

ARTICLES

Regulating Industrial Chemicals: Lessons for U.S. Lawmakers From the European Union's REACH Program

by Adam D.K. Abelkop, Ágnes Botos, Lois R. Wise, and John D. Graham

Adam D.K. Abelkop is a doctoral student in Public Policy at the Indiana University School of Public and Environmental Affairs. Ágnes Botos is a doctoral student at Central European University, Budapest, and REACH Consultant, GHS-expert Ltd., Hungary. Lois R. Wise is a Professor at the Indiana University School of Public and Environmental Affairs and Director of the Indiana University West European Studies and European Union Center. John D. Graham is Dean and Professor at Indiana University School of Public and Environmental Affairs.

Summary

Should Europe's chemicals law, called REACH, be considered by U.S. policymakers interested in reform of TSCA? The new REACH registration process, while burdensome, is more workable than was originally feared. However, it appears that REACH is much more complex than it needs to be to accomplish its objectives. U.S. policymakers should consider simplifications of the REACH program.

The phenomenon of globalization usually refers to economic factors, but there is also a small but growing body of literature on the cross-national diffusion of legislative innovations.¹ In the United States, it is well known that legislative reforms in one state may be replicated or refined in other states or even on a national basis. But a similar process of experimentation, learning, and policy diffusion is operating on a cross-national and cross-regional basis as well.² The diffusion process can sometimes result in a coherent international treaty or global regulatory regime, but our interest here is the transfer of a legislative idea from one nation or region to another.

A variety of transnational actors, including networks of actors, have been shown to play a role in the diffusion of legislative ideas.³ A multinational corporation, for example, may see value in some degree of policy convergence in the various nations where it has production facilities or where it sells products and services. Networks of multinational firms, or even nongovernmental organizations (NGOs), may have greater influence on policy diffusion than actions by any single firm or organization, even a large and aggressive one. The roles of multinationals and NGOs are particularly evident in the field of environmental policy, where different parts of the world may face similar environmental threats and where companies may be particularly averse to a proliferation of costly and conflicting policies.

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1. See generally ANNE-MARIE SLAUGHTER, *A NEW WORLD ORDER* (2004); David Lazer, *Global and Domestic Governance: Modes of Interdependence in Regulatory Policymaking*, 12 EUR. L.J. 455 (2006). On environmental law, see Joanne Scott, *From Brussels With Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction*, 57 AM. J. COMP. L. 897 (2009); Tseming Yang & Robert V. Percival, *The Emergence of Global Environmental Law*, 36 ECOLOGY L.Q. 615 (2009); Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817 (2009); DAVID VOGEL & JOHAN F.M. SWINNEN, *TRANS-ATLANTIC REGULATORY COOPERATION: THE SHIFTING ROLES OF THE EU, U.S., AND CALIFORNIA* (2011); MARK A. POLLACK & GREGORY C. SHAFFER (eds.), *TRANSATLANTIC GOVERNANCE IN THE GLOBAL ECONOMY*, ROWMAN AND LITTLEFIELD (2001); GEORGE A. BERMAN ET AL., *TRANSATLANTIC REGULATORY COOPERATION: LEGAL PROBLEMS AND POLITICAL PROSPECTS* (2001).
2. Scott, *supra* note 1; Yang & Percival, *supra* note 1; Sachs, *supra* note 1.
3. Daniel Beland & Mitchell A. Orenstein, *Transnational Actors and Public Policy*, JOHNSON-SHOYAMA GRADUATE SCHOOL OF PUBLIC POLICY WORKING PAPERS SERIES (2010); Diane Stonnee, *Global Public Policy, Transnational Policy Communities, and Their Networks*, 36 POL'Y STUD. J. 19 (2008); Jaqui True & Michael Mintrom, *Transnational Networks and Policy Diffusion: The Case of Gender Mainstreaming*, 45 INT'L STUD. Q. 27 (2001); Matthew Potoski & Aseem Prakash, *Regulatory Convergence in Nongovernmental Regimes? Cross-National Adoption of ISO 14001 Certifications*, 66 J. POL. 885 (2004); Michael Frenkel, *The Politics of Translation: How State-Level Political Relations Affect the Cross-National Travel of Management Ideas*, 12 ORG. 275 (2005); David March & J.C. Sharman, *Policy Diffusion and Policy Transfer*, 30 POL'Y STUD. 269 (2009); Per-Olof Busch & Helge Jörgens, *The International Sources of Policy Convergence: Explaining the Spread of Environmental Policy Innovations*, 12 J. EUR. PUB. POL'Y 860 (2005).

In this Article, we explore the regulation of industrial chemicals—already a growing topic of possible cross-national policy diffusion. In fact, the United States, the European Union (EU), Canada, Japan, the Republic of Korea, Switzerland, and the Russian Federation are implementing or considering new regulatory systems for industrial chemicals. From the EU's perspective, its 2006 chemicals law—called Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)⁴—represents more than a regionalization of industrial chemicals regulation. Rather, it is seen as a potential step toward globalization of chemicals policy, whether through EU persuasion of other countries or through some form of international treaty.⁵ Japan, for example, has enacted a new system that includes some but not all of the elements of REACH.⁶ In that vein, we ask what features of REACH (if any) should be “imported” into U.S. regulatory law when the United States decides to modernize the Toxic Substances Control Act (TSCA) of 1976.⁷ In particular, we highlight the lessons to be drawn from the first years of the EU's implementation of REACH and explore how those lessons can be used in the United States to create REACH-like legislation that is subject to targeted modifications in legislative design and organizational authority. In effect, we assume that U.S. policymakers are considering enactment of a REACH-like system and ask what refinements or modifications the REACH system might be worthy of.

It is unlikely that the REACH program will be adopted wholesale in the United States, as the process of policy diffusion tends to operate in a partial and idiosyncratic manner. Scholars of the transformative perspective on policy insist that policies tend to mutate when they move from one country to the next.⁸ Those mutations, which we call refinements, modifications, or reforms, result from a

variety of contextual factors, such as different traditions of political institutions, unique socioeconomic factors in a particular country or region, distinct preferences of key legislative actors, and different distributions of power between different branches of government and the private and public sectors.⁹

We also assume that the U.S. Congress will eventually modernize TSCA, but there is certainly no assurance that this will occur soon.¹⁰ Both the U.S. chemical industry¹¹ and national environmental groups declared interest in reform of TSCA after President Barack Obama was elected in 2008 and before the Republican Party won control of the U.S. House of Representatives in 2010.¹² But the pace of TSCA reform is slow, in part because there is no consensus on the substance of reform. Consequently, it is instructive for U.S. policymakers to look across the Atlantic to determine what lessons can be drawn from the early EU experience with REACH.

In Part I, we briefly describe the contours of the REACH regulation. Part II describes our method of qualitative analysis. In Parts III through VI, we discuss our findings. This Article is a reproduction of a larger report by the same name, which includes detailed background explanations of REACH's legislative mandates.¹³ Here, however, we presume that the reader is familiar with the legislative

4. European Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, 2006 O.J. (L 396) 1 (EC) [hereinafter REACH].
5. Veerle Heyvaert, *Regulating Chemical Risk: REACH in a Global Governance Perspective*, in REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES (J. Eriksson et al. eds., 2010), 217, 221 (arguing that the forces of globalization induced the EU to enact REACH, as the EU strives to lead the global chemical industry via the force of regulation), 229 (“EU is actively lobbying foreign governments to contemplate the adoption of REACH”) [hereafter Heyvaert, RCR]; European Commission, Q&A on the New Chemicals Policy, REACH, MEMO/06/488, 2006, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/488>.
6. See, e.g., Yoshiko Naiki, *Assessing Policy Reach: Japan's Chemical Policy Reform in Response to the EU's REACH Regulation*, 22 J. ENVTL. L. 171 (2010). A more comprehensive analysis should certainly consider the full range of innovations in national chemicals legislation. Our focus, though, is limited to REACH.
7. 15 U.S.C. §§2601-2692, ELR STAT. TSCA §§2-412.
8. Tom Christensen et al., *Transforming Administrative Policy*, 80 PUB. ADMIN. 153 (2002); Katharina Holzinger & Christoph Knill, *Causes and Conditions of Cross-National Policy Convergence*, 12 J. EUR. PUB. POL'Y 775 (2005); CHRISTOPH KNILL, THE EUROPEANISATION OF NATIONAL ADMINISTRATIONS (2001).

9. Christensen et al., *supra* note 8; Christoph Knill, *Introduction: Cross-National Policy Convergence, Concepts, Approaches and Explanatory Factors*, 12 J. EUR. PUB. POL'Y 764 (2005).
10. See, e.g., Sachs, *supra* note 1 (suggesting that the enactment of REACH may make TSCA reform more likely). For comparisons of TSCA and REACH, see John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721 (2008) [hereafter Applegate, *Synthesizing*]; John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365 (2008); U.S. GOVERNMENT ACCOUNTABILITY OFFICE (GAO), GAO-07-825, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS (2007), available at <http://www.gao.gov/new.items/d07825.pdf>; U.S. GAO, GAO-06-217R, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION (2005), available at <http://www.gao.gov/new.items/d06217r.pdf>; RICHARD A. DENISON, Environmental Defense Fund, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION, AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS (2007), available at <http://www.edf.org/article.cfm?contentid=6147/>; Conrad Benedetto, Comment, *Is the European Laboratory Over-REACH-ing? The Experimentation, Reaction and Product Yielded by the European Union's Registration, Evaluation, and Authorization of Chemicals*, 21 VILL. ENVTL. L.J. 75 (2010).
11. Sara Goodman, *Industry Group Calls for “Modernization” of Toxic Chemical Law*, N.Y. TIMES, Feb. 27, 2009.
12. See, e.g., Mark N. Duvall & Alexandra M. Wyatt, *First TSCA Reform Congressional Hearing of 2009 Held February 26*, BEVERIDGE & DIAMOND, P.C. CLIENT ALERT, Mar. 3, 2009, available at http://www.bdlaw.com/assets/attachments/First_TSCA_Reform_Congressional_Hearing_of_2009_Held_February_26.pdf (describing congressional testimony from NGO and industry representatives in favor of TSCA reform).
13. Adam D.K. Abelkop et al., REGULATING INDUSTRIAL CHEMICALS: LESSONS FOR U.S. LAW MAKERS FROM THE EUROPEAN UNION'S REACH PROGRAM (2012), available at http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf.

mandates and design of REACH. Each part includes a discussion of the positive aspects of REACH, the concerns we heard, and potential refinements or modifications. In Part VII we consider issues that cut across the four parts of REACH.

I. What Is REACH?

Prof. E. Donald Elliott has written that “environmental law is the most complicated and detailed body of law the world has ever known; [it has] won the (dubious) distinction of representing the ‘state of the art’ in legal complexity and detail.”¹⁴ Living up to this reputation, REACH is a compilation of four separate bodies of regulation (registration, evaluation, authorization, and restriction) that govern the cradle-to-grave manufacture, importation, sale, and use of industrial chemicals in the EU. Certainly, the most substantial and novel aspect of REACH is the registration system, and it is this system that is the subject of much of this report.¹⁵ As an innovation in environmental law, though, REACH is of general interest for several reasons.

First, REACH is a data-generating regulation. More so than TSCA, REACH compels manufacturers of substances, producers of articles, and importers to supply regulators a minimum safety-related data set for a large number of existing as well as new chemicals. Any company that wishes to manufacture or import a chemical in(to) the EU in an amount of 1 tonne or more per year must first register the chemical substance with the government. The registration “dossier” under REACH must contain a minimum set of data, or the substance may not be produced or imported. In fact, “[t]he lack of data on the hazardous properties of chemicals was the driving force behind the development of a new chemicals policy in the EU.”¹⁶ The legislation establishes the European Chemicals Agency (ECHA), an independent agency in the EU in Helsinki, Finland, which is responsible for the technical management of the REACH program.¹⁷

Some argue that REACH differs from TSCA primarily because REACH shifts the burden of proving safety from the government to industry, whereas TSCA places that burden on the government.¹⁸ This view is oversimplified

because one of the key objectives of TSCA, as explained in the law and its legislative history, was to place the scientific burdens of proving safety on the industry.¹⁹ Under §4 of TSCA, the U.S. Environmental Protection Agency (EPA) may promulgate a “test rule” requiring companies to produce more data, as long as the Agency believes that the substance “may present an unreasonable risk” due to the probability of exposure and the chemical’s possible toxicity.²⁰ A key factor that impedes regulatory activity under TSCA is a process of judicial review that compels EPA to justify in court its orders to keep a chemical off the market or to impose additional testing requirements.²¹ European regulators of chemicals have faced no comparable judicial oversight before or after enactment of REACH.²²

REACH’s new registration process is based on a key principle: “no data, no market.”²³ Gathering data on chemical uses, exposures, toxicity, and risk is a burdensome task that requires time, monetary resources, and technical expertise. Several experts who we interviewed in preparing this Article explained that the companies that actually manufacture industrial chemicals should have the most expertise and data regarding risk and exposure. REACH requires exposure scenarios and risk management techniques to be included with registration dossiers for substances classified as dangerous that are manufactured or imported into the EU in quantities greater than 10 tonnes per year.²⁴ Once safety data are obtained and safety techniques developed, the information travels through the supply chain to inform each company, including the downstream users, who may be in a position to implement measures that reduce exposures to the chemical. With greater information on the hazardous properties of chemicals, regulators intend for companies to improve risk management voluntarily, as a matter of good business practices. Buttressing this voluntary action is an enforcement responsibility under REACH that is to be carried out by the EU member states, with training provided to their enforcement authorities.²⁵

erally U.S. GAO, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT (2009); U.S. GAO, GAO-07-825, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS (2007).

19. 15 U.S.C. §2601(b)(1); S. REP. NO. 494-698, 1976, 5.

20. Kathleen Roberts, Chemical Testing Under TSCA, Mar. 7, 2007, available at http://www.socma.com/assets/File/socma1/PDFfiles/gcrrc/2007/presentations/TSCA_Fundamentals_Roberts.pdf.

21. Ortwin Renn & Donald Elliott, *Chemicals, in THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE* 223-56 (Jonathan B. Wiener et al. eds., 2011).

22. The Court of Justice of the European Communities will review acts of institutions of the European Community under the standards of “manifest errors of assessment” and “abuse of power.” Juliane Kokott & Frank Hoffmeister, *International Decisions: A. Racke GmbH & Co. v. Hauptzollamt Mainz. Case C-162/96. Court of Justice of the European Communities, June 16, 1998*, 93 AM. J. INT’L L. 205 (1999), citing Case C-156/87 Gestetner Holdings v. Council and Commission, 1990 ECR I-781, ¶ 63.

23. REACH, art. 5.

24. REACH, art. 14(1), (3).

25. Jerzy Majka, *REACH Registration Conference: What Did We Achieve in 2010—How Can We Ease the Way for 2013?*, Sept. 23, 2011, available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2 (Almost 600 enforcement personnel were trained on REACH in 2009 and 2010.). ECHA is sponsoring a training and enforcement cam-

14. E. Donald Elliott, *The Last Great Clean Air Act Book?*, 5 ENVTL. LAW. 321, 326-27 (1998).

15. Heyvaert, RCR, *supra* note 5, 231 (The most likely feature of REACH to be exported to other countries is the registration regime.).

16. EUROPEAN COMM’N JOINT RESEARCH CTR., INST. FOR HEALTH & CONSUMER PROT., ASSESSMENT OF ADDITIONAL TESTING NEEDS UNDER REACH: EFFECTS OF (Q)SARS, RISK BASED TESTING AND VOLUNTARY INDUSTRY INITIATIVES 5 (2003), available at <http://home.kpn.nl/reach/downloads/reachtestingneedsfinal.pdf>, quoted in Applegate *Synthesizing*, *supra* note 10, at 744.

17. For more information on the European Chemicals Agency, see the European Chemicals Agency website at http://echa.europa.eu/home_en.asp.

18. John Kvinge, *Morally Hazardous Chemical Regulations: Why Effective Reform of the TSCA Requires Reduction of the Toxic Data Gap*, 12 MINN. J. L., SCI. & TECH. 313, 326, 328-30 (2011) (arguing that TSCA places the burden of proving risk on the government, especially for existing chemicals); David Markell, *New Directions in Environmental Law: An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL’Y 333, 355, 370-71 (2010). See gen-

A second way that REACH is distinctive among the global suite of environmental laws is through its concept of “one substance, one registration.”²⁶ To reduce duplicative testing on animals, REACH functionally requires companies that produce or import the same chemical substance to share data with one another and to submit that data as part of one joint registration.²⁷ Data sharing under REACH, therefore, encourages communication and cooperation between firms that are competitors. Joint registration also eases ECHA’s burdens of evaluating the registration materials by consolidating much of the content from many companies into a single document.

REACH’s data-sharing requirements are not entirely foreign to U.S. regulators and industry. For example, the Occupational Health and Safety Administration’s (OSHA’s) Hazard Communication requirements for Material Safety Data Sheets require sellers of chemical substances to “share data.”²⁸ Moreover, the main U.S. law governing the safety of agricultural chemicals includes a provision for one applicant to obtain a registration based on animal test data compiled by another company and to pay for the use of the data.²⁹ And, even the inventory of existing substances under TSCA permits one manufacturer to rely on a data submission by a previous submitter, in effect making use of the “one substance, one registration” concept.³⁰ Yet, there is no doubt that REACH has compelled joint registration and data sharing on a massive scale, far greater than in the United States.

Finally, REACH’s approach to existing chemicals makes the EU legislation unique. The U.S. approach in TSCA focuses regulatory efforts primarily on new chemicals and “grandfathers” in existing chemicals, unless EPA takes affirmative action to compel the submission of additional safety data or restricts or prohibits the sale of existing substances for specific uses.³¹ As noted above, though, the lack of data on existing chemicals is exactly what prompted the EU to eliminate the distinction between existing and new substances by applying a new regulatory framework to chemicals that have been on the market for decades. Removing the regulatory leniency for older chemicals may spur innovation by putting new and existing chemicals on a more level playing field.³²

paigned called “EN-FORCE 2” to assist member states in enforcing REACH, and the focus is on downstream users—making sure that the risk-management measures described in registration documents are being implemented to protect human health and the environment.

26. See European Chemicals Agency, Frequently Asked Questions About REACH, 10. Joint Registration, Question 4, available at http://echa.europa.eu/reach/reach_faqs_en.asp?topic=joints&#joints (“The REACH Regulation, and in particular Article 11, is based on the ‘one substance one registration’ principle.”).

27. REACH, art. 11.

28. Occupational Safety & Health Administration, Hazard Communication, <http://www.osha.gov/dsg/hazcom/index.html>.

29. See *Ruckelshaus v. Monsanto*, 467 U.S. 986, 14 ELR 20539 (1984).

30. 15 U.S.C. §2607.

31. Applegate, *Synthesizing*, *supra* note 10, at 743–44 (“TSCA, for example, grandfathers existing chemicals by imposing a screening procedure (the PMN [premanufacture notification] process) only on new chemicals.”).

32. This is an example of a general phenomenon where regulators have a tendency to discourage innovation by regulating new risks more stringently

Although REACH has been in existence for almost six years, the available literature about this large regulatory program is quite limited. There is a literature on the polarized debate and compromises that preceded the enactment of REACH, and even some literature on how the enactment of REACH might impact legislative deliberations in the United States and other countries.³³ There is also a practical literature aimed at helping practitioners understand the law and how to comply with it. This Article fills a void by exploring the early phases of REACH implementation as they have been experienced by government officials and a variety of stakeholders.

REACH remains at an early stage of implementation, and some of the key challenges to the effectiveness of the program have not yet been encountered.³⁴ For example, it is not yet clear whether the design of REACH can resolve the heated disputes that will occur when a lucrative chemical in widespread use is shown to cause unacceptable risk to public health and the environment.³⁵ Manufacturers will seek to use risk assessments and socioeconomic analyses to defend the substance, and it is not clear yet whether the procedures and safeguards in REACH will operate as intended. At the same time, it is possible that NGOs and their allies in individual member states will seek discontinuation of substances that, in fact, do not pose an unacceptable risk. Whether the procedures and safeguards in REACH will work to protect industry in this scenario is also unknown.

II. Scope and Method of Qualitative Analysis

We have divided the REACH legislation into its four parts (registration, evaluation, authorization, and restriction) and examined what features and alternatives may be of

than old ones. See Peter Huber, *The New-Old Division in Risk Regulation*, VA. L. REV. 69, 1025–07 (1983); John Kvinge, *supra* note 18, 313, 332 (explaining how removing the regulatory bias in favor of existing chemicals may spur more innovation in green chemistry); Heyvaert, RCR *supra* note 5, 217, 233 (discussing how inclusion of old substances in a chemicals regulatory framework can spur global chemicals innovation).

33. Joanne Scott, *REACH: Combining Harmonization and Dynamisms in the Regulation of Chemicals*, in ENVIRONMENTAL PROTECTION: EUROPEAN LAW AND GOVERNANCE 56 (J. Scott ed., 2009); Dieter Pesendorfer, *EU Environmental Policy Under Pressure: Chemicals Policy Change Between Antagonistic Goals?*, 15 ENVTL. POL. 95 (2006); Henrik Selin, *Coalition Politics and Chemicals Management in a Regulatory Ambitious Europe*, 7 GLOBAL ENVTL. POL. 63 (2007); David Markell, *supra* note 18, 333, 374 (REACH will create incentives and disincentives for action in the United States.); James T.O. Reilly, *What REACH Can Teach Us About TSCA: Retrospectives on America’s Failed Toxics Statute*, 1 EUR. J. RISK REG. 40 (2010); David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH. U. J.L. & POL’Y 377 (2010); LINDA-JO SCHIEROW, CONGRESSIONAL RESEARCH SERVICE, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES (2007), available at <http://www.policyarchive.org/handle/10207/bitstreams/19946.pdf>; Applegate, *Synthesizing*, *supra* note 10; Elizabeth Fisher, *The “Perfect Storm” of REACH: Charting Regulatory Controversy in the Age of Information, Sustainable Development, and Globalization*, 11 J. RISK RES. 541 (2008).

34. Willem Halfman & Roland Bal, *Regulatory Futures in Retrospect*, in REGULATING CHEMICALS, EUROPEAN AND GLOBAL CHALLENGES (J. Eriksson et al. eds., 2010).

35. *Id.* at 339, 343.

interest to U.S. policymakers. The bulk of our analysis concentrates on registration, because that has been the focus of REACH implementation in the 2006-2012 period. We also offer some insights about the other three parts of REACH, despite the limited implementation activity to date. After the final section on restrictions, we also consider the interaction of the four parts of REACH, asking whether the EU approach might be streamlined in the United States without a loss of public confidence or diminished protection of public health and the environment.³⁶

To learn about the early experiences with REACH, we interviewed 20 stakeholders and government officials in the EU who are familiar with one or more parts of the REACH program. In the regulated community, our interviews included chemical manufacturers, importers, downstream users, and law firms and consultants who advised the regulated industry. We also interviewed key officials in the European Commission in Brussels (Directorate General-Environment and Directorate General-Enterprise), the European Chemicals Agency in Helsinki, and NGO representatives on both sides of the Atlantic who are tracking the implementation of REACH.

Our approach to interviews was to encourage candor by ensuring each interviewee that we would not assign specific viewpoints to specific individuals in our report. We were aware that government officials are not inclined to criticize publicly a program that they are administering, and industry officials are reluctant to criticize publicly an agency that will make decisions that impact the future of their business.

In addition to these more structured interviews, which occurred by phone, in person, or by e-mail, we also attended the 2011 ECHA Stakeholder Day and the 2011 Helsinki Chemicals Forum in Finland in May 2011.³⁷ At these two meetings, three of the four co-authors heard presentations and discussions on a wide range of REACH implementation issues, and we networked informally and individually with many of the more than 500 participants in the two days of meetings. Since our co-authors include a risk analyst, a chemical engineer, a lawyer, and a political scientist, we believe that both our structured interviews and our informal discussions with REACH practitioners are likely to have gathered a wide range of perspectives.

Finally, we provided all of our interviewees (and many others we met in Helsinki) an opportunity to provide a critique of a preliminary draft (July 2011) of this report. The process of drafting, critique, and revision has helped us minimize factual errors, clarify how REACH is being implemented, and flesh out some of the reforms that may be worthy of consideration by U.S. policymakers. During the process of revision, we also gathered insight from pre-

sentations made at the 2011 REACH Registration Conference in Brussels.³⁸

In light of the concerns we heard about REACH implementation, we suggest a variety of reforms for consideration by U.S. policymakers that might make a REACH-like system less burdensome and more effective in an American context. We explore reforms of each of the four parts of the REACH program. Since we have not performed a detailed analysis of each reform proposal, we are suggesting the reforms in the spirit of options for consideration and further analysis, and not as firm recommendations. Moreover, while some of the reforms could be considered by European policymakers, we are not expressing an opinion as to whether European policymakers should amend the REACH program at this early stage.³⁹ Our assessment of REACH is not aimed at determining whether REACH implementation has achieved health and environmental benefits, as it is far too early to expect or detect such benefits. It may never be feasible to undertake a rigorous ex post evaluation of the outcomes of REACH, because the legislation was never advocated on the basis of specific, quantifiable, and measurable improvements in human health and the environment. Our primary purpose is to inform the U.S. legislative debate about modernization of TSCA.

III. Registration

A. Positive Features

REACH's registration process has several positive features. Although it is too early to know whether these positive aspects will translate into significant health or environmental benefits, the process of registration led to some constructive activities.

Under the concept "no data, no market," more data on chemicals have been assembled and made available in the supply chain and to the public at large than ever before. The registration process places the burden of gathering information on toxicity and exposure of industrial chemicals on the industry itself. Although both industry and regulators have limited resources, the companies that manufacture and import industrial chemicals are more readily able to generate information on toxicity, exposure scenarios, and risk-management measures than are government officials in Brussels or Helsinki. Consequently, it is more efficient to place the burden of information generation on industry than on government. In fact, it is difficult to imagine how the large volume of information generated by REACH could have been obtained without some form of compulsory registration process.

REACH has also stimulated communications throughout the industrial supply chain. One interview subject

36. *Id.* at 344 (noting that the growing complexity of the REACH regime arose out of the complexity of stakeholder politics in the EU).

37. European Chemicals Agency, Sixth Stakeholders' Day, May 18, 2011, http://www.echa.europa.eu/documents/10162/17203/agenda_stakeholders_day_20110518_en.pdf; Helsinki Chemicals Forum, May 19, 2011, http://finnexpo.multiedition.fi/gallery/main.php?g2_itemId=611.

38. European Chemicals Agency, REACH Registration Conference: What Did We Learn in 2010—How Can We Ease the Way for 2013?, Belgium, Brussels, Sept. 23, 2011.

39. *But see* Adam D.K. Abelkop et al., *How Can REACH Be Improved?*, in *THE EUROPEAN UNION REACH REGULATION FOR CHEMICALS: LAW AND PRACTICE* (L. Bergkamp ed., 2013) (discussing lessons for European regulators).

explained that shifting the burden of proof of safety from government to industry causes manufacturers to learn more about their entire supply chains and stimulates risk-management measures and chemical substitutions that enhance safety. Prior to REACH, some chemical manufacturers were unaware of some end uses of their products. REACH's registration obligations require manufacturers to seek information on end uses and potential exposure scenarios from companies down their supply chains. Importers and downstream users also have obligations to communicate and seek information on chemical properties from manufacturers.

The industrial sector has also come to better understand specific toxicities highlighted in REACH. For example, corporate training efforts on REACH compliance have raised general awareness of chemical hazards, specifically the challenges posed by carcinogens, mutagens, reproductive toxins, and persistent and bioaccumulative substances. Moreover, data sharing on hazard information has facilitated the harmonized classification of products and may have enhanced the quality of Safety Data Sheets, the key communication vehicle within the industrial supply chain.⁴⁰ Even within single companies that produce or import substances, REACH appears to have stimulated more communication between different operations within the companies, e.g., between production, marketing, research and development (R&D), and regulatory affairs professionals. Thus, some of our interview subjects indicated that fulfilling the registration data requirements under REACH resulted in an improvement in intra-firm communication about safety and regulatory compliance.

Finally, REACH's "one substance, one registration" approach, combined with data sharing and joint registration, has also had some positive effects. It diminishes duplicative animal testing, spreads the cost of testing over a larger number of companies, and reduces the burden on ECHA of reviewing multiple registration dossiers on the same chemical substance. Upon REACH's enactment in 2006, joint registration was a somewhat novel concept. Some industry representatives admit that they were initially skeptical of the workability of the EU's joint registration and data-sharing requirements, but they now believe that these provisions of REACH, while burdensome, worked better than they had anticipated.

Joint registration and data sharing do create some dangers and burdens. For example, the border between REACH and competition law in the EU is very thin, because joint submission of a registration dossier may require competing companies to share sensitive information. Even simple information such as "a specific use of the chemical" or "volume used in a specific use," which are a necessary part

of a registration dossier, can have business value, can be the subject of confidentiality claims, and can be associated with competitiveness impacts. When competitors collaborate on a registration dossier, lawyers need to be present to make sure that competition law (which can be associated with large sanctions for infractions) is respected and that confidential business information is handled properly. As U.S. policymakers contemplate the merits of joint registration, consideration needs to be given to U.S. competition law and the implications of involving costly attorneys in numerous deliberations about registration dossiers.

Fortunately, U.S. policymakers do have some experience with related endeavors. There is a long history of joint notifications of new substances in the United States (called joint premanufacturing notifications in TSCA), although these tend to involve companies with a common business interest. Joint action by competitors has occurred for high-production volume (HPV) chemicals under the EPA HPV Challenge program and the Organization for Economic Cooperation and Development's (OECD's) HPV program. When EPA seeks more information about the safety of a chemical, it is common for multiple manufacturers and users in the United States to collaborate through an established (or ad hoc) trade association. Thus, the notion of corporate collaborations on chemical safety issues in a regulatory environment is not unprecedented in the U.S. chemical industry.

B. *Alternative Approaches*

I. *Reduce Unnecessary Pre-Registrations*

Pre-registration under REACH is an optional process that provides an opportunity for companies to take advantage of extended registration deadlines.⁴¹ Companies that manufacture or import one tonne or more of a "phase-in substance" in(to) the EU per year must have pre-registered their substances between June 1, 2008, and December 1, 2008, to take advantage of extended registration deadlines. The first extended registration deadline was November 30, 2010. The extended registration deadlines thereafter are May 31, 2013, and May 31, 2018. Essentially, the pre-registration process serves two functions. First, it provides a distinction in the registration process for existing and new substances. Second, it provides a basis for determining which companies need to cooperate in a Substance Information Exchange Forum (SIEF) for data sharing and joint registration.

ECHA received 2.7 million pre-registration applications for the 2008 deadline, which covered 144,000 substances—almost five times the number that were anticipated.⁴² The vast number of pre-registrations overwhelmed both ECHA

40. However, elaborate expectations for extended Safety Data Sheets, which have grown in size from several dozen pages to several hundred pages, are creating consternation among manufacturers and producers who must compile the information and transmit it down the supply chain and downstream users who have difficulty processing the great deal of additional, complex information. See REACH, art. 31, for information on the data requirements for Safety Data Sheets.

41. See EUROPEAN CHEMICALS AGENCY, GUIDANCE ON DATA SHARING (2007) [hereafter ECHA DATA SHARING], available at http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf.

42. European Chemicals Agency, General Report of the European Chemicals Agency 2008, at 2, Apr. 24, 2009, http://echa.europa.eu/doc/about/organisation/mb/mb_17_2009_final_echa_general_report.pdf.

and many of the potential registrants, who found it difficult to identify other companies with whom they could form an SIEF. One of ECHA's goals for the pre-registration process was to determine which phase-in (existing) substances were actually still on the market. Due to the high volume of pre-registration applications, though, ECHA failed to accomplish this objective. In addition, lead registrants and SIEF facilitators faced the burdensome task of identifying which pre-registrants actually intended to register before the 2010 deadline. Their solution was to categorize the pre-registrants' SIEF status as either leading, involved, passive, or dormant; and the facilitators accomplished this simply by e-mailing all of the pre-registrants in their pre-SIEFs. Those pre-registrants who did not reply—often up to 90% of the pre-registrants contacted—were automatically assigned dormant status and did not participate in the formation of the SIEF or in negotiations on cost and data sharing.⁴³

ECHA received an overwhelming number of pre-registration applications for a number of reasons. First, the REACH legislation required any legal entity not pre-registering a substance manufactured or imported at more than one tonne per year to halt the manufacture or import of that substance immediately after the pre-registration deadline. Second, there were some clarifications of (or changes to, depending on one's perspective) the pre-registration process made by ECHA prior to the pre-registration deadline. Third, neither REACH nor ECHA established any barrier or disincentive to pre-register. Rather than accept the risk of a potential supply disruption, some companies chose the prudent approach of pre-registering more rather than fewer substances. Fourth, uncertainty surrounding the pre-registration process encouraged not only producers, manufacturers, and importers to pre-register, but also downstream users, who feared that they would be liable as potential importers if their suppliers somehow forgot to pre-register or misinterpreted ECHA's guidance during the pre-registration phase. Fifth, two firms pre-registered not only the chemicals that they produced or imported in quantities greater than one tonne, but *every* chemical substance that was on the European Inventory of Existing Commercial Chemical Substances,⁴⁴ the European List of Notified Chemical Substances,⁴⁵ or the No-Longer Polymers lists⁴⁶—a total of about 100,000 chemical substances.⁴⁷ They were apparently unsure of the exact substances that were in the articles or mixtures that they imported. As a result, these companies pre-registered nearly *every*

chemical to be sure that they covered all of their imported substances. Finally, several firms pre-registered chemical substances that they did not even produce or import in an attempt to earn profit from involvement in substance registration by acting as an importer for companies who missed the pre-registration deadline.⁴⁸

If pre-registration is attempted in the United States, a modest fee for pre-registration should be considered as a device to discourage submissions that are not considered carefully. In addition, a more modest financial penalty for a first-time failure to pre-register (rather than an immediate halt of production) might prevent panic among companies who fear complete loss of a product. With these modest reforms, EPA might receive a more manageable number of pre-registrations to review.

Moreover, some question the value of the pre-registration process altogether. They identified some redundancy in ECHA's pre-registration and registration training programs and indicated that the label "pre-registration" was confusing because it signified an ambiguous obligation on the part of potential registrants. If the governmental objective is to identify which existing substances are still on the market and facilitate the development of SIEFs, then U.S. policymakers could simply require the development of an ongoing "substance identification inventory," without using a "pre-registration" label. The process could be similar to REACH's pre-registration process, but the obligation could simply be for companies to reveal to the regulator whether or not they introduce substances to the marketplace that match the registration parameters. The initial registration phase could then be accelerated because the number of initial registrations should be more limited, and this would also avoid redundant submissions and multiple information technology trainings.

2. Reduce the Universe of Substances Subject to Formal Registration

The general registration provision requires that "any manufacturer or importer of a substance . . . in quantities of 1 tonne or more per year shall submit a registration to the Agency."⁴⁹ While it might seem ideal to cover all chemical substances with pre-registration and registration requirements, the burden on industry and government can be lessened if the universe of substances subject to formal registration is limited based on potential for risk. For example, Canada's Chemical Management Plan and California's proposed Green Chemistry Initiative have prioritization processes that take place before industry and government are compelled to produce and review dossiers.⁵⁰ In the

43. See Jan Schüller, *SIEF Formation: How to do It Well*, Eastman Chemical BV, at 58, presented at ECHA's Sixth Stakeholders' Day, May 28, 2011, available at http://echa.europa.eu/doc/press/events/stks_day_20110518/presentations/echa_6th_stakeholders_day_presentations_schuller_20110518.pdf.

44. O.J. C 146A, 15.6.1990.

45. Directive 92/32/EEC, the 7th Amendment to Directive 67/548/EEC.

46. European Chemicals Bureau, No Longer Polymers List, available at http://www.reach-clp-helpdesk.de/reach/de/Downloads/NLP-Liste?__blob=publicationFile&v=3.

47. See European Chemicals Agency, *ECHA Ensures That EUGACHEM Closes Its Database*, ECHA NEWS ALERT, June 14, 2011, available at http://echa.europa.eu/news/na/201106/na_11_25_eugachem_20110614_en.asp (describing a lawsuit involving one of these firms).

48. *Id.*

49. REACH, art. 6(1).

50. See, e.g., Government of Canada, Chemical Substances: The Rapid Screening Approach, updated June 17, 2011, available at <http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/rapid-eng.php>; California Department of Toxic Substances Control, Green Chemistry Initiative, July 2012, available at <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsNoUnderlineJuly2012.pdf>.

current timetables for registration, REACH emphasizes a registrant's production volume and the intrinsic properties of the substance (especially some indicators of hazardiousness). The question becomes how a smaller universe of substances can be defined and defended, particularly a subset of substances based on potential risk to human health and the environment. A variety of possibilities are worthy of consideration.

If production volume is a valid surrogate for exposure and risk to human health and the environment (admittedly a questionable assumption),⁵¹ it would seem that industry-wide production volume is more relevant to overall risk than the volume manufactured or imported by any specific company. Using industrywide volume as the metric, the first registration deadline could be for all companies that manufacture or import a substance whose industrywide volume (production plus importation) is equal to or greater than a pre-set threshold. As a practical matter, all firms—big and small—that manufacture or import high-volume substances would face near-term registration deadlines. Substances with lower industrywide volumes would be subject to later deadlines for registration, presumably reflecting the fact that, on average, they pose less chance of damage to human health and the environment.

At first blush, this modification might seem to work against the interests of small and medium sized enterprises (SMEs). Currently, REACH's registration obligations are phased in according to a firm's manufacturing or importation volume, and thus most small businesses are only obligated to register in 2013 or 2018, rather than in 2010.⁵² SMEs under REACH are members in SIEFs from the day the SIEF is formed (even if they do not intend to register until 2013 or 2018), but it appears that most SMEs have not yet been involved in SIEF formation and decisionmaking.⁵³ Earlier involvement by SMEs, though, may be better in the long run. When small businesses are not involved early, the large companies are free to set the terms for how key SIEF decisions are made—for example, how sameness of substances will be determined, setting of fees and pricing for data sharing, and stipulation of a range of contract and governance terms.⁵⁴ If an SME seeks access to the joint dossier later than 2010, the SME must obtain a "letter of access" from the lead registrant based on a price determined prior to the 2010 deadline. Moreover, some SMEs

may have more to gain from early knowledge of best safety practices than large multinational companies. Thus, rather than hurting the welfare of SMEs, registration deadlines based on industrywide volume may bring them into the process earlier in a way that enhances risk management and protects the interests of SMEs in SIEF operation. A drawback to this entire approach, however, is that EPA may not have access to accurate data on industrywide U.S. production volume and importation for all substances of interest. Therefore, EPA may need to use estimates.

If industrywide production volume is not considered a valid indicator of risk or is not feasible due to data limitations, policymakers could focus priority setting on the intrinsic properties of substances. Currently, REACH focuses the first phase of registration (2010) on substances classified as carcinogenic, mutagenic, or toxic to reproduction (CMR), persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB). A case can be made, however, that other measures of toxicity such as acute toxicity are equally (or more) important than the properties specified in REACH.

One option is to use the substances covered by the Globally Harmonized System (GHS) for Classification and Labeling of Chemicals.⁵⁵ While GHS has achieved international recognition, it is not clear whether the GHS list for hazard communication is a small enough subset to provide adequate priority setting for a registration process or whether it will adequately cover the environmental hazards of concern in the United States. Alternatively, one could start with a large list (as in REACH or GHS) and then provide registration exemptions or delayed compliance dates for certain categories of common substances whose uses are likely to be low in risk—for example, most polymers due to their relatively low bioavailability, intermediates used in strictly controlled conditions due to their limited opportunity for exposure, or substances that are already known by EPA to have a relatively rich database. As explained above, the current REACH system does provide some flexibility for intermediates, and thus some degree of prioritization already exists. Ideally, one would like to see a risk-based priority-setting process for registration that reflects a combination of surrogates for both exposure potential and hazard—the two key risk ingredients. For example, Canada, Japan, and the United States are each working on complex prioritization schemes for existing chemicals, and these schemes should be evaluated as U.S. policymakers consider whether to follow, refine, or reject the REACH approach to registration.

3. Reconsider the Minimum Data Requirements in a Registration Dossier

The cost to a manufacturer of preparing a registration dossier is influenced significantly by the minimum data

51. Production or importation volume by a specific company is more an indicator of a substance's commercial value than it is an indicator of human/environmental exposure to the substance.

52. In 2010, 86% of the registrations were submitted by large companies rather than SMEs. ECHA is expecting that the number of registrations by SMEs will grow rapidly in 2013 and 2018. Janez Potocnik, European Commission, Remarks at REACH Registration Conference, Brussels, Belgium, Sept. 23, 2011.

53. Note that if an SME has production volume between one and 10 tonnes per year, it will be charged in the SIEF only for those tests that are required for registration in that tonnage range.

54. Martin Kayser, Senior Vice President of Product Safety, Regulations, Toxicology and Ecology, BASF, REACH Registration Conference, Brussels, Belgium, Sept. 23, 2011. (For the 2010 deadline, the largest German chemical company submitted 661 dossiers at a cost of 50 million euros and work by 250 full-time staff. Another 2,500 dossiers are projected to be submitted by BASF before the 2018 deadline.).

55. See U.S. EPA, Global Harmonized System for the Classification and Labeling of Chemicals, updated Feb. 16, 2011, available at <http://www.epa.gov/oppead1/international/globalharmon.htm>.

requirements for each substance. For a high-volume substance, even highly expensive data requirements may be tolerable. So far, the registration process has impacted primarily these higher volume substances in the European marketplace. As the REACH process begins to impact lower volume substances in 2013 and 2018, the minimum data requirements may become too expensive for the commercial viability of some substances. If this prediction is accurate, some substances may disappear from the market—not because they present a safety problem, but because the cost of meeting REACH's minimum data requirements is prohibitive. There may be particular problems for some low-volume specialty chemicals now sold in Europe.

The design of the minimum data requirements under REACH is somewhat sensitive to these economic realities. For example, the higher the production volume, the more extensive are the required batteries of toxicological tests.⁵⁶ A key question is whether such flexibility is adequate. For example, some scientists argue that the two-generation reproductive testing requirements under REACH are overly complex and burdensome and could be streamlined without significant loss of information.⁵⁷ Others argue that the structure-activity modeling tools used by EPA are a more cost-effective learning strategy than the minimum data requirements in REACH, at least in some circumstances.⁵⁸ For low-volume chemicals, however, the REACH testing requirements may in fact be too weak.⁵⁹ Before enacting REACH's minimum data requirements, U.S. policymakers should compare the likely benefits and burdens of alternative minimum data requirements.

More generally, a revolution of toxicological testing techniques is underway, and many of the innovations are alternatives to the whole-body animal testing that has dominated the field for decades. Four U.S. federal agencies—EPA, NIH, NTP, and the FDA⁶⁰—have a memorandum of agreement to encourage and develop these techniques.⁶¹ Before U.S. legislators adopt the minimum testing requirements in REACH, a careful assessment of the alternative techniques is required, including their availability, reliability, and cost.⁶²

4. Replace Registration With Iterative Screening Prior to Regulation

The number of registrations under REACH is enormous relative to the staffing resources of ECHA. Unless the size of ECHA is multiplied (which seems unlikely in the prevailing fiscal environment), the REACH registration process may ultimately be seen as more a system of data collection and warehousing than a procedure for protecting the public and the environment from exposures to hazardous substances. As we explain below, a majority of the data submitted under the registration process may never be evaluated. An alternative regulatory strategy, already initiated by the Canadian and Japanese governments, is an iterative screening approach.⁶³

Under screening, rather than beginning by compelling submission of large amounts of information on thousands of substances, regulators can use currently available information, structure-activity-relationship modeling, and expert judgment to identify a subset of substances or uses that require further attention. In other words, regulators might set aside a vast array of substances or uses at the beginning, e.g., many polymers and intermediates, on the grounds that they are unlikely to cause unacceptable risk. Once the substances or uses of interest to regulators are identified, industry should be given an opportunity to submit additional information on uses, toxicity, or exposure to clarify whether further regulatory attention is required. If regulators are not reassured or satisfied with the additional information, they can either request additional data (a multistep iterative approach) or they can proceed directly to regulatory action.

A disadvantage of iterative screening by government and industry is that it requires a multiplicity of judgment calls by regulators that are difficult to make in a fully transparent and objective fashion. Even if those calls are reasonable, there may be no opportunity for NGOs or legislators to oversee and understand what is being done by EPA and why. Currently, much of the perceived problem with existing chemicals regulation under TSCA is that NGOs do not have confidence in the priority-setting determinations of EPA. A registration process is more cumbersome, i.e., less nimble and flexible, than iterative screening, but it has a key advantage of making specified amounts of information available to the public as well as EPA.

5. Reduce Registration Requirements for Intermediates

An “intermediate” is a substance that is manufactured for the purpose of being transformed into another substance through chemical processing.⁶⁴ The outcome of the chemical processing is a distinct manufactured sub-

56. Sven Ove Hansson & Christina Ruden, *REACH: What Has Been Achieved and What Needs to Be Done?*, in *REGULATING CHEMICAL RISKS: EUROPEAN AND GLOBAL CHALLENGES* 71, 79-80 (J. Eriksson et al. eds., 2010) (providing a good discussion and tabular presentation of how minimum testing requirements in REACH vary by production volume).

57. Thomas Hartung & Costanza Rovida, *Chemical Regulators Have Overreached*, 460 *NATURE* 1080 (2009).

58. Renn & Elliott, *supra* note 21, at 231.

59. Hansson & Ruden, *supra* note 56, at 79, 81.

60. National Institutes of Health (NIH); National Toxicology Program (NTP); Food and Drug Administration (FDA).

61. NIH, NIH Collaborates With EPA to Improve the Safety Testing of Chemicals, NIH News Release, Feb. 14, 2008, available at <http://www.niehs.nih.gov/news/newsroom/releases/2008/february14/index.cfm>.

62. NATIONAL RESEARCH COUNCIL, *TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND STRATEGY* (2007); E. Donald Elliott, *Needed: A Strategy for Implementing the Vision*, 29 *RISK ANALYSIS* 482 (2009).

63. Naiki, *supra* note 6, at 11, 15-17 (“[T]he Canadian-type reform had more compatibility with the existing Japanese chemical system than REACH-type reform.”).

64. REACH, art. 3(15).

stance. Because intermediates are not themselves present in products available to consumers, they potentially enjoy relaxed registration requirements.⁶⁵ While REACH does offer some regulatory relief for intermediates, there is considerable debate about which substances and uses qualify for the exemption, and there remains concern that, given ECHA's interpretations of the conditions of use, the burden of registering intermediates remains too large. For example, monomers are a type of intermediate but are treated differently under REACH. They must be registered even when not physically present in an imported polymer. On the other hand, government officials in Germany have expressed concern that registration dossiers for intermediates are being submitted with insufficient data.⁶⁶ The argument against less regulation of intermediates is that even if consumers are not exposed to intermediates, workers may be exposed, and a basic data set is needed to help protect them. But worker health and safety in the EU are governed by a suite of other laws that are overseen by the European Agency on Safety and Health at Work.⁶⁷ U.S. policymakers are therefore advised to take a careful look at how intermediates are regulated.

6. Offer More Explicit Guidance on Information Technology Tools

To electronically submit registration dossiers to ECHA, registrants must use a variety of information technology (IT) tools, and several interview subjects expressed concerns related to these IT tools. Overall, the tools are robust and work well if the registrant has both the time and money to learn how to operate them. Furthermore, ECHA constantly improves upon the IT tools. For example, a technical completeness check of registration dossiers yielded only a 46% success rate for 2009 registrations⁶⁸ but a 98% success rate for 2010 registrations, indicating a leap in registrants' ability to fill out the registration dossiers correctly using the required software.

Regulatees expressed two primary issues with the IT tools. First, the OECD's IT tool, which is used for REACH registration, is quite complex. It takes several days to learn, and it functions primarily in English. With 23 official languages spoken in the EU, an English-only software program caused difficulties.⁶⁹ In addition, ECHA's guidance and instruction activities for inexperienced registrants were

held only two weeks before the first registration deadline, causing a bottleneck of last-minute registrations. A second concern is that ECHA updated its IT tools too often. Transferring data from one version of the software to the next caused fear of lost data and other complications for companies. The REACH experience therefore suggests that unnecessary burdens on industry and government can be avoided if careful planning and directed improvements to the IT tools are designed in a way to make the software more stable in application. Interviewees report that webinar training under REACH for industry was very useful but would have been much more helpful had it been offered sooner than the month of the registration deadline. It is difficult for training sessions to be highly effective unless careful IT planning has already occurred and few changes to software are likely in the foreseeable future. Though registrants experienced difficulties initially, the software eventually worked well and accomplished its objectives.

A key question becomes what IT tool(s) U.S. policymakers should choose. EPA employs e-PMN [premanufacture notification] software, whereas OECD uses the International Uniform Chemical Information Database (IUCLID) system. Fortunately, both are extensible markup language (XML)-based software systems, which means they have significant versatility—for example, each of the information elements is “tagged” so that, without requiring the information to be retranscribed, the information can be exchanged and utilized by another XML system that has a “thesaurus” identifying the tags. Whatever IT tool regulators select for use in the United States, it is critical that it be capable of importing and exporting data in collaboration with IUCLID users.

7. Offer More Explicit Guidance on Data Sharing, Compensation, and Joint Registration

Among the primary principles guiding the registration process is “one substance, one registration.”⁷⁰ To that end, joint registration, whereby multiple manufacturers and importers share data, is virtually required. One of the primary issues that regulatees raised in our interviews concerned high transaction costs associated with negotiations over contracts covering data and cost sharing within SIEFs. In fact, one interview subject indicated that the attorneys fees for contract negotiations may have exceeded the value of the information that the company was trying to protect in the first place. High transactions costs do not necessarily justify the elimination of mandatory data sharing. Without sharing, the costs of duplicative testing on animals, coupled with the extra burdens on regulators facing mul-

65. REACH, art. 17, 18.

66. Alexander Nies, Deputy-Director, Federal Ministry for the Environment, Bonn, Germany, REACH Registration Conference, Brussels, Belgium, Sept. 23, 2011.

67. For information on the EU's worker safety legislation, see European Agency for Safety and Health at Work, European Safety and Health Legislation, available at <http://osha.europa.eu/en/legislation>.

68. European Chemicals Agency, General Report of the European Chemicals Agency 2009, at 12, Apr. 24, 2010, available at http://echa.europa.eu/doc/about/organisation/mb/mb_12_2010_general_report_2009_final_en.pdf.

69. For 2012, ECHA has plans to distribute REACH-IT Manuals in 22 languages, including multilingual help with IUCLID. Christel Musset, ECHA, *Raising Awareness for Deadline May 2013*, REACH Registration Conference: What Did We Achieve in 2010—How Can We Ease the Way for 2013, Brussels, Belgium, Sept. 23, 2011.

70. European Chemical Agency, Frequently Asked Questions, 10. Joint Submission of Data by Multiple Registrants, 4, available at http://echa.europa.eu/reach/reach_faqs_en.asp?topic=jointsub&#jointsub (“The REACH Regulation, and in particular Article 11, is based on the ‘one substance one registration’ principle.”).

multiple registrations for the same chemical substance, might be prohibitive.

One potential solution would be for the legislation to compel data sharing without compensation from other joint registrants. Opposition to this solution should reasonably be expected from the current owners of large amounts of chemical toxicity data, since without some compensation, the incentives for industry to engage in scientific research, innovation, and safety testing are diminished. In fact, in the United States, compelling data sharing without compensation may rise to the level of a regulatory taking, since the government is effectively eliminating the commercial value of proprietary data. Some mechanism for government compensation to the data owner, therefore, may be a necessary component if the United States adopts compulsory data sharing without compensation from joint registrants. The United States, however, already has some experience with data and cost sharing, including some government compensation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁷¹

The sharing and compensation process is further complicated, though, when multiple studies of differing quality are available and are owned by different companies. Compensation schedules may need to be variable based on study quality, assuming the studies address the same endpoint, e.g., reproductive toxicity.

A more modest reform might be a legislative scheme to provide direct guidance on proper SIEF operation, data sharing, and compensation. For example, regulations could require that compensation to data owners be based explicitly on the cost that would be incurred if the study in question was conducted now, e.g., in 2012, with costs to be distributed equally among members of the SIEF or according to market share.⁷² The legislation should also specify how future costs or costs to newcomers are to be handled. Any newcomer to the SIEF, for example, could be obligated to make a payment to each SIEF member, reducing the cost of data sharing to all SIEF members equally. Adjustments to a joint registrant's compensation obligation could also be made on the basis of that firm's production volume or whether it needs to reference the data in its own registration dossier.

As noted above, REACH requires that parties sharing data must make "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way."⁷³ Unfortunately, the meanings of these terms are subject to many interpretations, even many plausible ones. In our interviews, we gathered anecdotal reports of what seemed to be unfair behavior by certain lead registrants. In theory, a joint registrant has the option to opt out of the SIEF entirely, but that course of action can be more costly than paying the data owner's asking price for data (even if that price is inflated).

As a practical matter, the registration deadline gives the lead registrant a structural advantage in setting the data compensation rules for an SIEF and controlling the resolution of disputes. If a joint registrant felt that it was being treated unfairly and refused to pay the data owner's asking price, then the data owner could simply wait the joint registrant out. The joint registrant could then either choose to pay the asking price or fail to register by the 2010 deadline. But failure to register is tantamount to forgoing an entire line of business, so the joint registrant does not have much leverage. Since REACH does not provide for a stable and predictable dispute resolution mechanism, the operation of SIEFs may work to the advantage of the data-owning firms and against the interests of smaller and less powerful firms in a sector.⁷⁴

Any American REACH-like scheme, therefore, should include a dispute resolution mechanism, whereby disputes within SIEFs are referred to low-cost arbitration—or perhaps administrative law adjudication—that must be resolved under explicit guidance on data sharing and compensation rules. In addition, there should be a mechanism available to SIEF members to penalize the data owner (or if the data owner is the lead registrant, strip it of its title) if the members can show that the data owner is abusing its position. Given that most disputes have arisen over the high cost of certain test data, SIEFs could be required to allow SMEs that would have difficulty paying for the expensive data to pay for the data over time through a payment plan, rather than in a lump sum. In enacting REACH, the EU authorities deliberately left the establishment of SIEF rules to the industry, thereby providing the greatest amount of flexibility in its novel data-sharing requirements. This was not an unreasonable move, given that REACH is the first legislation of its kind, but a common response in our interviews was a desire from industry for more-specific criteria governing SIEF operation and data-sharing mechanisms, including the provision of dispute-resolution methods.

One can even question whether data sharing should be mandatory. A U.S. system could call for voluntary data sharing, with incentives or rewards to companies that share their data. For example, registration fees could be reduced if a company registers through a data-sharing SIEF that meets certain minimum management practices. More research is needed to reveal the advantages and disadvantages of different approaches to mandatory and voluntary data sharing.

8. Publicly Disseminate the Identity of Lead Registrants

Under REACH, there is a lead registrant for every joint registration submission. Although efforts are underway to make the identities of lead registrants publicly avail-

71. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-35.

72. Many SIEFs mandate that joint registrants pay an equal sum for the data regardless of differences in their production volumes.

73. REACH, art. 27(3).

74. Chinese firms exporting into the EU claim they have been harmed by REACH's joint registration process. See *Chinese OR Hits Back at REACH Consortia Fees*, CHEMICAL WATCH, Jan. 5, 2011, available at <http://chemicalwatch.com/6253/chinese-or-hits-back-at-reach-consortia-fees>.

able on a voluntary basis, the identity of many of the lead registrants is not necessarily public information. Therefore, a company considering registration in 2013 or 2018 may encounter difficulty in determining who to contact in order to join an SIEF in preparation for registration. Such a company would either have to write to ECHA or to SIEF members, asking for them to disclose the identity of the lead registrant. ECHA's current policy is to not disclose the lead registrant in response to requests, but to refer the requester's contact information to the lead registrant, thereby allowing communication to occur.

Maintaining the secrecy of the lead registrant is somewhat perverse. First, secrecy adds an unnecessary complication to the registration process for the SMEs that will be registering in 2013 and beyond, and it opens the door for further abuse by data-owning lead registrants. Second, the public has at least a qualified right to know which companies are placing which chemical substances on the marketplace—the key qualification being an appropriate, case-specific demonstration that the name of the company should be treated as confidential business information. Indeed, there may be a limited number of cases where a company is widely known to be associated with a particular substance, mixture, or product, and knowledge of that company's involvement would disclose proprietary information. For example, revealing the identity of importers of substances within mixtures can potentially assist competitors who may deduce the composition of the importer's formulation. In fact, ECHA has indicated that it will publish the identities of registrants subject to a confidential business information (CBI) exception.⁷⁵ Additionally, ECHA recently announced that it will encourage nominated lead registrants to identify themselves as a way of providing more assistance to new registrants in the formation of SIEFs. In cases where the lead registrant agrees to the publication of its name, however, it would surrender the claim that its company name is CBI. Recognizing that publication of lead registrant names may lean toward more public disclosure than is typical of current international practice in the chemical industry, we nonetheless recommend that the identity of lead registrants be made publicly available, unless a case-specific CBI demonstration is made to the regulatory authority.

9. Publicly Disseminate Chemical Safety Reports, Unless Specific Passages Are Approved Exclusions Based on a Valid Claim of CBI

Greater amounts of information are required for chemicals that are manufactured or imported in higher volume. Once the 10-tonne threshold is reached for a registrant, a Chemical Safety Report (CSR) for the substance must be

added to her registration dossier.⁷⁶ The CSR must usually include a chemical safety assessment, including information on hazards to human health and the environment, physiochemical hazards, and an assessment on whether the substance qualifies as PBT or vPvB.⁷⁷ The CSR is the meat of the registration dossier, because it includes, where necessary, the information on specific uses, exposure scenarios, and the risk/safety of the chemical substance (including risk-management measures). Under REACH, CSRs (or portions of them) are shared with relevant actors in the industrial supply chain, sometimes in the form of extended Safety Data Sheets, but the CSRs are treated by ECHA as CBI. As a result, the CSR for each registered substance is not published on ECHA's website.

We reviewed the data made available by ECHA on its website for several substances, e.g., benzene and formaldehyde, where it is reasonable to expect NGOs, reporters, legislators, and academics to have an interest in the safety of specific uses, including risk-management measures. Although ECHA makes an extensive amount of raw data and references available to the public, the agency discloses neither the key calculations concerning risk and safety in specific uses nor the impacts of risk-management measures (presumably because they are part of the CSR, which is treated as CBI).⁷⁸

We recognize that public disclosure of how a chemical is used in a specific application may raise CBI concerns. In the chemical industry, firms gain competitive advantages by inventing new uses of existing chemicals or by discovering new ways that multiple chemicals can improve a production process or form ingredients of an improved consumer product. For example, there is significant competition in the automotive supply chain over the selection of chemicals and related processes for use in making the batteries that power electric cars. There may be situations where the supplier of a chemical for use in batteries does not want to lose a competitive edge by letting her competitors know which chemicals are used in the manufacture of batteries and related components or precisely how those chemicals are used. A CSR for a chemical produced for subsequent use in battery production may need to examine exposure scenarios involving workers at the battery plant, the vehicle assembly plant, the workers who service the batteries, the owners of the vehicle, and community residents living near waste facilities where byproducts of batteries are stored. The question becomes how much of this information should be publicly available in a U.S. version of REACH.

For many standard bulk and commodity chemicals, there may be very limited information in a CSR that is confidential. For specialty chemicals, however—most of which have yet to be registered under REACH (due to their smaller production and import volumes)—a CSR

75. European Chemicals Agency, Additional Information on Chemical Substances to Be Published, Press Release, July 24, 2012, http://echa.europa.eu/en/web/guest/view-article/-/journal_content/ACDE6540-CFBC-420C-B0CF-0B58485C7DA9.

76. REACH, arts. 10(1)(b); 14(1).

77. REACH, art. 14(3).

78. For information made publicly available through various REACH processes, see ECHA CHEM at http://echa.europa.eu/chem_data_en.asp.

may contain significant amounts of CBI. For instance, a CSR for a specialty chemical may contain information on starting materials, solvents used, tonnages produced, type of manufacturing equipment used, frequency and size of batches, temperatures used for manufacture and downstream processing, technical function of the substance, ratio of the substance incorporated into a final product, sales information for each end use, and even market information on the geographical locations of customers. Much of this information will be of use to the registrant's competitors, but will not be central to a reader's understanding of safety issues. There is international recognition of the concept that different actors in the value chain have different needs for information and differing capabilities to process and use technical information. Not all actors in the supply chain need access to all the information in the CSR, and disclosure of different sections of the CSR may raise different degrees of sensitivity. It is therefore reasonable for companies to request that certain passages or sections of CSRs be treated as CBI. However, we question ECHA's current stance that CSRs as a whole are presumptively CBI. Notably, if CSRs are made publicly available under a U.S. system, interviewees indicated that the format of the document would need to be different than the one used in Europe, given the bundling of CBI with publicly important information in European CSRs.

TSCA reform should, whenever feasible, provide for public access to the risk-related information in CSRs, specifically the risks/safety of specific uses (including risk-management measures). If any listing process based on substances is replaced by a list of specific uses, then some form of disclosure will be crucial. Not only do members of the public have a right to know the risks associated with the substances used in the marketplace, but there is also an economic rationale for public disclosure of safety information in CSRs. Better public information about risks could facilitate chemical safety measures and substitution as a function of marketplace pressures, thereby improving regulatory efficiency and possibly alleviating the administrative burden of direct regulation.⁷⁹

In the U.S. context, some of the public information about chemical risks will be supplied to workers through OSHA requirements and to consumers through Consumer Product Safety Commission (CPSC) requirements. If the information in the CSR regarding risks to workers and con-

sumers in specific uses does not offer any additional insight compared to what OSHA and CPSC standards are already achieving, then the case for more public disclosure is weakened. But even then, it seems likely that NGOs, reporters, legislators, and others may gain insight into whether the use-specific safety information in the CSR provided to EPA is consistent with what the public is learning from other agencies and regulatory bodies in other countries.

10. Consider Unintended Impacts on International Trade

The impact of REACH on international trade and the regulation's compatibility with the principles of the World Trade Organization (WTO) have been a source of controversy since the program was first proposed by the European Commission almost a decade ago. In our interviews, we heard a range of opinions on whether REACH imposes disproportionate or comparable burdens on importers versus European producers and manufacturers. As of this writing, no WTO decision has been made on the legality of a specific REACH requirement or on REACH's general compliance with WTO law.⁸⁰

While many businesses were wary of REACH from the moment of its conception,⁸¹ some large chemical companies, especially those based in Europe, may have seen some commercial advantages from REACH in a competitive, global economy. If a company is large, produces chemicals in Europe, has good connections in the EU, and has its own chemical testing capabilities, it may find it easier to comply with REACH than if a company is small, produces its chemicals outside of Europe, is unfamiliar with the EU, and lacks in-house chemical testing capabilities.⁸² In addition, since enforcement of REACH is unlikely to be uniform across the EU (the legislation leaves implementation and enforcement to individual member state authorities), it is possible that European companies with strong ties to particular member states will be treated with more deference than importers who lack connections to officials in the member states. The second and third rounds of REACH registration are likely to cover more small companies operating outside of the EU than did the first round, and thus it is too early to make a confident statement about the trade impacts of the REACH registration system or its impacts on SMEs.

Some argue that REACH creates a functional or de facto trade barrier for non-EU companies that aim to export industrial chemicals into the EU.⁸³ Companies

79. See RICHARD J. LAZARUS, *THE MAKING OF ENVIRONMENTAL LAW* 189-90 (2004) (discussing the importance of public participation in environmental rulemaking); Roy Peled & Yoram Rabin, *The Constitutional Right to Information*, 42 COLUM. HUMAN RIGHTS L. REV. 357, 357-70 (2011) (describing the four theoretical rationales for the public's right to information access: proper functioning of democracy; information access as a fundamental right; government-held information is the property of the public at large; and the public oversight of government); Marci A. Hamilton & Clemens G. Kohnen, *The Jurisprudence of Information Flow: How the Constitution Constructs the Pathways of Information*, 25 CARDOZO L. REV. 267 (2003) (describing the history of the right of information access in American jurisprudence); John M. Ackerman & Irma E. Sandoval-Ballesteros, *The Global Explosion of Freedom of Information Laws*, 58 ADMIN. L. REV. 85 (2006) (providing a comparative view of freedom of information laws and the rationales for them).

80. See, e.g., Doaa Abdel Motaal, *Reaching REACH: The Challenge for Chemicals Entering International Trade*, 12 J. INT'L ECON. L. 643 (2009).

81. At the time it was passed, REACH was seen as a possible source of numerous transatlantic trade conflicts. See Reinhard Quick, *Transatlantic Regulatory Cooperation on Chemicals: An Idealist's Dream?*, in SYSTEMIC IMPLICATIONS OF TRANSATLANTIC REGULATORY COOPERATION AND COMPETITION 241-85 (Simon J. Evenett & Robert M. Stern eds., 2011).

82. Halfman & Bal, *supra* note 34, 345 ("[T]he largest players in a market with complex regulation may even support increasing regulation, as it allows them to take control.").

83. See generally Motaal, *supra* note 80.

that are not based in the EU are not permitted to register their substances directly with ECHA. REACH was apparently designed this way because the EU does not have legal authority over non-EU companies. If a non-EU company exports industrial chemicals into the EU marketplace, then any of its European clients that import those chemicals into the EU must fulfill REACH's registration mandates. Moreover, each and every client of an importer must register if their REACH-defined volume exceeds one tonne per year. In an effort to avoid having to fulfill the obligations of importers, it is possible that some European clients of importers may turn instead to EU manufacturers.⁸⁴

REACH is not entirely silent on this matter, and indeed created a mechanism to address the problem: re-sourcing to an "only representative" (OR) of the non-EU manufacturer.⁸⁵ An OR is a legal entity in the EU that may fulfill REACH's registration obligations on behalf of a non-EU company that exports industrial chemicals into the EU. The non-EU exporter must notify its clients of its appointment of an OR, and the OR will fulfill the registration obligations of importers, rather than the manufacturer's clients, which would have otherwise been importers themselves.⁸⁶ Almost one in five registrations submitted to ECHA in 2010 was submitted by an OR.

There are three models for establishing an OR. First, most foreign exporters use sister or affiliated companies based in the EU as ORs. Second, non-EU companies may charter new companies in the EU to act as ORs. Finally, an OR may be any natural or legal person, and there are several companies that provide services as ORs.⁸⁷

Further consideration may be necessary to account for the case of a non-EU distributor of substances. Our reading of REACH is that the creation of the OR entity is available only to a manufacturer or formulator, not a distributor.⁸⁸ Further study is therefore necessary to determine whether the non-EU distributor is placed at a competitive disadvantage under REACH.

11. Provide More Clarity on the Continuing Obligation to Update Registrations

Registration responsibilities continue beyond the submission of a registration dossier. Indeed, REACH obliges registrants to continually update their registration dossiers

"without undue delay" in a variety of circumstances.⁸⁹ The obligation to update a registration dossier when substantive changes regarding the chemical substance have occurred, such as new uses or the discovery of new risks, makes logical sense and should be included in any U.S. REACH-like regulation.

Interview subjects objected to REACH's lack of clarity and reasonableness on the circumstances that may trigger an obligation to update a registration dossier. One interviewee, for example, questions whether new guidance documents that ECHA decides to release could activate a burden to update one's registration dossier. One criterion that triggers an obligation to update is "new knowledge of the risks of the substance to human health and/or the environment . . ."⁹⁰ This criterion raises the question of how often a company must check the peer-reviewed literature regarding the substance that it manufactures. Some may suggest once per year, while others may argue for consistent monitoring of the literature. There may be several plausible ways to resolve this issue, but a clear, reasonable, and predictable resolution should be apparent in legislation or agency guidance.

Finally, ECHA lacks the power to enforce REACH's mandates. REACH provides for no fee or power to limit the use of a substance if a registrant shirks its responsibility to update its registration dossier. The lack of enforcement authority, though, is unique to the structure of the EU: ECHA must notify the member states if a registrant fails to comply, and the member states must bring an enforcement action or levy a penalty against the noncompliant registrant. Any U.S. legislation should empower EPA with enforcement authority.

12. Consider Cross-Atlantic Recognition of Registration Dossiers

One final desire that many interview subjects expressed was that a potential U.S. REACH-like regime should recognize and/or accept the submission of registration dossiers prepared for REACH.⁹¹ Any new format for the same data is likely to create additional cost without achieving additional benefit. The presence of CBI in registration dossiers may, however, be a barrier to full sharing of dossiers with regulators on both sides of the Atlantic. We urge industry to work with U.S. and EU policymakers on a negotiated agreement on how to handle the CBI in dossiers, so that sharing of dossiers can occur. There will also be proposals in the United States to expand the minimum data requirements beyond those compelled in REACH, or to correct perceived deficiencies in the REACH data requirements. Since different data requirements in the United States will add cost and undercut efforts at trans-Atlantic cooperation, Congress should expect compelling benefits from any

84. Naiki, *supra* note 6, at 20 (acknowledging major concerns about whether REACH registration obligation creates discriminatory effect against non-EU manufacturers (or importers) of polymers because they need to register monomers in polymers while EU polymer manufacturers need not do so, as monomers will be directly registered by EU monomer producers).

85. REACH, art. 8.

86. REACH, art. 8. See also Pricewaterhouse Coopers (PwC), Only Representative Services, available at <http://www.pwc.com/nl/nl/reach/only-representative-services.jhtml>.

87. PwC, for example, provides only representative services. See PwC, Only Representative Services, *supra* note 86. Additionally, *Chemical Watch* publishes an annual list of REACH service providers, including companies that provide OR services. *Service Providers Guide*, CHEMICAL WATCH (2011), http://chemicalwatch.com/REACH_services.

88. REACH, art. 8.

89. REACH, art. 22.

90. REACH, art. 22(1)(e).

91. John Kvinge, *supra* note 18, at 331 (noting that when TSCA is modernized, cooperation with REACH will be required to avoid duplication of effort).

changes or expansions to the minimum data requirements. Finally, a more ambitious idea that is worthy of consideration is mutual recognition of work done by regulators on both sides of the Atlantic.⁹² Congress, for example, could authorize or require EPA to accept the evaluation of a dossier performed by ECHA when the evaluation activity is demonstrated to have met the quality standards expected in the United States.

IV. Evaluation

A. Positive Features

Any REACH-like regulation in the United States that includes registration would be incomplete without a formal evaluation procedure. REACH's evaluation framework builds a measure of scientific integrity into the regulation. Evaluation includes compliance checks that are meant to verify that the registration dossiers fulfill all of the registration data requirements.⁹³ They can be considered a form of spot-checking, not dissimilar from the process that the U.S. Internal Revenue Service employs to check income-tax returns for error and fraud. REACH mandates that ECHA must conduct a compliance check on no less "than 5% of the total [number of dossiers] received by the Agency for each tonnage band"⁹⁴ REACH does not obligate ECHA to examine the other 95% of registration dossiers for substantive compliance. In response to the first registration deadline in November 2010, ECHA received roughly 25,000 registration dossiers covering about 4,000 substances.⁹⁵ By implication, ECHA must check 1,250 dossiers from the 1,000 tonnage band for compliance, and it appears that ECHA aims to complete this round of compliance checks before the 2013 registration deadline. Even though ECHA will not evaluate the vast majority of registration dossiers—as much as 95%—the sample of dossiers that it will evaluate is probably large enough for ECHA to develop an accurate idea of the quality of the entire population of dossiers.

B. Alternative Approaches

1. Consider Merging Compliance Check and Substance Evaluation

REACH employs dual evaluation procedures: substance evaluation and dossier evaluation, of which compliance checks are a subset. The aim of the substance evaluation

process is to clarify the risks to human health and the environment associated with certain uses of chemical substances.⁹⁶ As a result, it is expected that the substance evaluation processes will be triggered by risk-based concerns. Substance evaluation differs from dossier evaluation in three meaningful ways. First, the member states carry out the substance evaluation process, with ECHA involved only as a coordinator of the process.⁹⁷ Second, dossier evaluation involves examination of a single dossier by one or more companies, whereas substance evaluation involves examination of a substance on an EU-wide basis.⁹⁸ As such, substance evaluation may entail assessment of *all* registration dossiers of the target substance, as well as any other source of available information. A member state may even conduct its own tests on the substance. Finally, during substance evaluation, requests for additional information from registrants may go beyond the minimum data requirements that REACH specifies in registration.⁹⁹ In other words, the data requirements for registration are a floor that substance evaluation information requests of registrants may surpass.

Under REACH, dossier evaluation conducted by ECHA and substance evaluation conducted by member states are completely distinct processes, but we see them as closely related. ECHA also foresees a potential connection between the two processes by noting that dossier evaluation can lead to substance evaluation. Not only may both processes result in requests for further information, they each may entail evaluation of risks and risk-management measures. There are, however, key differences between the two procedures that relate to scale and timing. A dossier evaluation pertains to a single registrant's dossier, whereas substance evaluation concerns every registrant of a substance and may generate information beyond the data floor set by the REACH legislation. Moreover, the dossier evaluation process is understood to occur in a limited time frame after a registration dossier is received by ECHA, while substance evaluation can occur at any time.

Insofar as substance evaluation is a means to empower the EU member states, it is a process that may not be necessary in the United States¹⁰⁰—or, at least, it does not need to be a distinct process. A federal agency such as EPA could partially merge compliance checks and substance evaluation procedures. ECHA selects 75% of the dossiers for compliance checks based on concern for safe use—the same concerns that may trigger a substance evaluation. Therefore, it is not unreasonable to foresee a U.S. regulatory framework in which the two processes are conducted concurrently. Congress, EPA, or members of the public could identify substances of concern, with processes of

92. Heyvaert, RCR, *supra* note 5, at 217, 228 (commenting on the track record of mutual recognition and trade liberalization, and how the centralized nature of REACH was designed to facilitate mutual recognition).

93. EUROPEAN CHEMICALS AGENCY, GUIDANCE ON EVALUATION (2007) [hereafter ECHA EVALUATION], available at http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.pdf.

94. REACH, art. 41(5).

95. European Chemicals Agency, *First REACH Registration Was a Success!*, ECHA NEWSL. No. 6, at 3, Dec. 2010, available at http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2010_6.pdf.

96. ECHA EVALUATION, *supra* note 93; EUROPEAN CHEMICALS AGENCY, REACH FACT SHEET: SUBSTANCE EVALUATION 1 (2011) [hereafter Evaluation Fact Sheet], ECHA-11-FS-03-EN, available at http://echa.europa.eu/doc/reach/substance_evaluation_fact_sheet_20110414_en.pdf.

97. Evaluation Fact Sheet, *supra* note 96, at 1.

98. *Id.*

99. *Id.*

100. Heyvaert, RCR, *supra* note 5, at 234 (REACH's complex substance evaluation process is too onerous for "transport" to other countries and regions without a governance structure similar to the EU.).

public comment, scientific peer review, and judicial review used to ensure that EPA's final identification decisions are reasonable. Substance identification may then trigger a process under which EPA evaluates the substances themselves, the lead registrants' dossiers, and if necessary, a portion of the relevant joint registration dossiers. As of this writing, substance evaluation under REACH is not a fully defined process. Thus, the precise benefits and drawbacks of merging the compliance check and substance evaluation processes in the United States are necessarily uncertain.

2. Provide for Public Nomination of Substances for Substance Evaluation

Under REACH, ECHA determines which dossiers to evaluate based on criteria concerning risk and safe use and some randomization. Member states and ECHA similarly determine which substances will undergo substance evaluation, presumably through a process that also considers hazard and risk. Neither process provides for public, e.g., NGO, nomination of chemicals for evaluation.

In the case of dossier evaluation, the REACH process is structured as a two-way communication between a specific registrant and ECHA, and ECHA will have access to portions of the registration dossier that are not available to the public. Given this dynamic, it would not be wise to invite public nominations of specific registration dossiers for compliance check evaluations. However, the substance evaluation process has a broader scope, e.g., all manufacturers of the same substance, and is initiated by regulatory authorities. Assuming Congress provides for a substance evaluation process, it may be desirable to supply the public an opportunity to suggest specific substances (and related uses) as priority candidates for substance evaluation. Notably, if the public has an opportunity to nominate substances for restrictions of some kind, then public nomination of substances for evaluation may not be necessary. Under U.S. law, final authority to select substances should, however, remain with EPA under congressional and judicial supervision.

If NGOs and the public are provided an opportunity to nominate substances for possible substance evaluation in the United States, EPA should be required to respond to such nominations in a timely manner based on scientific and risk considerations. The Administrative Procedure Act's (APA's) notice-and-comment requirements provide a practical basis for implementing this suggestion,¹⁰¹ though there is some debate about the impact of public comment on the decisions of U.S. regulators.¹⁰² If EPA responds to a petition in an arbitrary or capricious manner, an avenue for judicial relief should be provided under the APA and a modernized version of TSCA. However, EPA should be

given wide deference to prioritize substances for evaluation and should not be forced to waste resources defending the prioritization of one chemical over another if both are worthy of evaluation.

3. Provide for a More Targeted Compliance Check Process

Under REACH, recall that ECHA must evaluate a minimum of 5% of the registration dossiers that it receives for each tonnage band, and of that 5%, ECHA selects 25% at random and 75% based on technical or hazard-related concerns. This is a reasonable model for selection. An element of randomness in the selection process is desirable because it encourages registrants to prepare their registration dossiers with knowledge that there is a chance—albeit a small one—that ECHA will evaluate their registration dossier. Likewise, including a directed selection approach based on risk is also desirable because, after all, REACH's ultimate objective is to reduce risks to human health and the environment. The dossiers for the worrisome chemicals and uses, therefore, are the ones that should be evaluated.

On the other hand, one interviewee expressed concern that REACH has forced companies to generate a large amount of information and paperwork that may never be used or even read. Certainly, the vast majority of registration dossiers—as much as 95%—will never see the light of day by undergoing a substantive examination. One could argue that the regulator should evaluate a larger percentage of the registration dossiers. In the United States, failure to review as many as 95% of the registration dossiers would undermine public confidence in the regulatory system—the same problem that already undercuts TSCA. Neither EPA nor ECHA have the personnel or budgetary resources to evaluate 25,000 dossiers within a reasonable time frame, and even large increases in staffing would be insufficient.

The theory behind REACH's registration process is that benefits to public health and the environment occur when manufacturers decide not to register a hazardous substance (and presumably a safer one is used instead), or when manufacturers decide against registering selected uses that trigger significant exposure or risk, or when manufacturers implement additional risk-management measures to reduce exposure, thereby allowing a substance to be registered. In other words, the potential benefits of the REACH registration process occur before ECHA actually receives the dossiers. If this is always the case, the evaluation process has no additional value. But it is not obvious how to validate this theory of public benefit after a registration system has begun to operate, and any such validation would seem to require a careful look at the quality of the CSRs contained in (at least some of) the registration dossiers.

An alternative and potentially more cost-effective solution is to target the registration process at a smaller universe of worrisome chemicals and fund the regulatory authority to review a large percentage of the dossiers submitted for worrisome chemicals. Moreover, the regulator

101. Administrative Procedure Act, 5 U.S.C. §553(b), (c) (2011).

102. See William West, *Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making*, 64 PUB. ADMIN. REV. 66 (2004) (examining the effect of notice-and-comment procedures on bureaucratic outcomes).

could evaluate more dossiers with the same resources if it were to evaluate fewer parts of each dossier. For example, the regulator could examine a random sample of 2% of the dossiers to identify common data entry fields with significant compliance deficiencies. Upon determining which fields registrants have the most problems with, the regulators could then expose a larger subset of dossiers, e.g., 20%, to a review of *only* those problem fields. ECHA may be expending resources inefficiently if it is conducting compliance checks on data fields without a significant frequency of problems. Thus, it may be a better use of resources for a regulator to discover and correct deficiencies than to check compliance on data fields that the registrants likely complied with anyway. ECHA's guidance document on evaluation echoes this point:

It is highly recommended that, besides the criteria for dossier selection under Article 41(5), dossiers be selected mainly at random in the first years after entering into force of REACH in order to be able to identify the main reasons for non-compliance. Such an analysis could help improve guidance for the registrants, to develop criteria for selection of dossiers for a non-random compliance check, and eventually also to target the compliance check. This procedure may also ensure that the quality of the submitted dossiers increases over time.¹⁰³

One way for a regulator to influence dossier quality over time is to subject dossiers from registrants with a history of problematic registration submissions to heightened scrutiny through a higher likelihood of evaluation. Registrants may put more care into their dossiers if they know that they will face both a higher likelihood of evaluation and more-intense scrutiny if their previous dossiers were found to be deficient.

Finally, if the regulator selects a sample of dossiers to undergo compliance checks based on non-random criteria, then a clear standard for defining those criteria may be needed. REACH provides some guidance on prioritization for non-random selection,¹⁰⁴ and ECHA regulators in practice select 75% of the dossiers that undergo a compliance check based on the substance's dispersion, classification as a substance of high concern, or technical issues. Since the aim of REACH is to reduce risk to human health and the environment, then perhaps a more targeted approach to registration and evaluation would be warranted in an American REACH-like scheme.

4. Consider Contracting Evaluation to External Experts

Under REACH, ECHA evaluates dossiers, and agencies within member states evaluate substances. Under a REACH-like regulation, the United States could consider contracting panels of external experts, such as academics or toxicological consultants, to conduct the evaluation

processes, rather than staff at a regulatory agency such as EPA. Utilizing external experts in the evaluation process generates three benefits. First, contracting out the evaluation process could ease both financial and personnel burdens on EPA. Second, external evaluation by experts would ensure adequate expertise for the evaluation process, since it is difficult for EPA to have adequate internal expertise in all fields of science relevant to risk assessment and management. Our intent is not to insinuate that ECHA evaluators are (or that EPA evaluators would be) unqualified for the evaluation task, but rather that including external experts in the evaluation process would augment the regulators' proficiency to conduct thorough evaluations. Finally, including nongovernment experts within the evaluation process might add external legitimacy to the regulatory process. Industrial experts could be included when they do not have any conflict of interest, while participation by qualified scientists from NGOs could address concerns regarding lack of public participation in evaluation. For example, one interview subject indicated that, even where ECHA discovers risk-management deficiencies through the evaluation process, neither NGOs nor labor unions have the opportunity to propose new risk-management measures, even though they may have considerable expertise about management measures.

One can object to outsourcing evaluation on the grounds that governmental authorities are delegating their safety responsibilities to people who are not politically accountable. To address this concern, the external reports could be advisory to the regulatory body, a pattern that is common at U.S. agencies, such as the FDA. In fact, EPA already makes extensive use of external scientific organizations in a variety of its programs. Thus, EPA could consider contracting dossier evaluation to panels of the National Research Council/National Academy of Sciences or to standing panels modeled after California's Biomonitoring Scientific Guidance Panel, for example.¹⁰⁵ In this way, the governmental body remains accountable for the final decisions about safety.

V. Authorization

A. Positive Features

The basic purpose of the REACH authorization process is to protect public health and the environment by substituting substances of very high concern (SVHC) with suitable, safer alternatives.¹⁰⁶ A SVHC is a CMR, a PBT, a vPvB, or a substance of equivalent concern, like an endocrine

103. ECHA EVALUATION, *supra* note 93, at 43 (internal citations omitted).

104. REACH, art. 41(5).

105. See California Office of Environmental Health and Hazard Assessment, California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel, *available at* <http://oehha.ca.gov/multimedia/biomon/spp-bios.html>.

106. REACH, art. 55; EUROPEAN CHEMICALS AGENCY, GUIDANCE ON THE PREPARATION OF AN APPLICATION FOR AUTHORISATION 2 (2011) [hereafter ECHA AUTHORIZATION], *available at* http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf.

disruptor.¹⁰⁷ Unless the European Commission approves authorization requests for specific uses, the SVHC must be phased out. When suitable alternatives to an SVHC are available, an authorization request must be supported by a socioeconomic analysis and a substitution plan. If suitable alternatives are not currently available, an authorization request must also include an R&D plan for suitable substitutes. In either case, it is expected that authorizations will be granted for only a limited and specified period of time.¹⁰⁸

In theory, the REACH authorization process stimulates implementation of suitable substitutes while allowing the continued use of SVHCs when risks are adequately controlled or when the benefits outweigh the risks. Unlike the REACH restrictions process under REACH, discussed below, which places the burden of proof on the regulator, the authorization process creates a presumption of a ban on uses of an SVHC until a company makes an adequate case for continued use.

Since there will be some stigma on chemicals that have been listed under the authorization process, companies are unlikely to seek authorization unless the case for continued use is fairly strong. Even if the benefit-risk case for authorization is quite strong, some companies may choose to withdraw the substance from the EU market, either of their own volition or due to “deselection” by their customers who may not wish to have the name of their company associated with controversial substances. Note that the market process of deselection is a positive outcome for safety if higher risk substances are replaced by lower risk substances; however, deselection may also lead to adverse commercial consequences that are unrelated to safety. The balance of positive versus negative aspects of authorization is difficult to determine with certainty, because the EU does not yet have practical experience with authorization requests.

B. Alternative Approaches

I. Merge Candidate List and Authorization List Into a Single List

The authorization process begins with placement of SVHCs on the Candidate List, which means that the substance is a candidate to be placed on the formal Authorization List.¹⁰⁹ Inclusion of a substance on the Candidate List triggers certain obligations for producers, manufacturers, and import-

ers.¹¹⁰ Once substances are placed on the Candidate List, a process of “prioritization” occurs to determine which of the candidates will be placed on the official Authorization List.¹¹¹ The Authorization List currently contains a total of 14 substances.¹¹² Once a substance is placed on the Authorization List, the substance can no longer be marketed in the EU, unless the European Commission grants authorization for specific uses.¹¹³ If the substance has an established safety threshold, the application must demonstrate that the health and environmental risks from the specific use are “adequately controlled,” as documented in the CSR.¹¹⁴ If no safety threshold can be established, e.g., in the case of PBTs, vPvBs, and some carcinogens, the application must demonstrate that the socioeconomic benefits of continued use outweigh the risks and that there are no suitable alternative substances or technologies.¹¹⁵ An applicant must present a substitution plan, if suitable alternatives are available, or an R&D plan to discover a suitable alternative, if one is not readily identifiable.¹¹⁶

Whether both listing procedures are necessary in the United States is questionable.¹¹⁷ We also question whether each member state should have such a substantial influence in the listing process, though this feature of REACH may reflect a measure of deference to member states that is typical of EU institutions.¹¹⁸ In the United States, the power to list should be delegated by Congress to EPA, with listing decisions subject to public notice and comment, some form of external scientific peer review, and judicial review to discourage arbitrary and capricious listings. In other words, the proposal stage of notice-and-comment rulemaking may serve many of the same functions in an American context that the Candidate List serves in a European context.

107. REACH, arts. 55, 56(1), 57 (laying out the parameters for what constitutes a substance of very high concern); ECHA AUTHORIZATION, *supra* note 106, at xiii. For a description of potential harm to human health and the environment from endocrine disruptors, see Patricia Hunt, *Toxins All Around Us*, *Sci. Am.*, Oct. 11, 2011, available at <http://www.scientificamerican.com/article.cfm?id=toxins-all-around-us>.

108. REACH, art. 56. See generally ECHA AUTHORIZATION, *supra* note 106 (describing the process of applying for authorization).

109. EUROPEAN CHEMICALS AGENCY, GUIDANCE ON INCLUSION OF SUBSTANCES IN ANNEX XIV 12 (2008) [hereafter ECHA ANNEX XIV], available at http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf.

110. See European Chemicals Agency, Notification of Substances of Very High Concern (SVHC) in articles, ECHA-11-L-06-EN, 2011, available at http://echa.europa.eu/doc/publications/leaflets/sia_leaflet_web.pdf; European Chemicals Agency, Summary of Obligations Resulting From Inclusion in the Candidate List of Substances of Very High Concern for Authorization, available at http://echa.europa.eu/chem_data/authorisation_process/candidate_list_obligations_en.asp.

111. See EUROPEAN CHEMICALS AGENCY, GUIDANCE ON INCLUSION OF SUBSTANCES IN ANNEX XIV 25 (2008), available at http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.pdf; European Chemicals Agency, Results of the Prioritisation of the SVHCs on the Candidate List With the Objective to Recommend Priority Substances for Inclusion in Annex XIV, June 15, 2011, available at http://echa.europa.eu/doc/consultations/recommendations/prioritisation_results_3rd_rec.pdf.

112. European Chemicals Agency, Authorization List, http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp.

113. REACH, art. 56.

114. REACH, art. 60(2).

115. REACH, art. 60(4).

116. REACH, art. 60(4)(a)-(d).

117. There are differences in regulatory obligations triggered by the two lists.

118. EU constitutional law coupled with the “Meroni doctrine” prevent EU institutions from entrusting too much authority in agencies. Even before REACH was enacted, the history of EU chemical regulation displayed deference to member state authorities. See Veerle Heyvaert, *Coping With Uncertainty: The Regulation of Chemicals in the European Union* (Ph.D. Dissertation, European Univ. Inst., Florence, Italy, 1999); Pesendorfer, *supra* note 32, at 105-08.

2. Increase Role of the Regulatory Authority in Listing of Candidates

A common concern we heard is that the process of listing substances is cumbersome and slow, while the total number of listed substances seems small compared to the number of substances in use that are known to have worrisome intrinsic properties: For example, the total number of carcinogens or PBTs may exceed 1,000 substances.¹¹⁹ Recognizing this concern, the European Commission in 2011 had pledged to list an additional 136 substances by 2012, though given the complexity of the listing process, the Commission had difficulty honoring this pledge.¹²⁰ Part of the problem is that the number of substance nominations emerging from the EU member states is not large enough to support a rapid increase in the number of listings. ECHA and the Commission may need to play a more proactive role in the candidate listing process if the 2012 goal of the Commission is to be achieved in short order. In any event, the Commission, ECHA, and the member state authorities may lack the resources to ramp up the listing process.¹²¹

3. Establish a Public Nomination Process for Agency Consideration of Substances for Authorization

In the United States, it might be advisable to give NGOs (and the public generally) the legal opportunity to nominate substances for consideration by EPA as candidates for listing. Such a right does exist under TSCA §21, though that right refers generally to regulatory action, rather than a specified list of SVHCs. If EPA does not respond to such a nomination in a timely manner or if the Agency responds in an arbitrary and capricious manner, then opportunity for judicial review of the Agency's response can serve as a useful check on Agency power. We recognize, though, that this type of judicial review is not typical of the European regulatory system.

4. Clarify Decision Response Time on Applications for Authorization

An additional concern relates to the potential inability of the Commission to make a timely decision on an authorization request by an applicant. A delay in decisionmaking by the Commission could occur due to resource constraints, due to priority being given to other issues/decisions, or due to an inability of the Commission to find the necessary degree of consensus. Although this scenario has

not yet been tested, we encountered differing views about whether the Commission's indecision works for or against the registrant's interests. According to one view, REACH allows an applicant to continue marketing the substance until the Commission makes an explicit decision on the authorization request. This arrangement seems workable if the number of such cases is small, but the credibility of the process in the eyes of the public will be undermined if many uses are allowed to continue due to the inability of the Commission to reach a decision. An alternative view, rooted in a reading of Article 64 of REACH, the comitology procedure under Article 133(2) of REACH, and the Article 3 advisory procedure, is that the registrant may lose the right to market the substance if the Commission does not make an explicit decision. Ultimately, if numerous registrants are harmed through inaction by the Commission, REACH may encounter a more serious credibility problem.

5. Strengthen Risk-Risk Analysis of Substitute Substances and Processes

The authorization process seems to be designed on the premise that mandatory replacement of SVHCs with suitable substitutes will be good for human health and the environment. However, there is no requirement under REACH that it be shown, either with certainty or even with a better-than-even chance, that the substitute will create less risk to human health and the environment than the SVHC. Fortunately, it appears that the Commission and applicants for authorization are permitted under REACH to consider the safety of proposed substitutes, but the Commission is not compelled to produce a careful risk-risk analysis in support of its decision to deny an authorization request.

One could argue that it is the burden of the manufacturer seeking an authorization request for an SVHC to demonstrate that continued use of the SVHC is a safer option than the available substitutes that are suitable for a specified use. However, scientific knowledge about a substitute's safety will often be possessed by companies other than the one submitting the authorization request. REACH does call for information on substitutes to be submitted to the Commission, but it is not yet entirely clear how this process will unfold and whether it will be workable. When different chemical substances or processes are compared for relative risk for different uses, it is our view that the regulatory body is in a better position to perform an objective risk-risk analysis than one of the competing manufacturers. Moreover, the value judgments that are necessary in a risk-risk analysis, e.g., comparing a low risk of cancer to a higher risk of acute toxicity, are better addressed by regulatory analysts than by corporate entities. In sum, if U.S. policymakers should mandate a substitution process, they should ensure that a strong risk-risk

119. See International Chemical Secretariat, 378 Substances of Very High Concern, available at <http://www.chemsec.org/list/about-sin> (describing the Substitute It Now (SIN) List generated by NGOs).

120. Janez Potočnik, *Reaching for Resource Efficiency and Innovation in the Chemicals Sector*, Speech at the Helsinki Chemicals Forum, May 19, 2011, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/11/344&format=HTML&aged=0&language=EN&guiLanguage=en>.

121. *Id.*

analysis is prepared, preferably by regulatory analysts in the government or by independent analysts under contract to the government.¹²²

VI. Restriction

A. Positive Features

The restrictions procedure under REACH is sometimes described as a “safety net” for substances that pose an unacceptable risk to human health and the environment but cannot be addressed effectively or promptly through the other provisions of REACH (registration, evaluation, and authorization), or through procedures in other EU legislation, e.g., occupational health regulations, the EU directive on carcinogens, and so forth.¹²³ The restrictions authority is not new to REACH and, in fact, is largely a carryover of authority that the EU exercised prior to REACH’s enactment in 2006. In the REACH legislation, the time lines in the previous restrictions process are made more stringent, the rationale for restrictions is streamlined, and ECHA is brought into the deliberative process.¹²⁴ Currently, there are 59 categories of restricted substances in REACH Annex XVII, involving more than 1,000 substances, a majority being oil and tar derivatives.¹²⁵ These restrictions currently cover substances such as asbestos, benzene, lead, AZO dyes, PAHs, and PFOS.¹²⁶ EU actions since 2009 have enacted restrictions covering some uses of selected colorants, cadmium, nickel, and phthalates.¹²⁷

One of the commendable features of the restrictions process is that it does focus on worrisome uses of chemicals, rather than the substances themselves. Restriction is also usually informed by a process of risk assessment and socioeconomic analysis that is somewhat familiar to U.S. policymakers. The restrictions authority may be particularly useful when a worrisome chemical has a large number of uses, most involving little or no exposure or risk. Rather than stigmatize the chemical through a listing under authorization, it is feasible for the Commission, at the suggestion of ECHA, or the member states, to initiate a targeted restriction aimed at the few uses associated with significant risk. In this respect, the restrictions authority can be a more subtle and targeted regulatory instrument, compared to the rather blunt REACH authorization process (which is designed to phase out SVHCs).

B. Alternative Approaches

1. Priority Setting for Restrictions

Concerns were raised that the priority-setting process for chemical restrictions under REACH is not as rigorous and transparent as it should be. The Commission does run a process (CARACAL—Competent Authorities for REACH and Classification, Labeling, and Packaging) where, with assistance from the EU member states, some analytic papers are generated to help set priorities—Risk Management Option analysis papers, for example.¹²⁸ But there does not appear to be a systematic risk-ranking process in the EU that informs which uses of chemicals become targets of restrictions. In fact, each member state can initiate restrictions for whatever reasons it believes are compelling. For example, Denmark recently made a restriction proposal on classified phthalates using a variety of rationales, one being the alleged “cocktail effects” of phthalates. The same substances are now on the Authorization List. One of the aims of the Danish action is to address the risk of phthalates in imported articles, which are not directly addressed by the fact that they are on the Authorization List.¹²⁹

Concerns were also raised that ECHA and the European Commission continue to justify new restrictions of substances through an analytic process that assumes that the processes of registration, evaluation, and authorization do not exist. For example, in 2010, before the REACH registration process began, ECHA’s Socio-Economic Analysis Committee started work on the first of four restriction proposals that concern dimethyl fumarate (DMFu), lead in jewelry, and two applications of mercury.¹³⁰ The Committee initiated opinions on these proposals in 2011, before the relevant registration and evaluation processes had been completed. This type of restrictions activity may be a temporary phenomenon attributable to the phase-in period for registration that was included in the REACH registration. Once all worrisome chemicals are registered, ECHA and the European Commission may choose to make less use of the restrictions authority and more use of the regulatory tools in registration, evaluation, and authorization.

2. Reframe Authorization as a Subset of the Restrictions Process

Instead of creating the multiple lists under the authorization process, a REACH-like reform in the United States could provide authorization as one of its tools under a

122. JOHN D. GRAHAM & JONATHAN B. WIENER, *RISK VERSUS RISK* (1995).

123. See EUROPEAN CHEMICALS AGENCY, GUIDANCE ON RESTRICTION, available at http://guidance.echa.europa.eu/restriction_en.htm (“The restriction is designed as a “safety net” to manage risks that are not addressed by the other REACH processes.”).

124. REACH, arts. 70, 71.

125. Chemical Inspection & Regulation Service, REACH Restricted Substances List (RSL), available at http://www.cirs-reach.com/Testing/REACH_Restricted_Substances_List.html. See also European Chemicals Agency, Existing Restrictions, available at http://echa.europa.eu/reach/restriction/existing_restriction_en.asp.

126. See ECHA, Existing Restrictions, *supra* note 125. See also European Chemicals Agency, Restrictions Under Consideration, available at http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp.

127. See ECHA, Existing Restrictions, *supra* note 125.

128. See European Commission, Chemicals: Competent Authorities for REACH and CLP (CARACAL), available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm.

129. Paige Marie Morse, *Phthalates Face Murky Future*, 89 CHEMICAL & ENGINEERING NEWS 28, May 30, 2011.

130. European Chemicals Agency, *Consultation on Restrictions: Lead in Jewelry and DMFu in Articles*, ECHA NEWSL. No. 2, at 7, Apr. 2011, available at http://echa.europa.eu/doc/press/newsletter/echa_newsletter_2011_2.pdf.

restrictions process. In other words, if EPA seeks to take action against an SVHC but does not have sufficient information from registration dossiers to justify restrictions against specific uses, EPA could “restrict” or even prohibit all uses of the substance unless companies successfully apply to EPA for authorization of specific uses. The advantage of this approach is that EPA has less analytic burden, and thus can move quickly to address public concern, and the industry remains responsible for developing the necessary technical data to defend specific uses (assuming they choose to do so).

VII. Cross-Cutting Suggestions for Reform

To this point, we have analyzed the four parts of REACH—registration, evaluation, authorization, and restriction—as largely independent processes. In this section, we consider the potential interaction of the processes and the potential for regulatory inconsistencies, duplicative burdens, and gaps that require further attention. Furthermore, we focus on how the four processes might be streamlined and coordinated in a U.S. effort to modernize TSCA.

A. Establish a Coherent and Consistent Conception of Safety

In the U.S. literature on risk regulation, it is recognized that zero risk is an unattainable goal, and thus legislators and regulators must answer a difficult question: How safe is safe enough?

The legislative frameworks for safety determinations that are used in the United States fall into roughly five categories: (1) those that seek to reduce *only significant or non-negligible risks*; (2) those that seek to protect public health and the environment with an appropriate *margin of safety*; (3) those that seek to reduce risk to the lowest level that is technically and economically *feasible*; (4) those that seek to provide protection through a process of risk-risk analysis that *minimizes net risk*; and (5) those that seek to address *unreasonable risk* through a process of risk-benefit and/or cost-benefit analysis. Table 1 summarizes the five frameworks, provides an example of a U.S. law or regulation that employs them, highlights how the different frameworks have different information requirements, and notes that some of these frameworks appear—at least in some form—in REACH.

Table 1. Frameworks for Safety Determinations in U.S. Law*

Safety Frameworks	Legal Application	Information Required	Use in REACH Program
Insignificant Risk	Occupational Safety and Healthy Act	Risk assessment only	None
Adequate Margin of Safety	Clean Air Act	Risk assessment only	None except in calculation of “safe” exposure scenarios
Lowest Feasible Risk	Occupational Safety and Healthy Act	Engineering feasibility of controls plus financial affordability	None except perhaps “suitable” alternatives under authorization
Minimize Net Risk	Safe Drinking Water Act	Risk comparison	None
Unreasonable Risk	Consumer Product Safety Act and TSCA	Benefits and risks assessed	Socioeconomic analysis under authorization

*Derived from LESTER B. LAVE, *THE STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY* (1981); JOHN D. GRAHAM ET AL., *IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK* (1988).

One of the drawbacks of REACH is that there is no coherent and consistent definition of safety that governs decisionmaking throughout the four parts of the program. On the one hand, the restriction section is aimed at eliminating “unacceptable risk to human health or the environment,”¹³¹ even though “unacceptable risk” has no clear and consistent meaning in science, environmental philosophy, or law.¹³² The authorization section calls for a phaseout of SVHCs unless the registrant shows that the potential risk is “adequately controlled,”¹³³ but the meaning of adequacy in this context is not defined. If registrants seek to market a PBT, vPvB, or a substance of “equivalent concern”—particularly a substance with no safe exposure level—a phaseout of the substance is required unless the registrant demonstrates that the benefits of continued use outweigh the risks for specific uses and there are no suitable alternatives for those uses. Note here that information on benefits and substitutes plays a role, even though such information does not appear to have a role in registration or evaluation.

In fact, there appear to be inconsistencies in the four parts of REACH with respect to the safety concepts that are implicitly suggested and the types of information that are required or permitted for consideration. Although consistency is not always a necessary (or even desirable) feature, a law should not be designed in a manner that leads to inconsistent regulatory outcomes. For instance, when the same chemical substance used in the same way is subject to different safety determinations and regulations under dif-

131. REACH, art. 68(1).

132. Hansson & Ruden, *supra* note 56, at 71, 74.

133. REACH, art. 69(1).

ferent provisions, there is internal inconsistency. REACH may suffer from this flaw.

For example, consider a manufacturer who seeks to register a high-volume substance under REACH for several highly beneficial uses. Assume further that this substance is considered a CMR, and as is typical of carcinogens, there is no scientific proof that there is a no-effect level of exposure for this substance, i.e., there is no known dose below which there is no added risk of cancer. Let us assume further that if analysts use standard methods of exposure measurement and dose-response assessment, they can show that the levels of risk to human health, e.g., exposures and risks to consumers or workers, associated with the beneficial uses are likely to be small but greater than zero. For simplification purposes, assume also that there are no known risk-management measures that can adequately control the small cancer risks and that suitable substitutes, which may be available in five to 10 years, are not currently available. In other words, from a risk-benefit perspective, let us assume that, even though this chemical substance is a carcinogen, it has several highly beneficial uses that might readily pass a thoughtful regulator's risk-benefit test.

Under the REACH authorization process, it appears that this manufacturer may be capable of obtaining authorization for several uses of this substance, since the authorization process allows for socioeconomic analysis, which is generally assumed to encompass a form of risk-benefit analysis. However, a manufacturer is not asked or required to submit authorization requests under REACH until the substance of concern is added to the formal Authorization List. Since that listing process can take many years, what is the manufacturer to do about her present registration obligation? If the manufacturer does not register the substance for those specific uses, then a downstream user is legally precluded from using that substance in those uses (at least in commercial transactions with that manufacturer or importer).

Here is where the inconsistency under REACH is revealed. REACH's registration process does not call for any information on the benefits of a substance in a registration dossier. Indeed, there is no indication in REACH that the benefits of a chemical are considered relevant to the question of whether it should be registered by a manufacturer or importer. REACH presumes instead that manufacturers will submit registration dossiers only for substances whose intended uses are safe, in the sense that the levels of exposure in each exposure scenario will be safe or that enough risk-management measures will be implemented to ensure that any residual exposures will be safe.

Perhaps, this means that, under REACH, this carcinogenic substance should not be submitted to ECHA for registration. However, if a high-volume substance is not registered by the deadline, the substance is not permitted to be produced or imported in(to) the EU. Without a registration, the substance has no commercial viability, even though its benefits are likely to outweigh its risks for at

least the next five to 10 years, when suitable substitutes may become available.

When we raised this apparent contradiction between registration and authorization of the same substance with REACH specialists in government and industry, we received a wide range of explanations. In our view, none of the explanations is completely satisfying.

One view is that REACH's registration process only requires that certain data be submitted to ECHA. According to this view, manufacturers do not have to submit a safety determination or in any way vouch for the safety of their substances. No licensing or governmental approval of registration is implied by a manufacturer's decision to submit a registration dossier. On this view, the manufacturer in the above example can submit the carcinogenic substance for registration under REACH—with a presumably honest assessment of the small cancer risks that will occur from several uses—and wait to see whether ECHA is satisfied with the registration dossier.

A contrary view is that the manufacturer, when submitting the registration dossier, is vouching for the safety of the substance in the specific uses covered by the CSR. At least for substances above the 10 tonne threshold, Article 10 expects the registration to include guidance on safe use. Without safe use—which means acceptable exposure scenarios—the registration dossier is not adequate. Thus, we tend to side with the view that, under REACH's registration process, a manufacturer is not simply submitting data that meets the minimum requirements of REACH, but is making a safety determination for review by ECHA and ultimately the EU authorities.

Even if the manufacturer is only submitting data in a registration dossier, and is therefore not viewed as making a safety determination, how is ECHA or ultimately the Commission supposed to make a reasoned evaluation in this case (a nonthreshold substance) without any information on benefits, alternatives, or a socioeconomic analysis? There is no indication in the REACH evaluation process that a specific use may be defensible on the basis of benefit-risk comparison vis-à-vis alternatives, rather than on the basis of a safety assessment alone.

A third view we heard is that the registration and authorization processes are completely independent, and there is nothing that prevents a manufacturer from submitting an authorization request *before* a registration dossier. Although we agree that the two processes are independent, we think it is clear from the statutory design—and the actions of the European Commission and ECHA to date—that authorization requests are not envisioned or requested until *after* a substance is placed on the Authorization List. Moreover, at the time manufacturers had to make a decision about registration for the 2010 registration deadline, the European Commission and ECHA had barely begun to clarify their guidance on the authorization process—presumably because it was perceived that such guidance was not relevant to registration and was not necessary until after substances were placed on the Authorization List. Even if this

resolution of the inconsistency is accurate, it would seem to be preferable for REACH-like legislation to use the same safety framework in registration as it uses in authorization and the other two sections. Otherwise, the prospect of contradictory regulatory outcomes for the same substance or use cannot be eliminated.

A fourth view is that the apparent contradiction reflects a legislative drafting error. The complex language on authorization that appears in the final version of REACH arose not from the Commission's original proposal, but from amendments added by the European Parliament—amendments that occurred relatively late in the legislative process. When the amendments to the authorization section of REACH were made, the legislators may not have considered the possible contradiction that was created with the registration and evaluation sections. We believe that this view is plausible.

More generally, as Congress considers whether REACH-like legislation should be adopted in the United States, we recommend that a coherent and consistent definition of safety be apparent throughout the statutory design. While it may be easier for legislators to achieve consensus by remaining silent on the critical question—how safe is safe enough?—ambiguity on such a crucial issue creates a plethora of implementation problems for regulators and the industry.

B. Redesign the Lists Under REACH to Focus on Specific Uses Rather Than Chemical Substances

Lists of chemicals are generated under REACH at several stages: during the substance evaluation process, in the authorization phase, and at the outset of the restriction process. In each of these stages, it may be preferable for U.S. legislators to call for lists of specific *uses* rather than *substances*. Stigmatizing all uses of a worrisome chemical based on intrinsic properties is inefficient, because some uses of a worrisome chemical may be associated with little or no exposure or risk, e.g., when the chemical is used in a fully closed system, with little or no opportunity for release or exposure, or when the resulting exposures to a worrisome substance are quite small. Little or no additional protection is accomplished when chemical substitution occurs in an industrial use that was already adequately controlled.

Consider the official list of SVHCs in the authorization stage of REACH. Publishing the Candidate and Authorization Lists can result in market decisions against continued use of SVHCs even before industry has an opportunity to make its case for specific uses in the authorization process. This concern is accentuated by the fact that inclusion of a substance on the Candidate List triggers a legal obligation to notify all downstream users of the substance's inclusion on the list. Those downstream users, which are often consumer-oriented companies, may fear bad press associated with using an SVHC, even if their specific use does not create significant exposure and risk. To avoid controversy, they may instruct their suppliers to switch substances. We

briefly discussed this process of deselection above. Based on our interviews, this concern is certainly not hypothetical. Some ECHA authorities and stakeholders refer informally to the Candidate and Authorization Lists as the “grey” and “black” lists, respectively.

One way to address this concern is to revamp the listing process, so that it contains uses of chemicals rather than chemical substances *per se*. The idea is to list all specific uses that may reasonably be anticipated to result in significant release, exposure, and risk. For example, instead of placing formaldehyde (a widely used carcinogen) on an Authorization List, the responsible regulator might list specific uses of formaldehyde—use of formaldehyde in selected building materials, for example—that are known or suspected to result in unintentional releases and unwanted exposures to consumers. Once the use has been listed, the burden of proof shifts to industry to justify the substance's continued use, implement stronger risk-management measures, or phase in alternative substances or technologies.

A subtle advantage of a use-specific listing process is that it may reduce the reluctance of authorities to make listing decisions. Based on our interviews, we suspect that stigma caused by a chemical listing decision, coupled with the stringency of the REACH authorization process, i.e., a presumptive ban on any use, may act to discourage all of the nominating parties (EU member states, ECHA, and the Commission) from moving more substances through the listing processes. Similar patterns have occurred in the United States, where federal overregulation with regard to stringency has been shown to cause underregulation in the number of chemicals or facilities subject to federal regulation.¹³⁴

If one believes in the integrity of the REACH registration process (including the dossiers submitted by industry), then a use-specific listing process is feasible. ECHA has access to the information on uses, exposure scenarios, and safety contained in the CSRs of registered substances. In an American context, if EPA were to require more information to support a listing decision, it should have the authority to instruct the registrant to supply the necessary information.

C. Reduce the Number of Regulatory Procedures From Four to Three or Even to Two

Much of REACH's complexity is attributable to the fact that there are four independent regulatory procedures that must be implemented by government and industry and monitored by stakeholders, legislators, and reporters. Some of this complexity is attributable to features of the EU and the desire to give different actors in the EU some role in the regulatory process.¹³⁵ If REACH-like legislation

134. JOHN M. MENDELOFF, *THE DILEMMA OF TOXIC SUBSTANCE REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION* (1988).

135. Heyvaert, RCR, *supra* note 5, at 217, 232 (Much of REACH's complex institutional design is generated by the EU governance structure, and this is not likely to “travel” to other countries.). See also Fisher, *supra* note 33.

were enacted in the United States, it might be feasible to streamline the number of regulatory procedures from four to three or even two.

One option is to combine registration with a restriction process, removing both the evaluation and authorization processes. In effect, the registration dossier is the registrant's case for continued production or importation. EPA could initiate restrictions if the registrant's scientific case was considered to be inadequate. Once restrictions for specific uses are proposed by EPA, registrants could be given an opportunity to buttress their registrations (seeking to persuade EPA to withdraw the restrictions proposal), voluntarily halt certain uses, voluntarily add new risk-management measures for some uses (again to persuade EPA to withdraw the restrictions proposal), or comply with EPA restrictions.

A second option would be to retain registration, the compliance check aspect of evaluation, and the restrictions authority. The advantage of this approach, compared to the first option, is that it allows for EPA and industry to iterate on the quality of a dossier via the compliance check process before the Agency needs to propose formal restrictions. Under U.S. law, it will be difficult for industry and EPA to collaborate on a scientific basis once a formal restrictions process has been initiated by the Agency (and both sides give lawyers as much influence as scientists). In other words, adding the compliance check process may reduce the number of cases that need to be handled in a legalistic restriction process.

Finally, a third option might be to embed authorization in the registration process, with EPA authorized to respond to a registration dossier by listing specific uses of substances that shall be phased out unless registrants are capable of buttressing their dossier to the point that EPA is willing to

withdraw the authorization proposal. Under this option, EPA authorization authority should be expanded beyond SVHCs to include any unreasonable risks from registered uses of substances. By linking authorization to registration, one can also avoid the situation where EPA might try to propose restrictions before a substance has been registered or before the authorization process has begun. For example, some industry representatives are concerned that the European Commission or the member states will proceed to restrictions of phthalates before the affected companies can fully make their case under the registration and/or authorization procedures. Furthermore, if the authorization authority is made sufficiently broad, one might not need any substance evaluation or restriction authority in the United States. If Congress contemplates the inclusion of all four REACH processes, however, it might be worthwhile to limit the restriction authority to settings where there is imminent hazard or where the residual risks (after registration, evaluation, and authorization) can be shown to be significant.

In summary, we have suggested modifications and refinements of REACH in the spirit of options for consideration. None of the options, however, has been studied with sufficient depth to justify a formal recommendation. Moreover, we have suggested some alternative approaches to assist U.S. policymakers who face a difficult legislative challenge in the years ahead. Our intent has not been to suggest that EU policymakers make any amendments to REACH, particularly at this early stage of the REACH implementation process. Rather, we aim to discuss issues related to the cross-national transfer of regulatory policies from one world region to another with the understanding that policy initiatives can be modified and altered to fit new national contexts.¹³⁶

136. Heyvaert, RCR, *supra* note 5, at 235 (referring to possible "globalization of REACH," predicting that countries outside EU will "navigate carefully" between the extremes of wholesale approximation of REACH to complete modification of REACH). See also Veerle Heyvaert, *Globalizing Regulation: Reaching Beyond the Borders of Chemical Safety*, 36 J. L. & Soc'y 110 (2009).