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Note

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*John Kvinge**

I. INTRODUCTION

> Most Americans had no idea, until relatively recently, that they were living so dangerously. . . . They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later.[1]

Many Americans believe that if a chemical is sold or used within the United States, it must have gone through an extensive battery of tests to determine its effects on health and the environment. Although the chemical industry is one of the most heavily regulated in the United States, our actual knowledge about many of its products is shockingly small. Until recently, the EPA had a full set of health and safety data for less than seven percent of the chemicals produced in or imported into the United States in quantities in excess of one million pounds per year.[2] While recent voluntary efforts by the industry have filled some of the gaps in our knowledge, the picture is far from complete. These chemicals are found in our homes, our offices, our children's toys, and in shockingly high quantities within our own bodies.[3] The Toxic Substances

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1. Dr. Russell E. Train, Former Adm'r, Envtl. Prot. Agency 1973-77, *as quoted in* S. REP. NO. 94-698, at 3 (1976).

2. *See* U.S. ENVTL. PROT. AGENCY, CHEMICAL HAZARD DATA AVAILABILITY STUDY 2 (1998).

3. *See generally* U.S. CTRS. FOR DISEASE CONTROL, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2010) (finding

Control Act (TSCA) was created in 1976 to give the EPA the power to investigate and regulate chemicals that were not covered by other laws.[4] As an attempt to require testing of chemicals before they enter the stream of commerce, the TSCA has been largely a failure. It appears that Congress will attempt to reform or modernize the TSCA in the near future, and everyone—from government officials to industry executives and citizen activists—have proposed their thoughts on what the reform should look like.[5]

This Note aims to examine the toxic data gap that has resulted from the ineffective TSCA and seeks to identify the features of an effective reform that would solve the data gap. Part I of this Note covers the history of the TSCA and compares some of its shortfalls to the European Union's recently enacted regulatory system. Part II of this Note presents several proposals that would improve our knowledge of the chemicals in commerce. This Note concludes that the most important feature of any proposed reform is the provisions that give the EPA the power to force manufacturers to conduct testing before they market a chemical, and reset the TSCA inventory to give Americans a realistic picture of the chemical dangers present in their everyday life.

measureable levels of 212 environmental chemicals in tissue samples of test subjects).

4. S. REP. NO. 94-698, at 1 (listing the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act as examples of other health statutes; and stating, "The bill is designed to fill a number of regulatory gaps which currently exist").

5. *See, e.g.*, AMERICAN CHEMISTRY COUNCIL, 10 PRINCIPLES FOR MODERNIZING TSCA (2009), *available at* http://www.americanchemistry.com/TSCAPrinciples (follow "download PDF" hyperlink); SAFER CHEMS., HEALTHY FAMILIES COALITION, A PLATFORM FOR REFORM OF THE TOXIC SUBSTANCES CONTROL ACT (2009), *available at* http://www.saferchemicals.org/PDF/SCHF_Campaign_Platform.pdf; U.S. ENVTL. PROT. AGENCY, ESSENTIAL PRINCIPLES FOR REFORM OF CHEMICALS MANAGEMENT LEGISLATION (2009), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/principles.pdf; COALITION FOR CHEMICAL SAFETY, ISSUES AND POLICY, http://www.coalitionforchemsafety.com/issues.aspx (last visited Sept. 9, 2010).

II. HISTORY OF THE TSCA AND OTHER REGULATORY SCHEMES

A. ENACTING THE TSCA

Title I of the Toxic Substances Control Act became law on October 11, 1976.[6] Congress intended the legislation to serve as a method "to regulate chemical substances that present an unreasonable risk of injury to health or the environment."[7] Afterwards, Congress enacted titles II through IV to deal with specific toxic threats through the expansion of EPA power under the TSCA.[8] The TSCA was not the first federal program created to control pollution and hazardous substances, but was rather intended as a gap-filler that would focus on toxic chemicals produced in large quantities that evaded federal control under other pollution and health measures.[9] Initially, the targets of the TSCA were polychlorinated biphenyls (PCBs) and other workplace chemical hazards such as kepone, vinyl chloride, and asbestos.[10]

A primary goal of the TSCA is the collection of test data about health and environmental effects caused by the chemicals marketed in the country.[11] Congress expected that the provisions of the TSCA would force chemical manufacturers to be the primary information producing entity, and the EPA would act to collect and organize the results of the tests.[12] To facilitate collection of comprehensive data, and appease industry opposition to a wholesale regulatory scheme, the final bill included many concessions that limited the EPA's power to institute regulations in the absence of substantial evidence of a "reasonable basis to conclude" that a chemical "will present an unreasonable risk of injury to health or the environment."[13] Furthermore, any resulting regulations must be the "least

6. Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2692 (2003)).

7. 15 U.S.C. § 2601(b)(2).

8. The three subtitles deal with, respectively: Asbestos Hazard Emergency Response, 15 U.S.C. §§ 2641-2656; Indoor Radon Abatement, 15 U.S.C. §§ 2661-2671 and Lead Exposure Reduction, 15 U.S.C. §§ 2681-2692.

9. S. REP. NO. 94-698, at 1.

10. *Id.* at 4.

11. 15 U.S.C. § 2601(b)(1) ("[A]dequate data should be developed with respect to the effect of chemical substances and mixtures . . . development of such data should be the responsibility of [manufacturers].")

12. S. REP. NO. 94-698, at 2.

13. 15 U.S.C. § 2605(a).

burdensome" possible.[14] In practice, the EPA has been unable to institute regulations based on these criteria.[15]

B. SPLITTING THE UNIVERSE

To facilitate testing and cataloguing chemical health and safety risks, the TSCA split the universe of chemicals into two distinct categories: chemicals currently in production at the time the law took effect (existing chemicals) and potential new chemicals that companies were considering manufacturing for the first time.[16] Existing chemicals became part of the TSCA inventory, and absent a specific regulation, any company was free to produce or import that chemical provided they complied with other laws. Furthermore, no testing was required for existing chemicals.[17] The TSCA inventory initially contained about 61,000 "existing" chemicals reported to the EPA by manufacturers between 1975 and 1978.[18] New chemicals (other than those for exempted uses) undergo a review process, and if the EPA does not find a reason to regulate or prohibit them, they are added to the inventory.[19]

The process of adding a non-exempt new chemical to the TSCA inventory starts with a Pre-Manufacture Notice (PMN). A PMN must be completed at least ninety days before the manufacturer intends to begin importing or producing the chemical.[20] The PMN requires basic information about chemical properties, uses, production levels, and expected

14. *Id.*

15. Of the more than 83,000 chemicals contained in the TSCA inventory, the EPA has placed controls on only nine under TSCA. U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT 10 (2009).

16. *See* David Brownfield, *Reform of U.S. Chemicals Regulations May Not Be out of REACH*, 21 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 223, 227 (2008).

17. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION 4 (2005); *see also* Sarah Bayko, *Reforming the Toxic Substances Control Act to Protect America's Most Precious Resource,* 14 SOUTHEASTERN ENVTL. L.J. 245, 266 (2006) (noting that the EPA "required testing for fewer than 200" of the 62,000 chemicals in commerce when the EPA began reviewing chemicals).

18. *See* U.S. ENVTL. PROT. AGENCY, OVERVIEW: OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS 5 (2007).

19. *Id.* at 8.

20. *Id.* at 7.

exposures.[21] Additionally, the manufacturer must provide any health and safety data, but only to the extent that the data is in their possession or "reasonably ascertainable."[22] This is the greatest criticism of the TSCA and its ultimate downfall.[23] Because there are no minimum health and safety tests required prior to marketing a new chemical under TSCA, most manufacturers choose not to conduct any testing, and submit their PMN absent any test data at all. In 2005, about fifteen percent of PMNs included a full set of basic toxicity data for health and safety.[24]

If the PMN includes less than a full set of data, the options available to the EPA during the 90-day review process are significantly limited. Although the EPA has the ability to request additional testing on a product it believes may pose a threat to health or the environment, in order to make that request, the EPA must have enough information that demonstrates a potential risk or extensive exposure.[25] In the instances where a PMN is submitted without any testing, making even an initial determination of risk or exposure is extremely difficult. Since the TSCA was enacted in 1976, the EPA has required additional testing for only 200 chemicals.[26] When possible, the EPA relies on Structure-Activity Relationship analysis to attempt to predict the physical properties and health and environment effects of an untested chemical.[27] Each year, the EPA receives around 1500 PMNs,[28] and about half of the chemicals identified enter production and

21. *Id.*

22. U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS 7 (2007).

23. *See* Rachel Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENVTL. L. REV. 1, 32-33 (2009).

24. U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 11 (2005).

25. *See* Richard A. Denison, *Ten Essential Elements in TSCA Reform*, 39 ENVTL. L. REP. NEWS & ANALYSIS 10020, 10020 (2009) ("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.").

26. U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 15.

27. *Id.* at 8.

28. *Id.*

enter the TSCA inventory.[29] The other half are voluntarily withdrawn, frequently following the threat of EPA action.[30] Today, the inventory contains upwards of 82,000 distinct chemicals.[31]

C. GAPS IN THE KNOWLEDGE

Although the TSCA database is large, it is far from comprehensive. A majority of the chemicals it contains are "existing" chemicals left over from the initial population of the inventory in 1976.[32] Many of these chemicals are no longer in production, and have been replaced by (hopefully) safer and more effective alternatives.[33] In 1998, the EPA released a study on High Production Volume (HPV) chemicals.[34] HPV chemicals are produced or imported into the United States in excess of 1,000,000 lbs per year.[35] The EPA identified nearly 3000 HPV chemicals, and concluded that no publicly-available toxicity information existed for 43% of the HPV chemicals, and a full set of basic toxicity data existed for only 7%.[36] In an effort to remedy this shocking knowledge deficit, the EPA and chemical industry completed the HPV Challenge, an effort to create data for more than 2,200 of the HPV chemicals.[37] As the program reaches its conclusion in 2010, evaluation of its success is mixed. The EPA portrays the challenge as a huge success, but critics point to the remaining gaps in data and lack of transparency in reporting results.[38]

Even if the EPA has a full picture of what applications of its product a chemical producer anticipates at the time the chemical is added to the TSCA inventory, there can be

29. *Id*. at 10 tbl.1.3.

30. *Id*. at 9–11.

31. U.S. GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 24, at 2.

32. *Id.*

33. The EPA admits that it does not have a complete picture of what chemicals are actually used in the country. A plan was created to reset the inventory, but it was put on hold pending a serious overhaul of the TSCA. *See TSCA Inventory Reset*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/champ/pubs/hpv/tsca.html (last updated Apr. 29, 2010).

34. *See generally* U.S. ENVTL. PROT. AGENCY, *supra* note 2.

35. *See id.* at 2.

36. *Id.*

37. *See* U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 30–33.

38. *See* RICHARD A. DENISON, ENVIRONMENTAL DEFENSE FUND'S COMMENTS ON CHAMP 5 (2008).

significant changes over time, as different uses are discovered, or different end-users begin incorporating the chemical in their business.[39] To attempt to gauge these changes and update the inventory, the EPA created the Inventory Update Rule (IUR) in 1977 using its section 8(a) powers under the TSCA.[40] The EPA has since amended the IUR, the most recent change coming into effect in 2006.[41] The IUR presently requires manufacturers producing 25,000 pounds or more of certain chemicals to provide basic manufacturing information to the EPA every five years.[42] Manufacturers producing more than 300,000 pounds have additional reporting requirements.[43] In a problem that mirrors the initial reporting requirements for PMNs, IUR reports only require information that the manufacturers consider is "readily obtainable."[44] In the 2006 IUR summary, of the 2118 chemicals that reported commercial or consumer uses, 814 claimed determining if their product was intended for children was "Not Readily Obtainable."[45] The EPA readily admits that because of "Not Readily Obtainable" responses, "the reported industrial processing and use information represents an undercounting of the actual processing and use situations in the United States."[46] Furthermore, "companies reporting under the IUR might have incomplete knowledge of the processing and/or use of their chemicals."[47] If the producers of a chemical do not have a complete picture of how their product is being used, it seems unlikely that someone else does.

D. PARALYZED WITH (A LACK OF) DOUBT

The data gap is not only dangerous because of the lack of practical knowledge, but it causes significant headaches for the EPA when attempting to promulgate regulations on chemicals that it has good reason to suspect are dangerous. Two frequently-quoted examples come from the judicial decisions in

39. *See generally* Denison, *supra* note 25, at 10024-26.
40. *TSCA Inventory Reset*, *supra* note 33.
41. *See* Denison, *supra* note 25, at 10024-25.
42. *Id.*
43. *Id.*
44. *Id.*
45. U.S. ENVTL. PROT. AGENCY, 2006 INVENTORY UPDATE REPORTING: DATA SUMMARY 31 (2008).
46. *Id.* at 12.
47. *Id.*

Chemical Manufacturers Association v. EPA[48] and Corrosion Proof Fittings v. EPA.[49] In both cases, the Fifth Circuit ruled that the EPA had insufficient data to justify the action they were taking—requiring testing for isopropyl benzene in *Chemical Manufacturers* and banning asbestos in *Corrosion Proof*.

In *Chemical Manufacturers*, although manufacturers and processors released nearly three million pounds of isopropyl benzene into the atmosphere each year, and produced more than three *billion* pounds of the chemical each year, very little was known about the carcinogenic effects of the chemical.[50] Because isopropyl benzene was "produced in substantial quantities," and its use created the "potential for substantial human exposure." The EPA issued a final test rule that required manufacturers to perform testing on "health effects, environmental effects, and chemical fate."[51] The chemical manufacturers sued, and the Fifth Circuit agreed that the EPA had not articulated a standard to determine when exposure to isopropyl benzene was "substantial."[52] As a result, before the EPA can require additional data, they must set a standard for exposure, but before the EPA can set a standard for exposure, they need additional data.[53] The high burden of proof that must be met to promulgate a rule, combined with the underreporting of information from the manufacturers meant the EPA essentially was unable to require manufactures to conduct tests against their will.[54]

Corrosion Proof Fittings spelled the end of the EPA's attempts to institute significant rulemaking efforts that are not explicitly supported by industry.[55] Although the EPA based their ban on asbestos on more than "45,000 pages of analyses, comments, testimony, correspondence, and other materials,"[56]

48. Chem. Mfrs. Ass'n v. EPA, 899 F.2d 344 (5th Cir. 1990).

49. Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

50. Cumene; Final Test Rule, 53 Fed. Reg. 28195, 28196 (July 27, 1988) (codified at 40 C.F.R. pt. 799).

51. *Id.* at 28195.

52. 899 F.2d at 360.

53. *See* Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENVTL. LAW. 99, 116 (1999).

54. *Id.*; *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 24, at 18.

55. *See* U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 18-20.

56. Asbestos: Manufacture, Importation, Processing, and Distribution in

the Fifth Circuit largely vacated the rule on the basis that "the EPA has failed to support its ban with the substantial evidence needed to provide it with a reasonable basis."[57] After such significant and costly setbacks, it is perhaps unsurprising that in the thirty-three year history of the TSCA, the EPA has banned only five of the substances originally contained on the inventory, and placed controls on four new chemicals under section 5(f).[58]

This article opened with a quote by Dr. Russell E. Train, the administrator of the EPA during the inception of the TSCA. The Senate cited Dr. Train's comments about the ignorance of Americans regarding the dangers of chemicals present in their everyday life as a strong motivation for the passage of the TSCA.[59] Sadly, it appears thirty-three years later the situation has not significantly improved, and most Americans assume that because a chemical is allowed to be produced in the country, it must have passed a battery of tests to prove its safety. While this is true for a number of substances, such as pesticides, drugs, food, and cosmetics, these categories do not cover even a majority of the chemicals that Americans come in contact with on a daily basis. The regulatory gap that spawned the TSCA remains today.

The controversy over Bisphenol A (BPA) in 2008 is a perfect example of the faith the American people have in the regulatory ability of the US government, and their shock when they realize how little regulation actually occurs. Produced in quantities exceeding two billion pounds in 2004, BPA is frequently used in the manufacture of polycarbonate and epoxy resins.[60] The chemical entered the national lexicon in 2008 when it became known that the FDA had ignored significant safety concerns when evaluating the health effects of BPA that leeched into food and beverages from plastic containers.[61]

Commerce Prohibitions; Final Rule, 54 Fed. Reg. 29460, 29461 (July 12, 1989) (codified at 40 C.F.R. pt. 763).

57. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1226 (5th Cir. 1991). The ban is still effective with regard to new products using asbestos. *See* U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 19.

58. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 15, at 10 n.3.

59. S. REP. NO. 94-698, at 3 (1976).

60. *See* Bisphenol A Global Indus. Grp., *Bisphenol A: Information Sheet* (October 2002), http://www.bisphenol-a.org/pdf/DiscoveryandUseOctober2002.pdf.

61. *See, e.g.*, Julie Scelfo, *F.D.A. to Reconsider Plastic Bottle Risk*, N.Y. TIMES, Dec. 24, 2008, at D3.

Consumer backlash against products containing BPA led the six largest manufacturers of baby bottles to offer BPA free versions of their products, and led to a ban on BPA in children's products in Canada and several states.[62]

Furthermore, while the TSCA has one of the largest universes of chemicals to regulate, it has one of the smallest staffs and budgets of federal regulatory programs.[63] As a point of comparison, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates approximately 700 pesticides used in America each year.[64] The FIFRA operates on a licensing scheme, where a producer must prove safety of their product and be granted a license before the EPA allows distribution. In 2008, the Office of Pollution Prevention and Toxics (which administers the TSCA) had an operating budget of about $50 million for TSCA activity, and a staff of about 270 people.[65] Also in 2008, the FIFRA, in contrast, had a budget of about $160 million and a staff of over 900 people.[66] The FIFRA has a budget over three times greater to police a chemical universe less than one percent of the size of the TSCA.[67]

E. OTHER EXAMPLES

The European Union recently enacted legislation known as Registration, Evaluation and Authorization of Chemicals (REACH).[68] It took effect on June 1, 2007, and in many ways, represents the antithesis of the TSCA program.[69] Unlike the TSCA, REACH creates no distinction between "new" and "existing" chemicals; every chemical produced or imported into

62. *See* Denise Grady & Gardiner Harris, *U.S. Concerned About The Risks From A Plastic*, N.Y. TIMES, Jan. 16, 2010, at A3.

63. *See* Mark A. Greenwood, *TSCA Reform: Building a Program that can Work*, 39 ENVTL. L. REP. NEWS & ANALYSIS (SPECIAL ISSUE) 10034, 10036 (2009).

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *See* Lynn L. Bergeson, *Chemical Regulation: Preparing to Address the Challenges Ahead*, 39 ENVTL. L. REP. NEWS & ANALYSIS (SPECIAL ISSUE)10029 (2009). *See generally* European Commission Environment Directorate General, REACH in Brief (2007).

69. *See* John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 741–44 (2008).

the EU in sufficient quantities faces the same regulatory process.[70] Because REACH is based on the chemicals that are actually used in the EU, its universe is expected to be significantly smaller, around 30,000 unique substances, or just a little over a third of the size of the TSCA inventory.[71]

According to the quantity of the chemical produced and its known hazards, every manufacturer must submit technical data along with their request for registration.[72] Chemicals known to be safe, and those produced in small quantities have the lowest reporting requirement, but manufacturers are still required to produce detailed information about the chemical properties, expected uses, and safe handling requirements for their product.[73] Chemicals produced in larger quantities, and those that present biological or environmental hazards are required to undergo significant testing before REACH will authorize their use.[74] Further requirements are in place for downstream users to report their uses to their suppliers, and REACH encourages information sharing among governments and industry to create a complete picture of the exposure and uses present for each chemical.[75] REACH also includes significant regulatory authority, requiring evaluation and authorization for most chemicals before they reach the market.[76] REACH places the burden on manufacturers, for the most part, to prove their product's safety before distribution is allowed.[77] According to some estimates, high production volume chemicals (100 metric tons or more) will have to undergo an average of forty-eight tests before marketing under REACH, compared to just fourteen voluntary tests under the TSCA.[78]

70. *Id.* at 743–44.

71. *See* EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 68, at 9.

72. *See* Applegate, *supra* note 69, at 744–45.

73. *See* EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 68, at 6–10.

74. REACH encourages non-animal testing to the extent possible, and encourages companies with similar chemicals to pool resources and share data. *See* EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 68, at 10.

75. EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 68, at 8, 11.

76. *See* Applegate, *supra* note 69, at 744.

77. Applegate, *supra* note 69, at 745–46.

78. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 22, at 17.

F. CALLS FOR REFORM

Although calls for reform of the TSCA have been present for nearly all of its thirty-three year history, there has never been a significant revision to the substance of the TSCA.[79] The last significant attempt was the Kid Safe Chemical Act (KSCA), proposed in 2005 by Senators Frank Lautenberg and Jim Jeffords.[80] The KSCA would have given the EPA additional power to use the TSCA to regulate the industry to protect sensitive sub-populations, especially children, from exposure to chemicals that were known to be hazardous or that had not been significantly tested.[81] Replacing the "unreasonable risk" standard, the KSCA would have allowed the EPA to regulate chemicals that did not present a "reasonable certainty of no harm."[82] Critics of the reform dismissed this standard as unworkable and unattainable.[83]

With the change in leadership in Washington in 2009, talk began again about the necessity of reforming or modernizing the TSCA. On September 29, 2009, EPA Administrator Lisa P. Jackson released a document entitled "Essential Principles for Reform of Chemicals Management Legislation."[84] In her speech at the California Commonwealth Club announcing the principals, Administrator Jackson acknowledged the shortcomings of the current implementation of the TSCA and asked Congress to come up with legislation to resolve those problems.[85]

Industry has also been a vocal proponent of modernization of the TSCA. Coinciding with the EPA's drive for reform, the American Chemistry Council released its own set of ten

79. Greenwood, *supra* note 63, at 10034 ("TSCA is one of the oldest federal environmental statutes that has never seen substantial reform.").

80. Kid Safe Chemicals Act, S. 1391, 109th Cong. (2005); H.R. 4308, 109th Cong. (2005).

81. *See* S. 1391§ 2(b).

82. S. 1391 § 503(a)(1).

83. *See, e.g.*, SOC'Y OF CHEM. MFRS. AND ASSOCIATES, SOCMA POSITION ON REFORMING THE TOXIC SUBSTANCES CONTROL ACT (2009), *available at* http://www.socma.com/assets/file/socma1/PDFfiles/GR_PDF_files/SOCMA-Position-on-TSCA-031909.pdf (describing the reasonable certainty of no harm standard as "arguably . . . impossible to meet").

84. U.S. ENVTL. PROT. AGENCY, *supra* note 5.

85. Adm'r Lisa P. Jackson, Envtl. Prot. Agency, Remarks to the Commonwealth Club of San Francisco (Sept. 29, 2009) (transcript available on EPA web site).

principles for modernizing the TSCA.[86] Notably, the American Chemistry Council supports a regulatory scheme that requires manufacturers to conduct additional testing to allow the EPA to make confident decisions about safety.[87] Composed of over 150 businesses, trade organizations, and manufactures, the Coalition for Chemical Safety represents the strongest industry voice calling for reform.[88] According to the Coalition for Chemical Safety Blog, they have four guiding principles that all of the members agree upon: "[1.] Our country is long past due for an overhaul of its chemical safety laws; [2.] Any such overhaul should put safety first; [3.] It should also be a law that encourages American industrial innovation; and, [4.] It should protect American jobs."[89]

Thus with support from government, industry, and citizens, it is only a matter of time before a proposal is brought before Congress. In the meantime, the EPA has been testing the limits of its authority, establishing a "chemicals of concern" list and action plans that may place restrictions on phthalates, short-chain chlorinated paraffins, polybrominated diphenyl ethers (PBDEs), and perfluorinated chemicals.[90] The EPA has also been encouraging manufacturers of other dangerous chemicals to voluntarily phase out use and distribution.[91]

III. ANALYSIS

As Congress holds hearings on reform and toxic chemicals, it is important to consider the essential elements of a reform that would give the EPA the necessary authority and oversight to ensure that the chemicals in the United States are safe and effective. If any reform is going to be effective, it has to learn from the mistakes of the past and remedy the shortfalls of the current version of the TSCA.

86. AMERICAN CHEMISTRY COUNCIL, *supra* note 5.

87. *Id.*

88. *See generally About Us*, COALITION FOR CHEMICAL SAFETY, http://coalitionforchemsafety.com/aboutus.aspx (last visited Sept. 6, 2010) (describing the organization and providing a list of Coalition members).

89. *Who is CCS?*, COALITION FOR CHEMICAL SAFETY, http://blog.coalitionforchemsafety.com/2010/02/who-is-ccs/ (last visited Sept. 6, 2010).

90. Elizabeth Grossman, *What the EPA's "Chemicals of Concern" Plans Really Mean*, SCIENTIFIC AMERICAN (Jan. 11, 2010), http://www.scientificamerican.com/article.cfm?id=epa-chemicals-of-concern-plans.

91. *See id.*

First, reform must reset the chemical inventory and ensure that no chemical is given a free pass solely because it is already in production. Second, a reformed TSCA should place the primary burden on manufacturers to prove the safety of their product by imposing requirements for minimum initial testing before a substance is added to the inventory and approved for sale. Third, the data that results from increased testing must be shared with states and other agencies so that they can determine what, if any, additional regulations are required to keep us safe. Fourth, a reformed TSCA must provide benefits to manufacturers who conduct sufficient testing and produce innovative and safe chemicals for consumer and industrial use. Finally, the TSCA must establish a standard of review that takes advantage of the new influx of information and allows for flexibility in regulation.

A. FIRST STEPS: IT MAKES SENSE TO RESET THE CHEMICAL INVENTORY, AND PRIORITIZE THE EPA'S INVESTIGATION

In 1976, there were approximately 61,000 existing chemicals in commerce when the TSCA came into effect.[92] As existing chemicals, no additional testing was required before companies who manufactured these chemicals began to distribute their product, often in shockingly large quantities.[93] While a lot has changed over the last thirty-four years, the inventory has not been updated to reflect these changes.[94] Over 20,000 new chemicals have been added to the inventory, and other chemicals that were in wide use during the 1970s have dropped out of use completely.[95] As a method for explaining the number and types of chemicals that are in actual use in the United States today, the TSCA inventory is a complete failure.

A primary element that will be a part of any successful reform of the TSCA is an inventory reset. An inventory reset is not a new proposal.[96] The EPA announced a plan to reset the inventory in March of 2008 but discontinued the plan when it became apparent that a complete overhaul of the system was in

92. *See* U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 5.

93. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 17, at 4, 7, 11.

94. Jackson, *supra* note 85.

95. *See* ENVTL. PROT. AGENCY, BACKGROUND DISCUSSION PIECE: EPA'S TSCA INVENTORY RESET 1, 3 (2008), *available at* http://www.epa.gov/champ/pubs/hpv/INV_Reset_112508.pdf.

96. *Id.*

the works.[97] By purging the TSCA inventory and re-creating a new inventory that reflects the actual and intended uses of chemicals that are produced in or imported into the United States, the EPA will actually be able to reduce its workload when it comes time to evaluate the chemicals contained in a new inventory. All manufacturers and importers should be required to provide a list of all chemicals that they are producing, using, or importing in a given period (perhaps three years as was used for the original TSCA inventory) along with an approximate quantity of each chemical. In this way, the EPA will be able to prioritize their investigations based on the quantity of the substance in use in a given year. Old substances that are no longer in use have no place in the inventory. If a company wishes to use a discontinued substance in the future, they will be required to provide testing data for the chemical just as if it is a new discovery.

An inventory reset might be combined with a sunset clause on any chemical that is not used for more than a decade to ensure that the new TSCA inventory remains relevant. As time passes, we learn more about risks from substances that were considered harmless in the past.[98] Without continual monitoring of the substances we produce and release, their hazardous effects on our body and our environment take us by surprise.

The biggest advantage of an inventory reset would be the opportunity for the EPA to take another bite at the apple of regulation for some specific chemicals. Many of the 61,000 original chemicals are no longer produced and have not been evaluated for health and safety in the last decade, but a company could decide tomorrow to once again begin manufacturing the chemical in large quantities.[99] Assuming they were not going to use the chemical for a new purpose, the EPA would not have any significant ability to require new testing or prevent the company from going forward because the substance is already contained on the TSCA inventory.

An inventory reset and retesting requirement would not be a heavy burden on industry either. Thanks to the success of the EPA's High Production Volume Challenge, most companies

97. *Id.*

98. For a particularly shocking tale about the hazards of a popular microwaveable snack, see Andrew Scott Dulberg, *The Popcorn Lung Case Study: A Recipe for Regulation?,* 33 N.Y.U. REV. L. & SOC. CHANGE 87 (2009).

99. *See* U.S. ENVTL. PROT. AGENCY, supra note 95.

have relatively complete data about the health and safety effects of their most common products.[100] Additionally, because the European Union will have had their REACH program in effect for nearly half a decade by the time new legislation would take effect, most of the chemicals will have been tested under the REACH standards for safety already.[101] In the current system, companies that refuse to test or that under-test their products are given a huge benefit, while companies that are committed to fully ensuring the safety of their product spend millions on testing and are only rewarded with more regulatory hoops to jump through.[102] An effective regulatory program should not encourage willful ignorance about health and safety, regardless of how long a product has been on the market.

B. SHIFTING THE BURDEN: A REFORMED TSCA SHOULD PLACE RESPONSIBILITY TO PROVE SAFETY IN THE HANDS OF THE MANUFACTURER, BY REQUIRING MANUFACTURERS TO CONDUCT INITIAL TESTING OF THEIR PRODUCT

Under the current system, manufacturers are not required to conduct product testing before submitting their application to the EPA.[103] Because the EPA relies in part on the data sent by a manufacturer to determine if there are health or safety concerns that warrant additional testing, manufacturers who believe they might have a dangerous product are actually given incentives *not* to test under the current system.[104] While the EPA has the ability to test a product themselves, they do not have the resources or the knowledge of a manufacturer, and at current funding levels would not be capable of testing every product submitted to them.[105]

From a logistical standpoint, it makes the most sense to have manufacturers conduct their own testing. Manufacturers have the greatest interest in seeing their product come on the market, and they also have the best idea about the intended uses for their product and how much they intend to produce. Requiring manufacturers to conduct tests would equitably

100. *See* U.S. ENVTL. PROT. AGENCY, *supra* note 18, at 30–33.

101. *See* Bergeson, *supra* note 68, at 10030.

102. *See* Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629, 630 (2008).

103. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 24, at 11.

104. *See* Wagner, *supra* note 102, at 630.

105. *See* Greenwood, *supra* note 63, at 10036.

distribute the cost of comprehensive testing between the manufacturers who produce the product and the companies who use the chemicals in the greatest quantity.

From a legal standpoint, some courts have recently held that manufacturers have a duty to test their product under the common law—apart from the extremely limited duties imposed by the TSCA. The Fifth Circuit has been the most vocal proponent of common law responsibility to test, stating that "a manufacturer has a duty to test and inspect his product. . . . A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal."[106] Unfortunately, proving that a manufacturer has violated their common law duty to test is more difficult when the manufacturer completes insufficient testing, because first a plaintiff must prove that they were damaged by the product, which is nearly impossible without full testing.[107]

A common concern those opposed to mandatory testing have is control over trade secrets and confidentiality.[108] Producers claim that in the process of providing all of the health and safety data to the EPA they would be forced to divulge trade secrets that would give their competitors an unfair advantage. According to some estimates, nearly 95% of Potential Manufacture Notices include significant restrictions on the data they contain because they are identified as confidential business information.[109] Apart from the dubious quality of the argument that preserving trade secrets is worth risking the health and safety of millions of people, there are plenty of safeguards available to ensure that confidential business information can stay protected while potential safety risks are disclosed. It is reasonable for a company to want protection of their sensitive information for a period while patents are acquired or experimental procedures are tested, but allowing wholesale permanent exclusion of confidential business information causes far more harm to our safety knowledge than the benefit it provides to the company. Companies should be allowed to request confidential business information protection for specific information and for a limited

106. Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1090 (5th Cir. 1973).

107. Wagner, *supra* note 102, at 636.

108. *See* Denison, *supra* note 25, at 10027.

109. *Id*.

period. Furthermore, they must be required to provide justification for their requests, or inappropriate confidential business information requests will continue.

Finally, for industry to support a reform that requires them to conduct additional testing, there must be advantages for the manufacturers that embrace their responsibilities. One possible enticement might be a limit on the liability of a manufacturer who completes the most rigorous tests on their product.[110] If a manufacturer completes a full battery of tests and submits the results to the EPA for the public to see, they could be granted a cap on their liability for torts arising from that product. Toxic torts are one of the most expensive potential liabilities that a company exposes themselves to, and they would likely jump at the chance to limit their exposure.[111] Furthermore, complete testing data would allow the EPA to have the information they need to regulate the use and availability of a product, and inform the public about the risks of a chemical and proper procedures to limit that risk.

C. SHARING THE FRUITS OF OUR LABOR: A REFORMED TSCA MUST ENSURE HEALTH AND SAFETY RISK DATA IS SHARED WITHIN THE UNITED STATES AND INTERNATIONALLY

After the EPA creates a new chemical inventory and the chemicals it contains are subjected to extensive testing to ensure their safety, the question remains of what to do with the information contained in the inventory. There are two opposing options: preserve the secrecy of the data, or publish it freely for the use of the public. For reasons I will explain, the success and efficiency of the system requires that the chemical inventory data become publicly available without restrictions.

If the inventory data is protected and access to the information within is restricted, companies may feel more confident about submitting their data. They could be sure that their internal tests could not be "blown out of proportion" by consumers or the media, and they would know that their competitors could not use their own studies against them. Furthermore, a closed system of confidential test results would

110. *See* Haemer, *supra* note 53, at 133.

111. Robert Haemer points out that a similar program is in place for nuclear power generators through the Price-Anderson Act, 42 U.S.C. § 2210 (1994). Haemer, *supra* note 53, at 133.

cure any free rider problems. The first company to test a common substance incurs a large expense. In a system with freely available information, the original company's competitors can rely on the first test results to obtain approval for their product as well, without spending the money to conduct the tests themselves. A closed system, on the other hand, provides incentives for a company to conduct tests early and enjoy a monopoly on the market until a competitor can complete their own tests. Furthermore, companies would not have to be concerned about the security of their confidential business information.

On the other hand, a public and open chemical inventory would help to encourage confidence among consumers of chemicals. Anyone could log on to a central clearinghouse and get the full test results for a chemical they were considering using in their product, and have a complete picture of the level of safety the product they were considering would provide. Companies would be encouraged to conduct additional testing on their competitors' products, because if they could prove that a competitor had a product that was less safe or incompletely tested, they would enjoy a preference in a market that increasingly desires comprehensive information about the safety and health risks of various substances.[112] An open system could still provide protection for confidential business information, but consumers who have a preference for knowledge of their products may prefer the substance that has complete disclosure of risks, and disfavor products that are covered by extensive claims of trade secrets.

An open system has the added advantage of allowing easy collaboration between the EPA, and state and national governments. Cooperation with REACH, the European Union's chemical control program, will be essential to prevent duplication of efforts and allow thorough investigation of the properties of chemicals in the inventory. Keeping with the principles of federalism present in our government, individual states should be allowed to enact controls over substances of concern that the EPA chooses not to attempt to regulate. If other agencies and governments can be trusted to maintain the security of any confidential information contained within the inventory, there is no reason to deny them access.

112. *See* Wagner, *supra* note 102, at 640.

D. ENCOURAGING INNOVATION: WHY STRONGER CONTROLS WILL NOT STIFLE INVENTION AND PROGRESS

Rather than stifling innovation, a new regulatory scheme under a reformed TSCA will encourage new developments. Currently, existing chemicals enjoy a favored status under the TSCA. Because they are not subject to extensive testing for safety, an existing chemical may be an appealing choice for a company looking for a solution to a problem.[113] However, the premise that an existing chemical is automatically safer than a newly developed substitute has repeatedly been discredited.[114] If a reformed TSCA requires all chemicals to be tested, the bias towards existing chemicals could easily disappear if there are promising green replacements available.

Furthermore, the rapid pace of nanomaterial development requires a new approach to the new vs. existing chemical distinction. Carbon is carbon is carbon, as far as the TSCA is concerned. Nanomaterials, however, are engineered substances often produced from a single element (gold, or carbon, or silicon, for example).[115] The physical structure of these substances is on the molecular scale, and the arrangement of the molecules that constitute them has a direct impact on the potential health effects of the nanomaterials on humans. There is evidence that small carbon nanotubes may act similarly to asbestos fibers if inhaled,[116] but in the eyes of the current TSCA, the nanotubes are no more dangerous than the graphite in a pencil lead.

E. CHOOSING AN APPROPRIATE STANDARD OF REVIEW: WHY THE KID SAFE CHEMICAL ACT'S PROPOSED "REASONABLE CERTAINTY OF NO HARM" STANDARD IS UNWORKABLE AND UNDESIRABLE FOR A REFORMED TSCA

As mentioned before, a previous proposal to reform the TSCA was Senator Frank Lautenberg's Kid Safe Chemical Act (KSCA). The KSCA attempted to replace the TSCA's

113. *See* Bayko, *supra* note 17, at 254–55.

114. The EPA calls this phenomenon "new chemical bias." *See* U.S. ENVTL. PROT. AGENCY, *Regulation of New Chemicals and Chemicals Already on the Market*, US EPA, http://www.epa.gov/oppt/newchems/pubs/newvexist.htm (last visited Sept. 10, 2010).

115. *See* Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 361–63 (2007).

116. *Id.* at 360 n.72.

"unreasonable risk" standard with a more stringent requirement of a "reasonable certainty of no harm."[117] The goal of the KSCA was to reverse the inquiry: rather than requiring the EPA to prove that a chemical presented an unreasonable risk before allowing regulation, the manufacturer had to certify that their testing showed there was a reasonable certainty of no harm. Industry executives roundly decried this standard as unworkable and unrealistic.[118] Furthermore, the Act only required the chemical to be certified based on available knowledge.[119] Under the KSCA, just as under the TSCA, a company might attempt to plead ignorance regarding the effects of their chemical. Thus, a company could claim that, to their knowledge, there was a reasonable certainty of no harm if the testing to actually determine the safety of their product was too expensive or difficult to complete. The KSCA, in some cases, would have given the illusion of safety when in reality the necessary tests had not been completed.

REACH, in contrast, does not create a threshold inquiry at all. Rather, REACH encourages manufacturers to be proactive in evaluating the benefits and drawbacks of their product.[120] If there are readily available substitutes to a potentially dangerous chemical, then REACH requires the manufacturer and users to use the substitute, unless they can present a compelling justification for the continued use of the more dangerous product. The goal of an effective regulatory scheme should not be to set a minimum floor for safety or a ceiling for toxicity, but rather to provide the tools for a comprehensive, individualized determination of the economic, social, and health effects of allowing the sale, manufacture, and import of a certain chemical.

IV. CONCLUSION

The time is right for reform of the TSCA. It is politically popular, supported by industry, and aligned with regulatory initiatives in the European Union as well. The TSCA in its current form is ineffective and inaccurate. It gives the

117. Kid Safe Chemicals Act, S. 1391, 109th Cong. § 503(a)(1) (2005); Kid Safe Chemicals Act, H.R. 4308, 109th Cong. § 2(b)(2)(C) (2005).

118. *See* American Chemistry Council Statement on the Kid Safe Chemical Act, May 21, 2008 (describing some Kid-Safe Chemicals Act provisions as "impractical" and "duplicative").

119. S. 1391 § 501(a)(1); H.R. 4308 § 501(a)(1).

120. *See* Applegate, *supra* note 69, at 745–46.

appearance of safety to the chemical industry without actually ensuring that the products of the industry are reliable and safe.

This Note has shown that the most important step of effective TSCA reform is an overhaul of the inventory that describes the chemicals that are in use in the United States today. The inventory must be rebuilt from the ground up, including only those chemicals that are actually in use, and the manufacturers of the chemicals should be the parties responsible for providing the data to populate the inventory. The resulting database will be complete and give a realistic picture of the health and safety risks of the chemicals in the inventory as they are actually used. By sharing the database with agencies, and state and international governments, we can increase the effectiveness of the TSCA and ensure that we are protected from dangerous chemicals.

Congress continues to hold hearings on the TSCA and the EPA's ability to regulate toxic substances. It seems that it is only a matter of time until sweeping reforms are brought to the TSCA. Effective reform must incorporate some method of resetting the inventory and closing the toxic data gap. A well-crafted reform will greatly improve the safety of Americans and encourage invention of safer substitutes for dangerous chemicals. Public knowledge of the health risks of individual chemicals will encourage manufacturers to use safer alternatives, and reward companies who provide safer products. Increased cooperation with other agencies, and state, local, and international governments will improve the quality of our toxic substances inventory. The road to reform may take years, but it is important to take the time now to reform an act that at its inception in 1976 was already out of date.