William & Mary Environmental Law and Policy Review

Volume 38 | Issue 1 Article 5

Tick Toxic: The Failure to Clean up TSCA Poisons Public Health and Threatens Chemical Innovation

Kristen Ekey

TICK TOXIC: THE FAILURE TO CLEAN UP TSCA POISONS PUBLIC HEALTH AND THREATENS CHEMICAL INNOVATION

KRISTEN EKEY*

INTRODUCTION

The United States' failure to amend the 1976 Toxic Substances Control Act ("TSCA"), as implemented by the U.S. Environmental Protection Agency ("EPA"), is an affront against EPA's mission to protect health and environmental safety. In 1976, Congress enacted TSCA in an effort to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances."[1] TCSA was just one member in a family of environmental regulations passed in the early and mid-1970s, the most active time for federal environmental law-making in American history.[2] While TSCA was revolutionary at its time of inception, the Act has failed to keep pace with changing technology, and stands as an outdated and weak control stop for toxic chemical and product development and consumers' unavoidable daily chemical consumption. Specifically, TSCA lacks the needed incentives for growing green chemistry development and fails to control emerging technologies, such as now-pervasive nanotechnology.[3] In 1975, Deputy EPA Administrator John R. Quarles testified on behalf of the Act, stating that TSCA was critical because "[e]xisting [f]ederal laws fail to deal evenly and comprehensively with toxic substances problems . . . ."[4] Arguably, today, we stand in no better place, facing the fact that due to lack

---

* J.D. Candidate, William and Mary School of Law, 2014; Article Editor, *William and Mary Environmental Law and Policy Review*; B.A., Major in Psychology and Communications and Minor in Creative Writing, Virginia Tech, 2005. The author would like to thank her family and friends for their support and encouragement during law school—especially Mom, Dad, and her fiancé Jonathan. She would also like to thank the dedicated *Environmental Law and Police Review* board and staff for their assistance.

[1] S. REP. NO. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491.

[2] David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 334 (2010).

[3] *The Need for Chemical Reform in the United States*, PHYSICIANS FOR SOCIAL RESPONSIBILITY, http://www.psr.org/resources/the-need-for-chemical-reform.html (last visited Nov. 7, 2013).

[4] Press Release, EPA, Quarles Testifies on the Need for Toxic Substances Act (July 10, 1975), http://www2.epa.gov/aboutepa/quarles-testifies-need-toxic-substances-act.

of reform, TSCA fails to deal evenly and comprehensively with toxic substance problems. The following Note explores the original purposes of TSCA and addresses the changes in technology and environmental needs that have left TSCA inadequate in meeting its intended regulatory purposes. Finally, the Note supports the movement to reform TSCA, suggests alternative regulatory measures under TSCA's current statutory structure, including stronger state control in the short term, and offers a national call to action to change consumers' attitudes in the long term.

I. OVERVIEW OF TSCA AND CHEMICAL REGULATION

The 1970s witnessed the greatest influx of environmental regulation in U.S. history.[5] By the end of 1974, Congress had successfully passed critical statutory controls to protect against chemical pollutant distribution *post*-market, including authority under the Clean Air Act, Federal Water Pollution Control Act ("Clean Water Act"), and Safe Drinking Water Act, among others.[6] However, at the end of 1974, legislation still ignored the regulation of chemical development *pre*-market.[7] The 1974 family of Acts, although important and a head start for environmental protections, focused only on chemical regulation after production. As Quarles stated in 1974, the then-current acts "deal with toxic substances at the point at which they become emissions or effluents. Even the recently enacted Safe Drinking Water Act . . . deals with the problem at a point where the contaminants are very difficult to control."[8] The impetus of TSCA was a need to control and evaluate the spiking development of chemical substances and the increased release of new and relatively unstudied chemicals into the U.S. market.[9] TSCA was a response by lawmakers to the growing public concern about the adverse health and environmental effects caused by then-existing and new toxic chemicals.[10] In fact, experts estimated that some 700 new chemical compounds were being introduced annually for U.S. commercial use.[11] While chemical development rapidly increased, what was known

---

[5] *See Environmental Law & Treaties*, NAT'L RES. DEF. COUNCIL, http://www.nrdc.org/reference/laws.asp (last visited Nov. 7, 2013).
[6] *Id.*
[7] *Id.*
[8] Press Release, EPA, *supra* note 4.
[9] Jeffrey Rudd, *Regulating the Impacts of Engineered Nanoparticles Under TSCA: Shifting Authority from Industry to Government*, 33 COLUM. J. ENVTL. L. 215, 223 (2008).
[10] *Id.* at 222.
[11] Lyndsey Layton, *Law Allows Companies to Hide Risks of Chemicals*, WASH. POST POLITICS (Jan. 4, 2010), http://articles.washingtonpost.com/2010-01-04/politics/36829171_1_american-chemistry-council-chemicals-toxic-substances-control-act.

about the effects of new chemicals on the environment and human health remained largely unstudied or unreported.[12] In response, Congress introduced TSCA to meet heightened regulatory goals and collect data on existing and new chemicals entering the U.S. marketplace. Three objectives drove TSCA's regulatory structure:

> (1) [A]dequate data should be developed with respect to the effect of chemical substances . . . . (2) [A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment . . . . (3) [A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation . . . .[13]

Through TSCA, Congress gave EPA the regulatory power to police new chemicals (prior to market entry) and existing chemicals when they "pose an unreasonable risk to health or to the environment."[14] TSCA's scope includes all chemical substances, which are defined in TSCA Section 3(2) as "any organic or inorganic substance of a particular molecular identity."[15] However, the Act does not regulate pesticides, tobacco, nuclear material, alcohol, food, drugs, or cosmetics, which are regulated under the Federal Food, Drug, and Cosmetic Act.[16] In its inaugural year, nearly 61,000 chemicals used commercially in the United States fell within TSCA's domain.[17] Of these 61,000 chemicals, which were in existence before 1976 and fell within TSCA's domain, all were grandfathered in under the Act, meaning they were considered "existing chemicals" under the Act and did not require the same considerations as new chemicals entering the market.[18] However, fewer than 200 of the 61,000 chemicals grandfathered in—just two

---

[12] *See* John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 724 (2008).

[13] 15 U.S.C. § 2601(b) (2006). *See also* LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL34118, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES (2008) [hereinafter CRS REPORT], *available at* http://www.gmaonline.org/file-manager/Chemicals/CRS_Paper_on_TSCA.pdf.

[14] *Toxic Substances Control Act*, EPA, http://www.epa.gov/agriculture/lsca.html (last visited Nov. 7, 2013).

[15] 15 U.S.C. § 2602(2)(A) (2006).

[16] CRS REPORT, *supra* note 13, at CSR-2 to -3.

[17] *Id.* at CSR-3.

[18] *Toxic Chemicals: The Cost to Our Health*, SAFER CHEMICALS HEALTHY FAMILIES, http://www.saferchemicals.org/resources/health.html (last visited Nov. 7, 2013).

percent—have been reviewed by EPA for human health risks.[19] In other words, most of the existing chemicals in the U.S. marketplace have never been fully evaluated for potential toxicity.[20]

Beyond the 61,000 chemicals that were grandfathered in, it is estimated that nearly 700 new chemicals enter U.S. commerce annually, with little health and safety data available.[21] While TSCA generally requires that chemical companies submit premanufacture notices ("PMN") when they intend to create or import new chemicals, TSCA requires only that the companies self-report any *available* test data along with the PMN.[22] EPA estimates that only about fifteen percent of companies report any health or safety data and that most PMN's fail to include test data of any sort.[23] Under the current TSCA regime, chemical companies are responsible for self-reporting and no incentives are provided for running these background tests prior to submitting a notice—the research is expensive, often time-consuming, and not a necessary requirement of the PMN or critical to its passing.[24] Rather, when EPA lacks sufficient data from the companies themselves, EPA compares the proposed chemical to an existing chemical with a similar molecular structure for which EPA has existing health and environmental test data.[25]

The need for chemical control is clear given that short-term and long-term exposure to toxic chemicals pose significant environmental and human health risks.[26] In response to pervasive chemical consumption and production of toxic substances, the Centers for Disease Control and Prevention ("CDC") conducts regular biomonitoring, which is designed to assess the levels of chemical absorption across the general population.[27] The CDC released its *Fourth National Report on Human Exposure to Environmental*

---

[19] *U.S. Chemical Management: The Toxic Substances Control Act*, PHYSICIANS FOR SOCIAL RESPONSIBILITY, http://www.psr.org/environment-and-health/confronting-toxics/chemical-management/ (last visited Nov. 7, 2013).
[20] *Id.*
[21] U.S. GOV'T. ACCOUNTABILITY OFFICE, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT (2009) [hereinafter CHEMICAL REGULATION], *available at* http://www.gao.gov/new.items/d09428t.pdf.
[22] *Id.* at 7.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Vulnerable Populations*, PHYSICIANS FOR SOCIAL RESPONSIBILITY, http://www.psr .org/environment-and-health/confronting-toxics/vulnerable-populations.html (last visited Nov. 7, 2013).
[27] *Biomonitoring*, PHYSICIANS FOR SOCIAL RESPONSIBILITY, http://www.psr.org/environment-and-health/confronting-toxics/biomonitoring.html (last visited Nov. 7, 2013).

Chemicals, which includes data on more than 200 environmental chemicals and shows Americans' widespread exposure to industrial chemicals, including phenols (such as bisphenol A or BPA), fire retardants, and perfluorooc tanoic acid ("PFOA"), a chemical used in non-stick cookware.[28] More in-depth scientific research is needed to understand causal links between chemical exposure and adverse health impacts. Currently, however, chemical exposure has been linked to premature delivery in pregnant women,[29] disruption of thyroid function,[30] and increased cancer rates.[31]

The following sections outline the successes and failures of TSCA, offer suggestions for alternate regulatory regimes, and present a call to action for heightened chemical substances control and consumer education.

II. THE TSCA SCORECARD: EFFECTIVENESS OF TSCA REGULATION

TSCA currently meets its goal of archiving existing and new commercial chemicals in a comprehensive database. TSCA Section 8(a), also known as the Chemical Data Reporting ("CDR") rule, authorizes EPA to require manufacturers, processors, distributors, and importers of chemical substances to report chemical makeup data for collection and cataloguing in the TSCA Chemical Substance Inventory.[32] As a mark of TSCA's archiving and reporting success, the TSCA Chemical Substance Inventory contains more than 83,000 chemicals to date.[33] For this reason, the archiving function of TSCA has been named a success.[34]

The TSCA Chemical Substance Inventory is a critical tool for manufacturers, importers, and disseminators of chemical substances in the United States.[35] When using chemical components, manufacturers and the

---

[28] CTRS. FOR DISEASE CONTROL AND PREVENTION, DEP'T. OF HEALTH AND HUMAN SERVS., FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS, EXECUTIVE SUMMARY 3 (2009), http://www.cdc.gov/exposurereport/pdf/FourthReport_ExecutiveSummary.pdf.

[29] *Vulnerable Populations*, *supra* note 26.

[30] CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 28, at 6.

[31] *Vulnerable Populations*, *supra* note 26. *See also Toxic Chemicals: The Cost to Our Health*, *supra* note 18 (explaining that "much has changed since 1976: chemicals have become more pervasive in daily life and scientists have developed a better understanding of how toxic chemicals are connected to some of our country's most serious health problems, including childhood cancers, asthma, impaired fertility, birth defects, and learning disabilities.").

[32] 15 U.S.C. § 2607(a)(1) (2006).

[33] *US TSCA Inventory*, CHEM. INSPECTION & REGULATORY SERV., http://www.cirs-reach.com/Inventory/US_TSCA_Inventory.html (last visited Nov. 7, 2013).

[34] *See* TSCA Inventory Update Reporting Modifications; Chemical Data Reporting, 76 FED. REG. 50,816, 50,837–38 (Aug. 16, 2011).

[35] CHEM. INSPECTION & REGULATORY SERV., *supra* note 33.

like may search the TSCA Chemical Substance Inventory database to identify the status of their chemical substances and corresponding data.[36] The inventory is important for data sharing, as well as identifying new chemicals introduced into U.S. commerce.[37] If a manufacturer, importer, or distributor does not find a chemical archived within the TSCA Chemical Substance Inventory, the chemical is considered a "new chemical" and must be reported to EPA through the PMN review system, as authorized under Section 5 of TSCA.[38] Section 5 requires that manufacturers intending to produce or import a new chemical provide a PMN to EPA at least ninety days before initiating the activity.[39] Exemptions from PMN reporting and review include chemicals under test-marketing (before filing for a PMN, a manufacturer may test commercial use and customer feedback if the chemical is approved for test marketing by EPA); low volume users and producers (some new chemicals may be produced in low amounts of 10,000 kg or less without PMN review); low release and low exposure manufacturers (with EPA approval, low releases and low human exposure may earn an exception from PMN processing); and chemicals for research and development, and export only.[40] Despite exceptions, the TSCA Chemical Substance Inventory is broad, inclusive, and a vital database for tracking chemical release, commerce, and productions in the United States.

EPA also successfully manages chemical manufacturers' and distributors' "substantial risk" reporting under TSCA Section 8(e).[41] Section 8(e) took effect with the passing of TSCA on January 1, 1977.[42] Section 8(e) requires manufacturers, distributors, processors, or importers of chemical substances that enter U.S. commerce to report to EPA Administrator any information that "reasonably supports the conclusion" that a substance presents a "substantial risk" to the environment or human health.[43] The purpose of Section 8(e) is twofold. For one, EPA sees the reporting section as a vital, early protection and early-detection mechanism.[44] Secondly, the

---

[36] *See id.*
[37] *Id.*
[38] *Id.*
[39] *New Chemicals*, EPA, http://www.epa.gov/oppt/newchems/ (last visited Nov. 7, 2013).
[40] *Is a Filing Necessary for My Chemical?*, EPA, http://www.epa.gov/oppt/newchems/pubs/whofiles.htm (last visited Nov. 7, 2013).
[41] *Toxic Substances Control Act (TSCA) Section 8(e) Notices*, EPA, http://www.epa.gov/oppt/tsca8e/ (last visited Nov. 7, 2013).
[42] EPA, TSCA SECTION 8(E) REPORTING GUIDE 1 (June 1991), *available at* http://www.epa.gov/opptintr/tsca8e/pubs/1991guidance.pdf.
[43] 15 U.S.C. § 2607(e) (2006).
[44] TSCA SECTION 8(E) REPORTING GUIDE 1, *supra* note 42.

reported information is critical to archiving substance concerns and tracking U.S. chemical reports.[45] With increased reporting comes an increased information flow that allows EPA to better understand the current landscape of chemical production and distribution, and allows EPA to detect possible health concerns and chemical production trends that may pose a dangerous risk to human health or the environment.[46] TSCA's reporting regulations provide the foundation for robust information collection and database-keeping that equip EPA with sound data to make future rules and keep its finger on the pulse of chemical productions.[47] While Section 8 has allowed EPA to successfully create and maintain a comprehensive catalogue of chemicals, TSCA fails to provide EPA with the necessary leverage to effectively regulate production of new and existing toxic substances, and ineffectually keeps high-risk chemicals from distribution or development.

III. TSCA FAILS TO REGULATE HIGH-RISK CHEMICALS

In its history, EPA has restricted only five existing chemicals under TSCA (Section 6 authority): polychlorinated biphenyls ("PCBs"), chlorofluorocarbons ("CFCs"), dioxin, asbestos, and hexavalent chromium.[48] Additionally, EPA has effectively regulated only four new chemicals under TSCA (Section 5 authority), totaling nine chemical controls since 1976 out of the more than 83,000 identified chemicals in U.S. commerce.[49]

A. Existing Chemicals

The controversies regarding TSCA's regulation of existing chemicals (Section 6) may be understood as viewed through the history of TSCA's attempt and ultimate failure to fully regulate asbestos in the United States. In July 1989, EPA passed the Asbestos Ban and Phaseout Rule[50] pursuant to Section 6 of TSCA, which "gives EPA the authority to protect against unreasonable risk of injury to health or the environment from chemical substances."[51] Specifically, if EPA finds a "reasonable basis to conclude that

---

[45] *Id.*
[46] *See id.* at 15–16.
[47] *Id.* at 16.
[48] Bill Chameides, *In Search of the Toxic Five*, THEGREENGROK BLOG (June 13, 2011), http://blogs.nicholas.duke.edu/thegreengrok/insearchoftsca5.
[49] *Id.*
[50] Asbestos Ban and Phaseout Rule, 40 C.F.R. §§ 762.160–763.179 (1989), *available at* http://www2.epa.gov/asbestos/asbestos-laws-and-regulations#phaseout.
[51] *TSCA Section 6 Actions*, EPA, http://www.epa.gov/opptintr/existingchemicals/pubs/sect6.html (last visited Nov. 7, 2013).

the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk . . ."[52] then EPA may prohibit or limit its "manufacturing, processing, or distribution in commerce."[53] The purpose of Section 6 is to grant EPA the authority to reduce national risk of chemical exposure through rulemaking.[54] However, within Section 6, EPA must implement the "least burdensome means of adequately protecting against the unreasonable risk."[55] The tug and pull between EPA's authority to regulate and the least burdensome means to do so has created a tension that leaves Section 6 a watered-down version of what could be a stronger, authority-granting source for EPA. The Asbestos Ban and Phaseout Rule was promulgated as a result of a finding that asbestos poses an unreasonable risk to human health, based in most part on a ten-year EPA study that examined the impact of asbestos on human health and the environment.[56] The rule was implemented to prohibit the "future manufacture, importation, processing, and distribution in commerce of asbestos-containing products, and to require warning labels on products subject to the bans."[57] EPA's determination of asbestos risk was founded on in-depth data analysis and consumer concern.[58] In fact, asbestos is a known carcinogen, exposing humans to risk occupationally and in nonoccupational settings.[59]

Despite the well-documented causal link between asbestos and human health risks, the Asbestos Ban and Phaseout Rule was successfully challenged by the asbestos industry.[60] Upon EPA's publication of its considered asbestos regulation, a case was filed by an asbestos-using company, Corrosion Proof Fittings,[61] challenging EPA's finding of the substance's "unreasonable risk" to human health and EPA's proposed ban, arguing it was not the "least burdensome means" to regulate the substance.[62] The company argued that the data EPA supplied did not show "substantial evidence" (the standard required under TSCA) to show that asbestos proved

---

[52] 15 U.S.C. § 2605(a) (2006).
[53] 15 U.S.C. § 2605(a)(1) (2006).
[54] *TSCA Section 6 Actions*, *supra* note 51.
[55] *Id.*
[56] Linda Stadler, *Corrosion Proof Fittings v. EPA: Asbestos in the Fifth Circuit—A Battle of Unreasonableness*, 6 TUL. ENVTL. L.J. 423, 423 (1993).
[57] *Id.*
[58] *Id.* at 429–30.
[59] *Id.* at 428.
[60] *Id. See also* Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).
[61] *Corrosion Proof Fittings*, 947 F.2d at 1201.
[62] *Id.*

an unreasonable risk to human health.[63] The U.S. Fifth Circuit Court of Appeals agreed with Corrosion Proof on both accounts,[64] and most of the original ban and phaseout rule was vacated and remanded, setting aside the bulk of the 1989 ban.[65] Although small pieces of asbestos regulatory power remain intact (such as regulating floor felt asbestos use),[66] the asbestos ban was effectively overturned by the 1991 *Corrosion Proof Fittings* ruling. The strong-handed remand of this attempted regulation of a known carcinogen,[67] which also carried mainstream consumer concern, has frozen further efforts by EPA to regulate other concerning substances within Section 6 authority.[68] EPA's history with asbestos regulation demonstrates the weakness of TSCA's authority. The *Corrosion Proof Fittings* ruling left TSCA nearly defenseless against a well-documented carcinogen.

B. New Chemicals

EPA's regulatory authority to control new chemicals (Section 5) is equally criticized and has been deemed a failure by scientists and public policymakers alike.[69] TSCA leaves EPA in a vulnerable position, lacking the infrastructure or authority to control new chemicals that need further evaluation.[70] In fact, even EPA's Office of Toxic Substances stated that "[clearly], the current level of accomplishment of the existing chemicals program is inadequate."[71] With the intent to manufacture or distribute, a

---

[63] *Id.* at 1214.
[64] *Id.* at 1215.
[65] *Id.*
[66] EPA, EPA ASBESTOS MATERIALS BANS: CLARIFICATION (May 18, 1999), *available at* http://rms.unlv.edu/occupational/asbestos/EPA%20Asbestos%20Ban.pdf.
[67] *See Corrosion Proof Fittings*, 947 F.2d at 1223, noting that:

> EPA regularly rejects, as unjustified, regulations that would save more lives at less cost. For example, over the next 13 years, we can expect more than a dozen deaths from ingested *toothpicks*—a death toll more than twice what the EPA predicts will flow from the quarter-billion-dollar bans of asbestos pipe, shingles, and roof coatings.

[68] LOWELL CENTER FOR SUSTAINABLE PRODUCTION, THE PROMISE AND LIMITS OF THE UNITED STATES TOXIC SUBSTANCES CONTROL ACT 1, 3 (Oct. 10, 2003), *available at* http://www.chemicalspolicy.org/publications.reports.chemicalspolicyreform.php (follow "The Promise and Limits of the United States Toxic Substance Control Act" link).
[69] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[70] *ACC Proposes New Prioritization Tool to Increase Effectiveness of EPA's Chemical Review Process*, AM. CHEMISTRY COUNCIL, http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA/ACC-Proposes-New-Prioritization-Tool-to-Increase-Effectiveness-of-EPAs-Chemical-Review-Process.pdf (last visited Nov. 7, 2013).
[71] NICHOLAS A. ASHFORD & CHARLES C. CALDART, TECHNOLOGY, LAW, AND THE WORKING ENVIRONMENT 200 (Island Press 1996).

producer must submit the PMN to EPA ninety days prior to action.[72] However, as previously discussed, manufacturers are only required to submit their available test data and most do not include health or safety data.[73] Additionally, if EPA does not respond to the PMN within ninety days, the chemical may enter the market without any toxicity data.[74] Thus, Section 5 is viewed as a weak control, allowing most chemicals to enter the market with little to no health-risk review.[75]

IV. TSCA MACRO-LEVEL REGULATION IGNORES NANOTECHNOLOGY

Nanotechnology is the study and engineering of materials at the nano-level, meaning the isolation and manipulation of individual atoms and molecules within a substance.[76] Nano-scale material use is not a new concept.[77] In fact, medieval artists used alternate-sized particles of gold and silver to create the striking colors in the stained glass windows of medieval churches.[78] But, medieval artists did not realize that the process of glass-making led to foundational changes in the materials they used.[79] Today, nano-engineers and scientists purposefully isolate and manipulate materials on the molecular level in order to enhance characteristics of improved strength, malleability, and heat resistance, to name a few.[80] Compared to age-old nanomaterial use, the issue with modern nanotechnology is the rapid pace and advanced manipulations available with increased technology, understanding, and science.[81]

The impact of modern nanotechnology continues to surface across all facets of the consumer market. The expansive and growing landscape was highlighted in a 1999 inter-agency report that notes: "[a]s the twenty-first century unfolds, nanotechnology's impact on the health, wealth, and

---

[72] CHEMICAL REGULATION, *supra* note 21, at 1, 3.
[73] *Id.* at 6–7.
[74] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[75] *Id.*
[76] *What is Nanotechnology?*, NAT'L NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/nanotech-101/what/definition (last visited Nov. 7, 2013).
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *See* Anna Lamprou, *Nanotechnology Regulation: Policies Proposed by Three Organizations for the Reform of the Toxic Substances Control Act*, CENTER FOR CONTEMPORARY HISTORY AND POLICY 1, 7, 11, 13, 15 (2010), *available at* http://issuu.com/chemheritage/docs/nanotechnology-regulation?e=1220984/3519447.

security of the world's people is expected to be at least as significant as the combined influences in this century of antibiotics, the integrated circuit, and human-made polymers."[82] Since the late 1990s, consumer product development has utilized nanotechnology in the automobile industry (using nanotechnology-enabled material that resists denting and scratching for parts such as bumpers), sports equipment (golf balls that fly straighter, baseball bats with better flexibility and ultimately, a better "kick"), cosmetics (clear sunscreens, deep-skin creams), scratch-resistant coatings, improved electronic displays, and much more.[83]

TSCA did not take into account the advanced methods of chemical and substance manipulation provided by emerging nanotechnologies.[84] In fact, the development of the scanning tunneling microscope, which allowed scientists and developers to "see" individual atoms and gave rise to modern nanotechnology, occurred in 1981, six years *after* the passing of TSCA.[85] Given this shortcoming, under the current, unreformed TSCA structure, companies are effectively able to introduce newly designed nanoparticles (substances with manipulated atomic structures) of a TSCA-inventory chemical as an "existing" chemical within TSCA. The issue at play is TSCA's characterization of a chemical substance, which is categorized by its molecular identity, including the type, number, and arrangement of the atoms that comprise a molecule.[86] And, since the nano and bulk forms have the same molecular identity within TSCA (same type, number, and arrangement of the atoms that comprise the base molecule), they are considered the same substance within TSCA.[87] However, because of the nanomaterials' distinctive scale and size, the manipulated materials can exhibit unique physical and chemical properties apart from their bulk counterpart.[88] Compounding the problem, critics and scientists argue that the properties and environmental impact of nanoparticles are not fully understood due to the lack of testing required to introduce a nanoparticle into commerce.[89]

---

[82] *Nanotechnology Research Directions: Vision for Nanotechnology in the Next Decade*, U.S. NAT'L SCI. AND TECH. COUNCIL iii (Mihail C. Roco et al. eds. 1999), *available at* http://www.wtec.org/loyola/nano/IWGN.Research.Directions/.

[83] *Nanotechnology Timeline*, NAT'L NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/timeline (last visited Nov. 7, 2013).

[84] *TSCA Modernization*, AM. CHEMISTRY COUNCIL, http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA (last visited Nov. 7, 2013).

[85] *Id.*; NAT'L NANOTECHNOLOGY INITIATIVE, *supra* note 83.

[86] Lamprou, *supra* note 81, at 9.

[87] *Id.*

[88] *Id.*

[89] *Id.* at 7, 14–15.

Even though the language and protections of TSCA have yet to evolve, the United States has taken an especially focused and increased interest in nanotechnology development since the late 1990s.[90] In 2000, the United States launched the National Nanotechnology Initiative ("NNI"), which sparked a global boom in research and development on nanoscience and nanotechnology.[91] Since its first fiscal funding year in 2001, the total NNI investment through 2013 totals more than $18 billion.[92] However, comparatively, collective investments in "nanotechnology-related environmental, health, and safety research" since 2005 totals just $750 million.[93] And, investments in "education and in research on ethical, legal, and other societal dimensions of nanotechnology" add up to only $350 million since 2005.[94] While some investments are being made to better understand and educate on nanotechnology, the bulk of global and U.S. investments are directed at engineering and development, rather than education and safety.

Experts agree that nanoparticles pose a risk to human health and natural environments.[95] More alarming, however, is what is not known about their public health impact. Since many companies successfully claim that nano-manipulated chemicals are not a "new" chemical within the meaning of TSCA, new nanomaterials avoid review under the new chemical provisions of TSCA altogether.[96] Additionally, the cutting-edge and emerging technologies themselves are currently underevaluated. According to the EPA Inspector General, "EPA does not currently have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials."[97] For these reasons, TSCA requires modernization to give EPA authority to regulate and better understand nanotechnologies and the increased introduction of nanoparticles into U.S. commerce and regularly used consumer products.

---

[90] *See generally Nanotechnology Research Directions for Societal Needs in 2020: Retrospective and Outlook*, WORLD TECH. EVALUATION CTR. (Mihail C. Roco et. al. eds. Sept. 2010), *available at* http://www.wtec.org/nano2/Nanotechnology_Research_Directions_to_2020/.
[91] *Id.* at iv.
[92] *Frequently Asked Questions*, NAT'L NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/nanotech-101/nanotechnology-facts (last visited Nov. 7, 2013).
[93] *Id.*
[94] *FY 2010 Budget Brief*, NAT'L NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/node/163 (last visited Nov. 7, 2013).
[95] Rudd, *supra* note 9, at 221.
[96] *Id.* at 225.
[97] EPA, Rep. 12-P-0162, EPA NEEDS TO MANAGE NANOMATERIAL RISKS MORE EFFECTIVELY (Dec. 29, 2011), *available at* http://www.epa.gov/oig/reports/2012/20121229-12-P-0162.pdf.

V. TSCA AND GREEN CHEMICAL DEVELOPMENT

Green chemistry, or sustainable chemistry, effectively reduces dependence on hazardous chemicals.[98] EPA defines green chemistry as the "design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green chemistry applies across the life cycle of a chemical product, including its design, manufacture, and use."[99] In this way, green chemistry development supports discoveries and technology that decrease the release and use of hazardous materials in the environment.

EPA began its Green Chemistry Program in the 1990s and the agency continues to "support the development and use of innovative chemical technologies that prevent or reduce pollution in academia and industry."[100] Green chemistry is vitally important to future and sustainable chemical development as it reduces energy consumption and promotes safer products.[101]

Under TSCA, EPA and chemical developers lack the needed incentives to kick-start sustainable chemistry. In fact, the primary way that EPA encourages green chemistry discovery and technology is through the Presidential Green Chemistry Challenge Awards.[102] The awards program is currently the leading incentive, while EPA also supports green chemistry through research, development, and consumer education initiatives.[103] As a leading solution for hazardous chemical waste and a hotbed of new technology and possibilities for exportation and industry growth, green chemistry should be more closely studied and promoted in the United States.

Currently, TSCA's shortcomings fall into three main areas of concern, often referred to by chemical reformers as the "data gap," the "safety gap," and the "technology gap."[104] Each TSCA gap poses a roadblock to growing green chemistry in the United States.

---

[98] *Green Chemistry*, EPA, http://www.epa.gov/greenchemistry/ (last visited Nov. 7, 2013).
[99] *Basics of Green Chemistry*, EPA, http://www2.epa.gov/green-chemistry/basics-green-chemistry (last visited Nov. 7, 2013).
[100] *Green Chemistry Research*, EPA, http://www.epa.gov/research/greenchemistry/ (last visited Nov. 7, 2013).
[101] *Benefits of Green Chemistry*, EPA, http://www2.epa.gov/green-chemistry/benefits-green-chemistry (last visited Nov. 7, 2013).
[102] *Green Chemistry*, *supra* note 98.
[103] *Resources*, EPA, http://www2.epa.gov/green-chemistry/resources (last visited Nov. 7, 2013).
[104] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.

A. Data Gap

The data gap refers to the bulk of unanswered questions and data on thousands of mass produced chemicals—from the chemical properties to the hazards present throughout the life cycle of a mass-produced chemical.[105] TSCA currently categorizes and tracks chemicals within the Section 8 authorized TSCA Chemical Substance Inventory, cataloguing about 83,000 chemicals in U.S. commerce.[106] In fact, TSCA was itself an answer to the cavernous data gap of the 1970s.[107] Then, data was fractured and organized inconsistently across the industry. In 1976, TSCA answered the call for increased monitoring and began the immense process of collecting chemical data.[108] However, TSCA only provided the original groundwork and today, advanced data collection and techniques are required to further the goals of EPA.[109] While TSCA served as a strong start in the massive undertaking, a new data gap exists, leaving EPA and the public in the dark. Today, the data gap is the lack of toxicity profiles available to the public and known to EPA.[110] While TSCA accomplished its goal of taking roll of all U.S. chemicals, more information is needed to understand the toxicity concerns and support green chemistry development.

In an effort to respond, or at least begin understanding what data gaps existed, EPA completed the 1998 Chemical Hazard Data Availability Study to analyze toxicity data available for High Production Volume ("HPV") chemicals in the United States and to assess what was known about the risks associated with these pervasive chemicals.[111] HPV chemicals are defined as those produced or imported at a rate of 1 million pounds or more annually.[112] Of the almost 3000 HPV chemicals in the United States in 1998, EPA found that complete toxicity profiles were publicly available for a mere seven percent of the HPV class.[113] This finding is significant in showing the lack of data available to the public and EPA concerning the risks associated with the largest class of consumed chemicals.

---

[105] *Id.*
[106] *See TSCA Chemical Substance Inventory*, EPA, http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/ (last visited Nov. 7, 2013).
[107] Rudd, *supra* note 9, at 223.
[108] *Id.*
[109] EPA, CHEMICAL HAZARD DATA AVAILABILITY STUDY 2 (Apr. 1998) [hereinafter CHEMICAL HAZARD DATA], *available at* http://www.epa.gov/hpv/pubs/general/hazchem.pdf.
[110] *See* PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[111] *See* CHEMICAL HAZARD DATA, *supra* note 109, at 2.
[112] *Id.*
[113] *Id.*

As EPA observed in the 1998 report, the unavailability of basic toxicity data is alarming for several reasons.[114] Primarily, EPA regulators need data in order to strategically plan, assess current chemical risk, and safeguard public health.[115] Competent data is the foundation of informed decision making. Without increased profiling of chemical effects and risk assessment data, EPA is unable to effectively regulate or prioritize toxicity concerns.[116] The data gap leaves EPA, the public, and manufacturers unaware of the risks associated with their chemicals—and ultimately disincentivizes manufacturers to design safer chemicals or chemical processes.[117] Without data to hold manufacturers and distributors responsible for at-risk chemicals or chemical development, producers will not be pushed to engineer safer or more sustainable processes. The data gap stands in the way of green chemistry and long-range strategic planning.[118] Availability of hazard information on individual chemicals is critical to consumer and government understanding of the risks associated with current chemicals and fundamental to shifting attitudes and building an anti-pollution ethic among the public.[119]

Congress needs to respond to the dangerous data gap and provide EPA with stronger regulatory power under TSCA. Specifically, TSCA currently leaves the burden of proving the "unreasonable" risk of a chemical to EPA.[120] Within TSCA, EPA is granted some authority to force chemical testing and require oversight as necessary.[121] However, in practice, testing and data supply has remained thin and difficult to implement.[122] Without EPA's finding of an "unreasonable risk" classification, manufacturers are not required to submit additional chemical or toxicity data.[123] Reforms should shift the burden of showing chemical safety to the manufacturer, thus pushing the issue and cost of testing to the manufacturer. By requiring producers to show the safety of their chemicals, more data will be generated, studied, and understood.

Additionally, putting the burden on the manufacturer incentivizes expert data and premiere testing to prove the safety and squash possible

---

[114] *Id.*
[115] *Id.*
[116] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[117] *Id.*
[118] CHEMICAL HAZARD DATA, *supra* note 109, at 2.
[119] *Id.*
[120] 15 U.S.C. § 2605(a) (2006).
[121] CHEMICAL HAZARD DATA, *supra* note 109, at 2.
[122] *Id.*
[123] *See* CHEMICAL REGULATION, *supra* note 21, at 5.

toxicity concerns of their chemical compounds.[124] TSCA reforms can also make reporting requirements more robust overall, giving EPA the power to bring suit against HPV manufacturers for failure to report, much like a regulatory scheme that is employed in the Clean Water Act.[125] To push even further, TSCA reform should emulate the technology-forcing strategy of the Clean Air Act, which requires manufacturers to reach EPA-set standards, regardless of the price or testing needed to comply to enter the market.[126] By strengthening incentives for data collection, a reformed TSCA bill will further the original goals of TSCA and encourage safer and more sustainable chemistry processes.

B. Safety & Technology Gaps

The safety and technology gaps are equally debilitating to the advancement of green chemistry.[127] The safety gap refers to the lack of understanding of chemical toxicity, leading to the release of potentially harmful chemicals into mass circulation.[128] As discussed above, the limited knowledge of nano-particulates and nanotechnology designs themselves highlight the safety gap.[129]

The technology gap refers to the lack of incentives within TSCA to encourage alternative chemical development methods or the development of new, safer chemicals to replace grandfathered, existing chemicals.[130] In order to incentivize green chemistry techniques and technology, TSCA needs substantial reforms that will encourage sustainable chemistry and control green chemistry developments under a separate regulatory regime. By implementing a new classification system, EPA could effectively prioritize chemical control and organize toxicity concerns into three categories: low, moderate, and high.[131] The tiered classification system would allow

---

[124] *See id.* at 7.
[125] *See* 33 U.S.C. § 1342(a)(2), (b)(2)(B) (2006).
[126] 42 U.S.C. § 7412(a)(1) (2006). *See also* Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629, 658 (2008) (discussing the incentive-based market approach and technology forcing); ROBERT PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 565 (5th ed. 2006) (explaining the history of the technology-forcing mandate).
[127] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[128] *Id.*
[129] *See* EPA NEEDS TO MANAGE NANOMATERIAL RISKS MORE EFFECTIVELY, *supra* note 97, at 2.
[130] PHYSICIANS FOR SOCIAL RESPONSIBILITY, *supra* note 3.
[131] *Id.*

EPA to scale regulatory control depending on the toxicity classification.[132] Additionally, under a tiered approach, EPA can encourage sustainable chemistry by placing green chemicals into the "low" concern category. A low concern rating will incentivize developers to explore sustainable chemistry and urge manufacturers to use sustainable processing methods to secure EPA oversight within the low-risk category as opposed to a high-risk category, which would be enforced through a tighter, more demanding, and costlier high-risk EPA compliance process. Additionally, a tiered system will incentivize developers to find safer substitutes for any existing high-priority chemicals, in order to move out of the "high" priority category and the costly checks associated with the higher risk category.[133]

TSCA currently classifies the hazards of chemicals based on their by-products post-development.[134] To further encourage green development, classification of toxicity should be reported throughout the life cycle of the chemical.[135] Cataloguing data of toxicity and regulating the actual chemical development process more closely will further incentivize the development of sustainable chemistry and evaluate new chemicals based on their by-products at the development, manufacturing, and distribution stages.

Due to the intersection of the data, safety, and technology gaps, green chemistry remains a low priority among chemical manufacturers and distributors.[136] Additionally, due to a lack of education on green chemistry, it also remains a low priority among consumers and lawmakers.[137]

---

[132] Richard A. Denison, *How the Safe Chemicals Act of 2011 (S. 847) Would Fix the Major Flaws of the Toxic Substances Control Act (TSCA),* ENVTL. DEF. FUND (Apr. 2011), http://www.saferchemicals.org/PDF/bill2011/Denison-TSCA-vs-Senate-reform-legislation-summary-April-2011.pdf.

[133] *Id. See also* Letter from Green Chemistry Alliance Steering Team, Green Chemistry Alliance, to Maziar Movassaghi, Acting Director, Department of Toxic Substances Control, California EPA (June 24, 2009), *available at* http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GC_Green_Chemistry_Alliance_Input3.pdf (discussing the tiered, prioritizing approach to incentivize safer chemical development and green chemistry in California).

[134] Chemical Data Reporting, *supra* note 34, at 50,834.

[135] *See* Denison, *supra* note 132, at 2.

[136] *See* Megan R. Schwarzman & Michael P. Wilson, *Green Chemistry and Chemicals Policy: Influence of the E.U. in California*, *available at* http://www.ies.be/files/repo/Green%20Chemistry.pdf.

[137] Michael P. Wilson & Megan R. Schwarzman, *Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health*, ENVTL. HEALTH PERSPECTIVES, *available at* http://www.ncbi.nlm.nih.gov/pubmed/19672398.

VI. ALTERNATIVE REGULATORY CONTROL UNDER STATE ACTION

TSCA's preemption provision, Section 18, gives the states room to regulate the use of chemicals within state borders.[138] TSCA Section 18 preempts state actions that are applicable to chemical substances or mixtures regulated under TSCA Section 5 or 6.[139] However, a state may still regulate if the state action is identical to the federal requirement or prohibits use of a chemical substance or mixture within the state.[140] Notably, EPA may also grant a request from a state to issue a regulation if the requirement provides a "significantly higher degree of protection from risk than does the federal requirement."[141] Although federal reform is critical to consistent regulation, states may govern and protect against chemical substance risks by leveraging their authority to regulate within TSCA and help patch chemical industry oversight in the interim.[142]

California's Green Chemistry Initiative ("CGCI") provides a unique case study of state-based solutions for advancing green chemistry development and heightened chemical control within the current federal framework of TSCA. The history and success of CGCI provides a roadmap for state legislatures encouraging stronger chemical control. California provides an interesting framework because the state carries the largest economy of any state in the United States by a wide margin and ranks as the ninth largest economy in the world.[143] This economic power gives the California legislative initiative a broader impact, influencing all producers wishing to stay competitive in the California and U.S. markets. The heart of the initiative included two joined bills: AB 1879 (Hazardous Materials and Toxic Substances Evaluation and Regulation)[144] and SB 507 (Toxic

---

[138] Lauren Trevisan, *Human Health and the Environment Can't Wait for Reform: Current Opportunities for the Federal Government and States to Address Chemical Risks Under the Toxic Substances Control Act*, 61 AM. U. L. REV. 385, 385 (2011).
[139] 15 U.S.C. § 2617(a)(2)(B). *See also* LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL 31905, THE TOXIC SUBSTANCES CONTROL ACT: A SUMMARY OF THE ACT AND ITS MAJOR REQUIREMENTS 7 (2010).
[140] SCHIEROW, *supra* note 139.
[141] *Id.*
[142] Trevisan, *supra* note 138, at 385.
[143] Dan Walters, *California Slips to No. 9 in Worldwide Economic Rankings*, THE SACRAMENTO BEE (Jan. 11, 2012), http://blogs.sacbee.com/capitolalertlatest/2012/01/california-slips-to-number-9-in-world-economic-rankings.html.
[144] *See generally Health and Safety Code*, AB No. 1879, Ch. 559, CAL. DEP'T OF TOXIC SUBSTANCE CONTROL, *available at* http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/ab_1879_GCI.pdf.

Information Clearinghouse).[145] Both bills were designed to increase the state's control over chemicals in California commerce and were successfully adopted in 2008,[146] yet implementation was stalled until 2013.[147]

California's Toxics Information Clearinghouse ("TIC"), or SB 509, mandated a public, online system for the collection of chemical and environmental hazard trait data for all chemicals in the California marketplace.[148] The TIC takes the idea of TSCA's database one step further by offering a more interactive database of hazard trait data.[149] As opposed to providing just the basic chemical makeup information like TSCA's database, California's TIC will provide end-point data on hazardous chemical traits or toxicity as set by the government agency.[150] The TIC was proposed to prioritize chemicals of concern and identify areas of weakness in data collection.[151]

Also known as The Safer Alternatives for Consumer Products Rule, AB 1879 set out to target and enhance regulation over priority chemicals in consumer products.[152] First, AB 1879 requires the identification and prioritization of "chemical[s] of concern" (chemicals that pose possible health risks and those lacking sufficient toxicity data).[153] Secondly, if a chemical of concern is found or used in any consumer product, this triggers data testing requirements, including current exposure rates, life-cycle performance, and biomonitoring alternatives to assess consumer health risk and analyze the chemical.[154] From this data collection, final regulatory decisions are then issued, such as labeling requirements, restricted use, or an all-out ban of the chemical of concern in California.[155]

California's SB 509 and AB 1879 were adopted in 2008 as robust state action to find safer product alternatives, promote green chemistry, and encourage development of "benign-by-design" chemicals.[156] Although stakeholder concerns paused the forward momentum of CGCI, the joined

---

[145] *See generally Health and Safety Code*, SB No. 509, Ch. 560, CAL. DEP'T OF TOXIC SUBSTANCE CONTROL, *available at* http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/sb_509_GCI.pdf.
[146] *Id.* AB No. 1879, *supra* note 144.
[147] *Safe Consumer Product Regulations*, CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, http://www.dtsc.ca.gov/SCPRegulations.cfm (last visited Nov. 7, 2013).
[148] *Id. See also* Schwarzman & Wilson, *supra* note 136.
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] AB No. 1879, *supra* note 144. *See also* Schwarzman & Wilson, *supra* note 136.
[153] AB No. 1879, *supra* note 144.
[154] Schwarzman & Wilson, *supra* note 136.
[155] *Id.*
[156] *Id.*

bill was ultimately approved in August 2013 by California's Office of Administrative Law as the Safer Consumer Products regulations, which went into effect on October 1, 2013.[157] California's approval of the Safer Consumer Products regulations is the product of years of dedication among lawmakers and constituents to strength consumer protection and chemical regulation. The Safe Consumer Products regulations have already made an impact within the state, and the far reaching effects on policy and industry both domestically and internationally will be revealed in upcoming years.[158] The CGCI strategy represents a possible approach to state-based legislation and regulation that could change behavior of federal legislators and toxic-substance manufacturers.

While state-by-state regulations are not ideal compared to a strong, unified federal standard, state action incentivizes federal law amendment. For one, state action signals public demand for tighter regulation. Also, more state action puts added pressure on Congress to respond to manufacturers' needs to avoid a complicated and fractured state-by-state regime.[159] TSCA reform offers an opportunity to amend the current preemption standard and provide a national standard for chemical substance regulation. States will continue to uphold divergent chemical regulations and standards until more robust federal standards answer the regulatory gaps.[160] By utilizing certain sections of the statute in new and aggressive ways, EPA can effectively allow states to address chemical risks.[161] State level action will in turn pressure Congress to address growing concern and fractured state-by-state regulations.

Regulatory alternatives present themselves not only domestically, but internationally as well. Recently, much attention has been given to the European Union's 2007 chemical control legislation, "Registration, Evaluation, Authorization, and Restriction of Chemicals" ("REACH").[162] The critical feature of REACH is that it puts the burden on manufacturers, distributors, and importers to ensure that they do not produce, circulate, or use substances that adversely affect human health or the environment.[163]

---

[157] *See Safe Consumer Product Regulations*, *supra* note 147.
[158] *Id.*
[159] *See* Pat Rizzuto, *Congress: Latest Version of Safe Chemicals Act Called 'Remarkably Different' From 2011 Bill*, 36 CHEM. REGULATION REPORTER 979 (Sept. 15, 2012), *available at* http://www.khlaw.com/Files/15696_Chemical%20Regulation%20Reporter%20on%20Webinar%202012-09-.pdf.
[160] *Id.*
[161] *Id.*
[162] CHEMICAL REGULATION, *supra* note 21, at 4.
[163] *Id.*

Notably, REACH is supported by the "precautionary principle"[164] and requires that chemical companies provide data and develop testing to show the effects of their chemicals on human health and the environment.[165] TSCA, on the other hand, puts the burden squarely on EPA to clear numerous hurdles before the agency may request data and chemical testing. Before requesting chemical data from manufacturers, EPA must determine that the current data is insufficient; testing is needed; and that either the chemical presents (or may present) an unreasonable risk or that there is (or may be) substantial human or environmental exposure to the chemical.[166] Then, once the determination has been made, EPA must issue a proposed rule, request public comment, consider the comments, and then promulgate a final rule implementing chemical testing.[167] Given the high bar EPA must reach to initiate rulemaking, plus the time (two to ten years) and resources involved in rulemaking (hundreds of thousands of dollars and countless personnel), it is not surprising that the agency has finalized and issued rules for only about 200 chemicals to date.[168] REACH provides a better model for encouraging data sharing, incentivizing testing, and placing the cost of production on the industry, which is typically better positioned to bear the cost.[169]

With global chemical production growing three percent per year (doubling every twenty five years),[170] the impact of U.S. importation and exportation and global commerce will continue to call for international solutions and increased cooperation, which will grow opportunities to share best practices and better understand chemical toxicity. REACH introduces a thoughtful and strategic approach to chemical reform domestically and internationally and serves as a base for comparison in future U.S. chemical legislation.

VII. TSCA PROPOSED AMENDMENTS

Continued controversy over the aging TSCA statute incited proposals from both the Senate and House of Representatives to revamp the

---

[164] *Id.* at 4 (explaining that "[i]n general, the precautionary principle means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment.").
[165] *Id.* at 6.
[166] *Id.* at 5–6.
[167] *Id.*
[168] CHEMICAL REGULATION, *supra* note 21, at 5–6.
[169] *Id.*
[170] Schwarzman & Wilson, *supra* note 136.

legislation.[171] In spring of 2010, Senator Lautenberg (D-N.J.) introduced legislation (S. 3209), which focused on changes to TSCA Title I.[172] Following, July of 2010, the House introduced legislation to amend TSCA (H.R. 5820).[173] The two bills differed but both addressed key concerns. Notably, both bills agreed on shifting the burden of chemical safety demonstration to manufacturers and distributors by prohibiting the dissemination of any chemical substances in commerce until safety was validated through data submission to EPA.[174] Also, the bills supported a health-based standard for compliance and evaluation, rather than the current "unreasonable risk" and "least burdensome means" two-pronged test approach.[175] While both bills ultimately died,[176] they set the stage for future chemical reform.

The most recent movement to amend TSCA came in the form of the Safe Chemicals Act of 2011, sponsored by Senator Lautenberg.[177] In July of 2010, the U.S. Senate Environment and Public Works Committee passed the bill and its overhaul of TSCA.[178] While the bill was heavily marked by the committee, passing the Senate Committee was the furthest that any similarly proposed, TSCA-overhaul legislation had achieved in thirty six years.[179] This bill was introduced to Congress in July of 2012, but ultimately was not enacted.[180]

Like its predecessors, the proposed bill shifted the initial burden of evidencing a chemical's risk away from EPA. The Act put the burden on manufacturers, requiring the chemical producers to supply data showing the safety of their chemical substances.[181] Chemicals that could not be

---

[171] LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL41335, PROPOSED AMENDMENTS TO THE TOXIC SUBSTANCES CONTROL ACT (TSCA): SENATE AND HOUSE BILLS COMPARED WITH CURRENT LAW 1 (2010).
[172] *Id.*
[173] *Id.*
[174] *Id.*
[175] *Id.*
[176] *See id.*
[177] *See* Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011).
[178] *Summary of the Committee Mark-up of the Safe Chemicals Act of 2011 (S. 847)*, KELLER & HECKMAN LLP (Aug. 15, 2012), http://www.khlaw.com/showpublication.aspx?Show=5772.
[179] Ben Eisler, *"Toxic Spending" Report Investigates Industry Push for Fracking*, CBSNEWS.COM (Oct. 24, 2012), http://www.cbsnews.com/8301-505263_162-57539200/toxic-spending-report-investigates-industry-push-for-fracking/.
[180] *S. 847 (112th): Safe Chemicals Act of 2011*, GOVTRACK, http://www.govtrack.us/congress/bills/112/s847#overview (last visited Nov. 7, 2013).
[181] Cheryl Hogue, *Senate Committee Adopts TSCA Reform Bill*, CHEM. & ENG'G NEWS, July 25, 2012, http://cen.acs.org/articles/90/web/2012/07/Senate-Committee-Adopts-TSCA-Reform.html.

proven safe would be prohibited from production and distribution.[182] Also, chemical companies would have been permitted to keep trade secrets confidential, but health and safety information could never have been blocked and claimed as confidential.[183]

The specific standard that would trigger regulatory authority within the Safe Chemicals Act allowed EPA greater control. The proposed Act granted EPA authority to regulate, unless a manufacturer showed a "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance"—the same standard employed in the Food Quality Protection Act, which covers food-use pesticides.[184] While the standard has proven effective for food-use pesticides due to their limited uses, critics argue that the standard is unusable for chemicals that serve a variety of functions and in varying capacities that do not remain standard across the industry.[185] Additionally, the major criticism is that companies failing to meet the standard would not be subject to judicial review, which could potentially put manufacturers and distributors out of business without the means to seek judicial review of EPA ruling and due process of law.[186]

The proposed Safe Chemicals Act of 2011 would change EPA chemical regulation in a number of meaningful ways. First, the new regime would allow EPA to promulgate rules to establish the minimum data sets required from chemical producers and importers.[187] Currently, TSCA does not set any minimum data set requirements for new chemicals and relatively few data requests are issued by EPA given the difficulty of issuing the EPA ruling.[188] Second, the assessment of safety for new and existing chemicals would require data collection and testing.[189] Specifically, the Safe Chemicals Act would grant EPA the authority to condition a chemical's entry or continuation in the market on safety determinations (based on the best available science and advising of the National Academy of Sciences).

---

[182] *Id.*
[183] *Id.*
[184] *NEMA Summary of the Safe Chemicals Act of 2011 (S. 847)*, NEMA, http://www.nema.org/Policy/Environmental-Stewardship/Documents/NEMA%20Summary%20of%20Safe%20Chemicals%20Act%20of%202011.pdf (last visited Nov. 7, 2013); Rizzuto, *supra* note 159.
[185] Rizzuto, *supra* note 159 (explaining that "it would not be [an] appropriate [standard] for industrial chemicals that can have uses as varied as being in a space shuttle to never being found outside a closed system in which they are used to make other chemicals.").
[186] *Id.*
[187] Denison, *supra* note 132.
[188] *Id.*
[189] *Id.*

EPA would have the flexibility to categorize chemicals as intrinsically safe or require additional testing based on the best available science.[190] TSCA, on the other hand, fails to provide mandates for EPA to assess existing chemicals, and limits new chemical data collection, as previously discussed above.[191] Third, a major difference proposed in the Safe Chemicals Act is the tiered priority approach.[192] EPA's first charge would be prioritizing at-risk chemicals in order to assess and test high-concern chemicals.[193] Later, focus would be shifted to lower-priority chemicals and chemicals for which EPA currently has robust information.[194] This approach differs from TSCA, which fails to prioritize chemicals and thus, does not offer incentives for manufacturers to provide data or create safer chemicals that would be granted lower-priority status.[195] The Safe Chemicals Act addresses a number of shortcomings and pitfalls of TSCA.[196] While drafting issues stopped the bill in its tracks,[197] the Safe Chemicals Act is by far the most successful attempt to update U.S. chemical regulation and follow best practices, advanced by other states like California and other international players, such as EU's REACH.[198] The proposal offers thoughtful solutions to TSCA issues and quiets critics' main concerns about the current regime. The Safe Chemicals Act of 2011 will continue to influence reforms in the future and represents a critical step towards ultimate bipartisan agreement.

VIII. CALL TO ACTION & CONSUMER EDUCATION

EPA has successfully used integrated consumer education campaigns to further pertinent environmental issues, such as recycling.[199] In addition to updating the statutory language of TSCA, funds should be

---

[190] *Id.*
[191] *Id.*
[192] *The Safe Chemicals Act 2.0: Finding Common Ground*, SAFER CHEMICALS, HEALTHY FAMILIES 1, http://www.saferchemicals.org/PDF/resources/common_ground_factsheet.pdf (last visited Nov. 7, 2013).
[193] *Id.*
[194] *Id.*
[195] Denison, *supra* note 132.
[196] *Id.*
[197] *S. 847*, POPVOX, https://www.popvox.com/bills/us/112/s847 (last visited Nov. 7, 2013).
[198] *See, e.g.*, GOVTRACK.US, http://www.govtrack.us/congress/bills/browse?congress=112#Similar_to=s.847%2F11$current_status=5. *See also REACH*, EUR. COMM'N, http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (last visited Nov. 7, 2013).
[199] *WasteWise Program Success Stories*, EPA, http://www.epa.gov/smm/wastewise/success/state.htm (last visited Nov. 7, 2013).

appropriated to launch a strategic education campaign to raise awareness of chemical safety and promote green chemistry development. Currently, public awareness of green chemistry and chemical pervasiveness is understudied and unevaluated. A fully integrated effort to understand the public's perception of the issue and education on the issue is needed.

EPA took a unique and interesting approach in 1989 in response to the waste management epidemic.[200] In an effort to increase public awareness as to the environmental dangers of waste disposal and the benefits of recycling, EPA turned its attention to the younger population, noting that targeting future consumers may be the key to any long term programmatic success.[201] Likewise, targeting children through existing in-school programs to raise awareness of safe chemicals and product labeling may encourage the use of non-toxic alternatives, further interest in green chemical development, and ultimately grow support for better product labeling and chemical regulation.

In 2012, EPA took a small step in education initiatives by naming EPA Region 1 the targeted leader of green chemistry awareness and education development under the New England Green Chemistry Challenge program.[202] The Challenge was initiated in 2010, and a strategic plan launched the limited, inaugural programs in 2011–2012 to expand green chemistry awareness in the New England area.[203] While the New England Green Chemistry Challenge currently focuses on limited audiences (chemists, businesses, healthcare providers)[204] to achieve its goal, the pilot program helps establish an initial roothold to support the growth of future education opportunities and increased public awareness.[205] Building on this idea, EPA needs to jumpstart consumer awareness in a full-scale effort to surround Congress with calls of action from stakeholders in public and private sectors. Consumer education remains a critical piece of an integrated campaign to raise awareness of the current chemical state-of-affairs and ring the alarm bell as to the need for heightened chemical regulation.

---

[200] EPA, 530-SW-89-066, PROMOTING SOURCE REDUCTION AND RECYCLABILITY IN THE MARKETPLACE, POLICY, PLANNING, AND EVALUATION, SOLID WASTE AND EMERGENCY RESPONSE (Sept. 1989).
[201] *Id.*
[202] *New England Green Chemistry*, EPA, http://www.epa.gov/region1/greenchemistry/ (last visited Nov. 7, 2013).
[203] *Id.*
[204] *Id.*
[205] *Id.*

CONCLUSION

TSCA, revolutionary at its time of inception, has failed to keep pace with changing technology and lacks the needed incentives for growing green chemistry development. State-based solutions offer a possible regulatory scheme to patch the holes of TSCA in the short term. However, as we move forward, in a time of quickening product development and increased chemical dependence, an updated federal standard is vital to safeguarding the safety of domestic and international chemical manufacturing and consumerism. Growing global concern over the pervasiveness and understudy of chemical risks has pushed international leaders to create modernized chemical reform, such as the controls advanced by REACH.[206] As this Note has shown, the United States threatens human health and chemical innovation by keeping quiet on chemical reform. In order to modernize and globalize, the United States must amend TSCA, incentivize green chemistry, and raise public awareness of toxicity concerns.

---

[206] CHEMICAL REGULATION, *supra* note 21, at 2, 11.