

# Better Safe Than Sorry: A Precautionary Toxic Substances Control Act Reform Proposal

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## INTRODUCTION

It may come as a surprise to most that the majority of the chemicals used in everyday consumer products are largely untested and loosely regulated. Yet many of these chemicals are suspected of causing substantial health and environmental problems.<sup>1</sup> In 2011, the Natural Resources Defense Council (NRDC) released an issue paper on disease clusters in the United States.<sup>2</sup> The paper documented the phenomenon of unusually large groups of people afflicted with certain diseases in a

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1. See Nicholas Kristof, Op-Ed., *How Chemicals Affect Us*, N.Y. TIMES (May 2, 2012), [http://www.nytimes.com/2012/05/03/opinion/kristof-how-chemicals-change-us.html?\\_r=0](http://www.nytimes.com/2012/05/03/opinion/kristof-how-chemicals-change-us.html?_r=0) (noting the growing presence of endocrine-disrupting chemicals in the environment, which are suspected of causing breast cancer, infertility, low sperm counts, genital deformities, early menstruation, diabetes, and obesity); see also *infra* note 2, at 1823–24; Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1823–24 (2009) (“[M]ore than 82,000 synthetic chemicals have been introduced into commerce in the United States, and we produce or import over 73 billion pounds of chemicals per day. More than 100,000 chemicals have been introduced in the EU. Human intake of chemicals is widespread. Recent biomonitoring studies, which analyze chemical contaminants in human tissue samples, have confirmed that synthetic chemicals are ubiquitous in the human body. Industrial chemicals have been identified in the umbilical cord blood of developing fetuses and in human breast milk. Chemicals once thought to be safely contained in products, such as perfluorinated compounds used in textiles, cookware, and food packaging, are now present in virtually all people. And while exposure does not equal harm, detailed toxicity data that could connect exposure and harm has been scarce.”).

2. KATHLEEN NAVARRO ET AL., NAT. RES. DEF. COUNCIL, HEALTH ALERT: DISEASE CLUSTERS SPOTLIGHT THE NEED TO PROTECT PEOPLE FROM TOXIC CHEMICALS (2011), available at [http://www.nrdc.org/health/diseaseclusters/files/diseaseclusters\\_issue\\_paper.pdf](http://www.nrdc.org/health/diseaseclusters/files/diseaseclusters_issue_paper.pdf).

circumscribed place and time.<sup>3</sup> These heightened incidences of birth defects, cancer, and chronic illness have been linked to the presence of various toxic chemicals in the environment and consumer products.<sup>4</sup> These findings become even more shocking when considering events such as the 2014 Elk River chemical spill in West Virginia, where state officials could not find any meaningful safety data on the chemical that contaminated drinking water for hundreds of thousands of people.<sup>5</sup> With the increasing attention that is being paid to the common appearance of synthetic chemicals—namely, endocrine disruptors—permanently stored in our bodies, we are just beginning to understand the biological effects of these chemicals.<sup>6</sup> At the heart of this problem is the failure of America’s primary regulatory safeguard against harmful chemical exposure: the Toxic Substances Control Act (“TSCA”).<sup>7</sup>

This Note argues that (1) that the current US chemical regulatory system should be replaced with a regulatory scheme founded on the strong precautionary principle, which places the burden on chemical manufacturers to affirmatively prove the safety of their chemicals;<sup>8</sup> (2) that such a scheme will lower the

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3. *Id.*

4. *Id.*

5. Pat Rizzuto, *Data Deficit on Elk River Chemicals Shows Need for TSCA Reform, Legislators Say*, BLOOMBERG NEWS (Feb. 5, 2014), <http://www.bna.com/data-deficit-elk-n17179881899/>. In early January 2014, 4-methylcyclohexane methanol (MCHM) leaked into the Elk River in West Virginia, contaminating the drinking water supply for hundreds of thousands of West Virginians. *Id.* Subcommittee hearings on the topic led to calls for the reform of sections 4 and 8 of TSCA. *Id.*

6. See *supra* text accompanying note 1; see also Valerie J. Watnick, *Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals As A Case In Point*, 2004 UTAH L. REV. 1305, 1307–10 (2004); THEO COLBORN ET AL., *OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL?—A SCIENTIFIC DETECTIVE STORY* 106 (1996) (“Virtually anyone willing to put up the \$2,000 for the tests will find at least 250 chemical contaminants in his or her body fat, regardless of whether he or she lives in Gary, Indiana, or on a remote island in the South Pacific.”).

7. 15 U.S.C. §§ 2601–2692; see generally Applegate, *infra* note 8 and accompanying text; see also *infra* note 16 and accompanying text.

8. For other scholarship recommending this approach, see generally Noah Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 11 U. ILL. L. REV. 1285 (2011) (embracing the strong precautionary principle as a cornerstone for harm prevention in regulatory regimes, including chemical regulation); John S. Applegate,

demand for chemical safety information needed for regulation while incentivizing data production;<sup>9</sup> (3) that this information must be transparent and publicly available for peer-review;<sup>10</sup> (4) that there must be an administrative appeals process for challenging chemical safety decisions; and (5) that the entire scheme must acknowledge both the realities of data shortage and the significant demands that these requirements place on the chemical manufacturing industry.

Part I of this Note briefly discusses the current US chemical regulatory scheme, TSCA, and its shortcomings, while comparing it with Europe's chemical regulatory system—Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Part II discusses the importance of two cornerstone regulatory components in reforming TSCA: a *strong precautionary principle* and mechanisms to close the *data gap*. Part III advocates for a new chemical regulatory system built on the strong precautionary principle as a framework for permitting chemical manufacturing. It also advocates for prioritizing information generation, reducing the information demands of the regulatory system, and maintaining a publicly accessible chemical database. Part III also emphasizes the importance of

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*Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 *ECOLOGY L.Q.* 721, 747 (2008) (comparing TSCA and the European Union's chemical regime, REACH, and describing the desirable traits of REACH that could be adopted by a reformed TSCA, including placing an emphasis on harm prevention, shifting the burden of proving chemical safety to producers, and reducing the data gap).

9. See generally John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 *TEX. L. REV.* 1365 (2008) (discussing the various forms of risk-based regulation and the underlying assumptions of those regulatory schemes, and advocating for chemical safety data production in order to allow risk-based regulation to properly function).

10. Creating publicly accessible clearinghouses for chemical data is a frequent recommendation of chemical regulation reform advocates. See, e.g., Richard A. Denison, *Ten Essential Elements in TSCA Reform*, 39 *ENVTL. L. REP.* 10020, 10026 (2009) (advocating for the establishment of a publicly-accessible, transparent database of industry-generated safety data, among other things); Applegate, *supra* note 8, at 766; see also CAL. DEP'T OF SUBSTANCE CONTROL, CALIFORNIA GREEN CHEMISTRY INITIATIVE FINAL REPORT 27 (2008), available at [http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiatGre/upload/GREEN\\_Chem.pdf](http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiatGre/upload/GREEN_Chem.pdf) (California's Green Chemistry Initiative is a recent example of a new chemical regulatory system at the State level which mandates the creation of an online clearinghouse for chemical safety data).

having a flexible appeals system and realistic policy goals given the realities and limitations of chemical testing and industrial adaptation. While this Note does not purport to specify the exact parameters of a new chemical regulatory system, it does assert a number of important principles that should form the foundation of a new system.

## I. A PRIMER ON CHEMICAL REGULATION

### A. *The History and Failures of TSCA*

In 1971, the Council on Environmental Quality (CEQ) released a report entitled “Toxic Substances.”<sup>11</sup> The report detailed the need for toxic chemical regulation and became a basis for enacting TSCA.<sup>12</sup> The report noted that (1) toxic substances are entering the environment; (2) these substances can have severe effects; (3) existing legal authorities are inadequate; and (4) new legal authority is required.<sup>13</sup> In response, TSCA was enacted in 1976 “to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards.”<sup>14</sup> Under TSCA, once the Environmental Protection Agency (EPA) finds an “unreasonable risk” to human health or the environment, the agency can impose a wide variety of regulations on the

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11. COUNCIL ON ENVTL. QUALITY, TOXIC SUBSTANCES 105 (1971), available at [http://digitool.library.colostate.edu//exlibris/dtl/d3\\_1/apache\\_media/L2V4bGlicmlzL2R0bC9kM18xL2FwYWNoZV9tZWZpYS8yMjExODQ=.pdf](http://digitool.library.colostate.edu//exlibris/dtl/d3_1/apache_media/L2V4bGlicmlzL2R0bC9kM18xL2FwYWNoZV9tZWZpYS8yMjExODQ=.pdf).

12. *Id.*

13. *Id.* at 105–06.

14. 15 U.S.C. § 2601(b) (2006). After TSCA’s enactment, the CEQ explained its vision for TSCA’s system of regulation. “Manufacturers must give notice of plans to produce a new chemical or to market a significant new use for an old chemical. Producers may also be required to test selected chemicals or to report production quantities, uses, physical, chemical, and biological properties, and other information necessary for hazard assessment. In addition, the law requires recordkeeping and disclosure of significant health effects of dangerous chemicals.” COUNCIL ON ENVTL. QUALITY, ENVIRONMENTAL QUALITY: THE EIGHTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 5 (1977).

chemical.<sup>15</sup> While this system may seem prudent on its face, in practice, the scheme is severely undermined. In fact, as early as 1980, the General Accounting Office (GAO) stated that “neither the public nor the environment are much better protected” under TSCA than without it.<sup>16</sup>

First, TSCA gives new and existing chemicals a “strong presumption of innocence.”<sup>17</sup> Under this presumption, the EPA must affirmatively find that a chemical presents an unreasonable risk to human health or the environment before regulating it.<sup>18</sup> A number of studies, however, have shown that an affirmative requirement to show unreasonable risk is problematic.<sup>19</sup> Several governmental and non-governmental organization studies have revealed that toxicity data, which is required to show that a risk exists, is lacking, even for widely used chemicals.<sup>20</sup>

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15. TSCA’s functionality and regulation mechanisms are laid out in subsection (a) of 15 U.S.C. § 2605. Subsection (a) reads:

If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements. . . .

15 U.S.C. § 2605 (2012). Once the EPA Administrator makes a finding of unreasonable risk, the Administrator may propose a wide number of regulatory requirements including prohibitions, limitations, and labeling requirements. 15 U.S.C. § 2605(a).

16. See Charles Franklin, *TSCA Reform Versus Replacement: Moving Forward in the Chemical Control Debate*, 44 ABA TRENDS 9, 10 (2013) (quoting the GAO’s analysis of TSCA’s failures and explaining multiple factors for the failure of TSCA including staffing and budget shortfalls).

17. For a discussion of this presumption of innocence and its effects on TSCA’s functionality, see Denison, *supra* note 10.

18. 15 U.S.C. §§ 2601(b)(2), 2604(a).

19. See *supra* Applegate note 8; Denison, note 10; *infra* note 107.

20. See *infra* notes 115–19. A particularly revealing quote by a Senior Environmental Defense attorney, David Roe, illustrates the situation: “In 1997–98, however, the assumption that we have any real grasp of which chemicals are toxics was definitively shattered . . . . The studies’ [conducted by Environmental Defense, EPA, and the Chemical Manufacturers Association] implications were acutely unsettling: in a regulatory system that depends on identifying target chemicals before regulating them, less than 10% of the largest potential targets had been properly scanned for toxic effects.” David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 ECOLOGY L.Q. 623, 627–28 (2002).

Second, TSCA requires a showing that a chemical poses an unreasonable risk to health and the environment before mandatory action can be taken.<sup>21</sup> This standard has become nearly unattainable under current judicial interpretation.<sup>22</sup> In addition, any calculation of unreasonable risk by the EPA must consider the economic costs of regulating the chemical, the impact of regulation on small businesses and chemical development, any alternatives to the chemical, and the social benefits of the chemical.<sup>23</sup> The EPA must also demonstrate that the form of regulation proposed for the chemical is the least burdensome option and that no other federal statute can be used to regulate the chemical.<sup>24</sup>

In conjunction with the presumption of innocence for chemicals, the complexity and stringent requirements of the unreasonable risk standard makes mandatory chemical regulation under TSCA a difficult task. TSCA's "substantial evidence"

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21. 15 U.S.C. §§ 2601(b)(2), 2604(a).

22. See *infra* notes 104–07 and accompanying text; see also Applegate, *supra* note 8, at 736–37 (2008) (describing the unattainable interpretation of the unreasonable risk standard).

23. Subsection (c) of § 2605 reads,

(1) In promulgating any rule under subsection (a) of this section with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture, (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture, (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and (D) 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.

15 U.S.C. §2605(c)(1) (2012). See also Denison, *supra* note 10, at 10021–22. Environmental scholar Richard A. Denison notes that “[t]he result of [this regime] is a blurring together of what should be two distinct questions: Does a chemical pose a significant risk? If so, what should be done about it?” *Id.* at 10022. Denison explains that “TSCA precludes EPA from identifying a chemical that poses a significant risk unless it can also demonstrate that the risk could be or is *unreasonable*.” *Id.* “In what amounts to a classic Catch-22, government must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require the development of information sufficient to determine whether there is actual risk.” (emphasis in original). *Id.* at 10020.

24. See 15 U.S.C. § 2608 (2012).

requirement for sustaining EPA action upon judicial review, instead of the more common and deferential “arbitrary and capricious” standard, is a further barrier to effective regulation.<sup>25</sup> Perhaps unsurprisingly, the unreasonable risk burden “is so high that in the 32 years since TSCA was enacted, the EPA has required testing for only about 200 chemicals.”<sup>26</sup> The result of this scheme has been far from the vision depicted by the statute’s authors.<sup>27</sup>

### *B. The History and Practice of the European Approach, REACH*

#### 1. The Provisions of REACH Generally

In 2006, the European Union enacted its own chemical regulation regime called REACH.<sup>28</sup> Taking cues from the failures of TSCA, REACH regulates chemicals by placing an affirmative burden to prove chemical safety on chemical

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25. See 15 U.S.C. § 2618 (2012); see also Franklin, *supra* note 16, at 4.

26. Denison, *supra* note 10, at 10020; see also ENVTL. PROTECTION AGENCY, OVERVIEW: OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS 4 (2007), available at <http://www.epa.gov/oppt/pubs/oppt101c2.pdf>.

27. See Sachs, *supra* note 1, at 1818. Noah Sachs, an environmental law professor at Richmond University School of Law, has discussed this failure at length. Sachs notes that “[TSCA] lacks the sharp regulatory bite of most U.S. environmental laws. Virtually every expert panel that has examined the U.S. system of chemical regulation has concluded that it inadequately protects public health and the environment. Yet despite a chorus of criticism and growing concern over the health effects of chemical exposure, TSCA has been remarkably resistant to reform. It is among the weakest, and the least amended, of all of the federal environmental statutes.” *Id.*

28. Commission Regulation 1907/2006, 2006 O.J. (L 136) 3 [referred to in this article as REACH]. The EU’s website for the REACH program describes the EU’s goals and rationale for the program: “One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there is insufficient information on the hazards that they pose to human health and the environment. There is a need to fill these information gaps to ensure that industry is able to assess hazards and risks of the substances, and to identify and implement the risk management measures to protect humans and the environment.” *What is REACH?*, EUROPEAN COMMISSION (last visited May 6, 2014), [http://ec.europa.eu/environment/chemicals/reach/reach\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/reach_en.htm). Clearly, the motivations for REACH seem much the same as those for TSCA. But REACH operates by using a much more effective regulatory mechanism.

manufacturers.<sup>29</sup> REACH requires that “chemical risks should be controlled, eliminated, mitigated, or justified by their creators.”<sup>30</sup> Instead of a presumption of innocence for unknown or new chemicals, REACH requires firms to test the safety of all chemicals in use for which there is insufficient toxicity information.<sup>31</sup> REACH also requires minimum toxicity data for old and new chemicals, and aims to build the largest toxicity data bank in history.<sup>32</sup> These components are supported by REACH’s “No Data, No Market” principle—if a company fails to submit the required chemical testing and registration data designated by REACH, it is denied access to the EU’s now \$558 billion chemical market.<sup>33</sup>

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29. See Sachs, *supra* note 1, at 1821. “REACH, in contrast to TSCA, frames incentives in favor of research and disclosure by making the provision of toxicity data a condition of access to the \$537 billion European chemical market—the largest in the world. REACH also shifts certain burdens of proof from government to industry, makes some hazardous chemicals subject to government authorization, and focuses systematically on identifying and promoting safer substitutes for hazardous chemicals.” *Id.* Sachs also notes the influence of REACH beyond the borders of the EU, an effect called the “California effect.” *Id.* at 1850–51. “While REACH still faces significant challenges, this next-generation chemical regulation is likely to increase, at reasonable cost, protections for public health and the environment relative to U.S. law.” *Id.* at 1822. See also Andrew Austin, *Out of Reach? Effects of the EU’s New Chemicals Regime*, 49 No. 12 DRI FOR DEF. 64 (2007) (discussing the requirements of REACH and positing that “REACH is the most comprehensive chemicals regime in the world, and is likely to be one of the most burdensome with which to comply.”).

30. See Applegate, *supra* note 8, at 746.

31. See EUROPEAN COMMISSION, *supra* note 28. The European Union’s website for the REACH program also notes that “[m]anufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency (ECHA) in Helsinki.” *Id.*

32. See EUROPEAN COMM’N ENV’T DIRECTORATE GENERAL, REACH IN BRIEF 6-16 (2007), available at <http://www.hse.gov.uk/reach/resources/inbrief.pdf> [hereinafter REACH IN BRIEF]; see also ECHEMPORAL, <http://www.echemportal.org/echemportal/substancesearch/page.action?pageID=1> (last visited Feb. 18, 2014) (current chemical database that the European Union maintains, now linked to many other such databases); ESIS: *European Chemical Substances Information System*, EUROPEAN COMM’N JOINT RESEARCH CTR. INST. FOR HEALTH AND CONSUMER PROT., <http://esis.jrc.ec.europa.eu> (last visited Feb. 18, 2014) (current chemical database for the European Union Chemicals Bureau).

33. See REACH, *supra* note 28 at Art. 5. See also THE EUROPEAN CHEM. INDUS. COUNCIL (CEFIC), *The European Chemical Industry, Facts & Figures 2013* (Jan. 2014), available at <http://asp.zone-secure.net/v2/index.jsp?id=598/765/42548>; Sachs, *supra* note 1, at 1835. Sachs notes that “The ‘No Data, No Market’ principle is already making



REACH administers these components through its registration and authorization processes.<sup>34</sup> Unlike TSCA, REACH identifies chemicals of concern and gives them a deadline to register for authorization and proof of safety.<sup>35</sup> After this initial step, REACH allows manufacturers to justify their chemicals' use in the authorization stage and meet their affirmative burden of proving safe use.<sup>36</sup> For instance, REACH gives so-called chemicals of "very high concern" (VHCs) an effective deadline (a "sunset date") by which they must be removed from the European market unless they receive government authorization.<sup>37</sup> These chemicals can be authorized "if the applicant can demonstrate that the risk from the use of the substance is adequately controlled."<sup>38</sup> The chemical manufacturing industry may receive time extensions for these deadlines if they show (1) that the social and economic benefits of the chemical outweigh the risks they pose, and (2) that there is no suitable substitute for the chemical.<sup>39</sup> Through this process,

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toxicity testing a routine part of doing business in Europe, rather than the exception, as it is in the United States. Firms have an incentive to generate the toxicity data that will allow their products to undergo registration as quickly as possible. The system rewards knowledge, rather than ignorance." *Id.*

34. See REACH, L 136 at Arts. 5–7. See also REACH IN BRIEF, *supra* note 32, at 6–13.

35. For an overview of the registration and authorization timeline imposed by REACH, see EUROPEAN CHEMS. AGENCY, GUIDANCE ON REGISTRATION 48–50 (2012), available at [https://echa.europa.eu/documents/10162/13632/registration\\_en.pdf](https://echa.europa.eu/documents/10162/13632/registration_en.pdf).

36. For an overview of the authorization process, see *Authorisation*, EUROPEAN CHEMS. AGENCY, <http://echa.europa.eu/regulations/reach/authorization> (last visited June 8, 2014).

37. See REACH IN BRIEF, *supra* note 32, at 12–13. See also Sachs, *supra* note 1, at 1837–38. Chemicals of "very high concern" ("VHC's") include carcinogens, chemicals that cause birth defects and genetic mutations, and chemicals that are bioaccumulative and remain in the environment for sustained periods of time. REACH, L 136 at Art. 57. The language of REACH, art. 57 explains these VHC's include "[c]arcinogenic, mutagenic, or reprotoxic substances". REACH, L 136 at Art. 57. See also REACH IN BRIEF, *supra* note 32, at 18 (stating REACH authorization approval and revocation procedures and defining chemicals of "very high concern").

38. REACH IN BRIEF, *supra* note 32, at 13.

39. See REACH, L 136 at Art. 60(4). The substitution component of REACH authorization is important and aims to "ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available." *Id.* at para. 12. In line with this goal, the chemical authorization process requires manufacturers of VHC's to

REACH ensures that chemical risks are known and accounted for before those chemicals find their way into the market.

## 2. Risk Disclosure Under REACH

REACH also increases chemical safety awareness among downstream chemical users (e.g., common consumers and producers using chemicals in their manufacturing processes) by requiring that chemical manufacturers (1) disclose who their downstream users are; (2) notify them of the risks posed by each chemical they provide; and (3) identify chemical management techniques.<sup>40</sup> In addition, downstream users of chemicals may only use them for purposes approved by the government in the authorization process.<sup>41</sup> Downstream users must report any hazards they discover in using the chemicals to the manufacturer and notify the manufacturer if their risk management guidelines are inadequate.<sup>42</sup> REACH also contains significant provisions for disclosing chemical safety information to the public. Unlike TSCA, REACH creates an online database of chemical toxicity information for the public.<sup>43</sup> In addition, REACH allows consumers to demand safety information from chemical suppliers.<sup>44</sup> In many ways, REACH provides a useful model for future chemical regulatory systems. In particular, REACH demonstrates the benefits of incorporating the “precautionary

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prepare analyses that consider alternative substitutes for the VHC chemical, the risks of their use, and the feasibility of using them as substitutes. *Id.* at Art. 62(4)(e). If a feasible substitute is found, the European Commission will consider the benefits of the substitute and can mandate that the substitute be used. *Id.* at Art. 62(4)(f), 60(5)(a). *See also* REACH IN BRIEF, *supra* note 32, at 8 (noting that “the increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.”). This system of checking for substitutes and using them if they are available is a key component of REACH’s promotion of the safest possible chemicals in the European Market, to the exclusion of VHC’s wherever possible.

40. *See* REACH, arts. 31–32.

41. *See* REACH IN BRIEF, *supra* note 32, at 11.

42. *See* REACH, art. 37.

43. *See* REACH IN BRIEF, *supra* note 32, at 15; *see also* REACH, art. 77(2)(e).

44. *See* REACH, art. 33. These requests must be fulfilled by product suppliers if they contain more than 0.1% by weight of any substance that has undergone the REACH authorization process. *Id.*

principle,” chemical data generation, public access and transparency, and staggered implementation into a chemical regulatory scheme.

## II. THE TWO CORNERSTONE ELEMENTS OF U.S. CHEMICAL REFORM

Chemical regulatory reform is a realistic possibility. As demonstrated by recent developments in the Senate, including the late Senator Frank Lautenberg (D-RI) and Senator David Vitter’s (R-LA) efforts to champion chemical reform. The primary blueprint for TSCA reform that currently has the most political traction in Congress is the Chemical Safety Improvement Act (CSIA), introduced by Senators Lautenberg and Vitter.<sup>45</sup> In many ways, the CSIA represents a compromise between industry, environmentalists, consumer-protection advocates, and regulators.<sup>46</sup> The general consensus is that the CSIA represents the best chance of reforming TSCA in the 37 years since TSCA’s enactment.<sup>47</sup> Still, there are significant disagreements over how a new regulatory scheme should be

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45. S. 1009, 113th Cong. § 1 (2013), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113s1009is/pdf/BILLS-113s1009is.pdf>; see *The Chemical Safety Improvement Act: Hearing on S. 1009 Before the Subcomm. on Environment and the Economy of the H. Comm. on Energy and Commerce*, 113th Cong. (2013) (statements of Sen. Frank Lautenberg and Sen. David Vitter), available at <http://energycommerce.house.gov/hearing/s-1009-chemical-safety-improvement-act>.

46. See *Chemicals Policy Reform*, ENVIRONMENTAL DEFENSE FUND, <http://www.edf.org/health/policy/chemicals-policy-reform> (last accessed June 8, 2015) (referring to the CSIA as a “compromise bill” with strengths and weaknesses and suggesting possible improvements to the bill); see also *The Chemical Safety Improvement Act: An In-Depth Review and Analysis*, BERGESON & CAMPBELL, P.C., <http://www.lawbc.com/regulatory-developments/entry/the-chemical-safety-improvement-act-an-in-depth-review-and-analysis/> (last visited June 8, 2014) (describing the substantive changes the CSIA would make to TSCA including in the areas of chemical testing and regulatory thresholds).

47. See *Chemicals Policy Reform*, *supra* note 46; see also “ACC to Congress: It’s Time to Update TSCA, Pass the Chemical Safety Improvement Act (CSIA)”, AMERICAN CHEMISTRY COUNCIL, <http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-to-Congress-Its-Time-to-Update-TSCA-Pass-the-Chemical-Safety-Improvement-Act-CSIA.html> (last accessed June 8, 2014) (noting the historic bipartisan support for the bill and compromises made in the bill).

constructed and operated.<sup>48</sup> Despite marked progress, the specifics of the next US chemical regulatory system—if one is indeed created—remain unclear.

This Note focuses on five essential components of a new and effective chemical regulatory system. These components are (1) a “strong precautionary principle”; (2) prioritizing data generation while reducing demands for chemical data; (3) public transparency; (4) a flexible appeals process for industry; and (5) sensible acknowledgement of the realities and regulatory demands of chemical testing. Two of these components—the “strong precautionary principle” and closing the “data gap” by increasing chemical data supply while reducing data demand—should form the foundation of a new proposed regime.

#### *A. Embracing the “Strong Precautionary Principle”*

The precautionary principle is a cornerstone element of many international regulatory regimes, including REACH. As applied, the principle generally holds that the regulation of anticipated risks from a chemical should be allowed to proceed even in the face of scientific uncertainty. There are two interpretations of the principle—the “weak” and “strong” precautionary principles.<sup>49</sup> The “weak” version was most famously defined in the United Nations 1992 Rio Declaration, which held that “[w]here there are

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48. One of the most significant CSIA debates involves preemption. As noted, California has enacted the Green Chemistry Initiative, which places significant regulations on chemicals sold in California and—by virtue of its market share—the greater United States. See CALIFORNIA GREEN CHEMISTRY INITIATIVE FINAL REPORT, *supra* note 10. Industry advocates want a new federal chemical scheme to preempt any current State regulations, which could be more stringent than the regulations imposed under the CSIA. See “Panelists at Hearing Express Optimism that a Compromise on TSCA Modernization can be Reached but Substantial Policy Differences Remain”, MCKENNA, LONG & ALDRIDGE, <http://www.mckennalong.com/publications-advisories-3447.html> (last visited June 8, 2014) (describing divisions in support regarding CSIA preemption). This proposition is unpopular with the Senate’s Environment and Public Works Committee Chair, Senator Barbara Boxer (D-CA). See *Strengthening Public Health Protections by Addressing Toxic Chemicals Threats: Hearing Before the S. Comm. on Environment and Public Works*, 113th Cong. (2013) (statement of Sen. Barbara Boxer), available at [http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement\\_ID=c5097f2c-aeed-469c-8f19-f6c741efa550](http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement_ID=c5097f2c-aeed-469c-8f19-f6c741efa550).

49. See generally Sachs, *supra* note 8.

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.”<sup>50</sup> This version is considered “weak” because it is permissive and doesn’t require that any precautionary actions actually be taken by the government. Because of this, critics of the “weak” principle often describe it as a mere truism.<sup>51</sup> On the other hand, the “strong precautionary principle” holds that some regulation should *automatically* be undertaken in the face of serious risks, despite scientific uncertainty.<sup>52</sup> In conjunction, the “strong” principle places a burden on the proponent of the risky activity to prove that the risks are reasonable and justified.<sup>53</sup> The drug

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50. United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3-14, 1992, *Rio Declaration on Environment and Development*, princ. 15, U.N. Doc. A/CONF.151/5/Rev.1 (June 14, 1992), reprinted in 31 I.L.M. 874, 879 (1992).

51. Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1016 (Jan. 2003) (“The weak versions of the precautionary principle state a truism, one that is uncontroversial and necessary only to combat public confusion or the self-interested claims of private groups demanding unambiguous evidence of harm, which no rational society requires.”); see also Edward Soule, *Assessing the Precautionary Principle*, 14 PUB. AFF. Q. 309, 315 (2000).

52. According to Sachs, “the Strong Precautionary Principle suggests that some precautionary regulation should be a *default response* to serious risks under conditions of scientific uncertainty.” Sachs, *supra* note 8, at 1295. Regulation can cover a wide spectrum of responses—from labeling to use restrictions to outright bans. *Id.* See also Sunstein, *supra* note 51, at 1018 (“[The Strong Precautionary Principle suggests] that regulation is required whenever there is a possible risk to health, safety, or the environment, even if the supporting evidence is speculative and even if the economic costs of regulation are high.”); WINGSPREAD STATEMENT ON THE PRECAUTIONARY PRINCIPLE, PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 353–54 (Carolyn Raffensperger & Joel A. Tickner eds., 1999) (a document supportive of a strong precautionary principle adopted in 1998 that reads, “[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public should bear the burden of proof.”). As Sachs points out, while the Wingspread Statement is useful in understanding “strong precaution”, the Statement uses an unbounded definition of “threats.” See Sachs, *supra* note 8, at 1296. This means that in practice, the Wingspread Statement calls for the regulation of almost every activity—even trivial ones. Instead, as Sach’s points out, only “serious” threats should be regulated under “strong precaution” in order to prevent against congestion of the regulatory system with trivial “threats.” *Id.*

53. See Justin Wade, *Sunstein’s Blunder; Or, The Perils of Reconstructing Precaution*, 20 GEO. INT’L ENVTL. L. REV. 473, 485 (2008) (“Whereas the weak Precautionary Principle operates temporally by allowing action before full certainty, the

approval process of the Federal Drug Administration (FDA), which is detailed later in this Note, is an example of the “strong precautionary principle” in action.<sup>54</sup>

The “strong precautionary principle” does not prescribe any particular regulatory response in the face of serious risk.<sup>55</sup> Instead, the principle simply establishes a norm for regulatory decision-making.<sup>56</sup> There may, of course, be considerable variance in a government’s definition of “serious risk” and the default regulations imposed under a strong precautionary scheme.<sup>57</sup> Regardless, a strong precautionary scheme positions government as a preventative “gatekeeper” that forces the risk creator to justify the risk created.<sup>58</sup>

The “strong” version of the precautionary principle has been significantly criticized.<sup>59</sup> Some critics contend that strong precaution stifles technological growth and paralyzes regulators.<sup>60</sup> Critics also claim that the principle requires manufacturers to show “zero risk” from their activities—an unfeasible requirement.<sup>61</sup> In fact, critics cast the strong version of the principle as prohibiting *any amount* of activity that carries risk.<sup>62</sup> Instead of strong precaution, many critics call for cost-

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‘strong’ Precautionary Principle can be thought of in burden-shifting terms: a plausibly risky technology, such as genetic engineering, is considered presumptively unsafe until the manufacturer can *prove* the extent of the risk the technology poses to human or environmental health.”)

54. *See infra* note 95.

55. *See* Sachs, *supra* note 8, at 1293–94.

56. *Id.* at 1295.

57. *Id.* at 1298; *see also* REACH IN BRIEF, *supra* note 32, at 4–6 (describing different default regulatory responses for “very high concern” chemicals versus others not classified as such).

58. *See* Sachs, *supra* note 8, at 1298.

59. *Id.* at 1299; *see also* Sunstein, *supra* note 51, at 1018–20; Cross, *infra* note 60.

60. *See* Sunstein, *supra* note 51, at 1020; *see also* Frank B. Cross, Paradoxical Perils of the Precautionary Principle, 53 WASH. & LEE L. REV. 851 (1996) (generally criticizing the precautionary principle as stifling technological development and regulatory action).

61. *See* Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European “Fashion” Export The United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 517 (2008).

62. *See id.*

benefit or risk analysis by the government for each regulatory decision.<sup>63</sup>

Some criticism of the “precautionary principle” deserves attention.<sup>64</sup> These arguments are that: (1) the precautionary principle causes “opportunity benefits” to be lost;<sup>65</sup> (2) the precautionary principle structurally reinforces the problematic tendency to neglect the probability of a negative event’s occurrence and protect against that event without regard to the side effects of regulation;<sup>66</sup> and (3) the strong version of the precautionary principle paralyzes scientific and technological development.<sup>67</sup> Cass Sunstein’s article—*Beyond the Precautionary Principle*—does a thorough job of explaining these arguments.<sup>68</sup>

First, Sunstein argues that in some cases “regulation eliminates the ‘opportunity benefits’ of a process or activity, and thus causes preventable deaths.”<sup>69</sup> Sunstein points to “drug lag”—caused by our highly precautionary approach to approving drugs only after testing has proved safety—as an example of this.<sup>70</sup> Sunstein argues that this precautionary approach may protect people by demanding extensive drug testing, but it simultaneously prevents people from receiving the benefits of

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63. See Sunstein, *supra* note 51, at 1056–57. Valerie Watnick offers an interesting response—using endocrine disrupting chemicals as an example—to critics of the precautionary principle who instead argue for solely risk-based chemical regulation. See generally Watnick, *supra* note 6.

64. Cass Sunstein’s *Beyond the Precautionary Principle* provides a thorough collection of arguments against the precautionary principle and accounting of why—in his opinion—the principle seems so appealing. See generally Sunstein, *supra* note 51. Grappling with the entirety of Professor Sunstein’s paper is outside of the scope of this Note, but, I have tried to select and address a few of his points.

65. See Sunstein, *supra* note 51, at 1023.

66. See *id.* at 1010, 1036–54.

67. See *id.* at 1020–29.

68. See Sunstein *supra* note 51. Sunstein’s article opposing the strong precautionary principle is one of the most thorough that I have read and serves as an excellent catalog of many criticisms of the principle. But, Sunstein’s criticism of the strong precautionary principle can also be used to ensure that a precautionary chemical regime is effective while guarding against the evils of which he speaks. For more criticism of the precautionary principle, see *supra* notes 60, 61.

69. Sunstein, *supra* note 51, at 1023 (citing AARON WILDAVSKY, *SEARCHING FOR SAFETY* 48–50 (1988)).

70. Sunstein, *supra* note 51, at 1023.

those drugs until they are approved.<sup>71</sup> Sunstein also offers the example of genetically modified organisms (GMOs) in food, which could potentially produce higher yields of cheaper, healthier foods.<sup>72</sup> Sunstein implies that a precautionary approach to the uncertain health effects of GMOs could result in “numerous deaths, and a small probability of many more.”<sup>73</sup>

Second, Sunstein argues that among other things, “probability neglect” and “system neglect” could lead to unwise decision-making in the name of precaution.<sup>74</sup> He argues that our tendency to focus on emotional reactions to possible harms rather than the *probability* of those harms happening distorts effective decision-making—sometimes at considerable expense.<sup>75</sup> Next, he claims that when trying to address a perceived risk, we typically disregard the problems created by addressing the initial risk.<sup>76</sup> In other words, when one set of potentially improbable risks are addressed, we frequently create another set of new risks.<sup>77</sup>

Third, Sunstein argues that the precautionary principle is actually paralyzing as a regulatory scheme because it attempts to prevent all risk despite the fact that risks are inherent in any regulatory decision—including inaction.<sup>78</sup> Sunstein says that “if the precautionary principle is taken in its strongest form, it is offended by regulation as well as by nonregulation.”<sup>79</sup> Sunstein argues that this is true in light of the previous two points: by regulating potentially beneficial and life-saving technologies, we guard against one set of risks, but we also welcome another set of risks.<sup>80</sup> Under this reasoning, if regulation causes harm and lack of regulation causes harm, then the strong precautionary

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71. *Id.*

72. *Id.* at 1023–24.

73. *Id.* at 1023; Sunstein points to Bill Lambrecht, *Dinner at the New Gene Café*, as a general source for this contention and the varied objections to genetic modification. *See generally* BILL LAMBRECHT, *DINNER AT THE NEW GENE CAFÉ* (2001).

74. Sunstein, *supra* note 51, at 1044–54.

75. *Id.* at 1044–49.

76. *Id.* at 1049–54.

77. *Id.*

78. *Id.* at 1020–29.

79. *Id.* at 1024.

80. *See generally id.* at 1023.



principle—a system based on prohibiting the introduction of any new harm into the world—is paralyzing.<sup>81</sup> According to Sunstein, “[t]he precautionary principle appears to offer guidance only because people blind themselves to certain aspects of the risk situation, focusing on a mere subset of the hazards that are at stake.”<sup>82</sup>

These three arguments have merit and deserve attention in the crafting of a strong precautionary chemical regulatory scheme. But in the context of this proposal, these arguments fall short in many respects. As an initial matter, the strong precautionary principle is often cast as far more extreme than it actually is. Strong precaution—as applied by a sensible, realistic regime—does not prohibit all risky activities or require a showing of “zero risk” by the proponent of an activity.<sup>83</sup> Instead, the principle requires that the government establish a tolerable amount of risk allowed for a given activity.<sup>84</sup> If an activity poses more risk than the amount tolerated, then it must face at least *some* regulation as a default. The regulation need not be a blanket prohibition, as many critics imply.<sup>85</sup> The regulation instead could be as simple as usage restrictions, warning labels, or marketing restrictions.<sup>86</sup> With these in place, the burden is squarely on the risk creator to demonstrate that the risks are justified by the benefits.<sup>87</sup> Rather

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81. *Id.*

82. *Id.* at 1054–55.

83. In fact, if complete risk aversion *were* the case, a chemical regulatory system based on this type of principle *would* be paralyzing. The length of time needed to completely study the generational and synergistic effects of a chemical and then deem it to pose “zero risk” would theoretically grind chemical use to a halt for decades. The absurdity of this “straw man” version of the strong precautionary principle is obvious. *See also* Sachs, *supra* note 8, at 1305 (Sunstein and other scholars, however, have consistently criticized the Principle, rejecting it as paralyzing, inflexible, and extreme. However, the Principle does not call for the elimination of all risk, nor does it ignore trade-offs, as Sunstein has alleged. Rather, through burden shifting, the Principle simply requires risk creators to justify the risks they impose on society.).

84. *See* Sunstein, *supra* note 51, at 1054–55.

85. *See id.* at 1014; *cf.* Sachs, *supra* note 8, at 1312.

86. For instance, TSCA allows for a wide variety of regulatory action to be taken, including prohibitions, manufacturing and use limitations, and warning label requirements. *See* 15 U.S.C. § 2605(a).

87. This is the same general framework that occurs in REACH’s handling of VHC’s. *See* REACH IN BRIEF, *supra* note 32, at 12–14.

than forcing the government to abandon “sound science,” “strong precaution” actually encourages industry to develop more scientific data and chemical knowledge.<sup>88</sup>

Against this backdrop, Sunstein’s first argument—that foregone “opportunity benefits” lost by regulation of perceived risk only exchanges one harm for another begins to unravel. With a general lack of knowledge, and in many cases a complete absence of scientific data about chemical harms and benefits, a reasonable analysis of “opportunity benefits” in comparison to costs is impossible.<sup>89</sup> But this is likely what Sunstein would have a chemical regime do.<sup>90</sup> It makes no sense then to err on the side

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88. See Joseph Bast, President, The Heartland Inst., Speech to Responsible Industry for a Sound Environment (RISE): Whatever Happened To Sound Science? (Sept. 5, 2007) (transcript available at [http://heartland.org/sites/all/modules/custom/heartland\\_migration/files/pdfs/22010.pdf](http://heartland.org/sites/all/modules/custom/heartland_migration/files/pdfs/22010.pdf)) (speaking on behalf of the Heartland Institute to a collection of industry leaders decrying the lack of “sound science” and reliance of “junk science” in criticisms of global warming, second hand smoke, and pesticides); cf. Justin Gillis, *Study Affirms Consensus On Climate Change*, N.Y. TIMES, June 22, 2010, <http://green.blogs.nytimes.com/2010/06/22/evidence-for-a-consensus-on-climate-change/> (describing overwhelming consensus among peer-reviewed scientists on anthropogenic climate change); see generally William R.L. Anderegg et al., *Expert Credibility In Climate Change*, PROC. OF THE NAT’L ACAD. OF SCI. (Apr. 9, 2010), <http://www.pnas.org/content/early/2010/06/04/1003187107.full.pdf+html> (describing the scientific consensus regarding climate change).

89. In fact, that is precisely *why* we require extensive testing of drugs and medicines. It is important to note that Sunstein’s main point is not that opportunity benefits are foregone *per se*, but that foregoing those benefits creates a harm just as failing to regulate would. See Sunstein, *supra* note 51, at 1024. As I have explained, the strong precautionary principle is not so overly rigid as to be paralyzed by this “damned if you do, damned if you don’t” reasoning. Instead, I argue that at this stage, we cannot fairly compare these tradeoffs and the principle will help us generate the information to do so. Once we have actual data to use in the comparisons, we will be much better equipped to use and manage chemicals in a way that maximizes their benefits and isolates their harms.

90. In fact, a probable model for chemical regulation under Sunstein’s regime sounds a lot like TSCA. See Sunstein, *supra* note 51, at 1053–54. In discussing pesticide regulation, Sunstein dismisses the precautionary principle “in its most aggressive form” as a bad idea. *Id.* at 1053. Setting aside Sunstein’s overly rigid interpretation of the strong precautionary principle, his alternative regime for pesticide regulation sounds quite familiar. Sunstein says, “it would be far more sensible to adopt a precautionary approach to those pesticides that appear, *on the basis of existing evidence*, to create a significant risk of harm, even if that risk cannot be proved beyond a reasonable doubt.” *Id.* (emphasis added). After acknowledging pesticide regulation to embody the “weak” version of the precautionary principle, Sunstein notes,

of including “opportunity benefits” instead of protecting against potential risks when we have as little data about chemicals as we do. Instead, we should create strong incentives to fill in the gaps in our knowledge until we can make sensible decisions about chemical safety. Adoption of the strong precautionary principle in chemical regulation recognizes this reality

Sunstein’s second argument, however, is very useful in the context of chemical regulation. Sunstein calls attention to our disregard of the actual probability of, and overreaction to, viscerally negative events occurring.<sup>91</sup> This is a valid concern in the context of chemical production. For instance, concern with bioaccumulative chemicals and purported “endocrine disrupting chemicals”—despite our relative ignorance about the *probability* of harm from these chemicals—demonstrates Sunstein’s point.<sup>92</sup> Indeed, this Note—a call for regulatory safeguards against these possible harms—is evidence of such a response. But this is why an information-generating chemical regime is so important, so that future regulatory responses can be tailored to accurate determinations of probable harm. In order to minimize the adverse “systemic” effects that Sunstein warns of, we can lessen the burden of such a scheme using tools like the ones described in Part III of this Note.

These responses also speak to Sunstein’s third argument: that the strong precautionary principle is paralyzing. At present,

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“Even if significant risks can be found, it is also important to identify the risks associated with the substitutes for those pesticides, and to know whether those risks are also to be controlled if they are significant. After assessing the relevant risks, it remains to consider the economic costs of restrictions, *as indeed existing law requires . . .*”

*Id.* (emphasis added, referring to the current TSCA regime). Our experience with TSCA thus far should counsel against this sort of approach. For an extended discussion of the flaws with this risk-based system in the context of chemical regulation, *see generally* Watnick, *supra* note 6.

91. *See* Sunstein, *supra* note 51 at 1044.

92. There is much scientific uncertainty about whether bioaccumulative chemicals or suspected endocrine disruptors are harmful in the first place. *See* Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 290, 300 (1999) (noting the short history of endocrine disruption research and the lack of scientific understanding as to the causal mechanisms of endocrine disruption or some of the effects therefrom).

TSCA's ability to mandatorily regulate chemicals *is* effectively paralyzed.<sup>93</sup> Even if some portions of TSCA were fixed, by lowering the unreasonable risk threshold, TSCA would likely still be paralyzed by our systemic lack of chemical toxicity data. As proposed here, the strong precautionary principle would actually *fix* the current regulatory paralysis. By giving industry a strong incentive to produce chemical safety data, regulators can begin to fill the persistent data gap. In so doing, regulators and the public will finally be able to make sensible judgments as to what chemical risks can be tolerated and managed. Far from paralysis, this regime would actually advance society's understanding of chemical risks and benefits while protecting people in the process.

This is not just theoretical fantasy. The United States already uses the principle effectively in other types of protective regulations.<sup>94</sup> Perhaps the best example of this is the drug review process of the FDA, The Federal Food, Drug, and Cosmetic Act,<sup>95</sup> which presumptively bans the sale of any "drug" in the United States outright.<sup>96</sup> But, the drug can be marketed if the manufacturer proves the drug's safety and effectiveness through investigation, such as clinical trials.<sup>97</sup> In the face of serious threats to human health from untested drugs,<sup>98</sup> the FDA policy

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93. See *supra* text accompanying note 23.

94. See *infra* note 95.

95. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006). The original Food, Drug, and Cosmetic Act of 1938 (Pub. L. No. 75-717, 52 Stat. 1040 (1938)) was notably modified in 1962 (the Kefauver Harris Amendment) using the strong precautionary principle, to prohibit the marketing of any drug without the FDA's express approval.

96. 21 U.S.C. § 355(a).

97. *Id.* § 355(b)-(d); see also Sachs, *supra* note 8, at 1307–08 (discussing this process and the FDA approval process' embracement of the "strong" precautionary principle).

98. For example, consider the untested drug Thalidomide. Thalidomide was marketed as a sleep aid and anti-nausea drug given to expectant mothers to ease symptoms associated with morning sickness. See James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease*, TOXICOLOGICAL SCI, 122, 1 (Apr. 19, 2011), available at <http://toxsci.oxfordjournals.org/content/122/1/1.full.pdf>. Distributed in Britain, Thalidomide was untested and began unexpectedly causing serious birth defects. *Id.* Thalidomide was discontinued in 1962. *Id.* Learning from that experience, the Kefauver Harris Amendment was passed. See Emma

implements a particularly strong precautionary regulation—a complete ban.<sup>99</sup> But this strongly precautionary regime allows the drug manufacturer to overcome the ban by proving safety and effectiveness.<sup>100</sup> Despite the FDA’s strong precautionary regulation, the US pharmaceutical industry remains extremely profitable.<sup>101</sup> The strong precautionary principle hasn’t doomed the pharmaceutical industry. Instead, it has provided invaluable protection for the public.<sup>102</sup> The reasonable logic of the strong precautionary principle and its successful application by the FDA demonstrate its place in a new U.S. chemical regulatory scheme.

### *B. All Demand and No Supply Makes Jack a Dull Boy*

Perhaps TSCA’s biggest flaw is its insatiable appetite for information. As noted earlier, the root of this problem is the TSCA’s unreasonable risk burden of proof.<sup>103</sup> TSCA requires the EPA to produce evidence indicating that a substance presents or will present an unreasonable risk to human and environmental

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Wilkinson, *Thalidomide Survivors to Get £20m*, BBC NEWS (Dec. 23, 2009), <http://news.bbc.co.uk/2/hi/8428838.stm>.

99. See 21 U.S.C. § 355(a).

100. See *id.*; see also Sachs, *supra* note 8, at 1308.

101. See Matthew Herper, *The Best Drug Companies Of All Time*, FORBES (Aug. 3, 2011), <http://www.forbes.com/sites/matthewherper/2011/08/03/the-best-drug-companies-of-all-time/> (illustrating the number of drugs approved by the top drug companies of the last 60 years, including Merck (which produced vaccines for hepatitis B, measles-mumps-and-rubella, meningitis, and pneumonia), Pfizer (which produced Lipitor, Zithromax, and Viagra), and Eli Lilly (which produced Cymbalta, Prozac, and Gemzar), among other household names of Big Pharma). Admittedly, the industry is experiencing many difficulties from problems not attributable directly to the strong precautionary principle. See John LaMattina, *Pharma’s Reputation Continues To Suffer—What Can Be Done To Fix It?*, FORBES (Jan. 18, 2013), <http://www.forbes.com/sites/johnlamattina/2013/01/18/pharmas-reputation-continues-to-suffer-what-can-be-done-to-fix-it/> (these problems include drug affordability, public perceptions of the industry, and a lack of transparency regarding negative clinical trials).

102. See *Legislation*, FOOD AND DRUG ADMIN., <http://www.fda.gov/regulatory-information/legislation/default.htm> (last visited Feb. 10, 2013) (describing the passage of the Federal Food, Drug, and Cosmetic Act after a legally marketed elixir, “Elixir Sulfanilamide”, killed 107 people, including children, and noting that “The Food and Drugs Act of 1906 was the first of more than 200 laws that constitute one of the world’s most comprehensive and effective networks of public health and consumer protections.”).

103. See *supra* text accompanying notes 23, 24, 26.

health before regulation can occur.<sup>104</sup> Unfortunately, courts have interpreted this burden to be so high that the EPA has all but stopped regulating new chemicals under the TSCA.<sup>105</sup>

In *Corrosion Proof Fittings*,<sup>106</sup> the Fifth Circuit remanded the EPA's proposed ban on asbestos—effectively ending EPA regulation of new chemicals under TSCA.<sup>107</sup> The court opined that under TSCA, the more stringent the EPA regulations, the more proof the EPA must provide to justify the regulation.<sup>108</sup> With this in mind, the Court concluded that more than “45,000 pages of analyses, comments, testimony, correspondence, and other materials”<sup>109</sup> documenting the dangers of asbestos was insufficient to justify a complete ban.<sup>110</sup> Highlighting the complexity of TSCA's requirements, the court also took issue with “the manner in which the EPA conducted some of its analysis,” the EPA's failure to prove that an outright ban was the least burdensome alternative in regulating asbestos on a use-by-use basis, and the EPA's failure to assess the risks posed by potential asbestos substitutes.<sup>111</sup> Given the court's stringent interpretation of the “least burdensome alternative” and cost-benefit risk analysis requirements of TSCA, the burden of proof on the EPA became drastically higher than previously thought.<sup>112</sup> The impossibly high burden of proof established in *Corrosion*

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104. See 15 U.S.C. § 2605(a).

105. See *Corrosion Proof Fittings, Inc. v. EPA*, 947 F.2d 1201 (5th Cir. 1991); see also Applegate, *supra* note 8, at 736–37 (2008).

106. 947 F.2d 1201.

107. *Id.* at 1207; See Applegate, *supra* note 8 (describing the halt of mandatory EPA chemical restrictions and the defeat of the EPA's decade-long effort to restrict asbestos); John Kvinge, *Morally Hazardous Chemical Regulations: Why Effective Reform of the TSCA Requires Reduction of the Toxic Data Gap*, 12 MINN. J.L. SCI. & TECH. 313, 320–21 (2011) (describing the effect of *Corrosion Proof Fittings* on EPA attempts to make significant rules limiting chemical manufacturing not supported by industry).

108. *Corrosion Proof Fittings*, 947 F.2d at 1220.

109. Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29460, 29461 (July 12, 1989) (codified at 40 C.F.R. pt. 763) (this record served as the basis for the EPA's final rule).

110. *Corrosion Proof Fittings*, 947 F.2d at 1229–30.

111. *Id.* at 1215–30.

112. See Franklin, *supra* note 16, at 11.

*Proof Fittings* has led the EPA to abandon attempts to pursue mandatory regulations under Section 6 of TSCA.<sup>113</sup>

The stringent standards established in *Corrosion Proof Fittings* run up against the stark reality that little to no safety information exists for most chemicals currently in use.<sup>114</sup> For instance, the National Research Council's 1984 report entitled "Toxicity Testing" found no toxicity data available for more than 80% of all toxic substances in commerce.<sup>115</sup> The report also concluded that only 22% of high production volume (HPV) chemicals even had a minimum safety data set.<sup>116</sup> Not much had changed by 1997, when the Environmental Defense Fund published a study entitled "Toxic Ignorance."<sup>117</sup> The study found baseline "Screening Information Data Sets" available for only 29% of the 100 HPV chemicals they sampled, with the rest of the data being absent or incomplete.<sup>118</sup> Not surprisingly, the persistent "data gap" was one of the major reasons for the European Commission's REACH proposal in 2003.<sup>119</sup>

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113. *See id.* (asserting that the *Corrosion Proof Fittings*' result turned TSCA's mandatory rulemaking authority under section 6 into a "dead letter"); *see also* Dennison, *supra* note 10, at 10020.

114. *See infra* text accompanying notes 115, 117, 119.

115. NAT'L RESEARCH COUNCIL, *Toxicity Testing: Strategies to Determine Needs and Priorities* 12 fig.2 (1984), available at <http://www.nap.edu/openbook.php?isbn=0309034337>.

116. *Id.* at 310.

117. ENVTL. DEF. FUND, *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States* (1997), available at [http://www.environmentaldefense.org/documents/243\\_toxicignorance.pdf](http://www.environmentaldefense.org/documents/243_toxicignorance.pdf).

118. *Id.* at 15 fig.2-1. ("Screening data sets" are chemical safety information sets describing basic safety data pertaining to each chemical tested.)

119. Commission Staff Working Paper, Regulation of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Establishing a European Chemicals Agency and Amending Directive 1999/45/EC and Regulation (EC) [on Persistent Organic Pollutants], Extended Impact Assessment, at 26-27, COM (2003) 644 final (Oct. 29, 2003), [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003\\_1171\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003_1171_en.pdf)

("The availability of qualified monitoring data on environmental concentrations of chemicals is limited, and restricted to persistent organic pollutants (POPs), heavy metals and some pesticides. A joint EEA/European Science Foundation study on European monitoring of chemicals concluded that: 'Monitoring is partial, uncoordinated, sometimes out of date, and, on many occasions, irrelevant to current policy needs; centralised knowledge about chemical monitoring activities that are conducted for different purposes is incomplete;

With a lack of chemical data and a huge demand for information prior to regulation, the EPA has rarely asserted any mandatory chemical regulations under TSCA.<sup>120</sup> This experience shows that a new chemical regulation regime must require significantly less information prior to regulatory decision-making. At the same time, the amount of chemical information available must increase.

### III. ESSENTIAL COMPONENTS OF A NEW CHEMICAL REGIME

With TSCA reform being a realistic possibility in the near term, it is important that legislators consider the elements that have made TSCA such a failure and REACH a relative success. A new regime can improve upon both, but fundamental changes must be made to the US approach to chemical regulation.

First, a new system must regulate proactively, not retroactively. The system must require chemical manufacturers to ask for permission to manufacture safe chemicals, not forgiveness from *ex post facto* harm caused by untested chemicals. This can best be achieved by embracing the “strong precautionary principle” in chemical regulation. Second, chemical data generation must be a primary goal of a new regulatory regime. The regime must be structured to require less chemical safety data prior to regulatory action. The “strong precautionary principle,” data generation incentives for industry, and a lower regulatory burden of proof will help narrow the existing “data gap.” Third, such a scheme must be transparent,

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there is a lack of integrated exposure assessments that consider all relevant exposure routes; [and] there are huge data gaps in information on chemical exposures and impacts, especially concerning vulnerable groups and ecosystems . . .”) (internal citations omitted).

120. See U.S. GOV'T ACCOUNTABILITY OFFICE, *Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act* 10 n.3 (2009), available at <http://www.gao.gov/assets/130/121612.pdf> (explaining the flaws of TSCA and inability to regulate asbestos under TSCA). After all, “if the EPA can’t ban a known carcinogen, at which no level of exposure is safe, how can EPA regulate any toxic substance?” See also *Asbestos: Think Again: Asbestos is Still Not Banned*, ENVTL. WORKING GROUP (Mar. 4, 2004), available at <http://www.ewg.org/research/asbestos-think-again/asbestos-still-not-banned>.



with an easily accessed, publicly available chemical safety database subject to peer review. Fourth, there must also be an administrative appeals process whereby permitting decisions may be challenged. And finally, the scheme must be responsive to the practical realities of data generation and the imposition of new constraints on industry. Standards for acceptable techniques such as “read-across” and staggered phase-in requirements for chemical manufacturing permits can help achieve these goals.

*A. Make Industry Ask For Permission, Not Forgiveness*

A new chemical regulatory scheme must require chemical manufacturers to receive EPA permission *before* producing and selling their products without regulatory obstacles. As evidenced by TSCA’s performance thus far, a scheme that puts the initial regulatory burden on the EPA is ineffective.<sup>121</sup> Scholars have pointed to reasons why this is particularly problematic in the context of chemical regulation.<sup>122</sup> For instance, there is little understanding of the complex mechanisms by which chemicals work and interact in the body, the safe levels of exposure for these chemicals, the synergistic qualities of these chemicals, or their long-term and intergenerational effects.<sup>123</sup> If the EPA lacks an adequate understanding of these critical components, then the EPA cannot possibly determine safe levels of exposure for these chemicals. If a chemical regulatory system is to protect human and environmental health, this information must be obtained somehow. By putting the burden of producing this information on chemical producers, those most equipped and able to produce this information—the chemical industry—have a tremendous incentive to do so.

This type of licensing-based model is used in many major federal environmental statutes, such as the Clean Water Act and

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121. See Denison, *supra* note 10, at 10020. See also Applegate *supra* note 8, at 736–37 (describing difficulty of putting initial burden on EPA); see also Watnick, *supra* note 6, at 1325–26 (explaining the difficulties of this model in the context of EDCs).

122. See, e.g., Watnick article, *supra* note 6, at 1325–26; Sachs *supra* note 8.

123. See Watnick, *supra* note 6, at 1325–26.

the Clean Air Act.<sup>124</sup> In both regimes, environmental and human health is protected by a permitting scheme that generally requires emitters of air pollutants and dischargers of effluent to implement certain safety measures before they can emit or discharge air pollutants and effluent.<sup>125</sup> Both regimes also require safety assurances from the regulated, such as technology-based pollution controls, and define the relevant acceptable safety standards.<sup>126</sup> These schemes offer useful starting points for how a new chemical permitting regime could operate using elements of the precautionary principle.<sup>127</sup> Similarly, the FDA's drug approval process provides a model for using the strong precautionary principle in a licensing scheme.<sup>128</sup> While the activities being regulated are different,<sup>129</sup> this method of regulation could be directly adopted by a new chemical regime.

The central question is how serious the default regulations of a chemical should be under a strong precautionary regime. Based on a more stringent view, the default action could be a presumed prohibition on all chemicals without accompanying baseline safety data.<sup>130</sup> Alternatively, each chemical could be limited to a certain level of production (for instance, 25,000 tons per year, or a quarter of what is normally considered an HPV chemical) until

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124. See 33 U.S.C. § 1342 (2006); 42 U.S.C. § 7661(a) (2006).

125. See 33 U.S.C. § 1342 (2006); 42 U.S.C. § 7661(a) (2006); see also 33 U.S.C. §§ 1311, 1314, 1316 (2006); 42 U.S.C. §§ 7471, 7475, 7503 (2006).

126. 33 U.S.C. § 1342; 42 U.S.C. § 7661(a); 33 U.S.C. §§ 1311, 1314, 1316; 42 U.S.C. §§ 7471 (explaining statutory requirements for emitters and dischargers under the Acts).

127. The Clean Air Act and Clean Water Act are not exact blueprints for reformed chemical regulation in the US. However, we can learn and improve upon our regulatory regimes based on our experiences with the Clean Air Act and Clean Water Act and EPA's utilization of them. These laws represent important precautionary models of regulation in the form of permitting processes.

128. See, e.g., 21 U.S.C. §§ 301–399, §355(a)-(d).

129. For instance, drugs are marketed and sold to be directly administered to humans in order to alter a set of biological factors in the consumer. In contrast, chemicals are marketed and sold for a number of purposes not limited to human consumption or exposure, and if exposure occurs, the amounts and effects can vary drastically. See generally Watnick, *supra* note 6 (describing the variance in reactions to chemical exposure with emphasis on endocrine disruptors).

130. See 21 U.S.C. §§ 301–399 (using the example of FDA regulations for drug approval).

baseline data is available for the chemical.<sup>131</sup> A weaker regime could simply require warning labels, or impose marketing and use restrictions on all chemicals lacking baseline data. The ideal default regulatory response of this system would likely fall somewhere between mandating warning labels and a complete prohibition of the offending chemicals—perhaps a production limit on individual chemicals.

Embracing the general framework of the Food, Drug, and Cosmetic Act and the permitting structures of the Clean Water and Clean Air Acts,<sup>132</sup> a new scheme should impose significant restrictions on the manufacture and sale of a given chemical until baseline safety information is provided by industry.<sup>133</sup> Once this information is provided, the government should have a certain amount of time to decide whether the chemical is permissible or whether further testing is required.<sup>134</sup> Depending on the quantity of the chemical produced and the dangers posed by it,<sup>135</sup> the

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131. This particular regulatory strategy would guard against any HPV chemicals failing to have significant amounts of chemical data available for them. Scholars in the field have suggested the same or similar precautionary default responses, as well. *See* REACH IN BRIEF, *supra* note 32, at 7 (establishing this volume-based regulatory mechanism).

132. *See* 21 U.S.C. §§ 301399 (FDCA); 33 U.S.C. § 1342 (CWA); 42 U.S.C. § 7661(a) (CAA); 33 U.S.C. §§ 1311, 1314, 1316 (CWA requirements); 42 U.S.C. §§ 7471, 7475, 7503 (CAA requirements). This sort of chemical regulatory structure is not a novel idea. Others have suggested that this regulatory system can be an effective means of regulating chemicals while encouraging their safe use and development of relevant safety data. *See* Watnick, *supra* note 6, at 1331–32.

133. Presumptive prohibition of a chemical is certainly a strongly precautionary regulatory measure, but it may be too much. Unless the level of data required in order to satisfy the baseline safety data requirements of a new chemical regulatory scheme was low enough that compliance with the regime was reasonable for industry, this type of regulatory measure may be too strong, unlikely to achieve a broad political consensus, or simply impractical. Instead, the regime could impose other strong measures such as production or sales limits on particular chemicals. For instance, if chemical data is not offered in satisfaction of the regime's requirements, sales of the chemical could be limited to 50% of the total volume of the chemical sold the year prior to the regime's enactment.

134. A safety evaluation by the government could mirror that which is carried out by REACH. *See* REACH IN BRIEF, *supra* note 32, at 11–14. The timeline of approvals could also operate in a similar fashion to that of REACH. *Id.* at 6–9.

135. Aside from the concerns that arise after chemical testing, the EPA could use criteria such as: (1) neurotoxic effects from the chemical; (2) persistent, bioaccumulative, and toxic qualities (“PBT”) posed by the chemical; (3) probable or known carcinogenic effects of the chemical; (4) the chemical's use in children's products; (5) the chemical's

regime could demand higher levels of information beyond baseline safety data.<sup>136</sup> Along these lines, the EPA should have the ability to impose harsher restrictions on these VHC and HPV chemicals. For such a scheme to work successfully, a new regime should also abandon the “least burdensome alternative” requirement imposed by TSCA.<sup>137</sup> As evidenced by the decision of *Corrosion Proof Fittings*, this requirement can severely undermine the EPA’s ability to reasonably regulate harmful chemicals.<sup>138</sup>

There is one major caveat to imposing such a regime. Implementing the strong precautionary principle prior to exposure is impossible for much of the existing chemical universe, because both safe and unsafe chemicals are already being used in the United States. Requiring permits immediately for all existing chemicals in use would seriously disrupt the chemical market. To avoid this, a staggered set of deadlines would need to accompany this regime.<sup>139</sup> Using these dates, the regime’s requirements could be phased in to allow manufacturers ample time to collect baseline chemical data for their products.<sup>140</sup>

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possible or actual effects on children’s health; and (6) the detection of the chemical in biomonitoring programs as ways to prioritize chemicals for testing. The EPA has used these criteria in a recent work plan under TSCA to select chemicals for comprehensive risk assessments. See *Capital Report: EPA Studies Toxic Chemicals in Consumer Products*, AM. ASS’N FOR JUSTICE, Feb. 2014, at 56; *TSCA Work Plan Chemicals*, ENV. PROT. AGENCY (last accessed June 8, 2015), <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>.

136. This idea is generally implemented in REACH. See REACH IN BRIEF, *supra* note 32, at 6-8. It is important to note that industry representatives frequently oppose this proposition. Industry typically objects to the idea of allowing the EPA to require substantial chemical testing without any limit on what the EPA can ultimately ask for. See generally Testimony of Cal Dooley, “Legislative Hearing on the Safe Chemicals Act” (Nov. 17, 2011), transcript available at [http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore\\_id=a76a48ca-e5ca-4239-a80b-5db168b27898](http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=a76a48ca-e5ca-4239-a80b-5db168b27898). If this component is to be added to a new chemical regime, an ultimate limit on what the EPA may require from industry before taking regulatory action should be specified as well. Should the chemical manufacturer object to the regulatory action at that point, an appeals process could provide them with an arena to seek redress.

137. See *supra* note 24.

138. *Corrosion Proof Fittings*, 947 F.2d at 1220.

139. REACH creates a similar scheme of requirements, accompanied by “sunset dates” by which compliance must be attained. See REACH IN BRIEF, *supra* note 32, at 9.

140. For instance, the chemicals for which we currently have safety data could be assigned the earliest dates and the chemicals for which we have incomplete or no data

These dates could also be staggered in order to prioritize the more pressing threats posed by VHC and HPV chemicals.<sup>141</sup>

Regardless of the exact parameters of such a regime, the indispensable element is the responsibility of manufacturers to prove the safety of their products before production rather than placing the burden on government to prove their dangers. The surest way of accomplishing this is by implementing strong precaution.

*B. Priority #1: Generating Chemical Data To Feed A Reasonable Statutory Appetite*

The so called “data gap” in chemical regulation is well documented.<sup>142</sup> As scholarship and TSCA experience demonstrate, a new chemical regime must generate significant amounts of chemical data.<sup>143</sup> An effective regime must also narrow the “data gap” by limiting its demand for chemical information prior to regulation.<sup>144</sup>

The data creation priorities of a new system should be driven primarily by the “strong precautionary principle” and industry incentives.<sup>145</sup> Assuming, for instance, that the scheme presumptively prohibits the manufacture of all chemicals without a baseline amount of safety data, the industry would have a strong incentive to develop data for “unknown” chemicals.<sup>146</sup> But even if the scheme’s presumptive action was not so severe—for instance, a production limit or mandatory warning label—the

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could be delayed. In addition, chemicals of “Very High Concern” could receive earlier sunset deadlines, as they do in REACH. *Id.*

141. See COMMISSION OF THE EUROPEAN COMMUNITIES, *supra* note 119, at 10–11 (describing the various phases of REACH implementation).

142. See Applegate, *supra* note 9, at 1395–96, 1407; see generally Kvinge, *supra* note 107.

143. See generally Applegate, *supra* note 9 (describing the data gap); Watnick, *supra* note 6; see also *supra* note 16, at 12).

144. See generally Applegate, *supra* note 9 (same as above).

145. These do not necessarily represent the only mechanisms that should be used to “fill the gap” and generate chemical safety data. However, these two components are critically important to any new chemical regime.

146. This generally operates in the same fashion as REACH’s “No Data, No Market” principle. See *supra* note 33 and accompanying text.

incentive would remain. Requiring levels of data beyond baseline safety data for HPV and VHC chemicals could also allow the EPA to emphasize safety information on the chemicals we most need to know about.<sup>147</sup> Specific incentives for industry could be put in place, as well. For instance, some scholars have proposed limiting toxic tort liabilities for torts arising from use of chemicals that go through complete testing.<sup>148</sup> Manufacturers who create safer substitutes (with complete testing data) for existing chemicals could be rewarded as an incentive.<sup>149</sup>

A new chemical regulatory scheme must also be able to operate on less chemical information, or a “narrower” data gap.<sup>150</sup> If default regulations are imposed on all chemicals without baseline safety data, regulatory paralysis can be effectively avoided. The chemical regime would be doing its job—protecting the public and environment from known and unknown chemical harms as a default—while leaving the door open for industry to prove its chemicals safe and enjoy the profits from them. Should further regulation be needed after safety data is obtained, the data gap can be narrowed further by lowering the burden of proof that the government must meet in order to act. For instance, rather than TSCA’s unreasonable risk standard,<sup>151</sup> a new chemical regime should impose a lesser burden of proof, such as the “potential harm” standard used in the Canadian Environmental Protection Act.<sup>152</sup> Another

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147. This regulatory strategy also appears in REACH. See REACH IN BRIEF, *supra* note 32, at 6–14. This proposition assumes that risk is calculated as chemical potency multiplied by exposure.

148. Kvinge, *supra* note 107, at 330; see also Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENVTL. L. 99, 133 (1999).

149. See generally Wendy E. Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. (2008).

150. See Applegate, *supra* note 9, at 1407.

151. See 15 U.S.C. § 2605.

152. Canadian Environmental Protection Act, 1999 S.C. 1999, c. 33 § 73, available at <http://laws-lois.justice.gc.ca/eng/acts/c-15.31/FullText.html> (a lesser burden of proof could, for example, be based on the CEPA’s *potential* harm caused model rather than on existing or imminent exposure). See also Denison, *supra* note 10, at 10022. Denison makes a useful comparison with Canada’s CEPA § 64, which allows for regulation to be triggered by a chemical being labeled “CEPA-toxic.” *Id.* The chemical must not be

alternative could be using the “reasonable certainty of no harm” standard that is already applied to food-use pesticides and drugs.<sup>153</sup> Combined with incentives to create more chemical safety data, this regime could do more with less and with greater frequency.

### C. Transparency in the Process

A new chemical scheme should also be publicly accessible and include a system for appeal.<sup>154</sup> Creating a publicly available database of chemical safety data would serve many useful purposes. First, the database would directly protect the public by providing chemical safety information for it to use.<sup>155</sup> With readily available safety data, consumers can make safer decisions about the chemicals to which they are exposed.<sup>156</sup>

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definitively found to be toxic, however. Instead, this label can apply to chemicals that cause concern either because of their level of exposure *or* their hazardous properties. *Id.*

153. See Franklin, *supra* note 16, at 12.

154. One example of the creation of a useful toxic chemical database is the Toxics Release Inventory (“TRI”). The TRI was mandated by Congress in 1986 as a database where industrial facilities were required to report the release of particular chemicals into the environment. Emergency Planning and Community Right-to-Know Act of 1986 § 313, 42 U.S.C. § 11023 (2000); U.S. ENVTL. PROT. AGENCY, EPA-260-R-002-004, HOW ARE THE TOXICS RELEASE INVENTORY DATA USED? (2003), available at [http://www2.epa.gov/sites/production/files/documents/2003\\_TRI\\_Data\\_Uses\\_report.pdf](http://www2.epa.gov/sites/production/files/documents/2003_TRI_Data_Uses_report.pdf). After the TRI’s creation, the EPA reported that covered industrial facilities reduced their releases of TRI chemicals by forty-four percent between 1988 and 1994. Toxic Chemical Release Reporting, 61 Fed. Reg. 51,322 (Oct. 1, 1996) (codified at 40 C.F.R. pt. 372). An Environmental Defense Fund analysis of the TRI attributes its success entirely to the influence of public disclosure of this information. DAVID ROE ET AL., ENVTL. DEF. FUND, TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES 36 (1997). Scholars have advocated for this same type of database to be created as part of a new chemical regulatory system before. See Watnick, *supra* note 6, at 1331.

155. See *supra* note 154.

156. Similar consumer-awareness devices are commonly used tools by consumers searching for information on the quality, consumer satisfaction, and safety of consumer goods. See Gwendolyn Bounds, *Meet the Sticklers*, WALL ST. J. (May 5, 2010), [http://online.wsj.com/article/SB10001424052748703866704575224093100014240.html#mod=todays\\_us\\_personal\\_journal](http://online.wsj.com/article/SB10001424052748703866704575224093100014240.html#mod=todays_us_personal_journal) (noting Consumer Reports’ 7.3 million subscribers for print and Web publications); see also Ben Fox, *WebMD Net up on Higher Visitors; Outlook Weaker*, MARKETWATCH (Nov. 2, 2011), <http://www.marketwatch.com/story/webmd-net-up-on-higher-visitors-outlook-weaker-2011-11-02> (noting that despite falling

Second, with access to this data, consumers can pressure industry actors to use safer chemicals in manufacturing processes.<sup>157</sup> A recent example of effective consumer pressure is the public backlash against the use of bisphenol A (BPA). The public outcry against the use of BPA caused the Campbell Soup Company to declare that it was going “BPA free” in the near future.<sup>158</sup> Third, a public chemical database can be peer reviewed so that chemical data can be scrutinized for accuracy. Not only will a public chemical database provide a safety-net for chemical testing, but it will incentivize industry to conduct proper safety testing so as to avoid public backlash from publishing faulty data.<sup>159</sup>

#### *D. Two Bites at the Apple*

An appeals system where government conclusions regarding chemical safety can be challenged should accompany the establishment of a public database.<sup>160</sup> If government can regulate in the absence of scientific certainty, industry should be able to appeal a safety ruling if new evidence suggests a chemical is safe under certain conditions.<sup>161</sup> On the other hand, interested parties such as citizen groups should also be able to challenge

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revenues for the company, WebMD reported 107.3 million unique monthly visitors on average, with 2.24 billion page views in total in 2011).

157. Industry and retail responses to consumer demands have been demonstrated in a number of settings. For example, restaurants have increasingly begun to post “calorie counts” on their menus as a result of consumer demands to know the nutrition content of the foods they purchase. See Stephanie Strom, *McDonald’s Menu to Post Calorie Data*, N.Y. TIMES (Sept. 12, 2012), <http://www.nytimes.com/2012/09/13/business/mcdonalds-to-start-posting-calorie-counts.html>. See also *infra* text accompanying note 158.

158. Jon Entine, Op-Ed., *Campbell’s Big Fat Green BPA Lie—And The Sustainability Activists That Enabled It*, FORBES (Sept. 18, 2012), <http://www.forbes.com/sites/jonentine/2012/09/18/campbells-big-fat-green-bpa-lie-and-the-sustainability-activists-that-enabled-it/>. Entine’s piece describes Campbell’s interesting predicament: there was no readily available substitute for BPA in their manufacturing process, but Campbell’s nonetheless made the “BPA free” declaration to appease the public. *Id.*

159. *Id.*

160. Articles 91, 92, and 93 provide corollaries for this idea in REACH. See REACH, arts. 91–93. Certain decisions under these articles can be appealed to the Board of Appeal of the ECHA. *Id.*

161. This could operate in a similar fashion to REACH’s re-registration principles that require the constant retesting and re-evaluation of chemicals. See REACH, art. 91.



affirmative safety findings from the permitting process if credible evidence exists to the contrary.<sup>162</sup> Ideally, this would allow the peer review function of the chemical database to meaningfully re-examine and challenge potentially faulty chemical testing data. This appeals system should also move away from the “substantial evidence” standard applied by TSCA, and instead embrace the deferential “arbitrary and capricious” standard under the Administrative Procedures Act.<sup>163</sup> Such a change would make the appeals process more familiar and understandable for all parties involved.

#### *E. Understanding Reality*

Although multinational firms have been adapting to the constraints of REACH since its enactment, a new US scheme would have significant impacts. Any requirement of producing massive amounts of chemical safety data will certainly be a major shock to the chemical industry.<sup>164</sup> For instance, when REACH demanded chemical testing information from companies marketing chemicals in the European Union, firms

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162. Such citizen actions could take a form similar to those allowed for in the Clean Water and Clean Air acts. *See* 33 U.S.C. § 1365 (2006); 42 U.S.C. § 7604 (2006).

163. *See* 5 U.S.C. § 706(2)(A)(2012); *see also* Franklin, *supra* note 16, at 13 (advocating for the same change in standards of review).

164. For instance, when REACH was initially proposed, industry officials lamented the new costs it imposed. *See* Harvey Black, *Chemical Reaction: The U.S. Response to REACH*, 116 ENVTL. HEALTH PERSP. A124, A125–27 (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2265068/>. Black explains that American companies “are not crazy about REACH but . . . they also recognize that it is a set of regulations they have to live with if they wish to do business in Europe.” *Id.* at A127. On the other hand, Black also notes that U.S. companies like Dow Chemical have been supportive of the REACH regulations:

“Dow Chemical Company stated on its “Dow and REACH” website (<http://www.dow.com/reach/>) that the new policy “represents a significant opportunity for chemicals manufacturers, their suppliers, and customers to work together to protect the environment and preserve the future of the chemicals industry in Europe.”

*Id.* at A127. According to Dow spokesman Mark Walton, the REACH regulations will create a “more favorable and sustainable business climate for Dow and the chemical industry.” *Id.* (internal quotations omitted).

faced steep testing and registration costs.<sup>165</sup> One estimate puts the cost of screening a single chemical compound at \$250,000–\$300,000.<sup>166</sup> REACH has resulted in testing problems due to the regulation's demand for data.<sup>167</sup> For instance, many of the safety information dossiers submitted for authorization by the European Union contained faulty testing information and conclusions.<sup>168</sup> Some errors have been attributed to overreliance on a frequently-used technique called “read-across,” which is used to allow safety inferences to be made between similar chemicals.<sup>169</sup> Because of the subjective nature of the technique, data precision has emerged as a problem under REACH.<sup>170</sup> Opponents of animal testing have also voiced concerns that calls for significant amounts of chemical toxicity data will cause major increases in animal testing.<sup>171</sup> Certain assurances can be made to minimize animal testing, but the avoidance altogether of animal testing seems impossible.<sup>172</sup> Finally, the data produced through chemical

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165. See REACH IN BRIEF, *supra* note 32, at 16 (in its “Extended Impact Assessment,” the European Commission estimated the costs of REACH to the chemicals industry at a total of € 2.3 billion over the first 11 years following the Regulation's entry into force.); Rachel Massey, *Surviving REACH: A Guide for Companies that Use Chemicals* 11 (2005), available at <http://www.ase.tufts.edu/gdae/Pubs/rp/SurvivingReach.pdf> (noting that REACH's compliance costs equate to about .04% of average annual sales across the chemicals industry); see also REACH Chemical Law ‘Worth the Money in the End’, Says BASF, EURAACTIV (Mar. 9, 2012, 07:39 AM), <http://www.euractiv.com/sustainability/reach-chemical-law-worth-money-b-news-514565> (quoting Ronald Drews, vice president for chemical regulations and trade control at BASF, estimating REACH costs at an average of €50 million per year).

166. E. RESEARCH GRP., prepared for U.S. EPA, SUMMARY OF THE WORKSHOP ON THE ENDOCRINE DISRUPTOR SCREENING PROGRAM 2–7 (Dec. 27, 2007), available at <http://www.epa.gov/endo/meetings/121708minutes.pdf> (this estimate was put forward by Richard Becker of the American Chemistry Council).

167. See Natasha Gilbert, *Data Gaps Threaten Chemical Safety Law*, NATURE (July 12, 2011), <http://www.nature.com/news/2011/110712/full/475150a.html>.

168. *Id.*

169. *Id.*; see also Thomas Hartung & Costanza Rovida, *Chemical Regulators Have Overreached*, NATURE, 460, at 1080 (Aug. 2009), available at [http://www.researchgate.net/publication/26773780\\_Chemical\\_regulators\\_have\\_overreached?ev=prf\\_pub](http://www.researchgate.net/publication/26773780_Chemical_regulators_have_overreached?ev=prf_pub) (explaining the difficulties in obtaining consistently high quality data and the shortcomings of relied-upon testing techniques).

170. See Hartung & Rovida, *supra* note 169, at 1080.

171. See REACH IN BRIEF, *supra* note 32, at 4–7.

172. *Id.*

testing frequently rests on subjective assumptions and decision-making among scientists.<sup>173</sup>

In a new chemical regime, regulators must be mindful of these realities. While strong precaution and data generation must be the primary goals of a new regime, it must also be sensitive to the difficulties of producing chemical information reliably.<sup>174</sup> To assist the industry, a new regime should provide guidance on chemical testing methods and work with manufacturers to share best practices.<sup>175</sup> For instance, a new chemical regime could provide standards and guidance as to the appropriateness of “read-across” conclusions and encourage the peer review of such conclusions to ensure the efficiency and integrity of chemical testing. A set of staggered “sunset deadlines” for the chemical industry could also help to ease the transition into regulation for chemical firms. And in demanding this data, regulators must be mindful of protecting the confidential business information provided to them by industry.

Regulators in such a chemical regime should see their role not only as protectors of the public and the environment, but as important actors in a system charged with advancing useful chemicals to the market. Instead of viewing a chemical regulatory system as a hurdle standing in the way of chemical sales, regulators and market participants should view it as a way by which we promote the use and sale of safe and helpful chemicals. After all, chemicals are undoubtedly useful in our lives and indispensable to them.

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173. See Watnick, *supra* note 6, at 1320.

174. These difficulties are readily apparent from the chemical industry’s experiences with REACH, and amount not only to monetary difficulties, but also scientific difficulties in the testing process itself. See *supra* text accompanying notes 164–65, 169.

175. Similar guidelines and standards have been used in environmental regulations. See *Reach In Brief supra* note 32, at 7 (describing the general rules set out by REACH for “read across” and “Quantitative Structure Activity Relationship” testing procedures).

## CONCLUSION

In its unfortunate history, TSCA has failed to accomplish much of what it set out to do. One needs only to look to *Corrosion Proof Fittings* to recognize the failure of TSCA to effectively regulate harmful chemicals.<sup>176</sup> Yet TSCA has a very important job—protecting unsuspecting American consumers from unreasonable risks to their health and environment due to chemical exposure. Chemical safety reform should be a top priority for any responsible legislator.

There are a few critical components that must be embraced in a new US chemical regime. A new regime should be founded on the strong precautionary principle and should prioritize chemical data production and regulatory mechanisms that function in the absence of scientific certainty. In addition, the regime should have flexible appeal mechanisms and provide public access to a transparent chemical safety database. Finally, the regime must acknowledge the realities of chemical testing and maintain reasonable expectations of the regulatory system and its demands on industry. This is by no means a comprehensive set of recommendations for chemical reform. But, it provides some key principles that should be considered when the US chemical regulatory system is finally overhauled. For the sake of Americans and their environment, hopefully that day comes soon.

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176. See *supra* notes 105–13.