constricts far more than it reveals.

## 2. Stringent Information Demands

Within this data-poor environment, TSCA imposes stringent information demands on EPA before the agency can restrict a chemical, and the burden of proof on chemical safety lies with the government. EPA is authorized under TSCA Section 6 to restrict a chemical (e.g., ban, limit certain uses, or impose labeling requirements) only if it can show a “reasonable basis to conclude that . . . a chemical . . . presents or will present an unreasonable risk of injury to health or the environment.”<sup>52</sup> “Unreasonable risk” is an undefined term in the statute, but it has been interpreted to require a complex balancing of hazard, exposure, cost, and socioeconomic data,

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reporting to regulatory authorities, and it instead creates perverse incentives not to undertake voluntary testing of chemicals. Determining whether a study suggests a “substantial risk” from a chemical is left largely to the discretion of the manufacturer. *See* Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 736 (“Both Congress and the EPA define ‘substantial risk’ in a way that leaves reporting largely to the manufacturer’s own judgment.”). Moreover, manufacturer compliance with Section 8 has been sporadic. *See* *Hearing*, *supra* note 4, at 3 (testimony of Lynn R. Goldman) (noting recurring problems with companies withholding data required to be disclosed under Section 8). In the early 1990s, EPA established a self-audit program that offered firms reduced penalties and penalty caps in exchange for implementing a compliance audit program requiring them to submit overdue Section 8 data. More than 120 companies sent EPA more than 11,000 studies on chemicals that had never been seen by the agency and that should have been submitted years earlier. *See* Keith M. Casto & Tiffany Potter, *Environmental Audits: Barriers, Opportunities, and a Recommendation*, 5 HASTINGS W.-NW. J. ENVTL. L. & POLY 233, 251 (Spring 1999).

49. Freedom of Information Act of 1966, 5 U.S.C. § 552 (2008).

50. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321, 4331–35, 4341–47 (2000).

51. Emergency Planning and Community Right to Know Act, 42 U.S.C. §§ 11001–05, 11021–23, 11040–50 (2000).

52. Specifically, the statute states: If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall “to the extent necessary to protect adequately against such risk using the least burdensome requirements[.]” TSCA § 6(a).

all of which must be compiled by the government.<sup>53</sup> Moreover, EPA can enact restrictions on a chemical only after a full trial-type hearing; it must make a series of statutory findings prior to restrictions; it must choose the “least burdensome” regulatory requirement that will adequately protect against the risk; and it must demonstrate that no other statute could address the concern.<sup>54</sup> EPA chemical restrictions, like test rules, are then subject to the searching “substantial evidence” standard by a reviewing court.<sup>55</sup>

Confronted with a persistent data drought, yet bearing the burden of proof, EPA has imposed regulatory restrictions on only five chemicals under Section 6 in the thirty-three year history of TSCA.<sup>56</sup> The last attempt to do so was in 1989, when EPA promulgated a rule banning most uses of asbestos, based on ten years of hearings and a 100,000 page record.<sup>57</sup> That rule was set aside in *Corrosion Proof Fittings v. EPA*,<sup>58</sup> the first and only judicial interpretation of Section 6. In that case, the Fifth Circuit faulted EPA’s cost-benefit analyses, the broad sweep of the EPA rule, and EPA’s compliance with the “least burdensome” requirement. After *Corrosion Proof Fittings* set such high demands for data, scientific certainty, and proof of cost-effectiveness prior to regulation, EPA never again attempted to exercise its statutory authority under Section 6 to restrict or ban a chemical substance.

The regulatory model of TSCA is fundamentally flawed. It is akin to conducting a criminal prosecution without a factual investigation, or conducting a civil trial without discovery. The government bears the burden of proof but operates with severe

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53. See TSCA § 6(c) (outlining the factors that must be considered and published in any chemical restriction rule promulgated by EPA); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215–17 (5th Cir. 1991) (interpreting the “unreasonable risk” standard to include analysis of the costs of any proposed restriction); Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 756 (“The ‘unreasonable’ terminology in TSCA is notably unspecific, and intentionally so, but it is clear that EPA must consider cost as well as risk in the determinations of ‘unreasonable risk.’”).

54. TSCA § 6 (a), (c).

55. TSCA § 19(c)(1)(B).

56. GOV’T ACCOUNTABILITY OFFICE, *supra* note 39, at 18. The five chemicals or chemical classes are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium. *Id.*

57. See 40 CFR §§ 763.160–763.179 (1989) (Subpart I, prohibiting “the Manufacture, Importation, Processing and Distribution” of various asbestos products). As the GAO has noted, *Corrosion Proof Fittings* was widely considered to be a severe blow to EPA and to the effectiveness of TSCA because “asbestos is generally regarded as one of the substances for which EPA has the most scientific evidence or documentation of substantial adverse health effects.” GOV’T ACCOUNTABILITY OFFICE, *supra* note 39, at 20.

58. *Corrosion Proof Fittings*, 947 F.2d at 1229–30. For additional discussion of *Corrosion Proof Fittings*, see Farber, *supra* note 43, at 12–14.

information deficits. John Applegate has noted that under these conditions “agencies undertake less regulation, not because they have made a judgment that regulatory action is unnecessary, but because they cannot afford the high costs of developing a record that will be fairly certain to withstand judicial review.”<sup>59</sup>

### 3. Implications of TSCA’s Failures

After decades of chemical regulation in the United States, there is still widespread ignorance and uncertainty about the actual effects of tens of thousands of chemicals on human health and the environment. Some chemicals that have gone untested for decades may be completely harmless; others may be unidentified agents of endocrine disruption, birth defects, cancer, or neurological damage. The crucial point is that the United States lacks a sophisticated system for obtaining the risk data that would allow regulators, firms, and consumers to distinguish harmful (or potentially harmful) chemicals from harmless ones.

If TSCA were more effective at generating data on chemical risks, that data could feed other policy decisions—such as which substances to regulate as hazardous air pollutants under the Clean Air Act, how stringent cleanup standards should be for hazardous waste sites, or how to set permissible chemical exposure levels for workers under the Occupational Safety and Health Act. TSCA was designed to be a gap-filling, cross-cutting regulatory regime that could address risks from tens of thousands of chemicals across their life cycles, from production to disposal.<sup>60</sup> Indeed, Congress intended TSCA to complement other environmental statutes that are more focused on controlling end-of-pipe emissions into particular media, such as air or water.<sup>61</sup> Yet TSCA has never fulfilled its promise for generating the data that might advance priority-setting and bring coherence to the larger field of toxics regulation.<sup>62</sup>

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59. Applegate, *Perils of Unreasonable Risk*, *supra* note 3, at 266.

60. See S. REP. NO. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491 (“The purpose of S. 3149 is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. The bill is designed to fill a number of regulatory gaps which currently exist.”).

61. See Applegate, *Perils of Unreasonable Risk*, *supra* note 3, at 330 (“As an umbrella for collecting, coordinating, and creating information, [TSCA] . . . has the potential to be the vehicle for supplying data to other regulatory programs . . .”).

62. See John C. Dernbach, *The Unfocused Regulation of Toxic and Hazardous Pollutants*, 21 HARV. ENVTL. L. REV. 1, 2 (1997) (arguing that the differences among the lists of hazardous substances regulated under various environmental statutes are “a major underlying reason for costliness and inefficiency in the current regulatory structure.”).

Despite these flaws, TSCA has remained remarkably resistant to reform. Bills proposing increased mandatory testing of existing chemicals have been rejected in Congress.<sup>63</sup> Some minor provisions have been added to TSCA to address hazards from specific chemicals,<sup>64</sup> but the core legal tests and the underlying structure of American chemical regulation have not changed since the 1970s. The chemical industry's principal trade group, the American Chemistry Council ("ACC"), has long supported the TSCA status quo and has opposed mandatory testing requirements.<sup>65</sup>

Today, TSCA exists mainly as a statutory backdrop to a series of voluntary initiatives on chemical safety, negotiated between EPA and industry groups.<sup>66</sup> Many industry commitments under these initiatives remain unfulfilled,<sup>67</sup> and such initiatives are not a satisfactory substitute for an effective regulatory regime. When data gaps emerge in voluntary testing programs run by industry, EPA lacks the practical statutory authority to fill the gaps.<sup>68</sup> TSCA, it

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63. In 1984, for example, the Senate rejected a TSCA amendment that would have required toxicity testing for very high volume chemicals—those produced or imported in annual quantities of 100 million pounds or more. *See* S. 3075, 98th Cong. § 4(b) (1984).

64. TSCA had minor amendments in 1986 to address asbestos in schools, in 1988 to regulate indoor radon gas, and in 1992 to regulate hazards from lead paint. None of these amendments altered the core provisions or incentives of TSCA. *See* Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENVTL. L. 99, 119–22 (1999–2000).

65. *See* DARYL DITZ, CTR. FOR INT'L ENVTL. L., CLOUDY SKIES, CHANCE OF SUN: THE FORECAST FOR U.S. REFORM OF CHEMICAL POLICY 1, 2 (2006), available at [http://www.ciel.org/Publications/Cloudy\\_Skies\\_9May06.pdf](http://www.ciel.org/Publications/Cloudy_Skies_9May06.pdf) ("The chemical industry remains satisfied with the law as it stands.").

66. The largest of these voluntary initiatives has been the High Production Volume ("HPV") Challenge, launched with great fanfare in 1998 as a joint project of the ACC (then known as the Chemical Manufacturers Association), the EPA, and the Environmental Defense Fund. Under the HPV Challenge, industry agreed to provide toxicity data on 2800 chemicals produced in volumes exceeding one million pounds per year, and individual chemical manufacturers agreed to "sponsor" the testing for particular chemicals. RICHARD A. DENISON, ENVTL. DEF. FUND, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE 3–4 (2007), available at [http://www.edf.org/documents/6653\\_HighHopesLowMarks.pdf](http://www.edf.org/documents/6653_HighHopesLowMarks.pdf).

67. Eleven years after the HPV Challenge was launched, and five years after the data sets were due, about 280 of the HPV chemicals still remain "orphans," lacking a sponsor to pay for their testing. *See id.* at 4. Moreover, manufacturers have submitted final data sets on just over half of the chemicals that were sponsored for testing. *Id.* at 3. EPA committed to mandate testing for any orphan chemicals under the HPV program, but EPA did not issue a test rule until 2006, and that rule covered only 16 of the 280 orphan chemicals. *See* EPA Regulatory Actions for Un-sponsored Chemicals, <http://www.epa.gov/HPV/pubs/general/regactions.htm> (last visited Oct. 8, 2009). Thus, the most ambitious effort ever undertaken in the United States to assess the toxicity of widely-used chemicals is still incomplete a decade after its inception. The Environmental Defense Fund concluded in 2007 that the program is still "well away from delivering on the promises it made." DENISON, *supra* note 66, at 3.

68. *See* Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 740.

appears, has spawned voluntary testing initiatives by necessity.<sup>69</sup> Its mandatory provisions are hollow, and reform of U.S. chemical regulation is urgently needed.

### *B. Chemical Regulation Version 2.0: The Rise of REACH*

With the enactment of REACH in 2006, the EU launched a second generation of chemical regulation. The legislation is, in many respects, the “anti-TSCA”<sup>70</sup>—the transatlantic converse of the American regulatory regime. It fundamentally reshapes the €537 billion European chemical market<sup>71</sup> and embodies a new paradigm in global chemicals management in which the burden of proof on chemical safety is shifted from government to industry for the most hazardous classes of chemicals. REACH replaced an older package of EU chemical legislation (comprised of more than forty directives and regulations) that had been modeled closely on TSCA.<sup>72</sup> In enacting REACH, therefore, the EU largely rejected the American approach to chemical regulation, which had been the most influential regulatory regime from the 1970s through the 1990s, and embarked on a new path.<sup>73</sup>

Like TSCA, EU chemical legislation prior to REACH focused on testing of “new” chemicals (those introduced after 1981 in Europe), exempted most existing chemicals from testing, and placed the burden of proof on EU Member States to prove that chemicals were unsafe.<sup>74</sup> The older European legislation led to the same informational logjams and data gaps that the United States has experienced under TSCA. Of the 30,000 existing chemicals with annual production volumes in Europe of over one ton, only 140 had been identified as priorities for

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69. See GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 9 (because TSCA's testing provisions are “burdensome and too time consuming for EPA to administer,” EPA “uses voluntary programs to help gather more data to assess risks on certain chemicals”).

70. Applegate, *Synthesis of TSCA and REACH*, *supra* note 3, at 743.

71. See EUROPEAN CHEMICAL INDUSTRY COUNCIL, *supra* note 14.

72. For an overview of the origins of chemical legislation in the European Community, see RONALD BRICKMAN, SHEILA JASANOFF & THOMAS ILGEN, *CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES* 276 (1985). For a concise summary of the EU chemical legislation that existed prior to REACH, see FRANK ACKERMAN & RACHEL MASSEY, *GLOBAL DEV. & ENV'T INST., TUFTS U., THE TRUE COSTS OF REACH 19-23* (2004), available at [http://www.euractiv.com/29/images/TuftsStudyonREACH\\_tcm29-130918.pdf](http://www.euractiv.com/29/images/TuftsStudyonREACH_tcm29-130918.pdf).

73. For further information on European politics leading to REACH's enactment, see Henrik Selin, *Coalition Politics and Chemicals Management in a Regulatory Ambitious Europe*, 7 *GLOBAL ENVTL. POL.* 63 (2007).

74. See REACH IN BRIEF, *supra* note 15, at 3; *Commission White Paper on Strategy for a Future Chemicals Policy*, at 19, COM (2001) 88 final (Feb. 27, 2001) (noting the incentives for industry to delay risk assessments under the prior EU chemicals legislation).

testing under the prior legislation, and full risk assessments had been prepared for only about seventy of these chemicals.<sup>75</sup> Chemicals introduced since 1981 had been subject to rigorous toxicity testing in Europe, but they represented less than 1 percent of all the chemicals marketed in Europe.<sup>76</sup>

REACH was designed to break through these informational logjams by establishing, at reasonable cost,<sup>77</sup> a unified, precautionary regulation for existing and new chemicals produced or imported into Europe. REACH improves on the American model of chemical regulation in four major respects: it (1) increases the supply of data on chemical toxicity, (2) decreases the informational demands on regulatory authorities, (3) improves risk communication to the public and to commercial users of chemicals, and (4) promotes use of substitutes for hazardous chemicals.

### 1. Increased Information Supply: “No Data, No Market”

To increase the supply of information on chemical risks, REACH ends the distinction between “existing” and “new” chemicals and imposes on industry a default burden of data production as a condition of manufacturing or importing chemicals into the EU. In particular, REACH requires that all substances imported into or manufactured in Europe in annual quantities of one ton or greater (approximately 30,000 substances) be registered with a new European Chemicals Agency (“ECHA”) during a phase-in period that ends in 2018.<sup>78</sup> The amount of toxicity testing that must accompany the

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75. See ANDREW FASEY, LOWELL CTR. FOR SUSTAINABLE PROD., REACH IS HERE: THE POLITICS ARE OVER, NOW THE HARD WORK STARTS 3 (2008), [www.chemicalspolicy.org/downloads/REACHisHere4-2008.pdf](http://www.chemicalspolicy.org/downloads/REACHisHere4-2008.pdf); Memorandum from the Directorate General Communication of the European Commission, Q and A on the New Chemicals Policy, REACH, MEMO/06/488 (Dec. 13, 2006), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/488&format=PDF&aged=1&language=EN&guiLanguage=en>.

76. *Commission White Paper*, supra note 74, at 6. Of the new chemicals evaluated between 1981 and 2003, the European Commission concluded that 70 percent had one or more dangerous properties. *Commission Working Paper: Extended Impact Assessment*, at 26–27, COM (2003) 644 final (Oct. 29, 2003), available at [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003\\_1171\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003_1171_en.pdf) (discussing the knowledge gap created by the EU’s earlier chemical regulations and its effect on accurate assessment of the risks of certain chemicals).

77. The costs of REACH are addressed, *infra*, Part (I)(C).

78. See REACH arts. 5–7, 20. Under REACH, ECHA plays a coordination role and provides the scientific expertise for evaluating chemicals. Actual regulatory authority, however, remains with the European Commission and the various Member States of the EU. See Applegate, *Synthesizing TSCA and REACH*, supra note 3, at 741. Joint registration is permitted when numerous firms manufacture or import the same product. REACH art. 11. The term “substances” includes most chemicals but excludes foodstuffs, pharmaceuticals, many naturally occurring ores and minerals, and polymers. See REACH, Exemptions From the Obligation to

registration for each substance depends on the volume sold, with the greatest testing and information requirements applicable to chemicals produced or imported in volumes of more than 1,000 tons per year.<sup>79</sup>

REACH thereby achieves in Europe a major reform in chemical regulation that has long been advocated by American analysts—putting older and newer chemicals on equal footing and requiring a minimum toxicity data set for both.<sup>80</sup> REACH also expands, relative to U.S. practice, the number of required tests for adverse human health and environmental effects.<sup>81</sup> The registration process of REACH is the largest effort in history to collect comprehensive toxicity data for chemicals.

Unlike TSCA, REACH is a true market-access regulation. It is based on the core principle of “No Data, No Market.”<sup>82</sup> In other words, a company’s failure to submit the required chemical registration package, including the suite of toxicity data specified in the legislation, results in denial of access to the €537 billion European chemical market. The “No Data, No Market” principle is already making toxicity testing a routine part of doing business in Europe, rather than the exception, as it is in the United States. Firms have an incentive to generate the toxicity data that will allow their products to undergo registration as quickly as possible. The system rewards knowledge, rather than ignorance.

As part of the registration process, REACH requires submission of two distinct kinds of chemical data: hazard data and

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Register in Accordance With Article 2(7)(a), Annex IV; REACH, Exemptions From the Obligation to Register in Accordance With Article 2(7)(b), Annex V (exempting certain substances, such as sugars, oils, amino acids, fatty acids, and “basic elemental substances for which hazards and risks are already well known” from the registration requirement).

79. See REACH IN BRIEF, *supra* note 15, at 7 (explaining that under REACH, the tonnage of a chemical acts as a rough surrogate for potential exposure, so the amount of required testing escalates as the tonnage increases). *Id.* For the list of tests that must be conducted on substances in the different tonnage bands, see REACH Annex VII–X.

80. See GOV’T ACCOUNTABILITY OFFICE, *supra* note 39, at 41; Mark A. Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ENVTL. L. REP. 10034, 10040 (2009) (“[T]he best approach for addressing the age-old new versus existing chemical issue is to remove it from the discussion.”).

81. See GOV’T ACCOUNTABILITY OFFICE, *supra* note 39, at 17, 43–47 (comparing the number of chemical tests under TSCA and REACH). One common criticism of REACH is that at low volume thresholds (between one and ten tons per year), REACH imposes relatively few testing requirements. Prior EU law required notification for all new substances marketed in excess of ten kilograms per year, so it is true that REACH has raised the tonnage threshold for new chemical testing. See DENISON, *supra* note 25, at 8–10. However, the European Commission retains the authority to require testing for low-volume substances on a case-by-case basis. See *Commission White Paper*, *supra* note 74, at 18. For chemicals produced or imported above ten tons per year (approximately 10,000 substances), REACH represents a significant improvement over prior EU legislation and over TSCA.

82. REACH art. 5.

risk data. Hazard data refers to the intrinsic characteristics of a chemical, such as whether it is long-lived, persistent in the environment, or carcinogenic in laboratory mice. Hazard identification suggests a *capacity* to cause harm. Risk data, on the other hand, combines laboratory findings of hazard with analysis of actual human exposure to the compound. Risk, therefore, is the product of hazard and exposure. Risk assessment identifies the *probability* of harm. REACH requires that chemical manufacturers identify potential exposures and submit risk assessments as a part of the registration process, whereas in the United States risk assessments are a governmental responsibility and are not routinely performed for existing chemicals. Therefore, under REACH, the supply of risk assessment data on commonly used chemicals is likely to expand dramatically.

This shift in the burden of data production has a potential drawback, however. Unless government regulators specifically select chemicals for further evaluation, the principal documentation on risks and exposures of registered chemicals will be prepared by industry. To address the potential for abuse under this system, the ECHA and Member States must devote adequate resources to fulfill their crucial oversight and auditing roles.

## 2. Reductions in Information Demand: Authorization and Shifting Burdens of Proof

In addition to expanding the data supply, REACH also narrows the existing chemical data gap by adjusting the regulatory demand for toxicity information. Recall that under TSCA, EPA bears the burden of proof to show that a chemical poses an “unreasonable risk” to human health or the environment prior to restricting a chemical.<sup>83</sup> REACH, in contrast, shifts the burden of proving the safety of certain classes of chemicals to industry, significantly reducing the informational demands on regulatory authorities.<sup>84</sup>

Burden shifting is an important conceptual breakthrough in chemical regulation. It restructures the roles of industry and government in chemical regulation, sending a “normative message” that “chemical risks should be controlled, eliminated, mitigated, or

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83. TSCA § 6(a), 15 U.S.C. § 2601 (2006).

84. See GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 4 (“REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place on the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks . . .”).

justified by their creators.”<sup>85</sup> Shifting the burden of proof on chemical safety is a reform that has long been advocated for TSCA by American environmental law scholars.<sup>86</sup> Lynn Goldman, who oversaw TSCA implementation in the Clinton Administration, has argued that TSCA will “never be effective” unless it is amended to shift the burden of proof on chemical safety.<sup>87</sup>

Under a regulatory model that places the burden of proof for chemical safety on industry, scientific uncertainty will be resolved in favor of *not* allowing a chemical to be marketed. A governmental burden of proof, in contrast, heightens the possibility of false negative decisions (so-called “Type II errors”) in which harmful chemicals are freely marketed because the government cannot meet its burden of showing harm in a context of scientific uncertainty.<sup>88</sup> A well-designed chemical regulatory regime should aim, as REACH does, to minimize Type II errors because these errors can lead to adverse health and environmental effects from the distribution of harmful chemicals in commerce.

After extensive negotiations between the Council of Ministers and the European Parliament, the EU enacted an authorization procedure for REACH that shifts the burden of proof on safety to industry for the most hazardous classes of chemicals: those identified as “very high concern” (“VHC”) chemicals in the registration and evaluation stages of REACH.<sup>89</sup> These are chemicals that can cause cancer, birth defects, or genetic mutations, as well as chemicals that are persistent or bioaccumulative in the environment.<sup>90</sup> VHC chemicals are given a “sunset date” after which they cannot be sold in Europe without the industry proponent receiving government authorization.<sup>91</sup> The concept of a default sunset date for hazardous

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85. Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 746.

86. *Hearing*, *supra* note 4, at 4 (testimony of Lynn R. Goldman); Sachs, *supra* note 3, at 348–49; *see also* Applegate, *supra* note 6, at 1389 (advocating shifting the burden of proof on chemical safety to manufacturers a strategy to increase the supply of chemical data).

87. *Hearing*, *supra* note 4, at 2 (testimony of Lynn R. Goldman).

88. To be sure, an industry burden of proof heightens the possibility of Type I errors (false positive decisions in which a substance may be forced off the market even if it poses little or no actual risk). However, in balancing Type I and Type II errors, precautionary regulation should aim to minimize Type II errors, given the potential for adverse effects on human health and the environment. For more discussion on the balance of potential decision errors in a setting of scientific uncertainty, see Lars Koch & Nicholas A. Ashford, *Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH*, 14 J. CLEANER PROD. 31, 34 (2006).

89. REACH IN BRIEF, *supra* note 15, at 12–13.

90. *See* REACH art. 57 (substances subject to authorization); *see also* REACH IN BRIEF, *supra* note 15, at 16 (explaining that chemicals of very high concern include “[c]arcinogenic, mutagenic, or reprotoxic substances”).

91. REACH, art. 58(1)(c).

chemicals is itself a major achievement in the field of chemical regulation, and the European Commission anticipates that approximately 1,400 of the 30,000 substances (5 percent) that will be registered under REACH will be subject to such authorization.<sup>92</sup>

This shift in the burden of proof does not mean that all VHC chemicals will be withdrawn from the market. Instead, regulators may grant a time-limited authorization to continue to market a VHC chemical if the manufacturer or importer can demonstrate that the risks to human health and the environment are “adequately controlled,”<sup>93</sup> or if this showing cannot be made,<sup>94</sup> the proponent must demonstrate: (1) that the socioeconomic benefits exceed the risks, *and* (2) that there are no suitable substitute chemicals or technologies.<sup>95</sup>

This carefully crafted text both shifts the burden of proof to industry and brings cost-benefit analysis and product substitution into the heart of the legislation. REACH is premised on the idea that chemicals can simultaneously pose risks to human health and be beneficial to human welfare in a wide variety of commercial products. REACH therefore bifurcates regulatory action by: (1) identifying substances of “very high concern,” based on hazardous characteristics, and imposing a presumption that VHC chemicals should not be marketed; and (2) bringing exposure, risk, and socioeconomic concerns into the regulatory discussion in the authorization stage, by giving manufacturers an opportunity to overcome the presumption against continued marketing. The legislation is an example of how precautionary environmental legislation need not exclude cost-benefit analysis, but instead can incorporate it into an overall regulatory structure that still gives primacy to public health protection.

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92. REACH IN BRIEF, *supra* note 15, at 16. Industry groups have criticized REACH on the grounds that it lacks priority-setting mechanisms, given that industry must spend substantial resources on registration of thousands of chemicals, when only a small portion of these chemicals will ultimately be deemed “very high concern” under REACH. See Harvey Black, *Chemical Reaction: The U.S. Response to REACH*, 116 ENVTL. HEALTH PERSP. 125, A126 (2008). But comprehensive identification of hazard and exposure data in the registration process, far from being a drawback of the legislation, should be seen as an advantage. It means that risk assessments will be based on full, rather than fragmentary, information, and that substances will not presumptively be deemed safe without submission of the test data and exposure information to back up that claim.

93. REACH art. 60(2).

94. REACH presumes that risks cannot be adequately controlled for persistent and bioaccumulative chemicals and for chemicals that do not have a known safe threshold below which a lack of adverse effects can be documented. *Id.* art. 60(3).

95. *Id.* art. 60(4).

### 3. Improved Risk Communication

The third major innovation of REACH is its requirement of bidirectional risk communication. REACH requires that chemical manufacturers identify businesses that are downstream users of their products—from cosmetics and candy makers to furniture makers, farmers, and textile companies. Chemical manufacturers must communicate to these downstream users, through a safety data sheet accompanying chemical shipments, the known risks of each chemical and recommended risk management techniques.<sup>96</sup> Downstream users, in turn, must inform upstream suppliers of any new hazards they discover from a chemical, as well as any indication that the risk management instructions they received are inadequate.<sup>97</sup> Downstream users must also ensure that their specific use of a chemical was covered in the registration package submitted by the manufacturer, or they must prepare a new chemical safety report for any unanticipated uses.<sup>98</sup>

REACH thereby makes data on toxicity and risk management available up and down the supply chain, helping to overcome one of the primary barriers to effective chemical regulation: a lack of understanding of the actual uses and exposures to chemicals within the chain of commerce.<sup>99</sup> TSCA, in contrast, does not create a comprehensive system for tracking material flows and exposures throughout the chain of distribution, and it imposes no responsibility on downstream users to document how chemicals are used or how exposures may be occurring.<sup>100</sup>

REACH also emphasizes public disclosure and right-to-know to a greater extent than TSCA.<sup>101</sup> The legislation establishes an Internet registry of chemical data, which includes information about physical

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96. *Id.* arts. 31–32.

97. *Id.* art. 37; *see also* KEN GEISER & JOEL TICKNER, LOWELL CTR. FOR SUSTAINABLE PROD., *NEW DIRECTIONS IN EUROPEAN CHEMICALS POLICY: DRIVERS, SCOPE, AND STATUS* 1, 143 (2003), *available at* <http://www.chemicalspolicy.org/downloads/newdirectionsfinal.pdf> (“As chemical manufacturers and importers have responsibility to assess risks, there is an incentive for them to more effectively communicate with downstream users to obtain critical use data and for downstream users to ensure that they obtain hazard data from manufacturers.”).

98. REACH IN BRIEF, *supra* note 15, at 11.

99. *See id.* at 8 (explaining that REACH makes both chemical manufacturers and downstream users responsible for the safe handling and use of chemicals).

100. GOV'T ACCOUNTABILITY OFFICE, *supra* note 39, at 37; *see also* Tickner, *supra* note 36, at 6 (explaining that chemical manufacturers often know very little about the uses of their own chemicals more than one or two steps down the supply chain and arguing that “[i]t is virtually impossible to manage chemicals without this knowledge”).

101. For more information on the right-to-know provisions of REACH, *see* Applegate, *Synthesizing TSCA and REACH*, *supra* note 3, at 750–51.

properties and toxicity and will be accessible to both EU regulators and the public.<sup>102</sup> It contains narrower protections for confidential business information than TSCA.<sup>103</sup> In a critical right-to-know reform, REACH provides that suppliers of any product in Europe that contains a VHC chemical must alert the recipient of the product (such as a retailer) to the presence of the chemical and provide information on safe use.<sup>104</sup> Suppliers must also provide the same information to consumers, upon request.<sup>105</sup> These disclosures will help spotlight, for the first time, the presence of hazardous substances in a wide variety of consumer products sold in Europe (and elsewhere), such as toys, furniture, clothing, autos, and electronics.

As a package, the risk communication measures of REACH will help promote the emerging global field of “green chemistry”<sup>106</sup>—an approach to chemical manufacture and product design that minimizes toxic risks—by making safety information broadly available to the chemical marketplace. In the United States, firms that want to green their supply chain are often unable to make comparative choices about the safest chemicals for their needs because of the longstanding data drought on chemical toxicity.<sup>107</sup> Moreover, customers, investors, lenders, and other stakeholders cannot judge whether a firm is making sound choices between conventional chemicals and safer alternatives. The information-forcing devices of REACH, such as “No Data, No Market,” and the risk communication devices of REACH will benefit companies that reduce toxic risks from their products, in Europe and potentially in the United States.

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102. See REACH art. 77(2)(e) (mandating that information is to be made publicly available over the Internet, except where a specific request for confidentiality is deemed justified).

103. In a 2007 report, the U.S. Government Accountability Office noted persistent problems with overbroad confidentiality claims by the chemical industry under TSCA. GOV'T ACCOUNTABILITY OFFICE, *supra* note 19, at 26 (noting that challenging confidentiality claims is “resource-intensive” for EPA and that many confidentiality claims, when challenged, are found to be inappropriate). In contrast, “REACH places substantial restrictions on the types of data that chemical companies may claim as confidential.” *Id.* at 27.

104. REACH art. 33. This requirement is triggered if the product contains any substance that is subject to authorization, at greater than 0.1 percent by weight. *Id.*

105. *Id.*

106. Green chemistry refers to designing products and substances in ways that minimize chemical risks to human health and the environment. See PAUL ANASTAS & JOHN WARNER, GREEN CHEMISTRY: THEORY AND PRACTICE 11, 30 (1998) (defining green chemistry and outlining its twelve principles, including designing chemical substances that have little or no toxicity and using safer solvents and chemicals that degrade into innocuous substances).

107. See *Hearing, supra* note 4, at 2 (testimony of Michael P. Wilson) (explaining that in California, businesses that use chemicals do not have sufficient data to find the least hazardous choices).

#### 4. Incentives for Substitution

The fourth major innovation of REACH is that the legislation systematically promotes substitutes for known hazardous substances and introduces comparative analysis of the risks of chemicals into the regulatory process. According to the preamble, REACH is designed to “encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.”<sup>108</sup>

REACH promotes substitution through both implicit incentives and explicit requirements. Among the implicit incentives for substitution are the public disclosure of toxicity information in the registration process, the potential market risk from being identified as a VHC chemical, and the administrative burden of complying with the authorization process for VHC chemicals.

Substitution analysis is an explicit requirement of the authorization process. Under REACH, any applicant for authorization of a VHC chemical must include in its application an “analysis of alternatives considering their risks and the technical and economic feasibility of substitution.”<sup>109</sup> Where this analysis shows that suitable alternative chemicals are available, the applicant must prepare a formal substitution plan, including a timetable.<sup>110</sup> In reviewing these applications, the European Commission can consider a variety of factors in determining whether safer substitutes are indeed feasible, and it must determine whether the substitutes “would result in reduced overall risks to human health or the environment.”<sup>111</sup> To limit the possibility that applicants will cursorily conclude that their own product has no viable substitute, third parties are entitled to present information on substitutes to the Commission.<sup>112</sup>

A systematic comparison of the risks of alternative chemicals has never been a prominent part of the TSCA regulatory scheme. Chemical substitution is mentioned only once in TSCA, in Section 6, which requires that *regulators* identify substitutes along with the

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108. REACH pmbl. ¶ 12; *see also* REACH IN BRIEF, *supra* note 15, at 8 (stating that one objective of REACH is to “encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available . . . . The increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.”).

109. REACH art. 62(4)(e).

110. *Id.* art. 62(4)(f).

111. *Id.* art. 60(5)(a).

112. *Id.* art. 64(2).

economic benefits of any chemical they are considering restricting.<sup>113</sup> As noted above, however, the restrictions process of Section 6 has been invoked only five times in the history of TSCA.<sup>114</sup> Moreover, in this regulatory context, the requirement that the government identify whether safer substitute chemicals exist serves as one more hurdle for regulators considering chemical restrictions. TSCA does not promote a broader, ongoing search for safer alternatives as a routine part of U.S. chemical policy.

### *C. REACH Implementation and Cost Issues*

REACH's text establishes an aggressive new approach to research, disclosure, and management of toxic risks, yet REACH's ultimate efficacy will depend on the EU's handling of a complex set of implementation challenges. These challenges include reviewing tens of thousands of chemical registrations; establishing the authority and competence of the brand-new European Chemicals Agency, which opened its doors in June 2008; coordinating research, enforcement, and regulatory decisionmaking across twenty-seven Member States; evaluating thousands of chemicals for hazardous properties; and overseeing an authorization system that is bound to lead to disputes with manufacturers. Industry groups have charged that REACH will lead to chemicals being withdrawn from the European market because small enterprises will find that the burdens of testing outweigh their profit from low-volume substances.<sup>115</sup> They contend that supply-chain disruptions could result and that European manufacturers who rely on such chemicals will need to find substitutes quickly. These implementation challenges are formidable. However, it is not unusual on either side of the Atlantic for implementation of a regulatory regime of this magnitude to be complex, lengthy, and subject to many uncertainties. Effective REACH implementation needs to remain a priority of the European Commission and the Member States.

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113. See 15 U.S.C. § 2605(c)(1) (2009) (requiring the Administrator to publish a statement along with any rule restricting a chemical, which must include, among other things, the benefits of the restricted chemical, the availability of substitute chemicals, and "the reasonably ascertainable economic consequences of the rule . . .").

114. GOV'T ACCOUNTABILITY OFFICE, *supra* note 39, at 18.

115. Royal Society of Chemistry, *REACH: The RSC Response*, <http://www.rsc.org/ScienceAndTechnology/Policy/Bulletins/Issue1/REACH.asp> (last visited Oct. 8, 2009) ("There is concern that REACH could lead to useful chemicals being withdrawn unnecessarily due to the high cost of testing, rather than for health, safety or environmental reasons."). *But see* ACKERMAN & MASSEY, *supra* note 72, at 10 (arguing that if a chemical essential to downstream users is withdrawn from the market because its manufacturer believes it is not worth paying the costs of REACH compliance, then the chemical is probably underpriced).

Are REACH's public health protections worth the cost? Estimates for REACH compliance costs vary widely. The European Commission estimated the total cost to industry for testing and registration under REACH at €2.3 billion over the eleven-year phase-in period of the legislation.<sup>116</sup> The Global Development and Environment Institute at Tufts University calculated that REACH implementation will cost the chemical industry €3.46 billion over eleven years, or €315 million per year.<sup>117</sup> Industry-financed studies, on the other hand, have calculated direct costs of up to €13 billion over eleven years,<sup>118</sup> and there is wide variation in estimates for indirect costs, such as potential price increases for downstream users or potential unavailability of some chemical inputs.<sup>119</sup> As for the impact on the United States, the American Chemistry Council has estimated that REACH compliance will cost U.S. companies approximately \$400 million over eleven years.<sup>120</sup>

While these costs for industry are not insignificant, they are also not exceptional for the launch of a major new environmental program—a program designed to reverse three decades of inadequate, lax regulation of the chemical marketplace. REACH compliance costs should drop off dramatically after the initial phase-in period, when companies will have conducted all the required testing and submitted the registrations for chemicals now manufactured in or imported into Europe. Moreover, annual revenues of the European chemical industry are over €500 billion, so even if REACH compliance costs turn out to be €1 billion per year, near the high range of estimates, such costs would represent only 0.2 percent of annual industry revenues. This is a small price to pay for achieving a more complete understanding of chemical risks, reducing cancers and birth defects, and saving—according to the estimate of the European Commission—4,500 lives each year from occupational exposures to hazardous chemicals.<sup>121</sup>

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116. REACH IN BRIEF, *supra* note 15, at 11.

117. ACKERMAN & MASSEY, *supra* note 72, at 33.

118. *Id.* at 43.

119. For an extensive discussion of the various cost-benefit analyses prepared when REACH was under discussion in the EU, see GEISER & TICKNER, *supra* note 97, at 113–18.

120. *Id.* at 139.

121. ACKERMAN & MASSEY, *supra* note 72, at 51. Only a few studies have attempted to monetize the public health and environmental benefits of REACH. The European Commission monetized the benefits of reduced disease and death from occupational exposures to harmful chemicals at €50 billion over thirty years, using a figure for the value of each life saved that is lower than figures generally used in the United States. *Id.* Another study by the World Wildlife Fund-UK concluded that the benefits of REACH from reduced disease, mortality, and reduced

## II. THE TRANSNATIONAL REACH OF REACH

REACH and TSCA are two contrasting regulatory regimes, both of which govern information generation and disclosure in a highly globalized industry. Given that the annual chemical trade between the United States and the EU is more than \$70 billion,<sup>122</sup> REACH is bound to cause transnational externalities in the U.S. market. What are these likely impacts? How will they occur? Will the reaction to REACH in the United States be backlash and opposition, emulation, or something else?

In this Part, I argue that the implementation of REACH in Europe increases the probability that the United States will reform its own system of chemical regulation by coordinating with, or emulating the major principles of, the European model. The enactment of REACH in 2006 may ultimately be seen as the birth of a new global standard, with EU regulatory norms spreading to the United States and other major jurisdictions. TSCA reform is not inevitable, however, and the politics of chemical regulation reform in the United States are very much in flux. Even if TSCA reform does not occur, the transnational reach of REACH will nonetheless improve public health protections in the United State by providing toxicity data to national and subnational regulators and promoting beneficial changes in the U.S. chemical marketplace.

The analysis in this Part is grounded in transnational regulatory theory. It shows how legal norms, initially embodied in domestic legislation in one jurisdiction, can be transplanted horizontally to other jurisdictions. This Part explores the mechanisms for this transmission of legal norms and argues that information disclosure legislation such as REACH is becoming an important vehicle for the horizontal spread of legal norms in environmental law.

### *A. Regulatory Turbulence*

Just as one country's discharge of pollution can result in transnational externalities, one country's regulatory response to environmental risks can also result in transnational externalities by imposing costs on foreign firms, limiting or expanding political options

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productivity loss from chemical exposures will be €57 billion to €283 billion over twenty years. *Id.* at 52.

122. See Transatlantic Business Dialogue, Trade Facts: Transatlantic Trade, [http://www.tabd.com/index.php?option=com\\_content&task=view&id=19&Itemid=48](http://www.tabd.com/index.php?option=com_content&task=view&id=19&Itemid=48) (last visited Oct. 8, 2009) ("Imports of chemicals by the United States from the European Union rose . . . to almost \$78 billion in 2007.").

in foreign jurisdictions, changing foreign investment flows, and shaping foreign regulatory debates.

I refer to these transnational externalities from the enactment of internal legislation as “regulatory turbulence.” Regulatory turbulence is usually an unintended byproduct of one jurisdiction’s regulatory decisions. However, national regulators may also attempt to enhance their own prestige and national power through intentional, even coercive, efforts to spread their domestic innovations to other jurisdictions.<sup>123</sup>

Regulatory turbulence is antecedent to processes of legal transplant or legal export that have been much analyzed in political science literature.<sup>124</sup> Transplant and export refer to the adoption by one jurisdiction of legislative, regulatory, or judicial innovations of another jurisdiction.<sup>125</sup> Regulatory turbulence, in contrast, occurs before political actors have made a decision to adopt formally a foreign legal innovation. Regulatory turbulence is best described as a “legal irritant,”<sup>126</sup> as it can trigger unexpected economic, political, and cultural ripple effects in numerous jurisdictions—effects that may or may not be reflected, ultimately, in national legislation.

Regulatory turbulence is particularly pronounced when a jurisdiction imposes environmental standards for products traded in global commerce, as in the case of REACH. When a large jurisdiction enacts a *product* standard (such as a recycled content standard, an energy efficiency standard, or a design or labeling standard), multinational firms will have to meet that standard or risk losing that market. In contrast, enactment of domestic *process* standards, such as emissions limits for factories, power plants, and other sources of

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123. See, e.g., David Lazer, *Regulatory Capitalism as a Networked Order: The International System as an Informational Network*, 598 ANNALS AM. ACAD. POL. & SOC. SCI. 52, 64 (2005) (“[V]ery often policy makers have an interest in the dissemination of policies, either because of motivations around the beliefs of what is for the greater global good or because there is some benefit to the adoption by other jurisdictions of the policy maker’s innovation.”).

124. See Dobbin et al., *supra* note 12, at 450 (reviewing and distinguishing four theories explaining diffusion of policies across nations); David Dolowitz & David Marsh, *Learning from Abroad: The Role of Policy Transfer in Contemporary Policy-Making*, 13 GOVERNANCE: INT’L J. POL’Y & ADMIN. 5, 506 (2000) (analyzing the relationship between voluntary and forced policy transfer); Lazer, *supra* note 12, at 475 (highlighting three modes of regulatory interdependence and applying them to the regulation of fish inspection); Jonathan M. Miller, *A Typology of Legal Transplants: Using Sociology, Legal History and Argentine Examples to Explain the Transplant Process*, 51 AM. J. COMP. L. 839, 839 (2003).

125. See Miller, *supra* note 124, at 839 (defining legal transplant as “the movement of laws and legal institutions between states”).

126. See David Levi-Faur & Jacint Jordana, *Regulatory Capitalism: Policy Irritants and Convergent Divergence*, 598 ANNALS AM. ACAD. POL. & SOC. SCI. 191, 192–93 (2005) (“[W]hen a foreign rule is imposed . . . [i]t is not transplanted into another organism, rather it works as fundamental irritation which triggers a whole series of new and unexpected events.”).

pollution, is far less likely to cause regulatory turbulence in other jurisdictions.<sup>127</sup> Process standards, by their very nature, apply to stationary facilities within the territory of the sovereign that enacts them, whereas product standards have the potential to affect commercial relationships, design decisions, and profitability of firms around the world.<sup>128</sup>

REACH is a powerful engine of regulatory turbulence in the United States and in other jurisdictions because it acts as both a product standard, governing access to the most lucrative chemical market in the world, and as an information disclosure statute. Through its information generation and disclosure provisions, REACH will create a body of toxicity data that will be accessible to any other chemical regulatory authority in the world. REACH, therefore, is likely to have significant extraterritorial impact on U.S. firms and regulatory activity outside of Europe.<sup>129</sup>

Although REACH has been in force since only June 2007, signs of its regulatory turbulence may already be seen in the United States. REACH is easily the biggest regulatory change for the U.S. chemical industry in a generation—indeed, since TSCA's enactment. Most significantly, REACH has changed the legal terrain for U.S. firms that do business in Europe. Major U.S. chemical manufacturers such as Dow and DuPont are now conducting toxicity testing under REACH guidelines as part of the registration process for their products sold in Europe.<sup>130</sup> In the wake of REACH's enactment, American firms are developing EU-compliant toxicity data to avoid “toxic lock-out” for

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127. EU legislation on emissions controls for cement kilns, for example, would be unlikely to affect the cement industry outside the EU. The reach of the legislation would be limited to cement kilns located within the political boundaries of the EU.

128. See Richard B. Stewart, *Environmental Regulation and International Competitiveness*, 102 YALE L.J. 2039, 2043–45 (1993) (distinguishing between process standards and product standards and concluding that “the common interest in harmonizing process standards is typically weaker than the common interest in harmonizing product standards, where harmonization can increase the economic welfare of all nations by removing trade barriers”).

129. Two-way trade (exports and imports) between the United States and the European Union exceeded \$600 billion in 2007, which was almost twice as high as U.S.-China trade and nearly three times as high as U.S.-Japan trade. See Transatlantic Business Dialogue, Trade Facts: Transatlantic Trade, [http://www.tabd.com/index.php?option=com\\_content&task=view&id=19&Itemid=48](http://www.tabd.com/index.php?option=com_content&task=view&id=19&Itemid=48) (last visited Oct. 8, 2009) (noting that chemical exports from the United States to the European Union grew by 66 percent from 2003 to 2007).

130. Dow created twenty-three research teams to gather the chemical toxicity data needed for REACH's pre-registration deadline of December 1, 2008. Sara Goodman, *New European Disclosure Law Shifts 'Burden of Proof' to Industry*, GREENWIRE, June 23, 2008, <http://www.eenews.net/gw>. REACH also applies to any product that contains chemicals intended for release during normal or foreseeable use (such as air fresheners or ink-jet printer cartridges), REACH art. 7.1(b), so the legislation affects many large U.S. consumer product manufacturers selling in Europe, such as Procter & Gamble and Hewlett Packard.

their products in Europe,<sup>131</sup> and a cottage industry of REACH consultants has emerged to guide American firms and their European subsidiaries through the REACH process.<sup>132</sup>

### *B. Three National Responses to Regulatory Turbulence*

It is too facile to conclude that because one jurisdiction enacts stringent domestic environmental legislation, trading partners will inevitably follow with their own copycat legislation in a process of upward harmonization. Regulatory turbulence may, in some cases, lead to a transplant of regulatory innovations across jurisdictional lines, and numerous countries may ultimately adopt a version of a single influential regulatory model. But turbulence need not lead to this result in all circumstances. Instead, regulatory turbulence in environmental law can result in three distinct paths of transnational regulatory interactions.

#### 1. The Conflict Path

Transnational conflict is one possible response to regulatory turbulence. State A, for example, may challenge State B's internal environmental lawmaking as an unfair barrier to trade that disadvantages State A's exporters. State A, the aggrieved jurisdiction, may request diplomatic resolution, retaliate with its own trade measures, or file a formal complaint with an international body such as the World Trade Organization ("WTO"). Such challenges are frequent in the case of product standards, where a trading partner may allege that one jurisdiction's standards constitute a prohibited non-tariff barrier to trade. In the transatlantic context, the most prominent examples of such conflicts have been the disputes over the European ban on beef hormones and the European moratorium on the import and production of genetically modified foods. In both cases, the EU's internal regulatory policy, enacted ostensibly for public health reasons, had substantial extraterritorial effects. It served to exclude non-compliant American products from the European market, creating

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131. NINJA REINEKE, HOW IS THE US RESPONDING TO NEW EUROPEAN CHEMICALS LAW? THE IMPACT OF EUROPE'S REACH DEBATE ON CHEMICALS POLICY DEVELOPMENT IN THE US 10 (Feb. 2008), available at [http://assets.panda.org/downloads/how\\_is\\_the\\_us\\_responding\\_to\\_the\\_new\\_european\\_chemicals\\_law.pdf](http://assets.panda.org/downloads/how_is_the_us_responding_to_the_new_european_chemicals_law.pdf) (explaining that "toxic lock out" occurs when products are denied access to a market because of their toxic content or their non-compliance with environmental regulations).

132. See, e.g., ChemSafe, Consulting Services for Chemical Industry, [http://www.chemsafe-consulting.com/reach/consulting\\_firm.html](http://www.chemsafe-consulting.com/reach/consulting_firm.html) (last visited Oct. 8, 2009).

intense trade friction and legal and political acrimony. In both cases, the WTO ruled in favor of the United States.<sup>133</sup>

The United States and the EU have clashed in a number of other areas at the intersection of environmental protection and transatlantic trade.<sup>134</sup> David Wirth has referred to these trade-and-environment disputes as examples of “negative harmonization.”<sup>135</sup> These disputes are attempts to resolve the legal friction from divergent product standards by compelling one jurisdiction to modify or repeal its (usually more stringent) standard.<sup>136</sup>

## 2. The Coordination Path

Regulatory turbulence can also stimulate a process of coordination, in which trading partners seek to harmonize national standards across borders. Coordination of national policies, particularly with respect to product standards, both reduces trade barriers and provides economies of scale, as it allows firms to produce a single product that complies with the national requirements of numerous jurisdictions.

Coordination of national regulatory policies may occur through several mechanisms. It might occur through a straightforward process of learning, modeling, and sharing of ideas. A state might adopt a legislative program similar to one enacted by another state because that legislation appears to be an attractive “off-the-shelf” model that has proven workable in another jurisdiction. For example, numerous countries now have some form of environmental impact review legislation for major government actions, an innovation pioneered in the United States through the National Environmental Policy Act of

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133. See Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products*, ¶ 6, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) (ruling that the European Community’s measure was inconsistent with WTO law); Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, 1, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006) (ruling that parts of the European Community’s regulatory regime for the approval and marketing of biotech products violated the Agreement on the Application of Sanitary and Phytosanitary Measures).

134. In January 2009, for example, the United States filed a complaint with the WTO challenging an EU ban on U.S. poultry treated with pathogen reduction chemicals. Press Release, Office of the United States Trade Representative, U.S. Files WTO Case Challenging EU Restrictions on U.S. Poultry Exports (Jan. 16, 2009), available at <http://www.ustr.gov/about-us/press-office/press-releases/2009/january/us-files-wto-case-challenging-eu-restrictions-us-p>.

135. See Wirth, *supra* note 9, at 94 (finding that “structured negative harmonization” results in “relaxation of the rigor of regulatory standards”).

136. According to Wirth, the task of trade law is “to distinguish between those unilateral measures ostensibly intended to promote environmental, consumer protection, or public health goals that are legitimate exercises of governmental regulatory powers and those that are, by contrast, pretexts for protectionism.” *Id.* at 95.

1969.<sup>137</sup> Argentina's hazardous waste law is a virtual copy of U.S. legislation.<sup>138</sup> And, as noted in Part I, the EU's chemical regulatory regime prior to REACH was closely modeled on TSCA.

Coordination can also be stimulated through what Anne-Marie Slaughter has called "transgovernmentalism," or the regularized interactions of national regulatory officials operating in loose transnational networks.<sup>139</sup> Within these networks, officials spread information on best practices, highlight opportunities for welfare-enhancing harmonization, and build capacity to enforce and implement regulations.<sup>140</sup> The Organization for Economic Co-operation and Development, for example, has been active since the early 1980s in promoting voluntary harmonization of national policies on chemical labeling and mutual acceptance of test data.<sup>141</sup>

Pressure from private firms can provide yet another stimulus for the coordination path. This mechanism of coordination, which can unfold even without the purposive interactions of national bureaucrats, often occurs in two steps. First, if a large jurisdiction enacts an environmental standard for products, firms will have to comply with that standard or risk losing access to a major customer

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137. See Tseming Yang & Robert Percival, *The Emergence of Global Environmental Law* 10–12 (Vt. Law Sch. Legal Studies Research Paper Series, Research Paper No. 09-09, 2008), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1269157](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1269157) (describing the environmental impact assessment procedures adopted by various nations).

138. Miller, *supra* note 124, at 846.

139. Slaughter has defined "transgovernmental networks" as "pattern[s] of regular and purposive relations among like government units working across the borders that divide countries from one another and that demarcate the 'domestic' from the 'international' sphere." ANNE-MARIE SLAUGHTER, *A NEW WORLD ORDER* 14 (2004). Similarly, Kal Raustiala has defined transgovernmental networks as "loosely-structured, peer-to-peer ties developed through frequent interaction rather than formal negotiation." Kal Raustiala, *The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law*, 43 VA. J. INT'L L. 1, 5 (2002). Examples of these networks include the International Organization of Securities Commissioners, the International Association of Insurance Supervisors, the International Maritime Organization, and the Organization for Economic Co-operation and Development. See *id.* at 18 (explaining the "power-shift" from the state to nongovernmental organizations). For a detailed discussion on the role of the OECD in generating transnational legal norms, see James Salzman, *Decentralized Administrative Law in the Organization for Economic Cooperation and Development*, 68 LAW & CONTEMP. PROBS. 189, 220–21 (2005).

140. See Raustiala, *supra* note 139, at 52–53; Anne-Marie Slaughter, *Global Government Networks, Global Information Agencies, and Disaggregated Democracy*, 24 MICH. J. INT'L L. 1041, 1057 (2003) (arguing that although transgovernmental networks rarely make binding rules, the information-exchange function of policy networks is invaluable to domestic regulators looking for guidance on best practices).

141. Wirth, *supra* note 9, at 93. Wirth notes that the OECD has had less success in coordinating national policies on a minimum set of pre-market data for new chemicals. An OECD effort to establish such a minimum data set in the early 1980s failed when the United States did not accept the plan, largely because the proposal exceeded the requirements of TSCA and other domestic legislation. *Id.* at 99.

base. They may find it impractical to produce alternative versions for other markets and may therefore choose to produce a single product that conforms to the standards of the strictest jurisdiction.<sup>142</sup> In this process, one jurisdiction's domestic law becomes the de facto global norm governing the industry.

In the second step of coordination through pressure from private firms, governments may conform their legislation to approximate the law of the strict originating jurisdiction, either to avoid trade disruption or because they find it relatively costless to do so, since major domestic firms are already complying with the foreign standard.<sup>143</sup> Firms operating in multiple jurisdictions may also lobby for coordination of national policies at the level of the most stringent jurisdiction to avoid being placed at a competitive disadvantage vis-à-vis domestic competitors.<sup>144</sup> The end result of these processes is upward pressure on national regulatory standards, outside of the originating jurisdiction.

In this mechanism of coordination, the marketplace itself acts as the "transmission belt" for the legal norms of the originating jurisdiction.<sup>145</sup> This process has been dubbed the "California effect," after the U.S. state that has often played this first-mover role in American environmental law.<sup>146</sup> It has also been called a "race to the top" or "race to the hegemon" because regulatory activity by a major power exerts a gravitational pull on other powers to enact conforming domestic standards.<sup>147</sup> For the originating jurisdiction, transforming

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142. See Per-Olof Busch, Helge Jörgens & Kerstin Tews, *The Global Diffusion of Regulatory Instruments: The Making of a New International Environmental Regime*, 598 ANNALS AM. ACAD. POL. & SOC. SCI. 146, 152 (2005) (discussing the result of economic competition as a " 'race to the top' whereby countries seek to emulate new and ambitious regulatory approaches . . . and not lag behind other countries"); see also Jacob Park, *Unbundling Globalization: Agent of Policy Convergence?*, 4 INT'L STUD. REV. 230, 232 (2002) ("[I]t is frequently overlooked that it is more expensive for MNCs [multinational corporations] to maintain different regulatory standards than to maintain one global standard and to upgrade the environmental standards of the laggard facilities.").

143. See Lazer, *supra* note 12, at 477 (noting the incentive for jurisdictions to adhere to standards that are compatible with other jurisdictions).

144. See ELIZABETH DESOMBRE, DOMESTIC SOURCES OF INTERNATIONAL ENVIRONMENTAL POLICY: INDUSTRY, ENVIRONMENTALISTS, AND U.S. POWER 5–7 (2000) (describing the "phenomenon of internationalization of environmental policies").

145. See Yang & Percival, *supra* note 137, at 7 ("[R]egulatory innovations spread not only through the work of government regulators but also through the responses of the regulated communities.").

146. See DAVID VOGEL, TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY 5–8 (1995); Wirth, *supra* note 9, at 96–97 (discussing California effect).

147. See VOGEL, *supra* note 146, at 6. Vogel argues that the race to the top can occur under two conditions: (1) where domestic firms align themselves with environmental groups to push for strict domestic environmental standards to keep out foreign competition (a so-called "Baptist-

domestic product standards into global standards undoubtedly benefits domestic firms, which may have made early capital investments in compliance.<sup>148</sup> Indeed, a nation's ability to gain regional or global acquiescence to its own regulatory standards is now seen as a key element of national "soft power."<sup>149</sup>

The EU's enactment in 2003 of a directive on electronics provides one recent example of the coordination path.<sup>150</sup> That directive, on Restriction of Hazardous Substances ("RoHS"), banned six toxic substances from most electronics sold in Europe.<sup>151</sup> Due to the size of the EU market, the legislation had the effect of shifting the design and manufacture of electronic products globally. Electronics manufacturers in China, Korea, Taiwan, and Japan quickly changed product designs and eliminated the six toxic substances to maintain their access to the EU market.<sup>152</sup> Once manufacturers shifted their product designs to be "RoHS-compliant," other jurisdictions enacted legislation similar to the EU model. China, for instance, adopted legislation in 2005 (colloquially known as "China RoHS") that banned the same six substances in most electronics sold in China.<sup>153</sup> California also adopted a version of RoHS in 2005, banning the same six substances in covered electronics sold in California. In an example

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bootlegger" coalition), and (2) where multinational corporations selling in many national markets push for harmonized national standards to achieve economies of scale and reduce barriers to global distribution. *Id.* at 7–8, 20.

148. As Kal Raustiala explained, jurisdictions actively promote adoption of their standards abroad because they "reap the gains of convergence around their preferred outcome." Raustiala, *supra* note 139, at 68.

149. See JOSEPH S. NYE, JR., *SOFT POWER: THE MEANS TO SUCCESS IN WORLD POLITICS*, at x (2004) (defining soft power as "the ability to get what you want through attraction rather than coercion or payments").

150. Another example of a "California effect" in environmental regulation is the global spread of rules mandating double hulls for oil tankers. Such rules were enacted in multiple jurisdictions after the United States mandated double hulls for most tankers in its territorial waters, following the Exxon Valdez oil spill. See Oil Pollution Act of 1990, 46 U.S.C. § 3703a(a) (2009); NATIONAL RESEARCH COUNCIL, *DOUBLE-HULL TANKER LEGISLATION: AN ASSESSMENT OF THE OIL POLLUTION ACT OF 1990* 1 (1998) (noting that the Oil Pollution Act, and the subsequent adoption of a double-hull requirement in international maritime law, has led to double-hull tankers becoming the "industry standard").

151. Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, 2003 O.J. (L 37) 19.

152. See Rob Spiegel, *Is Asia Ready for RoHS?*, ELECTRONIC NEWS, Mar. 5, 2006, available at <http://www.edn.com/article/CA6313998.html> (outlining Asia's ability to meet the EU's RoHS directive).

153. See, e.g., Suzanne Deffree, *China RoHS: Ready or Not, It's Here*, ELECTRONIC NEWS, Mar. 12, 2007, at 2; Tam Harbert, *China Flexes Environmental Muscles*, ELECTRONIC BUSINESS, Sept. 1, 2006, at 34 (outlining China's regulation of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyl, and polybrominated diphenyl ether).

of how close the coordinative response can be, the California legislation provided that if the EU added to its list of six hazardous substances, those additional substances would automatically be banned in covered electronics sold in California.<sup>154</sup>

### 3. The Stasis Path

The third possible path of interaction among domestic regulatory regimes is stasis. In this path, countries choose to “go their own way,” maintaining divergent environmental standards for globally traded products, despite regulatory turbulence and probable interjurisdictional trade disruption.

Stasis is a frequent response to regulatory turbulence for several reasons: states may not be paying close attention to the domestic regulatory standards of their trading partners, the transaction costs to coordinate regulatory policy may be too high, or states may simply decide that the environmental standards of a foreign power would be welfare-reducing if adopted domestically. States may also seek competitive advantage by maintaining lax environmental standards if other jurisdictions are moving toward stringency.<sup>155</sup>

From a public choice perspective, even if certain bureaucratic elites see advantages in transnational coordination of regulatory policy (whether in the environmental field or in other policy areas such as banking, securities, or aviation), countervailing pressures, such as dissenting interest groups or political parties, may prevail in the domestic political process. Various lock-in effects and path dependency may also make it too costly to reform existing legislation to harmonize it with the legislation of a foreign jurisdiction. The cost of harmonizing regulatory policies across borders might range from near-zero (if jurisdictions have no preexisting regulatory path in a given issue area) to potentially billions of dollars (if jurisdictions have already made significant investments in a divergent regulatory apparatus).<sup>156</sup>

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154. Cal. Health & Safety Code § 25214.10(b) (West 2006); see also Noah Sachs, *Planning the Funeral at the Birth: Extended Producer Responsibility in the European Union and the United States*, 30 HARV. ENVTL. L. REV. 51, 93–94 (2006) (discussing the transnational effects of the EU’s RoHS directive).

155. See Peter P. Swire, *The Race to Laxity and the Race to Undesirability: Explaining Failures in Competition Among Jurisdictions in Environmental Law*, 14 YALE L. & POL’Y REV. 67, 88–89 (1996) (describing this inter-jurisdictional “race to the bottom”).

156. Raustiala, *supra* note 139, at 67–68; see also DREZNER, *supra* note 12, at 5 (“Whether regulatory coordination takes place is a function of the adjustment costs actors face in altering

One prominent example of jurisdictions choosing divergent regulatory systems for a highly globalized industry, despite regulatory turbulence and potential trade disruption, is the continuance of divergent cell phone standards between the United States and Europe. The United States and the EU also maintain divergent emissions limits and fuel economy standards for automobiles, different standards for pesticide residues on food, and different regulatory systems for cosmetics. Multinational firms must adapt to these divergent standards and, in many cases, produce different products for different markets.

#### 4. Transnational Regulatory Interactions and Globalization

Much of the literature on transnational regulatory interactions suggests that given the economic interdependence of globalization, transnational convergence around certain values, policies, or outcomes is somehow mechanistic or inevitable—especially in industrialized nations.<sup>157</sup> But as the above discussion illustrates, the coordination path is not predestined, and domestic regulatory policies frequently diverge even among close trading partners. As nations and economies become more interdependent, a pastiche of complex regulatory interactions emerges, resulting in conflict, coordination, and stasis. Despite predictions from many analysts that globalization would erode the power of the state vis-à-vis private capital,<sup>158</sup> states continue to enjoy considerable autonomy to regulate private markets within their borders; coordination is just one possible response to regulatory turbulence from foreign jurisdictions.

When transnational regulatory coordination does occur, it is important to question whether such coordination is normatively beneficial for economies, society, or the environment. Here again generalization is difficult, and the answer must be determined on a case-by-case basis. Regulatory coordination might lead to the rapid

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their preexisting rules and regulations. When the adjustment costs are sufficiently high, not even globalization's powerful dynamics can push states into cooperating.”).

157. See Colin Bennet, *What is Policy Convergence and What Causes It?*, 21 BRIT. J. POL. SCI. 215, 216 (1991) (critiquing the argument that industrialization sets in motion “certain deterministic processes . . . which tend over time to shape social structures, political processes, and public policies in the same mould”); Daniel W. Drezner, *Globalization and Policy Convergence*, 3 INT'L STUD. REV. 53, 53 (2001) (“An implicit assumption of most policy analysts and some academics is that globalization leads to a convergence of traditionally national policies governing environmental regulation, consumer health and safety, the regulation of labor, and the ability to tax capital.”).

158. See DREZNER, *supra* note 12, at 4 (discussing literature on the decline of the state in the era of globalization).

spread of valuable innovation in environmental law, without the laborious process of negotiating multilateral environmental treaties. On the other hand, pressure to conform national legislation to that of a major power might have deleterious effects. Such conformity pressure might cut off policy innovation or experimentation, for example, or it might lead to anticompetitive trade practices.

Given the complexities of transnational regulatory interactions, this Article does not articulate an overarching theory, applicable across all industries and all countries, that explains when regulatory turbulence will lead to the conflict path rather than the coordination or stasis paths. The outcome of transnational regulatory interactions depends critically on the relative strength of interest groups, the cost structures of the affected industries, the market power of the originating jurisdiction, the closeness of political and economic ties among jurisdictions, and a host of other factors. As one scholar concluded, there are simply “too many important microdifferences among industrial sectors to allow for any broad macroconclusions on policy convergence.”<sup>159</sup> My conclusions in this Article are therefore directed solely at U.S.-EU interactions on chemical policy, and not at a much broader range of regulatory interactions in other issue areas. In this one sector, the potential that REACH will raise global standards for chemical testing and management should be seen as a welcome extraterritorial benefit of the EU’s regulatory decisions.

### *C. Information Disclosure and Regulatory Turbulence*

In the Internet age, the disclosure of environmental data needs to be seen as a new vehicle for causing regulatory turbulence in other jurisdictions, distinct from the extraterritorial impacts of enacting product standards. REACH is just one example of environmental legislation with a significant information disclosure component. Other forms of information disclosure legislation require regulated entities to disclose product ingredients, associated health and environmental risks, or amounts and types of pollution released from facilities. Environmentally relevant information, once disclosed, is usually accessible to foreign political actors, who may rely on that information in developing new regulations or legislation, bringing enforcement actions, or setting policy.<sup>160</sup>

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159. Park, *supra* note 142, at 231.

160. Legislation that *tightens* information flows can have similar extraterritorial effects. Gregory Shaffer has demonstrated, for example, that an EU data privacy directive enacted in 1998, which authorized the European Commission to ban data transfers from the EU to countries that do not ensure “an adequate level of protection” for data privacy, had the effect of

In other fields of law, these kinds of transnational, informational ripple effects are so commonplace that we take them for granted. Adverse corporate information disclosed under a Chinese securities regulation can immediately affect share prices on exchanges in New York or London. Evidence of consumer fraud unearthed in one jurisdiction can be used to bring copycat fraud claims against the same corporation in other jurisdictions.

Yet despite the explosive growth of information disclosure rules as a tool for environmental protection, existing scholarship has rarely focused on the role of information disclosure legislation as a vehicle for the transmission of environmental law norms.

How, specifically, does information disclosure in one jurisdiction affect the regulatory systems of other jurisdictions? According to the political scientist David Lazer—one of the few scholars to examine information disclosure and transnational regulatory interactions<sup>161</sup>—nations are linked through an “informational mode” of interdependence.<sup>162</sup> Lazer posits that a jurisdiction’s regulatory activity can convey informational signals to other jurisdictions in three stages: policy deliberations, policy choices, and policy experiences.<sup>163</sup> First, an originating jurisdiction may make available the information that fed its deliberations about whether to adopt a certain policy (e.g., scientific research used in the policy deliberations).<sup>164</sup> Second, an originating jurisdiction conveys a transnational, informational signal when it makes a certain policy choice (which in itself might convince other countries to follow).<sup>165</sup> Third, an originating jurisdiction conveys ongoing informational signals about its post-enactment experience with new legislation or regulations.<sup>166</sup> In this last category, the key information being

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raising the stringency of data privacy protections globally. See Gregory Shaffer, *Globalization and Social Protection: The Impact of EU and International Rules in the Ratcheting Up of U.S. Privacy Standards*, 25 YALE J. INT’L L. 1, 7–8 (2000).

161. See David Lazer, *Global and Domestic Governance: Modes of Interdependence in Regulatory Policymaking*, 12 EUR. L.J. 455, 455–56 (2006) [hereinafter Lazer, *Global and Domestic Governance*]; Lazer, *supra* note 123, at 52; Lazer, *supra* note 12, at 474 (discussing the interdependence of different countries’ regulatory policies).

162. Lazer, *supra* note 12, at 480–82.

163. Lazer, *Global and Domestic Governance*, *supra* note 161, at 463.

164. Lazer, *supra* note 12, at 481 (noting that the initial epidemiological studies on the hazards of asbestos were conducted in Britain, and then spurred regulatory action in the United States).

165. See *id.* at 480 (“To the extent that states have similar policy preferences, this information becomes a public good, readily usable by any other states that might consider similar regulatory policies.”).

166. See *id.* at 475 (“The regulatory choices of other states provide signals . . . to good policy options.”).

transmitted, according to Lazer, is whether a given policy works and achieves an adequate balance of health, environmental protection, and cost.<sup>167</sup> Through all three types of informational signals, Lazer concludes, countries are constantly providing information to each other about what desirable policies are.<sup>168</sup> Of course, regulatory activity of one jurisdiction might also demonstrate to other jurisdictions what *undesirable* policies are.

Lazer's analysis is useful in highlighting the web of informational connections that link nations in their regulatory policymaking, yet he overlooks some critical features of transnational informational networks. By focusing on national sovereigns' interpretation of policy-relevant information coming from other jurisdictions,<sup>169</sup> he misses the numerous ways that information from abroad may affect political dynamics at the subnational level: among firms, consumers, state or provincial governments, and nongovernmental organizations ("NGOs"). These subnational actors may use information from foreign regulatory systems in domestic battles for political influence. They may also rely on foreign sources of information in developing new products, political strategies, and in the case of state governments, regulatory agendas.

Lazer also overlooks a fourth category of informational signals that is particularly important for understanding the REACH-TSCA interaction: raw data on health and environmental risks, produced after the enactment of information disclosure legislation in one jurisdiction, may have direct transnational effects on regulation in other jurisdictions. Information disclosure legislation in Country A, for example, might reveal information about a risk that regulators in Country B are required by statute to address (or might choose to address if they have regulatory discretion). Air emissions data in an environmental impact statement prepared in one jurisdiction might be used by regulators who are reviewing a similar project in another jurisdiction. In this respect, data on environmental or health risks from one jurisdiction might "feed" ongoing regulatory processes in other jurisdictions.

This kind of raw data is a fundamentally different type of information than the informational signals Lazer explores, which concern whether a certain policy, enacted abroad, is desirable.

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167. *Id.* at 480.

168. Lazer, *supra* note 123, at 53.

169. *See id.* at 53 (conceptualizing the international system as an informational network in which sovereign nations both produce and process information).

Transnational flows of raw data on environmental and public health hazards are less filtered by culture and politics than transnational signals about what desirable policies are. And disclosures of raw data may trigger regulatory action under existing statutes in other jurisdictions, without a drawn-out process of considering the desirability of foreign regulatory models. Whether environmental disclosures in one jurisdiction can be incorporated into existing regulation in other jurisdictions will depend on the degree of overlap in regulatory approaches. It will also depend on the degree to which actors abroad are monitoring environmental disclosures made in the originating jurisdiction.<sup>170</sup> As Harold Koh has explained, the horizontal spread of legal norms depends critically on whether there are “norm entrepreneurs,” such as NGOs, or “norm sponsors,” such as legislators, who are following foreign developments and are positioned to use foreign sources of information in domestic political debates.<sup>171</sup>

#### *D. The Impact of REACH on the United States*

With this theoretical background on transnational regulatory interactions and informational spillover effects, it is now easier to see the mechanisms through which REACH is influencing the United States. REACH’s transnational effects are magnified because it acts as *both* a product standard *and* an information disclosure regulation. Manufacturers around the globe, seeking to preserve their access to the EU chemical market, will compile the required dossiers and chemical safety reports on chemicals sold in the EU, most of which have never been tested in the United States or elsewhere. Because the hazard and risk information that will be disclosed in the EU pertains to globally traded *products*, as opposed to stationary production processes in Europe, the information is likely to be relevant to purchasers and regulators of those same chemicals in other jurisdictions around the globe.

What path of regulatory interaction between the United States and the EU is likely to flow from the regulatory turbulence from REACH: conflict, coordination, or stasis? Although REACH has only recently been enacted, there are already signs of a shift in

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170. See Lazer, *Global and Domestic Governance*, *supra* note 161, at 464–65 (noting that policymakers can pay attention to only a small fraction of the informational signals from other countries about policy options).

171. See Harold Hongju Koh, *The 1998 Frankel Lecture: Bringing International Law Home*, 35 HOUS. L. REV. 623, 647–48 (1998) (providing examples of transnational norm entrepreneurs and governmental norm sponsors).

transnational interactions on chemical policy, from a path of U.S.-EU conflict to one of coordination.

### 1. Conflict Interactions on Chemical Policy

From 2001 to 2006, while REACH was under discussion in Europe, conflict was the dominant path of regulatory interaction between the United States and Europe over chemical policy. Major U.S. chemical companies and industry trade associations were concerned about the impact of REACH on their profitability and competitiveness.<sup>172</sup> And in close cooperation with American industry, the Bush Administration launched an unusual lobbying campaign in Brussels to stop or weaken REACH.<sup>173</sup>

The campaign began in 2001, when the Department of Commerce and the U.S. Trade Representative (“USTR”) advised the American Chemistry Council “to develop an official position and strategy as soon as possible to assist in influencing the EU’s draft text” on REACH.<sup>174</sup> After consultation with the ACC and major U.S. chemical companies, the USTR, Secretary of State Colin Powell, and the U.S. Ambassador to the EU, Boyden Gray, began lobbying EU counterparts and Member State governments to weaken the initial drafts of REACH.<sup>175</sup> The campaign included not only traditional diplomatic communiqués, but also direct lobbying of members of the European Parliament by U.S. officials.<sup>176</sup> This direct lobbying was widely decried in Europe as inappropriate interference in the EU’s internal deliberations. Portions of diplomatic communiqués from the Bush Administration to EU counterparts came from memos prepared by the U.S. chemical industry, and U.S. environmental groups received only token consultation.<sup>177</sup> In June 2004, the U.S. Mission to the European Union presented a list of U.S. objections to REACH

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172. H.R. COMM. ON GOV’T REFORM—MINORITY STAFF, SPECIAL INVESTIGATIONS DIV., 108TH CONG., A SPECIAL INTEREST CASE STUDY: THE CHEMICAL INDUSTRY, THE BUSH ADMINISTRATION, AND EUROPEAN EFFORTS TO REGULATE CHEMICALS 2 (COMM. PRINT 2004).

173. For more information on opposition to REACH by the United States, see *id.* at 2–3; GEISER & TICKNER, *supra* note 97, at 137–38, and Marc Schapiro, *Toxic Inaction*, HARPER’S, Oct. 2, 2007, at 78, 81–82.

174. COMM. ON GOV’T REFORM, *supra* note 172, at 4.

175. See Schapiro, *supra* note 173, at 81–82 (detailing the reactions to REACH by various groups in the United States).

176. See Wirth, *supra* note 9, at 102 & n.30 (describing October 9, 2006 email from the U.S. Mission to the EU to members of the European Parliament containing the subject line “REACH Second Reading: U.S. Views” and beginning “Attached is our ‘voting’ list on some of the amendments you will be voting on tomorrow”).

177. GEISER & TICKNER, *supra* note 97, at 137–38; COMM. ON GOV’T REFORM, *supra* note 172, at 15.

(then still in draft form) to a WTO committee.<sup>178</sup> Although no formal WTO complaint against REACH has been filed to date, several observers of the U.S. role in REACH deliberations have concluded that the United States succeeded in weakening key elements of REACH.<sup>179</sup>

## 2. Toward a Coordination Path?

Now that REACH is in force in the EU, there are signs that transnational interactions on chemical policy are shifting from a conflict path to a coordination path. REACH is creating significant regulatory turbulence in the U.S. chemical market, highlighting the inadequacies of TSCA and expanding the scope of options that appear politically, economically, and scientifically feasible in chemical regulation in the United States.<sup>180</sup> While there are other reasons for the growing interest in TSCA reform (such as public concern over chemicals in toys and baby products), there is little doubt that at the state and federal level, REACH is “galvanizing attention on reforming TSCA.”<sup>181</sup>

Changes in the U.S. policy debate are occurring at numerous levels. In the past five years, several U.S. states have enacted legislation to address chemical hazards, an area of environmental law traditionally under federal authority. Governors and state legislators are looking to Europe for regulatory models.<sup>182</sup> As of December 2007,

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178. U.S. MISSION TO THE EUROPEAN UNION, U.S. SUBMITS COMMENTS ON EC'S REACH PROPOSAL TO WTO COMMITTEE, NOTIFICATION G/TBT/N/EEC/52 REGARDING EUROPEAN COMMISSION REGULATION COM (2003), *available at* [http://dublin.usembassy.gov/ireland/ecchemical\\_proposals.html](http://dublin.usembassy.gov/ireland/ecchemical_proposals.html). Among the U.S. concerns presented were that REACH was too complex and represented an “unworkable” regulatory approach; that its key definitions and terms were vague; that it would disrupt global trade; and that the legislation would impose “burdensome analytical, reporting and administrative requirements” on downstream users of chemicals. *Id.*

179. *See, e.g.*, GREENPEACE, TOXIC LOBBY: HOW THE CHEMICALS INDUSTRY IS TRYING TO KILL REACH 16–17 (2006), *available at* <http://www.greenpeace.org/raw/content/international/press/reports/toxic-lobby-how-the-chemical.pdf> (“Such an international lobbying strategy, closely coordinated with industry representatives, proved to be extremely effective especially in watering down the draft REACH proposal, leading to a much weaker final draft in October 2003.”).

180. *See* DITZ, *supra* note 65, at 2 (“The long stalemate over TSCA is beginning to shift. Public concerns about specific chemicals are giving way to a look at systemic failures and root causes.”).

181. UNIV. OF PITTSBURGH EUR. UNION CTR. OF EXCELLENCE & UNIV. OF PITTSBURGH GRADUATE SCH. OF PUB. HEALTH, A NEW EU APPROACH TO CHEMICAL SAFETY: LESSONS FOR THE UNITED STATES? A CONFERENCE ON THE EUROPEAN UNION (EU) REGULATION PROVIDING FOR REGISTRATION, EVALUATION, AUTHORIZATION, AND RESTRICTION OF CHEMICALS (REACH) 10 (2007), *available at* <http://www.ucis.pitt.edu/euce/events/policyconf/07/PDFs/ReachReport.pdf>.

182. *See* Michael Wilson & Megan Schwarzman, California Chemicals Policy and the European Union, Address at California-EU Regulatory Cooperation Project 3–4 (Feb. 22–23,

eleven states had enacted restrictions on brominated flame retardants, some of which have been found to be neurotoxins, following a 2003 EU ban.<sup>183</sup> In September 2008, Governor Arnold Schwarzenegger of California, spurred by the enactment of REACH, signed a landmark green chemistry law that focuses on evaluating chemical alternatives and promoting substitution of hazardous chemicals.<sup>184</sup> And in January 2008, the Massachusetts senate unanimously passed “safer alternatives” legislation, designed to encourage substitutes for ten known toxic chemicals.<sup>185</sup> The states are clearly serving a Brandeisian role as laboratories for policy experimentation. If a patchwork of state chemical regulation develops, it may provide an impetus for federal chemical policy reform, paralleling recent developments in climate change legislation.<sup>186</sup>

At the federal level, the Kid-Safe Chemicals Act,<sup>187</sup> which amends TSCA and contains several elements inspired by REACH,<sup>188</sup>

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2008), available at <http://repositories.cdlib.org/cgi/viewcontent.cgi?article=1157&context=igs> (noting that the California Green Chemistry initiative was spurred, among other things, by the enactment of REACH and lack of federal attention to chemical policy reform); see also Memorandum from Linda S. Adams, Cal. Sec’y for Env’tl. Prot., to Chairpersons and Dirs. of the Bds., Dep’ts, and Office 1 (Apr. 20, 2007), available at [http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/CalEPA\\_Green\\_Chemistry\\_Initiative\\_Memo.pdf](http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/CalEPA_Green_Chemistry_Initiative_Memo.pdf) (noting that in 2007 alone, fifty bills addressing chemical safety and regulation were introduced in the California legislature).

183. See Nat’l Caucus of Env’tl. Legislators, Enacted Laws, Executive Orders & 2007 Introduced Bills: PBDE Legislation (July 13, 2007), available at [www.ncel.net/articles/PBDE.Legislation.Laws.Website.doc](http://www.ncel.net/articles/PBDE.Legislation.Laws.Website.doc) (listing the eleven states with brominated flame retardant restrictions); Jennifer 8. Lee, *California to Ban Chemicals Used as Flame Retardants*, N.Y. TIMES, Aug. 10, 2003, at N14 (noting that California followed the EU’s lead).

184. Assem.B. 1879, 2008 Cal. Legis. Serv. 559 (West) (codified as amended at CAL. HEALTH & SAFETY CODE §§ 25252–55, 25257); accord. Margot Roosevelt, *California Officials Launch Green Chemistry Initiative*, L. A. TIMES, Dec. 17, 2008, at B1; see also S.B. 509, 2008 Ca. Legis. Serv. 560 (West) (establishing an online clearinghouse for information on toxic chemicals in consumer products).

185. An Act for a Healthy Massachusetts: Safer Alternatives to Toxic Chemicals, S. 2481, 2008 Leg., 185th Sess. (Mass. 2008).

186. See Daryl 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, 30 (2007) (“The current upsurge of state laws on chemicals aims not only to protect their own citizens, but also to create a political environment for long overdue national reform.”); cf. J.R. DeShazo & Jody Freeman, *Timing and Form of Federal Regulation: The Case of Climate Change*, 155 U. PA. L. REV. 1499, 1533 (2007) (arguing that state-level climate change legislation is hitting a political “sweet spot” that is creating pressure on federal legislators to adopt a climate change bill).

187. See *Democrats Roll Out Broad Chemical Risk Management Reform Bill*, INSIDE EPA WKLY. REPORT, May 30, 2008, at 18; accord. Pat Phibbs, *Report Lists Actions Congress Could Take to Improve EPA Assessments under TSCA*, 29 Chem. Reg. Rep. (BNA) 702 (July 18, 2005) (quoting Sen. Lautenberg: “Europe gave us the inspiration to look hard at our own chemical law and ways to improve it.”).

188. Kid-Safe Chemicals Act of 2008, S. 3040, 110th Cong. (2008); H.R. 6100, 110th Cong. (2008); S.1391, 109th Cong. (2005) (introduced as the Child, Worker, and Consumer-Safe

has been introduced in two separate Congresses, most recently in May 2008. The bill promotes alternatives to hazardous chemicals, shifts the burden to industry to demonstrate “reasonable certainty of no harm” from chemical products, limits confidential business information claims, and expands biomonitoring for the presence of toxic chemicals.<sup>189</sup> While the fate of the Kid-Safe Chemicals Act is uncertain in the 111th Congress, prominent members of Congress are supporting the use of REACH as a model for legislative reform—they are “norm sponsors,” in the terminology of Harold Koh. These supporters include Henry Waxman, Chair of the House Energy and Commerce Committee, and Barbara Boxer, Chair of the Senate Environment and Public Works Committee,<sup>190</sup> both of whom would have jurisdiction over a TSCA reform bill. U.S. legislators have the advantage of observing the REACH implementation process in Europe and learning from Europe’s experience with continent-wide chemical regulation reform.

In the small community of U.S. public interest lawyers and activists focused on chemical policy, REACH has become a lodestar for reform. Scientists and attorneys at groups such as the Environmental Defense Fund, the Center for International Environmental Law, Environmental Working Group, and the Science and Environmental Health Network are acting as “norm entrepreneurs.” These groups are issuing detailed reports on REACH, developing a media strategy, and providing testimony before legislative bodies to promote REACH as an important model for the United States. The enactment of REACH has increased NGO calls for a systematic overhaul of U.S. chemical policy, shifting the focus from ad hoc bans or restrictions on specific chemicals.<sup>191</sup> The activist community has been buoyed by progress at the state level and by a series of stinging reports on federal chemical

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Chemicals Act of 2005). Sen. Lautenberg has indicated he intends to introduce the Kid-Safe Chemicals Act in the 111th Congress. *Scientific Integrity and Transparency Reforms at the Environmental Protection Agency: Hearing Before the H. Comm. and Subcomm. on Oversight*, 111th Cong. (2009) (statement of Sen. Frank Lautenberg), available at <http://lautenberg.senate.gov/newsroom/Hearings/060909.cfm>.

189. S. 3040 § 3. The Kid-Safe Chemicals Act mandates that all existing and new chemicals be reviewed for prioritization, that a priority list of at least 300 chemicals be developed by EPA, and that EPA determine whether the manufacturer has met the “reasonable certainty of no harm” test within three years of a chemical being placed on the list.

190. See H.R. 6100 (listing Waxman as a co-sponsor); Zachary Coile, *EPA Was Stymied by White House*, *GAO Reports*, S.F. CHRON., Apr. 30, 2008, at A1 (indicating Boxer’s support for chemical regulation reform).

191. See REINEKE, *supra* note 131, at 4 (“NGOs believe that a more comprehensive approach is needed and would like to see some paradigm shifts similar to the ones REACH was aiming for.”).

regulation by the GAO.<sup>192</sup> While activist pressure on chemical policy has primarily been directed at the state and federal governments, activists may also begin to target particular firms deemed recalcitrant on issues of chemical testing and disclosure.<sup>193</sup> The movement for chemical policy reform is still inchoate in the United States,<sup>194</sup> but there is no doubt that REACH has become an influential regulatory model and has emboldened U.S. environmental activists.

In predicting whether the United States will adopt REACH-like reforms, the stance of the U.S. chemical industry is the major wildcard. Will we see a “California effect” in chemical policy, in which pressure from chemical manufacturers to harmonize U.S. regulation with REACH will lead to a ratcheting up of the stringency of U.S. law? Or will the U.S. chemical industry attempt to block TSCA reform with the same intensity with which it attempted to weaken REACH in Europe? In Senate testimony in February 2009, Cal Dooley, the CEO of the American Chemistry Council, stated emphatically that “ACC is *not* advocating the adoption of the European Union’s REACH system.”<sup>195</sup> Nonetheless, in a notable shift from prior positions, Dooley also stated in the same hearing that Congress should “begin the effort to modernize TSCA.”<sup>196</sup> In August 2009, the ACC followed up this statement by releasing a set of ten principles that should guide TSCA reform.<sup>197</sup> The debate is now shifting from whether TSCA should be reformed to when and how reform should occur.

There is some precedent for a “California effect” unfolding through U.S.-EU interactions in chemical regulation. In the late 1970s, in the wake of the U.S. adoption of TSCA, European chemical companies began to support Community-wide chemical legislation modeled on TSCA. The European chemical industry advocated that chemical regulation be shifted from the Member States to the Community level to provide a counterweight to the United States and

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192. See GOV’T ACCOUNTABILITY OFFICE, *supra* note 19, at 3–6; GOV’T ACCOUNTABILITY OFFICE, *supra* note 30, at 2; GOV’T ACCOUNTABILITY OFFICE, *supra* note 39, at 2–16.

193. See David P. Baron & Daniel Diermeier, Strategic Activism and Non-Market Strategy 4 (2006), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=897324](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=897324) (noting that activist campaigns may target manufacturers directly or may aim further “downstream,” such as by boycotting retailers that sell goods from certain manufacturers).

194. See GEISER & TICKNER, *supra* note 97, at 144 (noting that “the U.S. is at least several years behind European countries in public discussions on chemicals.”).

195. *Revisiting the Toxic Substances Control Act of 1976: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Prot. of the H. Comm. on Energy and Commerce*, 111th Cong. 2 (2009) (Statement of Cal Dooley, President, Am. Chemistry Council) (emphasis in original), available at [http://energycommerce.house.gov/Press\\_111/20090226/testimony\\_acc.pdf](http://energycommerce.house.gov/Press_111/20090226/testimony_acc.pdf).

196. *Id.* at 1.

197. AMERICAN CHEMISTRY COUNCIL, TEN PRINCIPLES FOR MODERNIZING TSCA (2009), available at [http://www.americanchemistry.com/s\\_acc/sec\\_mediakits.asp?CID=2178&DID=9938](http://www.americanchemistry.com/s_acc/sec_mediakits.asp?CID=2178&DID=9938).

to ensure that enactment of TSCA did not create trade barriers with Europe.<sup>198</sup> As the leading academic study of this process concluded: “The chemical industry’s desire to minimize differential treatment for products across national lines provide[d] a powerful economic impetus for the selection of common regulatory targets.”<sup>199</sup> Similarly, if the regulatory differences between TSCA and REACH create duplicative testing requirements or impediments to transatlantic trade, a California effect could emerge in which the U.S. chemical industry begins to support conforming changes to TSCA.

Another possibility is that as U.S. chemical companies become accustomed to REACH compliance, their opposition to substantial TSCA reform may soften. Defeating proposals to mandate testing and maintaining exemptions for existing chemicals may become less compelling legislative goals for American chemical companies as these same companies undertake the required toxicity research for both existing and new chemicals under REACH. And once multinational firms have produced the required health and safety information about their chemicals in Europe, there is little reason for them to object to EPA disclosure requirements for the same information. Such firms may, in fact, lobby for similar mandatory testing and disclosure rules in the United States to level the playing field with domestic competitors that do not do business in Europe. Gradual adjustment to REACH by U.S. industry could provide a political opening for significant amendments to TSCA, especially as the limits of voluntary initiatives on chemical testing become more apparent.<sup>200</sup>

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198. Giandomenico Majone, *Cross-National Sources of Regulatory Policy-Making in Europe and the United States*, 11 J. PUB. POL’Y 79, 98 (1991).

199. BRICKMAN, ET AL., *supra* note 72, at 302–03.

200. The limits of the High Production Volume Challenge program were discussed *supra*, notes 66–67. The future of a second voluntary testing program for lower production volume chemicals, called the Chemical Assessment and Management Program (“ChAMP”), is in question due to EPA’s surprise June 2009 decision to suspend risk assessments under the program. Cheryl Hogue, *EPA Suspends Part of Chemicals Program*, CHEMICAL & ENGINEERING NEWS, June 19, 2009, available at <http://pubs.acs.org/cen/news/87/i25/8725news7.html>. The ChAMP program, launched at the end of the Bush Administration, was widely seen as an attempt by the Administration to head off the pressure for REACH-like legislation in the United States. *To Head off REACH Effort, EPA Unveils a Series of Fixes for TSCA Rules*, INSIDE EPA WKLY. REP., Mar. 21, 2008, at 6; see also *Industry Intensifies Lobbying Against ‘REACH’-Like Chemical Bills*, INSIDE EPA WKLY. REP., June 20, 2008, at 4, 5. ChAMP was criticized by the NGO community, see Press Release, Env’tl. Def. Fund, ChAMP Just Doesn’t Have the REACH (May 2, 2008), available at <http://www.edf.org/pressrelease.cfm?ContentID=7873>, and the suspension of the ChAMP risk assessments may indicate that EPA is reconsidering its overall approach to chemical regulation.

### 3. Information Disclosure and the Spread of European Legal Norms on Chemical Regulation

In assessing transnational regulatory interactions in the chemical field, it is important to look beyond questions of legislative change in the United States. Regulatory turbulence can alter the economic, legal, political, and informational landscape of foreign jurisdictions, even absent any changes in national legislation—indeed, even over the strong objections of national officials. It is in this realm of business and consumer culture that REACH is likely to work its most dramatic effects in the United States, at least in the near term. Under the extraterritorial influence of REACH, the U.S. chemical marketplace may increasingly be governed by European legal norms.

Information disclosure in Europe is the key driver of these effects in the United States. By putting critical toxicity data in the hands of consumers, activists, attorneys, and state regulators in the United States, REACH will likely improve public health and environmental protection and spark substitution of hazardous chemicals, even without legislative changes to TSCA.

REACH will cause regulatory turbulence through four major types of informational spillover effects in the United States. First, U.S. chemical companies may incorporate EU toxicity testing and information disclosure norms into their own internal practices. For example, Dow Chemical announced in early 2008 that it will prepare REACH-qualifying dossiers on all its products, regardless of whether those products are actually being sold in Europe.<sup>201</sup> If other major chemical manufacturers follow, we could see a “regulatory revolution by surprise”<sup>202</sup> in which the EU’s own internal legislation quickly becomes the global standard followed by multinational chemical firms.<sup>203</sup>

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201. UNIV. OF PITTSBURGH EUR. UNION CTR. OF EXCELLENCE & UNIV. OF PITTSBURGH GRADUATE SCH. OF PUB. HEALTH, *supra* note 181, at 40. This may be indicative of a larger trend toward public disclosure of potential chemical risks by U.S. firms. In March 2009, the SC Johnson Co., manufacturer of Windex, Shout, Glade, and other household products, announced that it would voluntarily disclose product ingredients on the Internet. Press Release, SC Johnson, Phthalates Phasing Out and Innovative Ingredient Communication Launched (Mar. 12, 2009), available at [http://www.scjohnson.com/family/fam\\_pre\\_pre\\_news.asp?art\\_id=390](http://www.scjohnson.com/family/fam_pre_pre_news.asp?art_id=390). The website containing the ingredient disclosures is available at <http://whatsinsidescjohnson.com>.

202. David Levi-Faur & Jacint Jordana, *Preface: The Making of a New Regulatory Order*, 598 ANNALS AM. ACAD. POL. & SOC. SCI. 6, 8 (2005).

203. As the UC-Berkeley political scientist David Vogel has stated, in explaining the growing influence of EU environmental standards: “Even if a country does not adopt [European] standards, the firms that export to the EU do. And since most firms do export to the EU, they have adopted the EU’s more stringent standards.” Buck, *supra* note 9, at 13.

Second, REACH toxicity data will increasingly shape the chemical purchasing decisions of U.S. manufacturers, retailers, and consumers. REACH will likely promote the nascent green chemistry movement in the United States by closing data gaps, allowing comparative analysis of chemical risks, and providing a competitive advantage to safer products. Indeed, REACH may provide a spark for innovations in U.S. product safety that would be impossible to achieve without plentiful background information on chemical risks. U.S. manufacturers that purchase chemicals in bulk will now have the capability to track REACH disclosures in Europe, which may affect the chemical products they buy and the suppliers they choose. U.S. manufacturers may begin to require REACH compliance (or equivalent disclosures of toxicity data) as a condition of their purchases from chemical suppliers in the United States.<sup>204</sup>

Much of this U.S. private sector response to REACH could become contractually obligated. For instance, representations and warranties on REACH compliance may become standard terms in purchase and sale contracts between U.S. and European firms. And European chemical importers, subject to REACH registration requirements, may contractually “push down” the testing and data compilation requirements of REACH onto their U.S. suppliers.

The implementation of REACH will also affect U.S. retailers and their customers. Hundreds of chemicals that will likely be subject to authorization under REACH (because of their carcinogenicity, adverse reproductive effects, or potential to bioaccumulate) are widely marketed in the United States.<sup>205</sup> In response to EU decisions naming such substances as “very high concern” chemicals, U.S. retailers may voluntarily withdraw those same substances from the U.S. market, or the chemicals may lose market share—a process that industry

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204. See Samuel Boxerman, Christopher Bell, & Kristina Nordlander, *Are You Ready for REACH?*, CHEMICAL ENGINEERING, Mar. 2008, at 38–39 (noting that “the initial and most visible impact of REACH might be seen in contracts, purchase orders, and so-called ‘supplier declarations’ [on compliance with REACH]”).

205. In a 2008 study, which was updated in January 2009, the Environmental Defense Fund examined 267 chemicals that it believed met the definition of “very high concern” chemicals subject to authorization under REACH. It then examined the commercial profile of these same chemicals in the United States. It found that at least 37 percent of these chemicals are currently being produced or imported into the United States above 25,000 pounds annually, that at least 235 different companies are producing or importing these chemicals in the United States, and that only about one third of these chemicals have been subject to testing under TSCA or under voluntary programs such as the HPV Challenge. RICHARD A. DENISON, ENVTL. DEF. FUND, *ACROSS THE POND: ASSESSING REACH’S FIRST BIG IMPACT ON U.S. COMPANIES AND CHEMICALS* 4–5, (2008, rev. 2009).

insiders call chemical “deselection.”<sup>206</sup> Major retailers such as Wal-Mart may order their suppliers to cease use of chemicals on the EU authorization list,<sup>207</sup> and consumers in the United States may avoid products that contain chemicals subject to authorization in Europe, in a kind of “black-list” effect.<sup>208</sup> As Ernie Rosenberg, President of the U.S. Soap and Detergent Association, has explained, “When you regulate a chemical product, it has a global impact in the global information environment that we live in. An adverse finding about a chemical anywhere creates problems for that chemical everywhere.”<sup>209</sup>

A third informational spillover effect from REACH is that U.S. federal regulators can use the toxicity data from Europe in existing regulatory regimes, including TSCA and other environmental laws. There is clearly sufficient overlap between the chemical regulatory regimes in the United States and the EU such that toxicity data disclosed under REACH could, in many cases, have direct legal relevance under TSCA. EPA could rely on data disclosed under REACH, for instance, to support further testing requirements under Section 4 of TSCA.<sup>210</sup> Under Section 11(c) of TSCA, EPA would have the authority to subpoena documents prepared by U.S. firms in the process of complying with REACH.<sup>211</sup> And Section 8(e) of TSCA imposes a mandatory reporting duty when a firm obtains “information which reasonably supports the conclusion” that a chemical “presents a

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206. Ernie Rosenberg, *Changes Do Not Necessarily Bring About Change*, 39 *Env'tl. L. Rep.* (Env'tl. L. Inst.) 10,074, 10,076 (Jan. 2009) (noting that deselection can happen quickly because unlike formal legal controls on chemicals, purchasing decisions “are not subject to legal, political, or scientific discipline.”).

207. *2007 Outlook: REACH, New Regulations in U.S. States Suggest Volatile Year for Manufacturers*, 12 *Daily Env't Rep.* (BNA), at B-2 (Jan. 19, 2007); accord. WAL-MART, SUSTAINABILITY PROGRESS TO DATE 2007–2008, at 56, available at <http://walmartstores.com/sites/sustainabilityreport/2007/documents/SustainabilityProgressToDate2007-2008.pdf>.

208. See MICHAEL WALLS, REACH 101: UNDERSTANDING AND PREPARING FOR THE NEW EU CHEMICALS LEGISLATION 638 (2008), available at [http://files.ali-aba.org/thumbs/datastorage/skoobesruoc/pdf/CN044\\_chapter\\_27\\_thumb.pdf](http://files.ali-aba.org/thumbs/datastorage/skoobesruoc/pdf/CN044_chapter_27_thumb.pdf) (noting the “black-list” effect of being placed on the candidate list for authorization). Consumers may become aware of the chemical constituents of products sold in the United States through the disclosure requirements of REACH Article 33, which mandates disclosure and safe handling instructions for any articles sold in Europe that contain substances of very high concern. While REACH primarily applies to raw chemical inputs, rather than to finished consumer products, Article 33 is a notable exception. It will, for the first time, require disclosures of many hazardous product ingredients.

209. Stefan Baumgarten, *Regulatory Bubble*, ICIS CHEMICAL BUS., Jan. 21, 2008, at 14.

210. See TSCA § 4, 15 U.S.C. § 2601 (2006) and discussion *supra* notes 30, 52–59 and accompanying text, for further explanation of TSCA testing and information requirements.

211. TSCA § 11(c). EPA would have to be willing to use its existing subpoena power to obtain these documents. *But see* Greenwood, *supra* note 80, at 10,039 (noting that EPA has “virtually ignored” its Section 11 subpoena power to date).

substantial risk of injury to health or the environment.”<sup>212</sup> The United States is a party to OECD agreements on mutual recognition of chemical testing data and would likely be able to use EU data in TSCA decisionmaking.<sup>213</sup> REACH chemical toxicity and risk assessment data might also be used by federal agencies to make regulatory decisions under other environmental and public health laws, such as establishing cleanup standards for hazardous waste sites, establishing standards for food packaging or cosmetics, or addressing emerging regulatory issues around nanotechnology.

Finally, information disclosure under REACH is likely to have significant impacts on subnational environmental regulation in the United States. As states consider bans or restrictions on certain classes of chemicals, the toxicity data from Europe—as well as EU decisions on which chemicals are of “very high concern”—is likely to be influential.<sup>214</sup> Additionally, chemical toxicity data disclosed under REACH could be used by plaintiffs’ attorneys in the United States as the basis for tort suits over occupational or other chemical exposures. These suits have traditionally been very difficult to bring because of problems in proving causation, long latency periods, and a lack of basic toxicity data on commonly used chemicals.<sup>215</sup> The REACH data that will be generated in Europe over the next decade represents a wealth of information on chemical toxicity that has long been absent from American courtrooms.<sup>216</sup>

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212. TSCA § 8(e); *see also* discussion of EPA’s prior implementation of Section 8, *supra* note 48.

213. Organization for Economic Co-operation and Development [OECD], *Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, OECD Doc. C(81)30 (May 12, 1981), *as amended by* OECD, OECD Doc. C(97)186 (Nov. 26, 1997), *available at* [http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C\(81\)30](http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(81)30); OECD, *Decision-Recommendation on Compliance with Principles of Good Laboratory Practice*, OECD Doc. C(89)87 (Oct. 2, 1989), *as amended by* OECD, OECD Doc. C(95)8 (Mar. 9, 1995), *available at* [http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C\(89\)87](http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(89)87).

214. *See* MICHAEL P. WILSON ET AL., GREEN CHEMISTRY IN CALIFORNIA, A FRAMEWORK FOR LEADERSHIP IN CHEMICALS POLICY AND INNOVATION 63 (2006), *available at* [http://coeh.berkeley.edu/docs/news/06\\_wilson\\_policy.pdf](http://coeh.berkeley.edu/docs/news/06_wilson_policy.pdf) (arguing that REACH represents an opportunity for California “to gather information on the physical attributes and basic toxicological properties of many chemicals in commercial circulation” in the state).

215. *See* Sachs, *supra* note 3, at 326–41 (outlining hurdles to bringing tort suits over chemical exposures).

216. *See* Black, *supra* note 92, at A127 (stating that “information provided by REACH should begin to help overcome the difficulty in linking specific health problems with exposures to specific chemicals or mixtures of chemicals”); MARSH INC., REACH: NEW EU REGULATION FOR THE CHEMICALS INDUSTRY 3 (2007), *available at* [http://global.marsh.com/documents/Internationalbriefings/REACH\\_International\\_Bulletin.pdf](http://global.marsh.com/documents/Internationalbriefings/REACH_International_Bulletin.pdf) (noting that information generated for REACH compliance could be used in litigation in non-EU jurisdictions).

It is clear that information disclosure under REACH will have a number of regulatory and non-regulatory ripple effects in the United States. These effects from foreign legislation suggest that scholars in the information-and-environment field need to look beyond U.S. borders. American environmental law scholars have frequently focused on how to amend TSCA to require, or incentivize, more extensive toxicity testing for chemicals.<sup>217</sup> But it now appears that REACH will become the principal source of this much-needed increase in the supply of chemical toxicity information in the United States, and globally. If chemical toxicity data is an informational commons, as Wendy Wagner has suggested,<sup>218</sup> then it is a global commons, unconstrained by jurisdictional fences. New scholarship in the information-and-environment field must consider how these global information flows can be harnessed to improve U.S. environmental regulation.

### CONCLUSION

Chemical regulation is a case study in the politics of transnational regulatory interactions and information flows in the era of globalization. The international system is no longer characterized by sharp dividing lines between domestic and international law. Instead, innovations in domestic environmental law can become the springboard for transnational changes in regulatory policy. Similarly, transnational legal developments can shape domestic regulatory environments.

That EU legislation is now setting the terms of debate over chemical policy in the United States is a remarkable departure from past trends, in which the United States was the principal source of transnational regulatory innovation in environmental law. In chemical regulation, there is little doubt that policy currents from the EU are blowing westward across the Atlantic, putting the United States in the unfamiliar position of reacting to developments in the EU's internal environmental law.

As this Article has shown, while TSCA reform is by no means inevitable, the implementation of REACH does make reform more likely. New reform coalitions will emerge, toxicity data will become

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217. See, e.g., Wagner, *supra* note 2, at 631 (arguing that existing incentives not to undertake toxicity testing could be reversed if manufacturers could petition EPA to have their products certified as superior from the standpoint of safety); Applegate, *Perils of Unreasonable Risk*, *supra* note 3, at 328–29 (advocating replacement of the “substantial evidence” standard for judicial review of TSCA test orders with an “arbitrary and capricious” standard).

218. See Wagner, *Commons Ignorance*, *supra* note 3, at 1622–25.

available from the EU, and longstanding industry arguments that TSCA is adequately protective of human health and the environment will be undermined by the more stringent regulatory regime across the Atlantic.

Can the United States simply free ride on the data from Europe? Globalization and modern communications technology certainly create the possibility that a single large jurisdiction, such as the EU, could become what Anne-Marie Slaughter has called a “global information agency,”<sup>219</sup> coordinating research, testing, and disclosure of risk data that other jurisdictions could then rely upon for their own environmental regulation.

But there is reason to be skeptical that the broken chemical regulatory regime in the United States could be fixed solely through such free riding, without substantial reform to TSCA. TSCA suffers both from limited data supply *and* from stringent informational demands prior to regulation. REACH data from Europe will help close the supply side of the data gap in the United States, with the many positive effects discussed above. But as long as TSCA maintains its complex procedural requirements, its governmental burden of proof, and its high hurdles to restrict a chemical under Section 6, a gap will persist between information supply and information needs.

A comprehensive fix of chemical regulation in the United States will require piercing the armor that has protected TSCA from significant amendment for more than three decades. The United States should aspire to be a leader in chemical safety and product sustainability, and TSCA reform is essential to that task. The main principles of REACH—such as “No Data, No Market”; ending distinctions between new and existing chemicals; substitution for hazardous chemicals; and increased public disclosure of risk information—point the way toward the next generation of chemical regulation in the United States.

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219. SLAUGHTER, *supra* note 139, at 156–65.