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SYNTHESIZING TSCA AND REACH: PRACTICAL PRINCIPLES FOR CHEMICAL REGULATION REFORM

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Abstract

The European Union's newly enacted comprehensive regulation for industrial chemicals, known as REACH, draws heavily on three decades of experience in the United States under the Toxic Substances Control Act. Much of that experience has been negative, inasmuch as TSCA is widely regarded as a disappointment among US environmental laws, and so REACH deliberately reverses many of the legislative choices that Congress made in TSCA. REACH also takes advantage of important new regulatory concepts that were not available to the framers of TSCA thirty years ago. The passage of REACH has sparked renewed interest in reforming TSCA, and the reformers will undoubtedly look to REACH for ideas. This article contends that, while many aspects of REACH can fairly be understood as the Anti-TSCA, on closer examination REACH follows many of TSCA's fundamental approaches to chemicals regulation. The fundamental similarities offer a unique opportunity to develop a synthesis of the two regulatory regimes, which could form the practical basis for updating TSCA. While reform based on a synthesis of TSCA and REACH would be evolutionary rather than revolutionary, it could nevertheless greatly improve chemicals regulation in the US. This article offers principles for such reform. The article concludes with a discussion of the global impact of national regulatory systems like REACH.

I. Introduction

At the end of 2006, the European Union (EU) adopted a comprehensive new system for the regulation of industrial chemicals throughout Europe, which is known by its acronym, REACH, for **R**egistration, **E**valuation, and **A**uthorization of **C**hemicals. The immediate impetus for REACH was replacement of most of the complicated and confusing system of over forty different directives and regulations with a single (if complex) regulatory regime. However, the

¹ Executive Associate Dean for Academic Affairs and Walter W. Fosskett Professor of Law, Indiana University School of Law–Bloomington. I am grateful to Bernard Goldstein and the European Union Center of Excellence and Graduate School of Public Health of the University of Pittsburgh for the invitation to participate in an excellent conference on REACH; to the participants in the conference whose contributions greatly improved my understanding of REACH; to E. Donald Elliott for the opportunity to present this paper at his regulation seminar at Georgetown University Law Center; to him, Gail Charnley, and Ernest Rosenberg for many helpful comments; and to Wendy Wagner for her collaboration on the TSCA chapter of *CPR for the Environment* (<http://www.progressivereform.org>), where some of these ideas first appeared.

European Commission also saw an opportunity to develop a regulatory program that would address several substantive deficits in the existing regulatory structure. The Commission's *White Paper: Strategy for a Future Chemicals Strategy*, published five years earlier, focused particularly on the "data gap" for toxic chemicals, the requirement that government prove the need for regulation, the relatively lax standards applied to existing (as opposed to new) chemicals, and animal testing.²

In assessing the existing regulation of chemicals, the Commission had before it the experience on the other side of the Atlantic with the Toxic Substances Control Act (TSCA). Enacted exactly three decades earlier, in 1976, TSCA is widely regarded as a serious underperformer among United States environmental laws. This, despite having itself been based on a thoughtful "white paper," *Toxic Substances*, written by the US Council on Environmental Quality (CEQ) five years earlier³ to accompany the original legislative proposal. However, a highly compromised final statutory text, hostile judicial interpretation, and often timid implementation have undermined TSCA to the point that the Environmental Protection Agency (EPA) now relies primarily on informal, voluntary measures to regulate industrial chemicals, rather than risk the total evisceration of the statute by the courts. Not surprisingly, the Commission's White Paper can be read as an extended critique of TSCA, and REACH is the legislative product of that critique.

TSCA and REACH are thus a matched pair – *Toxic Substances* and TSCA in 1971 and 1976, respectively, and the White Paper and REACH in 2001 and 2006, respectively – and it can

² *Commission White Paper on Strategy for a Future Chemicals Strategy*, at 6, COM (2001) 88 final (Feb. 2, 2001). These themes are echoed in the Commission's Explanatory Memorandum that accompanied the formal legislative proposal in 2003. See *Commission Proposal for a Regulation of the European Parliament and of the Council Concerning REACH*, at 6-55, COM (2003) 655 final (Oct. 29, 2003).

³ Executive Office of the President, United States Council on Environmental Quality, *Toxic Substances* (1971) [hereinafter US CEQ].

be helpful to compare them in the Hegelian framework of thesis and antithesis. TSCA, the thesis, established a comprehensive approach to chemical regulation. The failures of the TSCA approach led to its negation in REACH, TSCA's apparent antithesis. A synthesis, the outcome of the Hegelian dialectic, would be achieved by reconciling the contradictions between TSCA and REACH, recognizing in them commonalities that serve as the basis for a new approach. The synthesis would, ideally, be realized in the overdue reform of TSCA in the United States. While the thesis-antithesis-synthesis structure can be overdrawn because TSCA and REACH do in fact share important features, the dialectic provides a useful framing device for analyzing these important, and importantly different, regulatory regimes for industrial chemicals. Without or without TSCA reform, they will guide the global chemical industry and regulate chemical risks for the foreseeable future.

II. Thesis: TSCA and Its Discontents

TSCA was intended to give EPA comprehensive authority to control the toxic hazards of industrial chemicals, so that the agency could address the problems identified in *Toxic Substances*. CEQ was particularly concerned about the gaps left by the media-based pollution statutes – that is, transfers among media and loss of the opportunity to prevent pollution in the first place – and the lack of adequate information concerning the effects of such substances. The universe of TSCA's coverage is therefore very broad, with only limited exceptions for chemicals that are regulated as chemicals by other statutes, such as the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In keeping with the goal of comprehensiveness, section 6 of TSCA provides broad regulatory authorities, giving EPA the ability to control the life cycle of chemicals from manufacture through disposal (the

latter has been rarely used, except for PCBs, which were a special concern of the statute) and export, and from potential risk to imminent hazard. EPA can regulate manufacturing processes, warnings, labels, uses, concentrations, recordkeeping, and downstream notification – pretty much anything that would reduce risk.

The central regulatory standard is “unreasonable risk,” which appears in section 6 (containing TSCA’s basic regulatory authorities) and in varying forms in the other operational sections of the statute, such as testing requirements and imminent hazards. “Unreasonable risk” is undefined in the statute, but the legislative history and subsequent judicial interpretation consistently interpret it as a greater-than-zero level that is determined by reference to health, benefits, and costs.

To effectuate CEQ’s goal of obtaining more chemical information, TSCA includes a menu of data-gathering provisions. New chemicals are subject to a notification process, called pre-manufacture notification (PMN), which gives EPA an opportunity to examine existing data on new chemicals or new uses of existing chemicals and to object if it finds an unreasonable risk or believes that additional data are needed.⁴ Existing chemicals are subject to reporting requirements for studies that show adverse effects,⁵ and EPA is authorized to require testing of existing chemicals upon certain preliminary findings.⁶

TSCA is procedurally complex. The procedures for rulemaking under the main regulatory authorities (section 6), a delay in the PMN process to obtain additional data, and test rules are all predicated on specific findings by EPA. Hybrid rulemaking procedures (that is, procedures in addition to the basic notice-and-comment procedures of informal rulemaking) apply to many of EPA’s actions under TSCA. And the judicial review provision is notable for adopting the

⁴ TSCA, *supra*, § 5.

⁵ *Id.* § 8.

⁶ *Id.* § 4.

“substantial evidence” standard of judicial review, which signals Congress’ intention that EPA’s actions under the statute be subjected to a more skeptical approach from reviewing courts.

A. Original Objectives

As originally conceived, TSCA was a far-sighted and potentially far-reaching statute. *Toxic Substances* identified the lack of adequate toxicological information and the multi-media nature of chemical pollution as the key challenges for chemicals regulation, and the preamble to TSCA expressly adopts these as its objectives.⁷ TSCA’s elegant structure was intended to be capable of covering all phases of chemical production and use in order to fill gaps left by other statutes, and to offer a range of techniques for informed chemical regulation. The regulatory structure contains several critical legislative choices, to which we now turn.

Prevention. In the first place, the TSCA system was intended to be preventive. CEQ had been explicit that the chemical regulation system should not merely respond to harms that had already occurred:

Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capabilities for monitoring and predicting, although inadequate, are now sufficiently developed that we need no longer remain in a purely reactive posture with respect to chemical hazards. We need no longer be limited to repairing damage after it has been done; nor should we allow the general population to be used as a laboratory for discovering adverse health effects.⁸

As described above, the touchstone of TSCA’s substantive provisions is “unreasonable risk,” and virtually all of its regulatory provisions are variations on that theme.⁹ Risk, of course, denotes the

⁷ Toxic Substances Control Act (TSCA) § 2, 15 U.S.C. §§ 2601-2692 (1992). (A word about numbering: it is customary to reference US statutes by their section numbers as enacted, rather than as codified in the United States Code (U.S.C.). To convert the numbers in TSCA, enacted § 2 is codified as § 2601, enacted § 3 is codified as § 2602, and so on.)

⁸ US CEQ, *supra* note , at 21.

⁹ For example, the basic regulatory actions are authorized for chemicals that “present an unreasonable risk” (TSCA § 6), information may be required about chemicals that “may present an unreasonable risk” (TSCA § 4), and urgent action may be taken against an “imminent and unreasonable risk (TSCA § 7(f)).

potential for harm, and it supports a regulatory system whose goal is avoidance of harm to human health and the environment, rather than after-the-fact compensation.¹⁰ Risk permits preventive action.

To accomplish this, *Toxic Substances* advocated a system of substantive standards to be met by new chemicals,¹¹ implicitly through some kind of licensing mechanism of the kind that exists for prescription drugs and pesticides. The Senate drafting committee reported:

The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest. Frequently, it is far more painful to take regulatory action after all of these costs have been incurred.¹²

In furtherance of this objective, Congress enacted the pre-manufacture notice (PMN) procedure, which requires a chemical manufacturer to notify EPA of its intention to offer a new chemical for sale for stated purposes and to provide identity and risk information in its possession at the time.¹³ EPA is given a limited time to object before the new substance (or significant new use of an existing substance) is released to the market and the environment.

Chemical information. CEQ's report was prescient in identifying lack of information about chemicals as a major challenge for effective chemical regulation.¹⁴ Congress agreed,¹⁵ and so one of the "basic policy objectives" of TSCA was to place the responsibility for generating the information on manufacturers¹⁶:

¹⁰ H.R. REP. NO. 94-1341, at 1-4 (1976); A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATIONS AT RISK: RESTORING A PRAGMATIC APPROACH 1-2 (2003); John S. Applegate, *Hazard and Probability: Two "Risks," Information Supply and Demand, and the Consequences for Chemical Regulation*, __ Texas L. Rev. (forthcoming 2008) [hereinafter Applegate, *Hazard and Probability*].

¹¹ US CEQ, *supra* note 3, at 22.

¹² S. REP. NO. 94-698, at 5 (1976).

¹³ TSCA, *supra* note 4, at § 5.

¹⁴ US CEQ, *supra* note 3 at iv, 9-10.

¹⁵ "This vast volume of chemicals have, for the most part, been released into the environment with little or no knowledge of their long-term health or environmental effects" (quoting H.R. REP. NO. 94-1341 at 3).

¹⁶ S. REP. NO. 94-1341, at 17 (1976).

It is the policy of the United States that . . . adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures¹⁷

Information about new chemicals was to be generated in the PMN process. For existing chemicals, a wider range of techniques was provided: “test rules” that require manufacturers to generate risk data; significant new use rules (SNURs) that trigger a further PMN process for existing chemicals; data on manufacturing and processing; updates of the Inventory of Chemical Substances; and the reporting of adverse health effects, published and unpublished health and safety studies, and “substantial risks.”¹⁸ In addition, EPA is authorized to conduct its own research.¹⁹

Risk. In addition to expressing TSCA’s preventive goal, risk contains two other fundamental strategic choices.²⁰ First, risk can be understood as a matter of degree, usually measured as the product of the severity of the hazard to be avoided and the likelihood or probability of harm. While the full implications of this strategy may not have been fully appreciated at the time, regulators and commentators soon began to distinguish between risk in the sense of hazard, which is the simple existence of danger and as such either exists or does not, and risk in the sense of probability, which creates a spectrum of likelihood from zero (impossible) to one hundred percent (certainty).²¹ In TSCA, Congress chose the probabilistic meaning,²² and it did not reject all risk, but only “unreasonable” risk.²³

¹⁷ TSCA, *supra* note 4, at § 2(b)(1).

¹⁸ TSCA, *supra* note 4, at §§ 4, 5, 8.

¹⁹ TSCA, *supra* note 4, at § 10.

²⁰ See Applegate, *Hazard and Probability*, *supra* note , at ____; John S. Applegate, *Introduction: Environmental Risk: Defining the Problem and Disciplining the Response*, in *The International Library of Essays in 1 Environmental Law: Environmental Risk* xiv-xix (Ashgate ed., 2004) [hereinafter *Introduction*]; Elizabeth Fisher, *Risk and Environmental Law: A Beginner’s Guide*, in *ENVIRONMENTAL LAW FOR SUSTAINABILITY* 97-125 (Benjamin J. Richardson & Stepan Wood, eds., 2006), for descriptions of the rise of risk-based regulation.,

²¹ Applegate, *Hazard and Probability*, *supra* note , at ____.

²² H.R. REP. NO. 94-1341, at 14 (1976).

The second implicit strategy choice is that risk-based regulation tends to be science-based regulation. The whole enterprise of determining a level of risk demands a high degree of scientific knowledge, because the relevant probabilities can only be ascertained through detailed understanding of the toxic properties of the chemicals and their degree of exposure of humans and the environment. If the goal is to quantify the risk²⁴ – and this is the logical consequence of thinking about probabilities – the data needs are intensified.²⁵ Whether or not Congress fully foresaw a science-based, information-intensive regulatory regime, its repeated calls for more data point strongly in this direction.

Support for the chemical industry. While the authors of *Toxic Substances* focused on health and environmental effects, Congress was also concerned about the impact of regulation on the important US chemical industry:

It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter.²⁶

The central substantive standard for chemicals regulation – unreasonable risk – also furthers dual objectives. While Congress expressly declined to define “unreasonable” in quantitative (risk levels or cost-benefit ratio) or qualitative (*e.g.*, comparative) terms, it did make clear that it was to be determined by a range of factors, including direct and indirect costs:

In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude

²³ *Id.*, at 15; John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 273-277 (1994).

²⁴ Moreover, quantification of risk became a de facto goal in all toxics areas after the “Benzene” case in the US Supreme Court, see *AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

²⁵ See Applegate, *Perils*, *supra* note , at .

²⁶ TSCA, *supra* note 4, at §2(c). In addition, § 2(b)(3) reads: “authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.²⁷

Congress, in other words, attempted to strike a balance between protective regulation and protecting this important segment of the US economy. This was not an unreasonable or unexpected approach, and it has important consequences for the substantive and procedural burdens that the industry was expected to bear.

Multi-media statutory authority. The authors of *Toxic Substances* were particularly concerned that the existing media-based pollution laws (mainly, air and water) failed to account either for individuals' total exposure to chemicals or for chemical pollution that shifts among media. By regulating chemicals *per se*, TSCA was supposed to avoid these gaps or to fill them when they appear, as well as to regulate more efficiently and effectively. In addition, the multi-media approach serves TSCA's preventive goals: the "obvious limitation of controls over effluents is that they . . . do not provide for obtaining information on potential pollutants before widespread damage has occurred."²⁸

Synoptic approach. It is ironic that TSCA has been an underachiever among the toxics statutes, because it has a carefully conceived comprehensive and integrated structure, developed in response to a coherent plan to respond to the particular problems of toxic chemicals. TSCA methodically covers identification of subjects of regulation (the Chemical Substances Inventory²⁹) information generation techniques for new and old chemicals, a wide range of

²⁷ H.R. REP. NO. 94-1341, at 13-14 (1976); *see also* S. REP. NO. 94-698, at 13 (1976). The statutory text reads: "In promulgating any rule . . . with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to . . . the reasonably ascertainable economic consequences of the rule, *after* consideration of the effect on the national economy, small business, technological innovation, the environment, and public health." TSCA, *supra*, § 6(c)(4) (emphasis added).

²⁸ US CEQ, *supra* note 3, at 20.

²⁹ TSCA, *supra* note 4, at § 8 (b); The Inventory is the basis for distinguishing between new and existing chemicals and uses. REACH relies on a similar device, the European Inventory of Existing Commercial Chemical Substances,

regulatory control options, the ability to coordinate regulatory action across media and across statutes – and the whole edifice is neatly tied to a single substantive regulatory standard, “unreasonable risk,” or variations thereon.

TSCA employs a “synoptic” approach, to use Professor Hornstein’s term for regulation that seeks to address all aspects of an identified problem.³⁰ The elements to be considered in taking regulatory action – human health and environmental effects, economic impact, social impact, and so on – are for all practical purposes unlimited.³¹ Since chemicals are, after all, useful products (as opposed to pollutants), TSCA’s risk-cost-benefit balancing seems appropriate, if not inevitable, for addressing the problem of regulating industrial chemicals. TSCA also requires some kind of comparative assessment of regulatory alternatives, since EPA has to choose the “least burdensome” alternative³² and to defer to other statutes when they are effective.³³ TSCA’s synopticism lends further support to the dual goals of protecting health and protecting the chemical industry, by enforcing a role for the statute that is limited in stringency (*unreasonable* risk, least burdensome regulations) and in scope (gap-filling). It also commits the agency to a fairly exhaustive investigation and analysis each time it seeks to exert regulatory control.

(REACH art. 3(20)); Commission Regulation 1907/2006, art. 3, Registration, Evaluation, and Authorization of Chemicals, 2006 O.J. (L 396) 1, 20 (EC) (defining “phase-in substance”).

³⁰ Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 386-87 (1993).

³¹ By contrast, the Clean Air Act has been repeatedly construed to exclude cost consideration. *Whitman v. American Trucking Ass’ns*, 531 U.S. 457 (2001).

³² TSCA, *supra* note 4, at § 6(a).

³³ TSCA, *supra* note 4, at § 9(a).

B. TSCA's Disappointments

TSCA has not, however, been the comprehensive and aggressive regulator of industrial chemicals that was recommended by CEQ, feared by industry, and predicted by both. Rather, its actual performance reflects the important legislative compromises that were necessary to enact it.

New chemical screening. While the Senate report spoke of the need to “assure that chemicals receive careful premarket scrutiny,”³⁴ Congress did not ultimately follow the licensing model that one finds in US food and drug and pesticides laws. Enacting TSCA after several failed attempts, it instead adopted the much weaker PMN procedure. PMN does not require the creation of any new safety data; EPA must take what it is given. If EPA wants more information, then it must take the initiative and assume the burden of proving need when it seeks to restrict a new chemical or new use.³⁵ EPA's experience under PMN has been pretty much what one would expect from this structure. In sharp contrast to the expectations of “careful premarket scrutiny,” EPA's own website acknowledges that, “[b]ecause many PMNs include little or no toxicity or fate data, the program uses several risk screening approaches to facilitate assessment in the absence of specific data.”³⁶

An informal practice of consent orders for further testing has developed,³⁷ which industry and EPA regard as quite satisfactory in obtaining necessary data. Chemicals are screened for their structural similarities to chemicals with known hazards, and requests for additional

³⁴ S. REP. NO. 94-698, at 3 (1976).

³⁵ TSCA, *supra* note 4, at § 5(f); Indeed, reading the fine print, it is ultimately the *courts* who decide whether there should be a delay in the distribution or sale of a new chemical or new use of an existing one, see TSCA, *supra* note 4, at § 5 (e)(1)-(2).

³⁶ EPA OPPTS WEBSITES, *supra* note 34; see also Denison, *supra* note 34, at IV-1.

³⁷ RICHARD DENISON, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION, AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS, IV-2 (2007), <http://www.environmentaldefense.org>; United States Environmental Protection Agency, OPPTS Website, <http://epa.gov/oppintr/chemtest/pubs/vision.htm> (last visited July 27, 2007); United States Environmental Protection Agency, OPPTS Website, <http://www.epa.gov/opptintr/tasca8e> (last visited July 27, 2007); United States Environmental Protection Agency, OPPTS Website, <http://www.ea.gov/chemtrk> (last visited July 27, 2007); EPA, TSCA § 5 New Chemicals Program, <http://www.epa.gov/opptintr/newchems> (last visited July 27, 2007); Chemical Information Collection and Data Development (Testing), <http://www.epa.gov.opptintr/chemtest/index.htm> (last visited July 27, 2007).

information are made accordingly.³⁸ In addition, voluntary control actions are sometimes taken.³⁹ Nevertheless, the Government Accountability Office reported in 2005 that only about 20 percent of new chemicals receive detailed review.⁴⁰ While simply counting chemicals and tests may be an imperfect measure, it is suggestive, and GAO concluded that “EPA lacks sufficient data to ensure that potential health and environmental risks of new chemicals are identified.”⁴¹ Moreover, despite the existence of the SNUR requirement, there is little to stop a manufacturer from expanding production significantly after approval, since there are no restrictions on expanding use, only reporting significant new *uses*.

Data on existing chemicals. The weak PMN screening system receives little support from the system for gathering information about existing chemicals, which constitute the vast majority of chemicals in commerce.⁴² EPA has the authority to require manufacturers to submit a variety of environmental and health effects data under section 8 of TSCA. However, it encounters several procedural and definitional barriers in the statute itself, and EPA has not been particularly aggressive in addressing them. Neither Congress nor EPA defines “substantial risk” in a way that does not leave reporting largely to the manufacturer’s own judgment.⁴³ GAO

³⁸ Janey Cohen, Toxic Substances: EU, Canada on “Leading Edge” of Paradigm Shift on Chemical Regulation, 30 Intl. Env't. Rep. (BNA) 779 (Oct. 3, 2007); Conrad, *supra* note , at 143-144.

³⁹ U.S. GEN. ACCOUNTABILITY OFFICE, *supra* note 35, at 16-17.

⁴⁰ U.S. GEN. ACCOUNTABILITY OFFICE, CHEMICAL REGULATIONS—OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICALS REVIEW PROGRAM, GAO-05-458, 12, 17-18 (2005).

⁴¹ *Id* at 10; This is not new. In 1983, the Office of Technology Assessment reported that about half of PMNs contained no toxicity information at all, and less than 20% contained data on long-term toxicity. OFFICE OF TECHNOLOGY ASSESSMENT, THE INFORMATION CONTENT OF PRE-MANUFACTURE NOTICES, 6-7, 49-54 (1983).

⁴² Denison, *supra* note 34, at IV-11-16.

⁴³ See EPA, TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 3, 2003). By contrast, EPA’s own regulations under the pesticide statute, FIFRA, is very precise and leaves far less discretion. See 40 C.F.R. § 159.158(a), and part 159 generally.

concludes, “EPA does not routinely assess existing chemicals, has limited information on their health and environmental risks, and has issued few regulations controlling such chemicals.”⁴⁴

EPA also has the authority under section 4 to require manufacturers to test existing chemicals, but in each case EPA must first make several formal findings which are subject to judicial review under the demanding “substantial evidence” standard.⁴⁵ Furthermore, the requirement that EPA *prove* that the chemical “may present an unreasonable risk” and that it needs additional information creates a regulatory Catch-22: EPA must have chemical information in order to prove that it needs it, but it needs the information because it doesn’t have the information.⁴⁶ As a result, EPA has required testing of fewer than 200 out of thousands of existing chemicals,⁴⁷ and of the 200, 140 were imposed by rule and 60 by consent.⁴⁸ EPA’s current website finds it necessary to “redefine success” under its chemical testing program by including voluntary approaches in its totals.⁴⁹

In principle, of course, it should not matter *how* chemical information is obtained. Neither reliance on voluntary programs nor the absence of formal action to obtain data is proof that the data do not exist. Industry asserts that voluntary programs have in fact been highly successful,⁵⁰ Cooperative programs like the HPV Challenge and the section 8(e) FYI program clearly have

⁴⁴ U.S. GEN. ACCOUNTABILITY OFFICE (US GAO), *supra* note 35 at 18-27; *see also* Denison, *supra* note 34, at IV-1-2; JOHN S. APPLGATE, ET AL., *THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES* (Foundation Press 2000).

⁴⁵ The more flexible “arbitrary, capricious” standard, which is typical for decisions of this kind, was provided in the original Senate bill, S. REP. NO. 94-698, at 28 (1976). Review was made more rigorous in the negotiations with the House version of the bill, H.R. REP. NO. 94-1341, at 17-18 (1976); H.R. REP. NO. 94-1679, at 61 (1976).

⁴⁶ John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory, Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 315-330 (1991).

⁴⁷ The TSCA Inventory contains about 62,000 chemical substances, but the majority are of limited regulatory significance. See Conrad, *supra* note , at 143-144.

⁴⁸ Richard Denison, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HPV CHEMICAL CHALLENGE, <http://www.Environmentaldefensefund.org> (2007); U.S. GEN. ACCOUNTABILITY OFFICE, *supra* note 34, at 18.

⁴⁹ EPA OPPTS WEBSITES, *supra* note 34.

⁵⁰ Cohen, *Leading Edge*, *supra* note (quoting industry spokespeople); Conrad, *supra* note , at [n.55].

their uses.⁵¹ However, since the testing is voluntary, when gaps remain, EPA has little ability to fill them. For example, EPA's touted HPV Challenge program has been severely criticized by one of its co-sponsors, Environmental Defense, as providing far fewer data than promised, and years late,⁵² and EPA's inspector general reports that EPA's many voluntary programs lack the kinds of data collection and internal controls that are needed to determine whether the programs are in fact successful.⁵³

Most important, it has been well documented that a severe data gap still exists for industrial chemicals.⁵⁴ EPA and the European Commission (the latter in anticipation of REACH) undertook several studies of chemical information in the last decade, and they have uniformly reached the conclusion that basic chemical data – even for high production volume (HPV) chemicals – is only minimally available. The 1984 study by the National Academy of Sciences, *Toxicity Testing*, found in its sample that no toxicity testing was available for more than 80 percent of all toxic substances in commerce and that even a minimum data set was available for only 22 percent of high production volume (HPV) chemicals.⁵⁵ More than a decade later, the Environmental Defense Fund (now Environmental Defense) published a report which found that a screening data set (that is, far less than would be needed to complete a risk assessment) was publicly available for only 29 percent of the 100 HPV chemicals (greater than 1,000,000 lbs/year) in their sample. No data or only part of the screening data set was publicly available for

⁵¹ James W. Conrad, Jr., *Open Secrets: The Widespread Availability of Information About the Health and Environmental Effects of Chemicals*, 69 LAW & CONTEMP. PROBS. 141, 143-46 (2006) (requiring disclosures); *Id.* at 153-57 (encouraging voluntary programs); US GAO, *supra* note 35, at 40-43), EPA OPPTS WEBSITES, *supra* note 34.

⁵² Denison, *supra* note 43.

⁵³ U.S. EPA, Office of Inspector General, Evaluation Report: Voluntary Programs Could Benefit from Internal Policy Controls and a Systematic Management Approach, Report No. 2007-P-00041 (Sept. 25, 2007) (available at <http://www.epa.gov/oig/reports/2007/20070925-2007-P-00041.pdf> (visited 2/28/08)).

⁵⁴ Applegate, *Hazard and Probability*, *supra* note , at ____.

⁵⁵ NATIONAL RESEARCH COUNCIL (NATIONAL ACADEMY OF SCIENCES), TOXICITY TESTING IN THE TWENTY-FIRST CENTURY: A VISION AND A STRATEGY 205-208 (2007).

71 percent of the sample. The Chemical Manufacturers Association (CMA, now American Chemistry Council) responded with its own study, with results that are not all that dissimilar. CMA found that a complete screening data set existed for 47 percent of chemicals, though others have interpreted the findings less generously. EPA undertook a third study of HPV chemicals and found, “No basic toxicity information . . . is publicly available for 43 percent of the high volume chemicals manufactured in the US and a full set of basic toxicity information is available for only 7 percent of these chemicals.”

In preparing for REACH, the European Commission sponsored several additional studies of chemical data. One study concluded that publicly available screening data set existed for only 14 percent of the HPV chemicals studied, less than a base set existed for 65 percent, and no data existed for 21 percent. Another study found a similar pattern (17-22%) across production amounts ranging from 10 to over 1000 metric tons per year, and yet another reached conclusions similar to EPA’s. These studies paint a remarkably consistent picture of the lack of data (publicly available data, to be sure, but the existence of private data cannot be verified) concerning HPV chemicals, the chemicals that one would expect to support the greatest amount of risk research.

Burden of proof. The critical element of a strong screening approach for chemicals is the allocation of the burden of demonstrating safety to the applicant (typically, the manufacturer), which in turn creates in the applicant a strong incentive to come forward with required information to obtain a license to sell the product.⁵⁶ TSCA’s PMN neither allocates the burden to the applicant nor requires any minimum set of toxicity information – with the above results. Instead, the burden of demonstrating *unsafety* is allocated to EPA. The effect of this allocation is

⁵⁶ The effectiveness of this technique was nicely demonstrated, albeit incidentally, by the 1984 National Academy of Sciences study of chemical data. It found a large data gap in all regulatory areas, but the gap was strikingly smaller in food and drug and pesticides regulation, where a licensing scheme placed the burden of proof on the applicant. NAS, *Toxicity Testing*, supra note .

intensified by the requirements that EPA make certain specific findings on toxicity, the adequacy of other federal laws, and alternative regulatory approaches.⁵⁷ As if that were not enough, here also EPA must support its findings with “substantial evidence” on judicial review.⁵⁸ The legislative history expressly states that Congress “intends that the reviewing court engage in a searching review of the Administrator’s reasons and explanations for the Administrator’s conclusions.”⁵⁹ Under these constraints, EPA has never taken a great deal of mandatory action under TSCA.⁶⁰

Mandatory restrictions came to a complete halt after the *Corrosion Proof Fittings* case in 1991. The Fifth Circuit (which happens to be located in the heartland of chemical manufacturing) ruled that EPA’s decade-long effort to restrict asbestos (yes, asbestos) products was insufficiently supported by the record and by EPA’s analysis. The court found in TSCA’s “least burdensome” language a principle that the more stringent the regulation is, the greater the degree of proof is required to justify regulation.⁶¹ Within this already challenging structure, the court criticized “the manner in which the EPA conducted some of its analysis,” “some of the methodology employed by the EPA in making various of the calculations that it did perform,” and the extent of reliance on “unquantified benefits” and the degree of reliance on population exposure.⁶² The court was unquestionably exploiting elements that were in fact present in the statute (the expectation of searching review, for instance), but its aggressive interpretation of those elements and attitude of extreme skepticism toward EPA’s evidence have brought the

⁵⁷ TSCA, *supra* note 4, at § 6.

⁵⁸ TSCA, *supra* note 4, at § 19(b).

⁵⁹ H.R. REP., NO. 94-1341, at 55-56; H.R. REP. NO. 94-1679, at 96; *see also* S. REP. NO. 94-698, at 28..

⁶⁰ US GAO, *supra* note 35, at 27-29.

⁶¹ *Corrosion Proof Fittings, Inc. v. EPA*, 947 F.2d 1201, 1220 (5th Cir. 1991).

⁶² *Corrosion Proof Fittings, supra*, at 1218-1219.

mandatory program to a standstill.⁶³ TSCA's most recent annual reports show very little activity that does not consist of voluntary programs.⁶⁴

Procedural complexity. EPA's procedural burden in TSCA is no accident, and it reflects two important legislative compromises. First, when addressing complex and technically arcane subjects, Congress inevitably delegates relatively broad powers to administrative agencies, because, *ex hypothesi*, it can only provide limited substantive constraints. Therefore, Congress also imposes procedural devices to ensure its ability to exercise continuing oversight to keep the agency's actions in line with the original legislative bargain.⁶⁵ Second, the original drafters of TSCA clearly recognized the asymmetry between government and the regulated industry with respect to chemical information – that is exactly why they emphasized the need to generate data and located responsibility for doing so with industry. However, as we have seen, the final text reflects a compromise between the asserted goal of industry responsibility and the economic protection of that industry.⁶⁶ The central mechanisms of the compromise are the burden of proof and the legislatively mandated procedures that proceed virtually all agency actions under TSCA. Professors McCubbins, Noll, and Weingast have observed:

Because policy decisions depend on what information is available to the agency, structure and process determine the quantity, quality, and completeness of available information and the extent to which policy decisions must be supported by this information. Political principals can control the influence of a constituency by using structure and process to affect the dependence of the agency on information the constituency supplies. * * * More elaborate procedures are generally regarded as favorable to regulated industries. Because

⁶³ Under TSCA's judicial review provisions, the challenger of a regulation can bring suit on its home turf. TSCA, *supra* note 4, at § 19(a)(1)(A). This makes it very difficult for EPA to obtain review in other courts, and it has made the Fifth Circuit, covering Texas and Louisiana, the *de facto* national court for TSCA,

⁶⁴ EPA OPPTS WEBSITES, *supra* note 35.

⁶⁵ Lisa Schultz Bressman, Procedures as Politics in Administration Law, 107 Colum. L. Rev. 1749, 1752-1753, 1768-1771 (2007).

⁶⁶ Wendy Wagener, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 697 (2007).

industries possess much of the information relevant to regulatory decisions, elaborate processes give them more power by increasing the importance of that information.⁶⁷

The authors, in fact, offer TSCA's rejection of strong pre-market screening as an example of strategic procedural complexity.⁶⁸

As one would expect, the greatest number of substantive and procedural requirements apply to the imposition of actual restrictions. Not only are several specific findings demanded, but EPA must go through an elaborate hearing process (designated "informal"; in fact, anything but), including oral testimony and even cross-examination. And, in case the point was not clear enough, these procedures are specially called out for enforcement in the judicial review section,⁶⁹ ensuring that EPA will always go through the entire panoply of potential procedures to avoid reversal after investing in a lengthy administrative process (as happened in *Corrosion Proof*).

In sum, TSCA was meant to be difficult to use, and as a result, despite CEQ's careful analysis in *Toxic Substances* and the high hopes of TSCA's proponents, TSCA has substantially underperformed as a generator of chemical information and a regulator of industrial chemicals.

III. Antithesis: REACH

REACH was designed to correct weaknesses in the existing chemical regulatory system in Europe. Some of the weaknesses were distinct to the European system, for example, the array of complicated directives and regulations covering the chemical industry and the widespread public desire to reduce animal testing. REACH was also designed to correct the weaknesses apparent from the US experience. While neither the White Paper nor the Explanatory

⁶⁷ Matthew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Structure and Process, Politics, and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 VA. L. REV. 431, 440-41, 469. (1989).

⁶⁸ Matthew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J. L. ECON. & ORG. 243, 268-69 (1987).

⁶⁹ TSCA, *supra*, § 19(c)(1)(B)(ii).

Memorandum that accompanied the actual legislation mention TSCA by name, it is hard to read them as anything other than an effort to be everything that TSCA was not.

REACH was in preparation for nearly a decade before it was enacted. In keeping with its initiating role under the EU constitutive treaties and its political and policy role as the “engine” of the European Union government, the European Commission identified the need for the regulation, undertook a thorough study of the issues, and proposed the legislation. The proposal went through the complex European legislative process and received the approval (with amendments) of the other main governmental organs – the Council and the European Parliament – in December 2006. The legislation is in the form of a regulation (as opposed to a directive), which means that it is self-executing and does not require further legislative action by each member state. The EU uses regulations when uniformity is of particular importance, and an important objective of REACH was to harmonize the existing system of multiple and overlapping regulatory systems that was believed to hamper the competitiveness of the Europe-wide industry.

Despite its commitment to centralization, REACH maintains an active role for the member states. Member state regulators (“Competent Authorities” is the REACH term) participate in most of the regulatory phases, in a variety of ways, but they may not take unilateral action, in deference to REACH’s goal of harmonization. A new European Chemicals Agency (ECHA), headquartered in Helsinki, is created to manage and coordinate all of the aspects of the process. Its regulatory decisionmaking authority is quite limited, however, such authority being reserved to the Commission and the member states acting in concert.

While it simplified the existing regulatory structure for chemicals, REACH is by no means a simple piece of legislation. For present purposes, the basic regulatory process breaks

down into five constituent parts, mostly reflected in the elements of the REACH acronym: Registration, Evaluation, Authorization, and Restrictions. The first phase, Registration, is primarily a data gathering procedure. It covers all chemicals produced or imported in quantities above 1 metric ton per year, both new and existing (or “phase-in”), as well as certain substances found in other products. There are various exemptions for low-risk chemicals and polymers, but the ECHA expects to need to register 30,000 chemicals and review 89,000 dossiers by 2011. All chemicals must submit a technical dossier, which is comprehensive information on the chemical’s inherent properties, including a base set of toxicological information, graduated by production volume. For chemicals produced in quantities above 10 metric tons, a much more extensive Chemical Safety Report is required, which includes toxicology and exposure data, as well as measures to reduce risks from the chemical. Chemical data is to be shared to avoid unnecessary testing, and information relevant to or obtained in registration is shared up and down the supply chain.

Evaluation involves three basic steps: an automatic “completeness check” for technical compliance with the REACH requirements; a dossier evaluation, which is essentially a quality control effort to be sure that objectives like avoidance of animal testing and data sharing have occurred; and substance evaluation, which actually examines the risks posed by a substance and the measures taken to control the risks. Evaluation leads to the final, optional, phases.

Authorization applies to substances “of very high concern” (VHC). VHC substances include carcinogens, mutagens, and reproductively toxic (CMR) substances; persistent, bioaccumulative, or toxic (PBT) substances; very persistent or very bioaccumulative (vPvB) substances; persistent organic pollutants (POPs); and other chronic hazards. The objective of Authorization is to ensure their progressive replacement, and so the centerpiece of the process is analysis of substitute

substances. Each proponent of a VHC chemical must present a replacement or research plan for alternatives; if no alternatives are in prospect, then the chemical's use must be justified under a cost-benefit test. In addition, Authorization requires that the substance be “adequately controlled,” and if it cannot be adequately controlled⁷⁰ (CMR substances, by definition, cannot be), then its benefits must outweigh its risks. ECHA expects that about 1500 substances will require Authorization. Finally, since Authorization does not necessarily include use restrictions, restrictions may be imposed centrally if the Commission, in cooperation with the member states, determines that the risk is not adequately controlled and that it needs to be addressed at the Community-wide level. Restrictions in this sense represent the “safety net” or last resort to ensure chemical safety, if it has not been adequately controlled through the previous processes, including replacement of the dangerous chemical through substitution. The legal standard for acceptability is not stated,⁷¹ other than a general commitment to a “high level of protection,” so such decisions are likely to be essentially political.

A. REACH as the Anti-TSCA

REACH adopts several techniques that tacitly reverse the TSCA approach, the most important of which are eliminating the distinction between new and existing chemicals, and shifting the burden of proof for producing information and demonstrating safety.

New vs. existing chemicals. The old-new distinction is a long-standing conundrum in environmental regulation, because new regulatory regimes are almost always engrafted onto existing technologies. It is generally cheaper to regulate only new entrants, since they can more

⁷⁰ REACH, *supra*, arts. 60(4), 64(4)(b).

⁷¹ REACH, *supra*, art. 68(1).

readily conform to new standards.⁷² This also reduces political opposition because it leaves existing investments largely untouched.⁷³ However, this approach leaves a large segment of the relevant industry minimally regulated beyond the threat of products liability, which has well known limitations in its application to toxic substances.⁷⁴ The old-new distinction also inhibits desirable innovation by encouraging the continued use of the old and more dangerous technologies that are subject to less regulatory scrutiny.

TSCA distinguishes between new and existing chemicals, since the screening process applies only to new chemicals (or significant new uses of existing ones). While the PMN process is not robust, to say the least, it is at least a gesture toward gathering safety information about new chemicals, and it establishes the only point at which the agency is *required* to focus on particular chemicals. There is no mandatory look-back provision for existing chemicals, even though existing chemicals represent over 99% by volume of chemicals in commerce.⁷⁵ Section 4 test rules are supposed to be triggered by a priority list created by the Interagency Testing Committee, but procedural and judicial hurdles have discouraged the promulgation of rules, as we have seen.⁷⁶ Section 8 requires reporting of studies and incidents to EPA, but the reporting is inconsistent and there is no requirement that EPA take action on the reports. In short, if TSCA's action-forcing is weak for new chemicals, it is virtually non-existent for existing ones.

⁷² For example, the Clean Air Act establishes new source performance standards (NSPS) which are significantly more stringent standards than the standards for existing sources. 42 U.S.C. § 7411.

⁷³ See generally Peter Huber, *The Old-New Division in Risk Regulation*, 69 Va. L. Rev. 1025 (1983).

⁷⁴ Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 *Cornell Law Review* 773, 774-76, 784-85 (1997).

⁷⁵ *Commission White Paper on Strategy for a Future Chemicals Strategy*, *supra note* , at 6, COM (2001) 88 final (Feb. 2, 2001).

⁷⁶ The PMN standard for preventing sale of new chemicals pending additional information in § 5(e) is very similar to the standard for obtaining information on existing chemicals in § 4(a).

REACH sets out very explicitly to eliminate the old-new distinction in order to remedy the “burden of the past,” as the Commission calls the data gap for existing chemicals.⁷⁷ “The Commission proposes to implement a step by step process to address the burden of the past and develop adequate knowledge for existing substances that industry wants to continue marketing.”⁷⁸ Over an eleven-year period, regulatory authorities are *required* to examine all 30,000 existing chemicals produced in volumes greater than 1 metric ton, and to categorize and evaluate them as they would new chemicals. Much of the controversy over REACH, in fact, and much of the administrative challenge, is the insistence on applying new standards of information and assessment to existing chemicals.

Burden of proof: information generation. The allocation of burden of proof is both a normative position and a means to an end. Normatively, it expresses a fundamental public policy message by placing the responsibility for convincing a decision-maker whether a chemical is safe or unsafe with the manufacturer or government, respectively. This has practical consequences for the number of chemicals that will be approved and the terms under which they will be approved for use. It signals to the decision-maker how selective to be. Allocation of the burden of proof also has the instrumental effect of encouraging one party or the other to generate information to persuade the decision-maker, because the party with the burden has a strong incentive to generate information to move the status quo in its favor. In the regulatory setting, a status quo of no-approval with the burden on the private applicant will encourage the applicant to provide the information needed to demonstrate, for example, that its product is safe and effective

⁷⁷ The White Paper defines “burden of the past” as “The 30,000 ‘existing’ chemicals estimated to be on the EU market, for which little or no information is available, in particular about their long-term effects on human health or the environment.” *Id.* at 28.

⁷⁸ *Id.* at 7-8.

for its intended purpose. The opposite burden has the opposite effect on private party behavior, and it requires the regulator affirmatively to seek out information.

TSCA, as we have seen, places the burden of proof squarely on the regulator to support a finding of the existence of an “unreasonable risk,” underscored by the “substantial evidence” standard of judicial review. Before REACH, European chemicals regulation did the same. As the Commission’s White Paper said,

The current approach requires authorities to provide convincing arguments, usually in the context of a risk assessment, before restriction measures are taken. Their task is further complicated because the current system does not encourage industry to support the assessment. On the contrary, delaying the process is “rewarded” with an extended marketing period.⁷⁹

On the US side, Professor Wagner has called TSCA “unprecautionary” on this and other grounds,⁸⁰ and the burden of proof clearly contributes to TSCA’s ineffectiveness.

REACH again takes the opposite tack. “The lack of data on the hazardous properties of chemicals was the driving force behind the development of a new chemicals policy in the EU,”⁸¹ and so REACH moves the status quo from “no data, no problem” to “no data, no market.” The fundamental requirement of REACH is embodied in article 5 (actually entitled “No data, no market”):

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

⁷⁹ *Id.* at 19.

⁸⁰ Wendy E. Wagner, *The Precautionary Principle and Chemical Regulations in the U.S.*, 6 HUMAN & ECOLOGY RISK ASSESSMENT 459, (2000) (suggesting that TSCA embodies an “unprecautionary principle”).

⁸¹ *Commission DG Joint Research Council Report on Assessment of Additional Testing Needs under REACH: Effects of (Q)SARS, Risk Based Testing and Voluntary Industry Institutions*, at 5, COM (2003).

Registration is primarily an information-provision process,⁸² with the addition of a chemical safety assessment⁸³ for existing substances produced in quantities over ten metric tons. In this way, REACH attempts to eliminate the old-new distinction in chemical data, at least for medium and high production volume (HPV) chemicals.

Burden of proof: safety. The normative burden of proof gives direction to regulators in their substantive evaluation of a chemical, telling them how doubts are to be resolved and how judgment is to be exercised. The requirement for specific findings in TSCA intensifies the general burden on the agency and therefore increases its reluctance to regulate. REACH once again takes the opposite approach. The first article of the legislation states:

[This Regulation] is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.⁸⁴

REACH thus requires manufacturers to take affirmative, substantial action in order to retain their markets. As a normative message, REACH says that chemical risks should be controlled, eliminated, mitigated, or justified by their creators. While registration itself “does not imply any form of approval by the Agency of the assessment or use of the substance,”⁸⁵ chemicals of “very high concern” based on intrinsic properties of toxicity, persistence, or bioaccumulation, require actual approval. Approval involves adequate control of a hazardous chemical and a substitution plan; if no substitutes are in prospect, then the manufacturer must present a socio-economic justification for continued marketing.⁸⁶ To turn a phrase, where TSCA urges caution in regulating industrial chemicals, REACH urges precaution in approving them.

⁸² Commission Regulation 1907/2006, art. 10, Registration, Evaluation, and Authorization of Chemicals (REACH), 2006 O.J. (L 396) 1, 20 (EC) [*hereinafter* REACH].

⁸³ *Id.* at art. 14.

⁸⁴ *Id.* at art. 1(1)(3)

⁸⁵ REACH in Brief, *supra* note , at § 2.2.1.

⁸⁶ *Id.* at art. 55,60.

In needs to be said, though, that REACH is not entirely consistent in this regard. The Restriction procedure, the last stage of the overall REACH process, in which the Commission actually imposes limitations on the use of a chemical, seems to return to the TSCA burden of proof. The Explanatory Memorandum describes restrictions as a “safety net” – a last resort – to be deployed only when all other controls are inadequate.⁸⁷ The Commission first assembles a dossier on the effects of the chemical, based on the manufacturer’s chemical safety report. If the dossier “demonstrates that action on a Community-wide basis is necessary,” then restrictions are imposed.⁸⁸ The grammatical construction “if this dossier demonstrates” and use of the term “necessary” suggest that the burden is on the *Commission* to justify action, which is a departure from the overall objective to place the burden on industry.⁸⁹ Moreover, the comitology within the Commission for imposing restrictions (opinions of Risk Assessment and Socio-Economic Analysis committees must be solicited and responded to⁹⁰), and the review process with other organs, adopt a level of procedural complexity⁹¹ which in some ways rivals TSCA.⁹²

B. New Ideas in REACH

REACH also differs from TSCA by adopting several important new ideas. Many of them were not yet current at the time of TSCA’s enactment, and so they offer a particularly interesting glimpse of the next generation of chemicals regulation, at least as enacted by the governments of industrialized countries.

⁸⁷ *Commission Proposal*, *supra* note 2, at 12,16.

⁸⁸ REACH, *supra* note 64, at 69 (3).

⁸⁹ Veerle Heyvaert, *Guidance without Constraint: Assessing the Impact of the Precautionary Principle on the European Community’s Chemicals Policy*, 6 Y.B. OF EUR. ENVTL. LAW 27, 50,56 (2006).

⁹⁰ REACH, *supra*, art. 64.

⁹¹ REACH, *supra* note, arts. 70, 73, 133(4); Heyvaert, *supra* note 70, at 49; Veerle Heyvaert, *No Data, No Market: The Future of EU Chemicals Control under the REACH Regulation*, 9 ENVTL. L. REV. 201, ____ (2007).

⁹² The Regulatory with Scrutiny review procedure, required by REACH art. 133(4), involves both another layer of internal Commission review, and also substantive involvement by the European Parliament and Council. Council Decision (EC) No.1999/468, art. 5a. A controversial restriction could be considerably delayed through this process.

Substitution of safer alternatives. REACH does not seek to avoid all use of industrial chemicals or to achieve a chemical-free future. Instead, like TSCA, it seeks to limit the risks posed by chemicals in commerce by deploying substantive standards that acknowledge both the utility and the dangers of these materials. Unlike TSCA, however, REACH also deploys regulatory techniques that expressly provide strong incentives for the development of new and toxicologically safer chemicals.⁹³ Dangerous chemicals are to be “progressively replaced by suitable alternative substances or technologies where these are economically and technologically viable.”⁹⁴ REACH hopes to achieve this goal principally by allocating the overall burden of proof of proving safety, so that safer chemicals will be easier to justify. In addition, manufacturers are held generally responsible for the safety of their chemicals, and they must provide hazard information to downstream users of chemicals and to consumers.⁹⁵ As California has found with its Proposition 65, pointed public information is a strong incentive to use only the safest chemicals.⁹⁶ The registration requirement is thus itself an incentive to use safe and well tested substances, since the registration information is public and the absence of testing will be exposed – and must be remedied – through the registration process.

The authorization procedure that is required for the most dangerous chemicals creates an even more intense regulatory incentive to find safer substitutes. Authorization is public, expensive, and if the chemical is not adequately controlled, the manufacturer must show that

⁹³ *Commission White Paper*, *supra* note 58, at 5,8.

⁹⁴ REACH, *supra* note 64, at art. 55; European Commission White Paper, *supra* note 58, at 8 (stating “It is essential to promote the competitiveness of the chemical industry and encourage innovation, and in particular the development of safer chemicals.”); TSCA, in contrast, emphasizes innovation generally and the concern is avoidance of negative effects on innovation rather than taking affirmative steps to direct it, TSCA, *supra* note 4, at § 2(b)(3)

⁹⁵ *Commission White Paper*, *supra* note 58, at 8.

⁹⁶ Clifford Rechtschaffen & Patrick Williams, *The Continued Success of Proposition 65 in Reducing Toxic Exposures*, 35 ELR 10850 (2005) (continuing effectiveness of Prop 65); Carl Cranor *Information Generation and Use under Proposition 65: Model Provisions for Other Postmarket Laws?* 83 IND. L.J. (FORTHCOMING 2008) (DITTO). Industry continues to resist such measures vigorously. The Bush Administration EPA recently published a rule that reduces considerably the information that must be reported to EPA under the Toxics Release Inventory; Toxics Release Inventory Burden Reduction Final Rule, 71 Fed. Reg. 76,932 (2006).

benefits outweigh costs. Especially in the context of the normative burden of proof, this highly judgmental analysis is not an attractive prospect for manufacturers. Finally, authorization and restriction require the disclosure and analysis of substitute substances.⁹⁷ A lawyer at a European branch of an American law firm was recently quoted as saying that “companies that make a chemical of high concern must ‘be ready for a long and never-ending battle’” to continue to market it,⁹⁸ surely a powerful incentive to look for substitutes.

The Precautionary Principle. Precaution made its first major appearance as a distinct principle in international law in the 1985 Vienna Convention for the Protection of the Ozone Layer, though it did not really enter the American environmental consciousness until the late 1990s. The Precautionary Principle was not available to the drafters of TSCA, but it was an important foundational concept for the drafters of REACH.⁹⁹ The EU Treaty incorporates the Precautionary Principle in the basic statement of European environmental policy,¹⁰⁰ and the Commission has issued an interpretive guide¹⁰¹ that has gained general acceptance from the other

⁹⁷ REACH, *supra* note 64, at arts. 55, 60 (4)-(5) (referring to authorization); REACH, *supra* note 64, at 68(1), Annex XV-XVII (referring to restrictions).

Massachusetts directly encourages substitution through the Toxics Use Reduction Act (TURA), Mass. Gen. Laws ch. 21I (2004 & Supp. 2006), which requires the creation of actual toxics reduction and substitution plans, which are not necessarily available to the public, to encourage internally motivated action by firms rather than to generate public pressure.

⁹⁸ Pat Phibbs-Rizzuto, *Compliance: European Hazardous Chemicals Lists May Give Clues on ‘Very High Concern’ Items*, 30 INT’L. ENVTL. REP. 396 (BNA 2007).

⁹⁹ While the Precautionary Principle clearly “played a highly prominent role” in the adoption of REACH, Professor Heyvaert persuasively challenges the assumption that the Precautionary Principle *actually* determined to content of the legislation in ways that would not have happened without the formal adoption of the principle in European law. Heyvaert, *supra* note 70, at 51. For present purposes, the influence of the Precautionary Principle will be considered relevant to the extent of its consistency with REACH provisions (which Heyvaert finds) and even providing “a language in which to express [pro-protection] concerns.” *Id.* at 45.

¹⁰⁰ Treaty of European Union, Consolidating versions of the Treaty of European Union and of the Treaty Establishing the European Community, art. 174 (2), Dec. 29, 2006, 2006 O.J. (C321) 1 [hereinafter Treaty on European Union].

¹⁰¹ *Commission Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000).

principal organs of European governance, including an enthusiastic judicial reception.¹⁰² The authors of REACH expressly recognized the importance of the Precautionary Principle to the new regulatory regime,¹⁰³ and article 1 of REACH states that its “provisions are underpinned by the precautionary principle.”¹⁰⁴

The central purpose of the Precautionary Principle is to authorize regulatory action in the face of scientific uncertainty. The most widely accepted version of the principle reads:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.¹⁰⁵

As Professor Fisher explains, this means that, procedurally, no evidence of harm is *not* to be equated with evidence of no harm.¹⁰⁶ For a regulatory system that is committed to preventing harm, this means that lack of data cannot justify inaction; rather, the (relative) safety of a chemical should be demonstrated by its proponents. Rhetorically, the Precautionary Principle takes away the argument that a chemical should be approved because its harmful effects remain uncertain. Supported by the allocation of the burden of proof, REACH takes this general approach. For example, REACH directs that safety assessments be based on the information that gives the greatest cause for concern¹⁰⁷ In contrast, the findings and substantial evidence requirements in TSCA by their nature declare that no evidence of harm has the same procedural

¹⁰² Elizabeth Fisher, *Precaution, Precaution Everywhere: Developing a “Common Understanding” of the Precautionary Principle in the European Community*, 9:1 MAASTRICHT J. OF EUR. & COMP. L. 7, 12 (2002); Heyvaert, *supra* note 70, at 28, 33,35.

¹⁰³ *Commission White Paper*, *supra* note 58, at 5.

¹⁰⁴ REACH, *supra* note 64, at art. 1(3); *see also id.* Preamble (9), (69).

¹⁰⁵ Rio Declaration of the United Nations Conference on Environmental and Development (UNCED), ¶ 15, June 14, 1992, 31 I.L.M. 874 [hereinafter Rio Declaration].

¹⁰⁶ Fisher, *supra* note 83, at 9.

¹⁰⁷ REACH, *supra* note 64, at annex I, §§ 1.1.4, 3.1.5 (suggesting general provisions for safety assessments and chemical safety reports); *Commission Questions and Answers on REACH*, <http://ec.europa.eu/environment/chemicals/pdf/qa.pdf> (last visited Aug. 16, 2007).

effect as evidence of no harm, and of course TSCA has spawned an entire industry of raising uncertainties as a defense to regulation under the statute.

Transparency and the right to know. Since the passage of TSCA, environmental law has seen the development of right-to-know legislation as a way to regulate chemicals. Like burden of proof, right-to-know laws have both normative and instrumental purposes. The normative purpose gives the legislation its name: citizens are entitled to know the chemicals to which they are exposed and their effects. They are potentially affected, and they can respond to the information with individual choices (such as purchasing), with litigation, with political action, or with all three. The instrumental purpose of right-to-know laws is to embarrass the users or emitters of chemicals, which acts as a strong incentive to reduce or replace the chemicals.¹⁰⁸ The seemingly universal availability of the Internet – another post-TSCA development – magnifies the potential of public information to affect individuals' decisions and to facilitate individual and collective action on chemicals.

REACH is at pains to facilitate and require the flow of information up and down the entire supply chain,¹⁰⁹ as well as to government agencies and the general public.¹¹⁰ It relies heavily and explicitly on the existence of publicly available data and its ready accessibility to anyone via the Internet to accomplish several instrumental goals.¹¹¹ Public information is another spur to industry to develop new, safer substitute products.¹¹² Not only can public information be expected to create a demand among the general public to reduce the use of toxic substances, as

¹⁰⁸ Cranor, *supra* note 77, at ____; see also Rechtschaffen & Williams, *supra* note 77, at 10850-10856 (reporting on continuing reductions of toxic substances in products and emissions).

¹⁰⁹ REACH, *supra* note 64, at arts. 31-39.

¹¹⁰ *Id.* at arts. 118-19.

¹¹¹ *Id.* at art. 77(2)(e), 119; *Commission White Paper*, *supra* note 58, at 26-27.

¹¹² *Commission DG Environment*, *supra* note 88, at § 6.2.1.

noted above, but the greater availability of specialized information will result in legal pressure – through regulation or litigation – by NGOs to reduce the use of toxic chemicals.¹¹³

Reduced animal testing. The use of animals to test the toxicological effects of chemicals is a major concern among a relatively small segment of the US population; however, it has widespread salience in Europe, and so reduction of animal testing is a major stated objective of REACH.¹¹⁴ This creates a dilemma: the reduction of animal testing runs directly counter to the commitment to generate more test data. Since testing has always been a major cost for industry, concern over animal testing has resulted in some strange political bedfellows. In the debates over REACH, industry and animal rights groups both emphasized the uncertainties of animal tests as a surrogate for humans, and they agreed on the desirability of finding alternatives.¹¹⁵ The upshot is a strong commitment in REACH to develop reliable quantitative chemical structure-activity (QSAR) and *in vitro* testing as a substitute for traditional animal testing. QSARs are the cheap, “fast track option to deal with data gaps on chemicals,”¹¹⁶ and they do not require the use of animal models (at least, not after the initial effect and potency models have been determined). Together, industry and animal rights groups engineered several regulatory innovations to reduce the need for testing while supporting a strongly data-based regulatory system. These include

¹¹³ In addition, the EU (REACH arts. 118-119) will be considerably less receptive to claims of confidential business information. *Commission DG Environment, supra* note 88, at § 13.1 (stating must affirmatively approve claims); Denison, *supra* note 34, at VIII-8-11).

¹¹⁴ *Commission White Paper, supra* note 58, at 7.

¹¹⁵ *Commission DG Joint Research Council, supra* note 63, at 6-8; *Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Env't (CSTEE) on the BUAV-ECEAE Report on “The Way Forward- Action to End Animal Toxicity Testing”* In the US, animal testing has encountered some skepticism in the US courts reviewing agency action (e.g., Gulf South), and so acceptance of non-animal testing will probably take some time. E.g. GAO, *supra* note 35, at 11-15 (suggesting QSAR not ready for prime time). EPA has in fact pioneered the use of QSAR techniques as part of its PMN review process, and the National Academy of Sciences recently reported that non-animal testing will become increasingly reliable and increasingly common. National Research Council, *supra* note 45, at _____. And, to the extent that such methods turn out to be reliable, cheap, and fast, they will further the protective goals of chemical regulation.

¹¹⁶ *Commission DG Joint Research Council, supra* note 63, at 7.

mandatory data sharing, “one substance one registration,”¹¹⁷ only invertebrate and in vitro testing for the lowest production volume chemicals,¹¹⁸ pre-registration and dossier review to determine whether animal testing can be avoided, acceptance of non-EU test results, discouraging repeated testing, and of course the widespread acceptance of QSAR and other non-vertebrate testing.¹¹⁹ New animal testing is to be a last resort in all cases.¹²⁰ To the extent that the mandate for non-animal testing results in faster and cheaper – and reliable – assessment of chemicals, it is a new idea that also holds promise for improved chemicals regulation.

IV. Synthesis: Shared Ideas and TSCA Reform

Synthesis, in the Hegelian conception, is a new paradigm that grows out of the conflict of thesis and antithesis. Therefore, in seeking a synthesis of chemical regulatory regimes, especially a synthesis that could be implemented as reform of TSCA, it will be most promising to examine elements common to TSCA and REACH, correction of the worst failures of TSCA, and the most useful new ideas in REACH.

The time is right to develop such a synthesis. TSCA is clearly overdue for reform, as the litany of disappointments and criticisms in Part II demonstrates. The passage of REACH has produced an avalanche of concern in the US about chemical regulation, because hundreds of American companies will need to learn how to comply to maintain important European markets¹²¹ and the chemical information that is generated in response to REACH will be available (more or less instantaneously) in the United States. Congress has begun to take a

¹¹⁷ REACH, *supra* note 64, at art. 25.

¹¹⁸ *Id.* at art. 12.

¹¹⁹ These are specifically mentioned in all of the Annex lists of required testing, especially Annex.XI, which provides for waivers of testing.

¹²⁰ *Id.* at art. 25(1).

¹²¹ US Department of Commerce website.

serious interest in REACH and its possible relation to TSCA reform, and environmental groups are creating pressure to do so. A recent article in the trade press reported that environmental organizations are engaged in a campaign to pass toxics legislation in the states, and that this will put pressure on Congress (with industry's encouragement) to reform TSCA to avoid an inconsistent, piecemeal regulatory scheme in this country.¹²² Under these circumstances, TSCA reform, long overdue, is realistically in prospect.

A. Plus ça change, plus c'est la même chose

While REACH is the Anti-TSCA in several important ways, in fact the two regulatory regimes have much in common. CEQ's 1971 *Toxic Substances* report perceptively identified the key challenges in regulating industrial chemicals, and the basic structure of TSCA represents an integrated, comprehensive approach. The European Union seeks to accomplish the same goals with REACH.

Twin goals. The fundamental objectives of both TSCA and REACH are protection of human health and the environment, and protection of the economic health of their respective chemical industries.¹²³ As between the two, both also give nominal primacy to protecting health and the environmental protection. TSCA:

authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation *while fulfilling the primary purpose* of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.¹²⁴ (emphasis added)

Likewise REACH:

¹²² Maria Hegstad, Fearing TSCA Push, Industry Steps Up Battle Over State Toxics Restrictions, Inside EPA, March 19, 2008.

¹²³ *Commission White Paper*, *supra* note 58, at 4.

¹²⁴ TSCA, *supra* note 4, at § 2(b)(3).

The purpose of this Regulation is to ensure a high level of protection of human health and the environment, . . . *as well as* the free circulation of substances on the internal market *while* enhancing competitiveness and innovation.¹²⁵ (emphasis added)

REACH was jointly sponsored by the Enterprise and Environment directorates general, and DG Enterprise repeatedly emphasized the benefits to the chemical industry of maintaining confidence in chemicals and of spurring innovation.¹²⁶ Each system balances one goal against the other. TSCA’s “unreasonable risk” standard takes into account economic and social factors. In REACH, this balance is seen as an embodiment of “the overriding goal of *sustainable development*,” to which the EU is committed.¹²⁷ In both systems, the regulation aims to shape rather than eliminate the chemical industry.

Chemicals as such. *Toxic Substances* devoted considerable space to explaining the many reasons to focus “on the pollutant rather than on the particular medium being polluted,”¹²⁸ and these views are repeated in the legislative history of TSCA.¹²⁹ First, regulating chemicals as such enables preventive regulation, *before* people or the environment are exposed to them. Second, regulating chemicals as such has the capacity to control them at their source, which is universally recognized to be the most efficient and effective point of control. This is especially the case for pollutants that persist in the environment for a long time and thus disperse widely and even globally (DDT, for instance). Persistent chemicals often bioaccumulate (DDT again), resulting in higher doses to affected populations. Third, regulation of chemicals can encourage the development of a true cradle-to-grave (production to disposal) management approach. Some chemicals, *i.e.*, pesticides, are in fact intentionally introduced into the environment. They are

¹²⁵ REACH, *supra* note 64, at art. 1(1).

¹²⁶ *E.g. Commission Q & A on the New Chemicals Policy-- REACH* (Feb. 2007) http://europa.eu.enterprise/reach/faq_en.htm (last visited July 28, 2007) [hereinafter *Commission Q & A*]

¹²⁷ *Commission White Paper, supra* note 58, at 4 (emphasis in the original).

¹²⁸ US CEQ, *supra* note 3, at v-vi.

¹²⁹ S. REP. NO. 94-698, at 1-2 (1976).

thus a major vector for introducing new hazards to human health and the environment and excellent candidates for a thorough approach to risks.¹³⁰ Fourth, reliance on the basic media-based pollution statutes (for air emissions, water effluents, and land disposal¹³¹) creates a serious danger of shifting waste products between media. One might avoid land disposal by incinerating, for example, or send water pollutants to a landfill. While it is possible to regulate in triplicate, so to speak, it is a highly complex undertaking. Standards and techniques for one medium frequently do not translate to another, because the physical forms and settings are very different.¹³² Finally, there are significant benefits to the regulated industry in the chemical-based approach. Regulation in triplicate is a compliance officer's nightmare, especially when regulatory programs are delegated to the states (as the media programs are in the US), so that multiple versions of each are applicable to different parts of the same enterprise.

TSCA addressed these concerns by regulating chemical substances and providing wide ranging control authorities to cover manufacture, use, and disposal.¹³³ It also encouraged EPA to use TSCA to coordinate the activities of the media-specific federal statutes.¹³⁴ REACH does not even discuss other approaches, probably because the idea of regulating chemicals as such was already well established in EU law. Europe also has a constitutional commitment that “environmental damage should as a priority be rectified at [its] source,”¹³⁵ which, as we have seen, favors the chemical-specific approach. Of even greater immediate importance to the drafters of REACH was the need to harmonize and rationalize the many different EU regulations

¹³⁰ Hornstein, *supra* note 28, at 393-400.

¹³¹ For these purposes, the workplace might be considered a fourth separate medium, distinct from the ambient air, water, and land environments.

¹³² US CEQ, *supra* note 3, at 20-21.

¹³³ TSCA, *supra* note 4, at § 6 (a)(1)-7.

¹³⁴ TSCA, *supra* note 4, at § 9(b); Applegate, *supra* note 20, at 330-32.

¹³⁵ Treaty on European Union, *supra* note 81, at art. 174(2).

and directives and their interpretations in all of the member states into “a single coherent system.”¹³⁶ The regulation of chemicals as such advances all of these goals.

Prevention. When TSCA was enacted in 1976, the idea of prevention as a complement to the tort system was perhaps not yet firmly established, and it was necessary to emphasize it.¹³⁷ The tort system only responds to harms that have already occurred and does not prohibit harm-causing activities; rather, it seeks to remedy past harms with money damages. As a compensatory system, this approach is flawed because many harms (death, dismemberment, pain) cannot be fully rectified by money; moreover, the failure to forbid in advance the infliction of physical harm violates a sense of human dignity and autonomy. Tort law is also supposed to act as a deterrent to future harm-causing activity, because subsequent risk-creators will realize that they will have to pay for the harm they cause. However, individual risk-creators will refrain from certain activities only to the extent that the cost of preventing the harm is less than the cost of the harm.¹³⁸ That is, the level of protection is set by the individual tortfeasor’s assessment of the comparative costs of prevention and liability, rather than by a collective public judgment of an acceptable level of harm. The emphasis on prevention in *Toxic Substances* and TSCA’s adoption of a system based on risk rather than harm represent such a collective judgment.¹³⁹

Thirty years later, the White Paper hardly needed to argue the point: “decisionmaking must be based on precaution to *prevent* damage to human health and the environment.”¹⁴⁰ By 2001, the debate had moved beyond prevention. For many observers, the Precautionary Principle

¹³⁶ *Commission White Paper*, *supra* note 58, at 16; *Commission Q & A*, *supra* note, 105; *see also Commission DG Environment & DG Enterprise and Industry* (Feb. 2007), http://europa.eu/environment/chemicals/reach/reach_in_brief04_09_15.pdf (last visited July 28, 2007);

¹³⁷ US CEQ, *supra* note 3, at 20-21.

¹³⁸ This assumes that the tort system accurately assesses the costs. For toxic substances, where causation is often very difficult to prove because of the nature of toxic injury, the tort system can be expected to understate the costs. Wagner, *Choosing Ignorance*, *supra* note , at ____.

¹³⁹ GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS*, 95-107 (1970).

¹⁴⁰ White Paper, *supra* note , at 5 (emphasis added).

marked a shift from avoiding known risks to anticipating suspected ones.¹⁴¹ However, the European Commission has resisted the more aggressive normative understandings of the Precautionary Principle and insisted on a science-based and cost-attentive approach.¹⁴² REACH follows the Commission's interpretation of the Precautionary Principle,¹⁴³ and we have seen that the authorization and restriction procedures involve risk-cost-benefit balancing. The REACH approach to prevention, in sum, is not fundamentally much different from TSCA's – it is prevention with a risk-benefit measure of acceptability.

The data gap. Concern over lack of chemical knowledge is perhaps the most striking commonality of the two legislative regimes. It was a primary concern in *Toxic Substances* in 1971, and TSCA provided a range of devices to fill the data gap. The developers of REACH sponsored studies of the data gap, which confirmed earlier findings of a serious problem,¹⁴⁴ but they went further and concluded that the data gap could not be filled by the TSCA approach: “In fact, not one country has yet been successful in overcoming the huge gap in knowledge of substances.”¹⁴⁵ However, while REACH adopts a different data-acquisition strategy from TSCA, it has the same basic objective to fill the data gap. Neither piece of legislation seeks to “bridge” the gap by adopting regulatory standards that would require less information to operate.¹⁴⁶ Instead, like TSCA, REACH provides mechanisms that are designed to generate comprehensive data on chemicals for use by regulators. Its various innovations – shifting the burden of proof,

¹⁴¹ John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & M. ENVTL. L. & POL'Y REV. 13, 17-20 (2002).

¹⁴² *Commission Communication*, *supra* note 82, at 3-5,7,14,18-21.

¹⁴³ *Commission Proposal*, *supra* note 2, at 19; Heyvaert, *supra* note 70, at 51.

¹⁴⁴ *Commission DG Joint Research Council*, *supra* note 63, at 5 & *passim* (citing earlier studies); Denison, *supra* note 43, at 6.

¹⁴⁵ *Commission White Paper*, *supra* note 58, at 5.

¹⁴⁶ Technology-based standards, for example, demand relatively little chemical information, while risk-based standards tend to require a great deal. Risk-based TSCA, in contrast, requires EPA to consider a wide array of information, including alternatives, and it backs this up with specific required findings and aggressive judicial review. Applegate, *Hazard and Probability*, *supra* note , at ___; John S. Applegate & Robert Fischman, *Missing Information: The Scientific Data Gap in Conservation and Chemical Regulation*, 83 IND. L.J. (forthcoming 2008).

eliminating the distinction between new and existing chemicals, and methodically addressing the “burden of the past,” reliance on non-animal testing, and so on – are simply different and presumably more effective techniques for accomplishing that goal.

The incorporation of the Precautionary Principle, as interpreted by the European Commission, is not to the contrary. By placing the Precautionary Principle within the larger framework of risk analysis, by limiting the use of the principle to situations of demonstrable uncertainty, and especially by requiring follow-up research to resolve uncertainties, the Commission clearly indicated that the Precautionary Principle is not a wholesale revision of the standards by which environmental decisions are made. Rather it is a means of avoiding stalemate and inaction in the common situation of scientific uncertainty.¹⁴⁷

Risk, proportionality, and cost. Both TSCA and REACH are based on the evaluation of probabilistic risk. By contrast, the 1958 Delaney Clause in the Federal Food, Drug, and Cosmetic Act simply bans as additives in foods or drugs any substance that “is found to induce cancer when ingested by man or animal.”¹⁴⁸ Delaney is based solely on the carcinogenic property of the chemical, and the chemical’s potency and the degree of exposure are irrelevant to the legal analysis. It relies on a simple, bi-modal (safe-unsafe) proposition: if the chemical is a carcinogen, then it must be banned. Few recent regulatory regimes have adopted this approach. Instead, the nearly universal tendency is to view chemical hazards as incrementally scalable based on their toxic potency and the amount of exposure to the chemical. This is especially true when one is focusing on a chemical hazard like cancer, which generally does not have a step-wise progression of doses with distinctive effects.

¹⁴⁷ *Commission Communication*, *supra* note 82, at 13-15, 20-21.

¹⁴⁸ Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 348 (c)(348)(A) [hereinafter FFDCFA]

TSCA itself does not define risk, but risk in the statute has uniformly been interpreted as a probabilistic statement of the product of toxicity and exposure, with an acceptable level lying at a point above zero.¹⁴⁹ REACH, too, relies on risk as the basis for regulation. Intrinsic properties – for example, carcinogenicity, mutagenicity, and reproductive toxicity (CMR) – trigger data and evaluation requirements, but regulatory controls are ultimately based on intrinsic characteristics *and* exposure levels. Both types of information are required in the base set of data for registration,¹⁵⁰ in the chemical safety report,¹⁵¹ and in the terms of control for authorization.¹⁵² Exposure levels are a key element of control in restrictions.¹⁵³ Here again, the Commission’s interpretation of the Precautionary Principle lends support, by placing the principle firmly in the context of risk management.¹⁵⁴

The use of probabilistic, greater-than-zero risk (that is, of the abandonment of the bi-modal hazard paradigm) and the commitment to proportionality for the regulation of chemicals begs the question how to fix the point for regulatory action on the incremental scale of zero to one hundred percent risk.¹⁵⁵ The “unreasonable” terminology in TSCA is notably unspecific, and intentionally so,¹⁵⁶ but it is clear that EPA must consider cost as well as risk in its determinations of “unreasonable risk.”¹⁵⁷ The establishment of any regulatory control must include “a statement with respect to” the human and environmental risks of the chemical, the benefits and available

¹⁴⁹ H.R. REP. NO. 94-1341, at 14 (1976).

¹⁵⁰ REACH, *supra* note 64, at art. 10(a), annex VI.

¹⁵¹ *Id.* at art. 14.

¹⁵² *Id.* at art. 60(2).

¹⁵³ *Id.* at arts. 69-70.

¹⁵⁴ *Commission Communications*, *supra* note 82, at 3.

¹⁵⁵ Applegate, *supra* note 42, at 271-77.

¹⁵⁶ H.R. REP. NO. 94-1341, at 13-14 (1976).

¹⁵⁷ S. REP. NO. 94-698, at 13,16,20 (1976); H.R. REP. NO. 94-1341, at 13-14, 35 (1976).

substitutes for the chemical, and the language, “the reasonably ascertainable economic consequences of the rule.”¹⁵⁸

In REACH, the data requirements of registration do not include the cost of regulation, though information concerning uses is required.¹⁵⁹ At the authorization phase, manufacture or import is presumptively banned based on key intrinsic properties (*e.g.*, CMR), but then it may be authorized for particular uses that either can be adequately controlled¹⁶⁰ or, if they cannot (and CMRs by definition cannot), then justified if benefits of the chemical outweigh its environmental costs.¹⁶¹ This, too, is in keeping with the Treaty on European Union¹⁶² and the *Communication on the Precautionary Principle*, both of which mandate the consideration of cost in imposing environmental restrictions. Restrictions require the opinion of the Committee for Socio-Economic Analysis,¹⁶³ and the Commission must justify a rejection of its recommendations.¹⁶⁴

Risk in the probabilistic sense and the consideration of cost and other non-health factors serve to ensure that the regulator’s response to the risk is proportionate to the scale of the problem identified. To underscore this point, TSCA’s regulatory measures are to be the “least burdensome” needed to address the problem,¹⁶⁵ and testing must be “necessary” to obtain information that is “relevant” to regulatory decisions.¹⁶⁶ The restrictions must fit the risk, in other words. Proportionality is also a basic principle of European law.¹⁶⁷ The Commission made

¹⁵⁸ TSCA, *supra* note 4, at § 6(c)(1).

¹⁵⁹ REACH, *supra* note 64, at art. 10(a).

¹⁶⁰ “PBTs [persistent, bioaccumulative, or toxic], vPvBs [very persistent or very bioaccumulative], and those CMR [carcinogenic, mutagenic, or reproductively toxic] substances for which a safe level cannot be defined, cannot be authorized based on adequate control of risk.” REACH in Brief, *supra* note , at § 2.7.

¹⁶¹ *Id.* at arts. 60(4), 64(4)(b).

¹⁶² Treaty on European Union, *supra* note 81, at art. 174(3); *Commission Communications*, *supra* note 82, at 19-20.

¹⁶³ REACH, *supra* note 64, at arts. 68(1), 71.

¹⁶⁴ *Id.* at art. 73(1).

¹⁶⁵ TSCA, *supra* note 4, at § 6(a).

¹⁶⁶ *Id.* at § 4(a).

¹⁶⁷ PAUL CRAIG & GRÁINE DE BÚRCA, *EU LAW: TEXT, CASES, AND MATERIALS*, 349-57 (2d. ed. 1998).

proportionality a major guideline for applying the Precautionary Principle,¹⁶⁸ and proportionality permeates REACH, from the amount of data to be provided in the registration phase¹⁶⁹ to the nature of the restrictions applied to VHC chemicals. REACH and TSCA, in sum, accept some level of risk from chemicals (as noted, neither envisions fundamental restructuring or replacement of the chemical industry), and so they adopt regulatory standards of probabilistic risk moderated by considerations of proportionality and cost.

Priorities. The acceptance of a spectrum of risk means that not all hazards are of equal regulatory concern, which counsels the wisdom (if not the inevitability) of setting priorities. It is a reflection of both aspiration and ignorance that early US environmental statutes tended to assume that environmental problems could be resolved once and for all within a fairly short period of time. TSCA was perhaps ahead of its time in recognizing that its look-back device for generating toxicological information, the section 4 test rule, would take time to implement fully, and it established an Interagency Testing Committee (ITC) to create and update a priority list for testing existing chemicals.¹⁷⁰ TSCA gives both flexibility (a very wide range of relevant considerations) and direction (carcinogens, mutagens, and teratogens are priorities) to the committee. However, while a priority list was developed and is regularly updated, it is a short list¹⁷¹ (limited to fifty) by comparison to the thousands of chemicals of regulatory concern. In any event, the testing deadlines – and indeed the list itself – have been essentially ignored.

REACH, proceeding from a burden on the manufacturer to obtain permission to sell or to continue to sell, has a far more robust priority setting mechanism. “Prioritisation is built into the

¹⁶⁸ *Commission Communication*, *supra* note 82, at 18.

¹⁶⁹ *Commission White Paper*, *supra* note 58, at 3.

¹⁷⁰ TSCA, *supra* note 4, at § 4(e).

¹⁷¹ *Id.* at § 4(e)(1)(A).

system throughout.”¹⁷² Since eliminating the data gap for existing chemicals is a central objective of REACH, it provides express guidance for a “step by step process to address the ‘burden of the past.’”¹⁷³ REACH sets priorities based on hazard *or* exposure.¹⁷⁴ For priority based on hazard characteristics (intrinsic properties), REACH goes beyond CMR (which is in the TSCA § 4(e) priorities) or HPV (the TSCA B-Policy), to focus in addition on persistence and bioaccumulation.¹⁷⁵

Comprehensive rationality. Finally, both TSCA and REACH adopt the general approach to regulation that Professor McGarity calls “comprehensive analytical rationality.” This approach reaches decisions by gathering and systematically analyzing all of the relevant information about a given problem and its potential, with the objective of implementing the optimal regulatory response. (Comprehensive rationality includes and goes beyond the idea of synopticism, discussed above.¹⁷⁶) The aspiration to comprehensiveness is inherently data-hungry. More, it implies that the data should be quantitative where possible to permit formal analysis, using tools like quantitative risk assessment and cost-benefit analysis. The comprehensive aspirations of REACH and TSCA are evident in their broad consideration of information concerning chemicals. The hazards are defined in terms of risk, itself a complex and multi-faceted concept, and the acceptable level of risk is determined through an open-ended analysis of costs, technologies, substitutes, and alternative approaches. While TSCA does not mandate particular regulatory tools, REACH in effect does so by requiring the involvement in later stages

¹⁷² *Commission Questions and Answers on REACH*, *supra* note 88, at § 2.5.2.

¹⁷³ *Commission White Paper*, *supra* note 58, at 7.

¹⁷⁴ *Commission Questions and Answers on REACH*, *supra* note 88, at § 2.5.2.

¹⁷⁵ In a further parallelism, both the CMR factors and production volume are testing priorities under TSCA. Section 4(a)(1)(B) (the so-called B-Policy for testing high volume chemicals), 4(e) (criteria for the Interagency Testing Committee).

¹⁷⁶ See text accompanying note [Hornstein synopticism], *supra*.

of the process of a Committee for Risk Assessment and a Committee for Socioeconomic Analysis.¹⁷⁷

Both TSCA and REACH share a fundamental regulatory commitment to science-based regulation. (It is not coincidental that the above committees take on the responsibilities of the Commission’s Scientific Committees in this area.¹⁷⁸) While this may seem almost too obvious to mention, the commitment has a history and important consequences. The history, very briefly, is that science was responsible for many of the insights that brought environmental law into being. For chemical regulation, Rachel Carson’s work serves as a good starting point. The novel and persuasive feature of *Silent Spring* was Carson’s use of science to demonstrate the extent of the problem of pesticides.¹⁷⁹ Since then, we have relied on science to reveal problems, and science has become the central justification for regulatory actions that are expensive or otherwise unpopular.¹⁸⁰ Perversely in view of this history, the slogan “sound science” has recently become the slogan of opponents of regulation, who demand that regulatory action be withheld without clear, almost incontrovertible scientific demonstration of the nature and extent of environmental harm.¹⁸¹

The debate over the role of science has been played out in the international environmental regimes to which the European Union, and REACH in particular, respond. The Precautionary Principle, of course, seeks to avoid obstructionist use of “sound science” by authorizing regulation in advance of certainty. Indeed, the standard formulation of the principle is couched as

¹⁷⁷ REACH, *supra*, art. 64.

¹⁷⁸ REACH, *supra*, Preamble (102).

¹⁷⁹ RACHEL CARSON, *SILENT SPRING* (1962).

¹⁸⁰ Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1651-1654 (1995) (suggesting that non-scientific considerations are often at work, despite the nominal reliance on scientific rationales.)

¹⁸¹ Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 KAN. L. REV. 897, 897-901, 904-908 (2004).

a rhetorical counter-move (“shall not be used as a reason”),¹⁸² rather than an affirmative substantive command. On the other hand, entities like the World Trade Organization, with a greater stake in economic activity than in environmental protection, insist that regulatory restrictions be based on scientific information.¹⁸³ The European Commission, seeking to reconcile European commitments to strong environmental protection and to free trade under the auspices of the WTO, interprets the Precautionary Principle to be based on scientific inquiry that establishes the existence of a potential harm, and then to require follow-up inquiry to resolve uncertainties if regulatory action goes forward without full certainty.¹⁸⁴ REACH, as we have seen, adopts a filling approach to the data gap and requires a “sound scientific basis” for restrictions on chemicals¹⁸⁵

The science-based approach in TSCA has been used to justify aggressive interpretation of the evidentiary and procedural requirements of the statute to advance an anti-regulatory agenda. In *Corrosion Proof Fittings*, the case that brought non-voluntary TSCA programs to a virtual standstill, the court was highly critical of the quality and definitiveness of EPA’s 100,000-page scientific record on the effects of asbestos. In view of the findings and substantial evidence provisions of TSCA, the record was deemed insufficient to support the restrictions that EPA had imposed.¹⁸⁶

In all of these respects, REACH and TSCA bear important and indeed fundamental similarities in their approaches to chemicals regulation. Both balance protection of human health

¹⁸² Rio Declaration, *supra* note 86, at ¶ 15.

¹⁸³ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, <http://www.wto.org> (last visited Aug. 19, 2007) [hereinafter Agreement]

¹⁸⁴ *Commission Communication*, *supra* note 82, at 13-15, 20-21.

¹⁸⁵ REACH, *supra* note 64, at arts. 69-73; *Commission Proposal*, *supra* note 2, at 16, 37.

¹⁸⁶ *Corrosion Proof Fittings*, *supra*.

and promotion of the chemical industry, they regulate chemicals as such to supplement the media-based statutes, they seek to prevent toxic harm before it occurs, they regulate on the basis of a risk characterized by less-than-absolute safety and defined by cost and other non-health considerations, they are information-intensive in that they aspire to fill the data gap (albeit in different ways), and each is committed to a comprehensive, analytical approach to regulation.

B. Practical Principles for TSCA Reform

The areas of commonality between TSCA and REACH, together with the most glaring failures of TSCA and the regulatory innovations in REACH, suggest four interrelated principles for improvement of chemicals regulation:

- Substantively, chemical regulation should be preventive and its restrictions proportionate to the risk presented;
- Chemical regulation should aim for progressive improvement in chemical safety;
- Regulation should be based on all available information, and lack of full information should not be a barrier to precautionary action;
- Procedurally, the regulatory system should be as transparent and simple as possible.

It bears emphasis that these principles are not necessarily the principles that one would adopt if writing on a blank slate, nor do they constitute anything like a paradigm shift in chemical regulation. Rather, they represent a synthesis between the two regulatory approaches, and therefore they offer the best prospect of adoption if (when) TSCA is revised in the near future.

Prevention and proportion. Substantively, chemicals regulation should be preventive and its restrictions proportionate to the risk presented. Prevention of harm before it occurs is the principal justification for governmental action to control chemicals as a complement to compensation for injuries. It has both the normative underpinning of prohibiting unconsented harm and the utilitarian goal of cost-effective environmental management, prevention being cheaper than repair. In an industrial society, perfect safety is an unattainable, if not incoherent,

goal; therefore, regulatory restrictions need to be related – though not precisely calibrated – to the prospective harm. This principle entails the following corollaries:

Risk-based regulation. Regulation based on risk supports both prevention and proportion. It is preventive, because it addresses probabilities of harm, rather than completed harm. Risk-based regulation also facilitates proportionate responses, because risk can be (and usually is) understood to be a scaled rather than a bi-modal quality, measuring expected loss in terms of likelihood of harm of a particular magnitude.

Chemical-based approach. For the reasons detailed above, regulating chemicals as such – that is, at the beginning rather than the end of their life cycle – is widely acknowledged to be the most efficient and effective way to achieve a preventive approach.

Cost-sensitive. Acceptance of a greater-than-zero residual risk from chemicals, which a risk-based approach and proportionality both imply,¹⁸⁷ necessitates the establishment of some criteria for determining the appropriate level of risk between 0 and 100%. Both TSCA and REACH take cost into account in making this determination. However, even in TSCA, which takes cost into account more frequently than REACH and places the burden of justification on the agency, cost does not necessarily determine outcomes. Moreover, neither demands a formal, quantitative cost-benefit justification for regulatory action.¹⁸⁸

Progressive improvement. Chemical regulation should aim for progressive improvement in chemical safety. Neither TSCA nor REACH adopts the goal of a chemical-free economy, but rather the *control* of dangerous chemicals before they cause harm to human health or the environment. “The European Union is aiming to achieve that, by 2020, chemicals are

¹⁸⁷ Conversely, one could say that risk and proportionality *reject* the hazard model of a bi-modal choice between safe and unsafe.

¹⁸⁸ H.R. REP. NO. 94-1679, at 9, 13-14 (1976) (stating that consideration of cost does not imply “any cost-benefit justification”).

produced and used in ways that lead to minimization of significant adverse effects on human health and the environment.”¹⁸⁹ A commitment to progressive improvement is, if not particularly encouraged by, at least consistent with TSCA. For example, the ITC process was clearly intended to identify the most problematic chemicals for further testing and subsequent restriction as indicated. As Professor Driesen has argued, given the difficulty of determining the precise costs and benefits of environmental harm, it makes more sense to point potentially harmful activities in the right direction than to try to define a static, optimal norm.¹⁹⁰

Identify and eliminate the worst chemicals. Because regulatory resources are limited, the failure to establish some priorities among the thousands of chemicals in commerce paralyzes regulatory action. The first step of progressive improvement, therefore, is to take action against the chemicals whose release into the environment in effect presents irreversible harm because of their toxicity or persistence. So that priority setting does not become an end in itself, priority-setting based on proxies like production volume, inherent characteristics, or persistence in the environment – triage, in effect – is sensible if not necessary. The Canadian Environmental Protection Act, 1999 is an excellent model. Focusing on relative rather than absolute hazard, it has made tremendous progress in a relatively short time.¹⁹¹

Learn how to live safely with what remains. The next step in progressively preventing harm is to learn how to live safely with what remains. The “safety case” is a familiar concept in Europe, but seldom used in the United States. It refers to a portfolio of information that characterizes a chemical and its uses, and that demonstrates, using appropriate information

¹⁸⁹REACH, *supra* note 64, at Preamble (4). REACH describes this objective as sustainable development, see *Commission White Paper*, *supra* note 58 at 4, because it tries to bridge economic growth and environmental protection.

¹⁹⁰DAVID M. DRIESEN, *THE ECONOMIC DYNAMICS OF ENVIRONMENTAL LAW* (MIT 2003).

¹⁹¹www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html. See also Denison, *Not That Innocent*, *supra* note , at I-4-5, II-3-8; Peter Menyasz, Toxic Substances: Canada Issues List of Priority Chemicals, Calls on Industry to Report Certain Emissions, 31 *Intl. Env't. Rep. (BNA)* 203 (March 5, 2008) (describing progress to date and ongoing efforts).

and assumptions, how it can be used safely through its life cycle. The chemical safety report required by REACH¹⁹² is essentially a safety case, especially since it includes appropriate use restrictions, as well as risk information. While the safety case concept does not presuppose any particular definition of what is acceptably safe, European environmental policy requires a “high level of protection,”¹⁹³ as befits economically and industrially advanced countries, and that is a fair description of most US statutory standards, as well.

Strong incentives for finding safer substitutes. Innovation is essential to the continued competitiveness of the chemical industry. By directing innovation toward safer alternatives, an economically healthy chemical industry can contribute importantly to safety. In addition to the techniques deployed in REACH, a direct way to create this incentive is to require that the justification for the use of a chemical include an “alternatives analysis” that evaluates a chemical in the context of its substitutes and their respective life cycles.¹⁹⁴ The Massachusetts Toxics Use Reduction Act, for example, requires the manufacturers and users of toxic chemicals to generate use reduction plans.¹⁹⁵ While the plans need neither be followed nor publicly disclosed, the investment in the development of the plans is expected to encourage their implementation.

Further progress. The idea of progressive substitution of safer chemicals can be extended to a continuing obligation to seize opportunities for greater chemical safety. This is expressed, for example, in the limited lives of REACH authorizations,¹⁹⁶ in contrast to TSCA. More importantly, it is expressed in the authorization requirement that, “Notwithstanding any

¹⁹² REACH, *supra* note 64, at art. 14.

¹⁹³ Treaty on European Union, *supra* note 81, at 174(2).

¹⁹⁴ Lars Koch & Nicholas A. Ashford, *Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH*, 14 J. CLEANER PRODUCTION 31-46 (1993).

¹⁹⁵ *Supra* note .

¹⁹⁶ REACH, *supra* note 64, at art. 60(8)-(9).

conditions of an authorization, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.”¹⁹⁷ The ALARA (“as low as reasonably achievable”) idea is also suggested in the *Communication on the Precautionary Principle*¹⁹⁸ as a way to deal with uncertainty. ALARA is not a widely used concept in US environmental law; however, it is a central – and quite successful – element of the somewhat esoteric area of nuclear safety,¹⁹⁹ and it could be more widely deployed.

Precaution. TSCA and REACH clearly make the filling rather than the bridging choice for chemical data, that is, they establish systems for the systematic evaluation of chemicals on a case-by-case basis. An inherently data-intensive and time-consuming approach, it must be tempered with precaution to avoid regulatory paralysis in the face of incomplete or uncertain information. Therefore, regulation should be based on all *available* information, and lack of full information should not be a barrier to preventive action.

Consider all relevant, available information. Regulation should not be based on deliberate ignorance, and regulators ought to be able to consider the range of relevant data, including scientific, technologic, economic, and social information, in reaching decisions. However, consistent with precaution, some points in the regulatory process (for example, data gathering) should proceed on the basis of limited data.

Generate information for existing and new chemicals. The demand for and supply of information is a central aspect of any chemical regulation scheme. Having created a demand for information, a regulatory system needs to supply it.²⁰⁰ As we have seen, REACH – with the advantage of thirty additional years of experience with chemical regulation in Europe and the US

¹⁹⁷ *Id.* at art. 60(10).

¹⁹⁸ *Commission Communication, supra* note 82, at 15.

¹⁹⁹ United States Nuclear Regulatory Commission, 10 C.F.R. §§ 20.1003, 20.1101; Applegate, *supra* note 40, at 427-43.

²⁰⁰ Applegate, Hazard and Probability, *supra* note , at ____.

– is more urgently focused on information needs than TSCA was. In addition, to the extent that European efforts to obtain reliable toxicological data without animal testing result are successful, they could result in a faster and cheaper regulatory process.

Follow a precautionary approach. Chemical regulation can only be truly preventive if it acts in advance of full information. The Precautionary Principle “underpins” REACH, it is a basic requirement of all European environmental law, and the idea of precautionary action has a long history in US environmental law.²⁰¹ For these purposes, the Precautionary Principle is not (and was never intended to be) a rule that gives specific direction in particular cases. It is, rather, a general statement of the relationship, especially as regards timing, between the exercise of governmental regulatory authority and available information.²⁰² As such, it is an essential baseline element of an information-dependent regulatory system.

Iteration. Some more recent versions of the Precautionary Principle require that decisions based on less than full information be revisited as more information becomes available.²⁰³ This requirement is designed to reconcile science-based regulation with preventive regulation, and the idea can be broadened to encompass the obvious logic in revisiting prior decisions on the basis of significant new information. Professor Doremus melds these aspects of precaution with other recent scholarship on regulatory use of new information to suggest that precaution works best in a regulatory system that is capable of learning, that is, adjusting in response either to previously unknown or uncertain information, or to observation of the

²⁰¹ John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6:3 HUM. & ECOLOGICAL RISK 413, 420-29 (2000).

²⁰² Fisher, *supra* note 83, at 20-23.

²⁰³ Applegate, *supra* note 18, at 31-33.

response to regulatory action.²⁰⁴ An iterative approach also supports progressive improvement of chemical safety.

Transparency and simplicity. Procedurally, the regulatory system should be transparent and simple, or at least as simple as basic procedural fairness and informed deliberation allow.

Provide the public with full chemical safety information. As we have seen, providing the public with full information about chemical safety and management permits individual decision-making and collective (*i.e.*, political or legal) action. Transparency concerning relevant information is also essential to meaningful public participation in the administrative process. The Internet has created the potential for widespread public access to chemical safety information in a number of forms and at different levels of technical detail. Regulatory systems should not only require the production of relevant information, but also organize it and make it available in broadly usable formats.

Limit procedural complexity. An iterative, learning system that seeks progressive improvement of chemical safety needs to be nimble in responding to new hazards and new information about existing areas of concern. The informal rulemaking procedure in US administrative law²⁰⁵ was designed to achieve this flexibility, but it has “ossified” over time.²⁰⁶ TSCA is perhaps the *ne plus ultra* of ossification. The extraordinary procedural elaboration deployed TSCA protects the no-regulation status quo,²⁰⁷ but it also slows responses to any new information. Some procedural complexity is inevitable in achieving a truly participatory system and, especially in the case of the EU, to recognizing the relationship between the Union and its

²⁰⁴ Holly Doremus, *Precaution, Science, and Learning While Doing in Natural Resource Management*, 82 Wash. L. Rev. 547 (forthcoming 2007), available at <http://ssrn.com/abstract=982203w>.

²⁰⁵ Administrative Procedure Act (APA), 5 U.S.C. § 553.

²⁰⁶ Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1385-85 (1992) (quoting E. Donald Elliott).

²⁰⁷ Daniel B. Rodriguez & Barry R. Weingast, *The Positive Political Theory of Legislative History: New Perspectives on the 1964 Civil Rights Act and Its Interpretation*, 151 U. PA. L. REV. 1417, 1444-45 (2003).

Member States. Nevertheless, procedural elaboration, including aggressive judicial review, should be avoided.

V. Conclusion: Chemical Regulation and Globalization

The premise of the essentially comparative approach of this article is that the chemical regulation systems of the EU and the US are well known to each other, that they have lessons for each other, and that they affect each other. Relationships between national legal systems are not new, of course, but the intensity and practically instantaneous nature of today's relationships are. In this sense, the relationship of TSCA and REACH exemplifies the phenomenon of globalization. Globalization is distinct from the traditional international legal order in that it involves transnational impacts in informal, non-hierarchical ways.²⁰⁸ International law in the strict sense of the law of nations has very limited domestic application. With globalization, the laws or norms of one state affect actors in other states, not directly, but because many actors have a global existence (for example, multinational corporations, or individuals who live and work in multiple states) and find it necessary or valuable to follow the laws of multiple states. Pollution and products travel across borders, bringing their hazards with them. Likewise, states in their domestic lawmaking react to each other through direct observation and informal discussion, more than through formal agreements in an overarching treaty.

Chemical manufacturing and distribution is truly a global industry. Production is dominated by several multinational corporations, many of whose names are familiar, with facilities and markets all over the world. Hundreds of other companies export and import smaller amounts across the globe. For both the US and Europe, chemicals are major export products and

²⁰⁸ Jost Delbruck, *Globalization of Law, Politics, and Markets—Implications for Domestic Law—A European Perspective*, 1 *IND. J. GLOBAL LEGAL STUDIES* 9, 10-11 (1993).

include substantial exports to each other.²⁰⁹ As a result, many chemical manufacturers and distributors, especially the larger ones, are subject to both TSCA and REACH. Efficiency, if nothing else, will demand that the chemical industry adopt practices that comply with both systems. Professor Wirth calls this the “California effect” in his study of the impact that REACH has and will have on US chemicals regulation.²¹⁰

It is no surprise, therefore, that US chemical manufacturers are looking with great interest at REACH’s demands, because they will have to meet them to maintain and expand markets in Europe.²¹¹ The trade press is full of advice in interviews, seminars, and papers, and the US Department of Commerce issues regular advisories and tutorials about compliance. Moreover, to implement REACH, US manufacturers and European regulators will undoubtedly (indeed, already do) rely heavily on data generated for TSCA and other mandatory and voluntary US programs, such as the HPV Challenge. For its part, the European Chemicals Agency sees an opportunity to create in effect a global regulatory community. It already works closely with US and Canadian authorities, and it hopes to establish a “‘world standard’ for chemical assessment and management.”²¹²

Even more fundamentally, the strong commitment to transparency in REACH, plus the Internet as the preferred means of presenting that information, will result in data generated on the east side of the Atlantic being more or less instantly available on the west side (and anywhere else) to virtually anyone who is interested. Indeed, the OECD has already created a website

²⁰⁹ *Commission White Paper*, *supra* note 82, at 4; American Chemistry Council, Industry Statistics, http://www.americanchemistry.com/s_acc; *Commission DG Enterprise and Industry*, *supra* note 115; *Commission Trade Issues, Chemical Sector*, <http://ec.europa.eu/trade/issues/sectoral/industry/chem> (last visited: July 28, 2007).

²¹⁰ David A. Wirth, *The EU’s New Impact on US Environmental Regulation*, 31:2 *Fletcher Forum of World Affairs* 91, 100-106 (2007).

²¹¹ The US government and US industry conducted an unprecedented lobbying effort in Europe to derail or weaken REACH as it was going through the legislative process. Greenpeace article.

²¹² Stephen Gardner, *Toxic Substances: New European Chemicals Head Outlines REACH Implementation Priorities*, 30 *Intl. Env’t. Rep. (BNA)* 931 (Nov. 28, 2007).

called eChemPortal that “provides free public access to information on chemical properties and direct links to collections of information prepared for government chemical review programmes at national, regional, and international levels.”²¹³ And this new knowledge, of course, will be the basis for demands on regulators and other legal action on both sides of the Atlantic.

TSCA was proposed in 1971 and enacted in 1976. It has many strengths, but also suffers from fundamental flaws. It has been ill-used in many ways by the courts, and it has devolved into little more than a forum for voluntary programs. TSCA is overdue for reform. The REACH approach, on the other hand, was conceived in 2001 with the TSCA experience very much in mind. And now, to complete the circle, TSCA is being reexamined by a newly receptive Congress. It is to be hoped that Congress will look to REACH for ideas, and that it can find in TSCA and REACH a synthesis of general principles and specific techniques that will assist it promptly to revise TSCA to be the effective protector of human health and the environment that was envisioned over three decades ago.

²¹³ Organization for Economic Co-operation and Development, eChemPortal and other databases for the Investigation of Existing Chemicals, <http://webnet3.oecd.org.echemportal/> (last visited July 5, 2007).