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Reform of U.S. Chemicals Regulations May Not Be Out of REACH

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*David Brownfield**

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I. INTRODUCTION

A 2002 study, led by Mount Sinai School of Medicine in New York, found an average of ninety-one industrial compounds, pollutants, and other chemicals

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in the blood and urine of nine volunteers.[1] The people tested did not work with chemicals, nor did they live near industrial facilities.[2] The researchers found a total of 167 chemicals.[3] Of those, seventy-six cause cancer in humans or animals, ninety-four are toxic to the brain and nervous system, and seventy-nine cause birth defects or abnormal development.[4]

Each year two thousand to three thousand new chemicals are submitted to the Environmental Protection Agency (EPA) for review before manufacture.[5] Eighty percent of all applications to manufacture new chemicals are approved without any health or safety data.[6] About eighty percent of those are approved within three weeks.[7] Of the 2,800 chemicals that are produced in quantities greater than one million pounds per year in the United States, only forty-three percent have been tested for their potential human toxicity.[8] Only seven percent have been studied for their possible effects on development.[9] "Americans tend to think that products are safe because they are in the market and must somehow have passed government regulation."[10] In reality, the risks to humans are largely unknown, and the U.S. regulation's lack of testing requirements are a large part of the problem.[11]

Prior to the 1970s, no meaningful oversight existed over the tens of thousands of chemicals on the market.[12] On October 11, 1976, Congress enacted the Toxic Substances Control Act (TSCA).[13] The stated purpose of the act was "to regulate chemical substances that present a hazard to health or the

1. Environmental Working Group: BodyBurden, Executive Summary: What We Found, http://archive.ewg.org/reports/bodyburden1/ (last visited Nov. 5, 2008) (follow *Enter here* link to enter page).

2. *Id.*

3. *Id.*

4. *Id.*

5. Philip J. Landrigan et al., *Environmental Pollutants and Disease in American Children: Estimates of Morbidity, Mortality, and Costs for Lead Poisoning, Asthma, Cancer, and Developmental Disabilities*, 110 No. 7 ENVTL. HEALTH PERSPECTIVES 721, 721 (2002), *available at* http://www.ehponline.org/members/2002/110p721-728landrigan/EHP110p721PDF.PDF.

6. Environmental Working Group: BodyBurden, *supra* note 1.

7. *Id.*

8. Landrigan, *supra* note 5.

9. *Id.*

10. Marla Cone, *Europe's Rules Forcing U.S. Firms to Clean Up; Unwilling to Surrender Sales, Companies Struggle to Meet the EU's Tough Stand on Toxics*, L.A. TIMES, May 16, 2005, at A1 (quoting Alastair Iles, a postdoctoral fellow at UC Berkeley's Energy and Resources Group); *see also* Euractiv.com, EU Chemicals Law REACH Inspires US Bill (July 18, 2005), http://www.euractiv.com/en/environment/eu-chemicals-law-reach-inspires-us-bill/article-142660 (quoting Sen. Frank R. Lautenberg, "Most Americans believe their government is making sure that chemicals used in the market place are safe. Unfortunately, that simply isn't true. Study after study has shown we have dozens, if not hundreds, of synthetic chemicals in our bodies, yet we have very little information about how they impact our health.").

11. Cone, *supra* note 10.

12. Mark Schapiro, *Toxic Inaction: Why Poisonous, Unregulated Chemicals End up in our Blood*, HARPER'S MAG., Oct. 2007, at 79.

13. Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (1976).

environment."[14] Although TSCA was progressive at the time, it never seemed to fulfill its purpose.[15] The regulation lacked the strength to cause any meaningful changes in the chemical industry.[16] As a result, toxic chemicals are everywhere in the environment and the human body.[17] In the late 1990s the European Union (EU) saw this as a problem, and responded by enacting a new regulatory framework.[18]

On December 18, 2006, the EU enacted new legislation to deal with the regulation of toxic chemicals.[19] The new legislation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), went into effect June 1, 2007.[20] With the passage of REACH, the European Union has bypassed the United States as the leader in toxic substances regulations.[21] Although REACH cannot provide a quick fix to the health and environmental concerns caused by the proliferation of toxic chemicals, this article will discuss how it is a significant step toward better control and safer use of toxic chemicals.

The EU has progressed in its regulation of toxic substances while the U.S. is committed to staying in the same place. Congress has not updated or amended the TSCA in the last thirty years despite reports that it is in need of a change.[22] Making matters worse, the Bush Administration and the chemical industry were committed to opposing REACH since its proposal in 2001.[23] Despite U.S. efforts,

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14. RAY M. DRULEY & GIRARD L. ORDWAY, THE TOXIC SUBSTANCES CONTROL ACT iii (1977).

15. Marla Cone, *EPA Is Faulted as Failing to Shield Public from Toxins*, L.A. TIMES, July 13, 2005, at A18. (quoting Sen. Frank R. Lautenberg, "In 29 years, the agency has formally requested health information on just 200 chemicals—out of about 80,000, according to the report.").

16. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) (invalidating the Environmental Protection Agency's ban on asbestos because the EPA lacked the requirements under the TSCA to prove a ban was needed).

17. *See* Schapiro, *supra* note 12, at 78 (a 2005 Centers for Disease Control and Prevention study completed screening for presence of 148 toxic chemicals in the blood of Americans and found a vast majority harbored almost all of the chemicals).

18. *Id.* at 78-79.

19. Europa, Regulatory Framework for the Management of Chemicals (REACH), European Chemicals Agency, http://europa.eu/scadplus/leg/en/lvb/l21282.htm (last visited Nov. 5, 2008) [hereinafter Europa, Regulatory Framework].

20. Europa: European Commission, REACH, http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm (last visited Nov. 5, 2008).

21. Toxic Substances Control Act, 15 U.S.C.A. §§ 2601-2692 (West 2008); *see* Schapiro, *supra* note 12 ("Europe is now compelling other nations' manufacturers to conform to regulations that are far more protective of people's health than those in the United States. Europe has emerged not only as the world's leading economic power but also as one of its moral leaders. Those roles were once filled by the United States.").

22. U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 4 (June 13, 2005), *available at* http://www.gao.gov/new.items/d05458.pdf [hereinafter USGAO, GAO-05-458] (advising on seven ways in which Congress could improve Chemical Regulation, including amendments to TSCA).

23. *See* MINORITY STAFF OF H. R. COMM. ON GOV'T REFORM, A SPECIAL INTEREST CASE STUDY: THE CHEMICAL INDUSTRY, THE BUSH ADMINISTRATION, AND EUROPEAN EFFORTS TO REGULATE CHEMICALS, (Apr. 1, 2004), *available at* http://oversight.house.gov/Documents/20040817125807-75305.pdf.

the EU passed a strong regulation that has left the U.S. in a position to play catch-up.[24]

Whether the U.S. provides new regulations, REACH will have worldwide implications.[25] The EU now has a larger market than the U.S., and U.S. industry must make a concerted effort to comply with the new regulation if chemical trade in the EU is to continue.[26] The strict regulation in a market of that size may also cause some of the most dangerous chemicals to flow into third world countries where regulations are less strict.[27] Perhaps the power of the European market will compel other countries to follow, or perhaps it will compel emerging countries to lessen regulations in hopes of spurring more industry.[28] Regardless of how other countries react, the U.S. toxic substances regulation is in need of reform. The EU has provided the U.S. with a guide for change. Unfortunately, the U.S. opposed the passage of REACH, and domestic efforts to pass new legislation thus far have failed.[29]

This comment proposes that REACH should be a model for the U.S. and other countries in the reform of chemicals regulations. Part II focuses on the TSCA, and the inability to effectively regulate chemical substances within its framework. Part III explains the key provisions of the recently enacted REACH legislation. Part IV highlights the U.S. and chemical industry opposition to the passage of REACH. Part V briefly looks at the anticipated costs and benefits of REACH's strict chemical regulations. Part VI focuses on the Kid Safe Chemical Act (KSCA), U.S. Congress's most recent attempt at domestic reform of chemicals regulations. Part VII explores the effects REACH could have on U.S. chemicals regulations.

II. THE TOXIC SUBSTANCES CONTROL ACT

A. *History*

To understand the significance of REACH, it is first important to understand the TSCA. Before the TSCA was passed in 1976, the federal government's

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24. Europa, *supra* note 19.

25. Cone, *supra* note 10.

26. *See id.* (stating "the EU, with 25 countries and 460 million people, surpasses even the United States as a market.").

27. *See* Schapiro, *supra* note 12, at 83 (when the U.S. imposed domestic restrictions on dangerous chemicals, U.S. companies responded by exporting millions of pounds of these chemicals to Third World countries where regulations did not exist).

28. *Id.* European consultants have traveled to China to show industry and government officials what will be needed to comply with REACH. European consultants also traveled to Brazil, Mexico, South Africa, South Korea, Thailand, and other major players in world economy. *Id.*

29. *See* Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005) *available at* http://www.govtrack.us/congress/bill.xpd?bill=s109-1391; *see also* Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005) (identical versions of this bill were introduced in the House of Representatives and the Senate, but never made it out of committee).

regulation was limited.[30] The existing regulations only applied to a particular use or to particular conditions of exposure, but did not allow for control of the substances before they were dispersed.[31] After six years of working on the toxic substances problem,[32] Congress passed the TSCA, which authorized the EPA to regulate chemicals that posed an unreasonable risk to human health or the environment.[33] The TSCA provided regulations for chemicals whether manufactured, imported, processed, distributed in commerce, used or disposed of in the United States.[34] Although the TSCA was an improvement over the existing regulations, it was never given the power to provide real protections to health or the environment.[35]

B. Scope

The TSCA has been largely ineffective because of its structure. One of the main issues is that TSCA divides chemicals into two groups: existing substances and new substances.[36] The existing substances were those already in commerce prior to 1979, while the new substances were anything not manufactured or processed as of 1979.[37]

The difference is important because the existing chemicals, which make up the bulk of the market, have far less stringent requirements than the new chemicals.[38] The TSCA authorizes but does not require the EPA to review the risks of existing chemicals.[39] The TSCA allows the EPA to require chemical companies to develop test data only under specific circumstances.[40] The EPA must find that a chemical: (1) may present an unreasonable risk of injury to

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30. DRULEY & ORDWAY, *supra* note 14.

31. *Id.* at 10-11.

32. *Id.*

33. Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (1976).

34. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-217R, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION 1 (Nov. 4, 2005), *available at* http://www.gao.gov/htext/d06217r.html [hereinafter USGAO, GAO 06-217R].

35. *See* Schapiro, *supra* note 12 ("Three decades after TSCA came into being, 95 percent of all chemicals in circulation have never undergone any testing for toxicity or their impact on the environment").

36. USGAO, GAO-06-217R, *supra* note 34.

37. *See* 15 U.S.C.A. § 2607(b) (West 2008); (15 U.S.C.A. § 2602(9) defines "new chemical substance" as "any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title;" section 2607(b) states the "list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules . . . .").

38. *See* JOSEPH DIGANGI, US INTERVENTION IN EU CHEMICAL POLICY 3 (Envtl. Health Fund 2003) (stating existing chemicals comprise more than 95% by volume of the chemicals used in production processes and consumer products); *see also* USGAO, GAO-05-458, *supra* note 22, at 2 (stating "[o]f the over 82,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when the EPA began reviewing chemicals in 1979").

39. USGAO, GAO-06-217R, *supra* note 34.

40. USGAO, GAO-05-458, *supra* note 22.

health or the environment; or (2) is or will be produced in substantial quantities and (a) there is or could be significant human exposure or (b) it may be reasonably anticipated to enter the environment in substantial quantities.[41] This creates a paradox: the EPA must find that a chemical presents an unreasonable risk before it can require testing, but to make that risk determination, the EPA first needs test data.[42] In practice, this requires the independent scientists to conduct studies, which typically takes decades.[43] Because of this, the EPA has required testing for less than 200 of more than 62,000 existing chemicals since 1979.[44] If, after review, the EPA finds that a reasonable basis exists to conclude a chemical presents an "unreasonable risk of injury to health or the environment," the TSCA generally allows the EPA to impose some regulatory requirement.[45] If the EPA does apply a regulation, it must apply the least burdensome regulation that is still adequate to protect against a chemical's risk.[46]

The EPA has not banned a single chemical since the asbestos ban was struck down in 1990 because of the "unreasonable risk" and "least burdensome" requirements.[47] In the Fifth Circuit case *Corrosion Proof Fittings v. EPA,* the EPA, pursuant to the TSCA, placed a ban on the manufacture, importation, and processing of asbestos in almost all products.[48] The EPA relied on over one hundred studies and conducted several public meetings before concluding that exposure to asbestos presented an "unreasonable risk" to human health.[49] In striking down the ban, the court said that the "complete ban on manufacturing is the most burdensome alternative .... [T]he EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA."[50] Making effective regulations more difficult, the court said the EPA is required to consider costs of any proposed regulations when evaluating whether a risk is unreasonable.[51] The court concluded that a cost of approximately $30-40 million per life saved was not reasonable.[52] As a result of this high burden in making regulations on any chemical, the EPA has been forced to rely on forming voluntary partnerships with the chemical industry.[53] In effect,

41. *Id.*

42. Environmental Working Group: BodyBurden, Findings and Recommendations, http://archive.ewg.org/reports/bodyburden1/findings.php (last visited Nov. 5, 2008).

43. *Id.*

44. USGAO, GAO-05-458, *supra* note 22.

45. 15 U.S.C.A. § 2605(a) (West 2008).

46. USGAO, GAO-06-217R, *supra* note 34, at 2.

47. Schapiro, *supra* note 12, at 80.

48. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1207 (5th Cir. 1991).

49. *Id.*

50. *Id.* at 1216 (noting that less burdensome regulatory options might include labeling of chemicals or limiting the total amount of chemicals an industry may use).

51. *Id.* at 1222.

52. *Id.* at 1223.

53. Cone, *supra* note 10 (EPA officials stated "forming partnerships with industry was quicker than trying to impose regulations and facing court challenges as they did with asbestos.").

the TSCA provides the EPA with very little authority and almost no enforcement over existing chemicals.

The EPA has slightly more control over new chemical substances.[54] Under the TSCA, companies are required to notify the EPA at least ninety days before beginning production, manufacture or import of new chemicals.[55] This is designed to give the EPA time to review the chemical's risks.[56] After this review, the EPA has three basic options: (1) It can take no action; (2) it can require controls on the use, manufacture, processing, distribution in commerce or disposal of the chemical; or (3) it can ban the chemical pending receipt of tests performed by the chemical's manufacturer.[57] The submitting companies are required to give data already in their possession relating to the chemicals' health and ecological effects, but most companies do not have this data at the time of submission.[58] Without a strict requirement, the chemical manufacturers simply do not have any incentive to conduct testing.[59] The tests could take over a year to complete with costs of hundreds of thousands of dollars.[60] In the absence of test data, the EPA mainly relies on scientific models to screen new chemicals.[61] Although the EPA believes the models are a useful screening tool, they are not always able to accurately determine the chemicals' properties and full extent of their adverse effects.[62]

The EPA can require further testing on new chemicals, but it generally does not require the manufacturers to develop additional data.[63] As of June 2005, the chemical manufacturers have provided health data for only about fifteen percent of chemicals,[64] and the EPA has taken action on only 3,500 of about 32,000 new chemicals submitted.[65] The TSCA was an improvement over the existing state of chemicals regulations at the time, but thousands of chemicals are on the market today with little or no regulation, and the thirty year old legislation is in need of reform.

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54. USGAO, GAO-06-217R, *supra* note 34, at 2.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. USGAO, GAO-05-458, *supra* note 22, at 11.

60. *Id.*

61. *See id.* at 10-11 (The EPA uses a method known as structure activity relationships analysis (SAR), also known as the"nearest analogue" approach, which involves using models to compare new chemicals with chemicals of similar molecular structures for which test data on health and environmental effects are available. The models come from chemicals that have already been assessed by the EPA.).

62. *See id.* at 10-12 (The EPA and the EU conducted a study to compare EPA's predictions of health or environmental effects with those identified by the EU test data. The joint evaluation showed that the accuracy of EPA predictions varied depending on effect or property being compared. For example, the models were highly accurate for toxicity of chemicals tested on rainbow trout, but were in error of about 25% of cases for determining chemicals' effects on growth of aquatic algae.).

63. Cone, *supra* note 10.

64. *Id.*

65. USGAO, GAO-06-217R, *supra* note 34, at 2.

III. THE REACH LEGISLATION

A. History

The European Union did not pass REACH until 2006, but problems with chemical regulation in Europe were evident several years prior.[66] The EU chemical regulations were complicated and dysfunctional. The regulations were composed of more than forty interlocking statutes with many loopholes.[67] In the early 1980s chemicals were divided into two groups: existing substances and new substances.[68] Similar to the regulatory scheme in the United States, new substances were those marketed after 1981, and existing substances were anything already on the market at that time.[69] Although the chemicals entering the market after 1981 were subject to testing, the existing chemicals comprised ninety-nine percent of the chemicals in use.[70] The need for more testing prompted the EU to adopt the Existing Substances Regulation in 1993.[71] This new regulation marked 141 existing chemicals for testing, and it placed the burden of testing on the government.[72] Over ten years, less than fifty of those chemicals were examined and less than five were ever regulated.[73]

The EU began the process of enacting REACH by the late 1990s. In April 1998, an Informal Environmental Council determined there was a lack of information on chemicals and the operation of EU legislation on chemicals.[74] A review was launched, and by June of 1999, the Council had completed a document inviting the European Commission to come forward with proposals for a new chemicals strategy.[75] The Commission responded to the Council's request with a White Paper on a Future Chemical Policy, which was adopted on February 13, 2001.[76] This policy proposal became known as REACH when released for public comment on May 7, 2003.[77] The final version was passed in December

66. *See* Europa: European Commission, REACH: Background, http://www.ec.europa.eu/enterprise/reach/whitepaper/background_en.htm (last visited Nov. 5, 2008) [hereinafter Europa, REACH: Background].

67. Frank Ackerman et al., *European chemical policy and the United States*, ENCYCLOPEDIA OF EARTH (Oct. 9, 2007), *available at* http://www.eoearth.org/article/European_chemical_policy_and_the_United_States.

68. DIGANGI, *supra* note 38, at 2.

69. *Id.*

70. *Id.*

71. *Id.*

72. *See* Europa: European Commission, Chemicals: Priority Substances, http://ec.europa.eu/environment/chemicals/exist_subst/priority.htm (last visited Nov. 5, 2008) (the chemicals placed on priority lists are based on several factors, including: the effects of the substance to man or the environment, the exposure of man or the environment to the substance, the lack of data on the effects of the substance on man and the environment).

73. DIGANGI, *supra* note 38.

74. *See* Europa, REACH: Background, *supra* note 66.

75. *Id.*

76. *Id.*

77. DIGANGI *supra* note 38, at 2.

2006 with the purpose of providing a higher level of protection to human health and the environment and promoting innovation in the chemical industry.[78]

B. Scope

With the passage of REACH, the EU closed many of the loopholes which existed under the prior legislation and set forth a much more comprehensive chemical policy. When the EU established REACH, it also established the European Chemicals Agency (ECA) to administer the program.[79] REACH made two key changes from the prior legislation.[80] First, REACH shifted the burden from the government to those who manufacture or import chemicals to make sure the chemicals are safe, and second, it abolished the distinction between new and existing chemicals.[81] The legislation covers substances whether manufactured, imported, or placed on the market in Europe because the EU did not want to give European industry any incentive to relocate to less restrictive countries.[82] REACH also applies to substances whether used on their own, or in preparation of other compounds.[83] As noted, the legislation lays out rules for registration, evaluation, authorization, and restriction of chemicals.

1. Registration

The first main provision of REACH is the registration requirement. If a substance is not registered with the ECA, it cannot be placed on the market or manufactured in Europe.[84] Registration requires the producers and importers to provide certain information about the chemicals, including precautionary measures to be taken when using them.[85] Not every registration will require new testing because REACH accepts the submission of existing information.[86] New testing will be required if there is no sufficient information available and other sources of information are not appropriate.[87] The amount of data required is also proportional to the production volume, applying the strictest tests only to the substances produced in the highest quantities.[88] The registration provision also contains several rules for data sharing to cut down on testing and reduce costs.[89]

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78. Europa, Regulatory Framework, *supra* note 19.
79. *Id.*
80. *Id.*
81. *Id.*
82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*

The regulation allows data to be exchanged between registrants and also allows those registering the same substance to submit their applications together.[90] The information will also be passed through the supply chain so that all users of the chemicals can minimize risk.[91]

2. *Evaluation*

The regulation also provides for evaluation by the ECA. The evaluation serves to minimize the need for animal testing and to determine the substances that pose a threat to human health or the environment.[92] This is accomplished by requiring evaluations on any proposals for animal testing.[93] Any substances found to pose a threat to human health or the environment may be subject to restriction or authorization procedures.[94]

3. *Authorization and Restriction*

Substances that are determined to be of "very high concern" may be authorized for specific uses.[95] Examples of substances of "very high concern" are reproductive toxins, substances causing cancer, damaging genetic material, and chemicals that cannot be broken down by nature and which build up in bodies of humans or wildlife.[96] If the applicant can show the risks arising from the substance can be appropriately managed, authorization may be granted.[97] If the applicant cannot show this, and no alternatives exist, then the ECA balances the level of risk and the advantages of using the substance to decide whether to authorize it.[98] Even if authorization is granted, it is subject to review after a period of time that is determined on a case-by-case basis.[99] When authorization is granted, additional restrictions may be placed on the substance, such as conditions of manufacture and use.[100] These substances are of special concern not only because of the danger they pose but also because they are used in a wide array of consumer products.[101]

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90. *Id.*

91. *Id.* Data transmitted would include the identification of the substance, its composition and its properties, the measures to be taken for use and transport without risk, the measures to be taken in case of fire or accidental release, and toxicological and ecological information. This information would go to those using chemicals in their production processes or manufacture of other chemical preparations. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. Corporate European Observatory, *Bulldozing REACH—the industry offensive to Crush EU chemicals regulation* 1 (March 2005) *available at* http://www.corporateeurope.org/lobbycracy/BulldozingREACH.pdf.

97. Europa, Regulatory Framework, *supra* note 19.

98. *Id.*

99. *Id.*

100. *Id.*

101. Corporate European Observatory, *supra* note 96, at 1-2 (citing Greenpeace study which found

4. Innovation

REACH also encourages innovation by providing several incentives.[102] The new regulations raised the registration threshold from 10 kg to 1 metric ton, meaning chemicals produced in small quantities will not be required to register.[103] To further encourage innovations, research activities are exempt from authorization or restriction, and substances manufactured for product and process oriented research and development may be exempt from registration for up to fifteen years.[104]

IV. THE FIGHT AGAINST REACH

REACH provides a strong regulatory framework for the production and disbursement of chemicals, but it was not enacted overnight. The European Union worked to put REACH into effect as early as 1998.[105] Some of the strongest opposition to REACH came from the chemical industry and the Bush Administration.[106]

A. European Chemical Industry Opposition

Following the European Parliament's adoption of the REACH White Paper in November, 2001, the European Chemical Industry Council (CEFIC) began an active role in opposing the new regulations.[107] The initial strategy was to dismiss the proposal as too costly and too bureaucratic, and push for voluntary industry initiatives on health and the environment instead of government regulation.[108] In attacking the proposal, the CEFIC used exaggerated industry funded studies to show the negative impacts of REACH.[109] One report estimated that REACH would cost 2.3 million jobs in Germany alone.[110] Despite conflicting reports by leading research institutes, the industry continued to use this type of exaggeration to oppose REACH.[111] One report from Halifax Bank of Scotland, which polled twenty-two chemical companies concluded that most of them "seem not to be in

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substances in children's pajamas, toys, household paint cleaners, computers, televisions, carpets and furniture).

102. Europa, Regulatory Framework, *supra* note 19.

103. *Id.*

104. *Id.*

105. Europa: REACH: Background, *supra* note 66 (Informal Environmental Council determined there was a lack of information on chemicals and the operation of EU legislation on chemicals).

106. *See generally* MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 3.

107. Corporate European Observatory, *supra* note 96, at 3.

108. *Id.*

109. *Id.* at 4.

110. *Id.*

111. *Id.* at 3 (conflicting reports argued the results were based on a "static model that does not take into account the dynamics and innovative drive of the economy;" the reports also did not take economic benefits of REACH into account).

a position to estimate the likely financial impact of REACH on their business though many express confidence that the impact would not be material."[112] Beyond the use of grossly exaggerated reports, the CEFIC was able to mobilize a large employer confederation, which strengthened its efforts because it included more downstream users.[113] While the European chemical industry was launching a full scale attack against REACH, the U.S. chemical industry was working on the issue from across the Atlantic.

B. *U.S. Chemical Industry and Bush Administration*

The U.S. chemical industry opposed REACH from the beginning, insisting the regulation would interfere with trade, increase costs, and hamper commerce.[114] Like the European industry, the U.S. industry called for voluntary measures where testing would not always be required.[115] Although usually not very close, the American Chemistry Council (ACC) and its European counterpart, CEFIC, united to launch strong lobbying efforts against REACH.[116] While the CEFIC was recruiting in Europe, the ACC was recruiting in the U.S.[117] With the help of ACC, the Bush Administration assisted in the fight against REACH.[118]

Prior to the introduction of the REACH legislation in 2001, the Executive office would not support lobbying efforts on chemicals' legislation in the EU.[119] In 1998, the Clinton Administration as well as the State and Commerce Departments lobbied on behalf of chemical industries.[120] They were attempting to stifle EU efforts to limit the use of phthalates in vinyl toys, suspected to affect health of children.[121] This prompted Congressmen Henry Waxman and George Miller to send the White House a letter asking if lobbying against public health legislation in foreign countries was a part of the Administration's policy.[122] The letter received a formal response from Vice President Al Gore asking for the State and Commerce Departments to stop lobbying against the EU legislation.[123] Gore's letter said, "We recognize and respect each nation's right to set legitimate

112. *Id.* at 12.

113. *Id.* at 5 (the employment confederation, UNICE, represented manufacturing companies that do not produce chemicals but do use them).

114. *See* MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 2.

115. *Id.*

116. Corporate European Observatory, *supra* note 96, at 5.

117. *Id.* at 6.

118. *See id.* at 6 (the Bush Administration worked hand in hand with the ACC).

119. DIGANGI, *supra* note 38.

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

public health and environmental standards and to take appropriate precautionary action."[124] The EU then passed a ban on some of the phthalates.[125]

The United States' policy changed with the election of President George W. Bush.[126] The chemical industry realized the importance of the Presidency in opposing REACH, and so it worked hard to gain an ally in the Oval Office.[127] Chemical manufacturers began fundraising efforts to promote Bush as a presidential candidate in 1999.[128] Fred Webber, the CEO of the ACC, raised more than $100,000 and also persuaded the CEO of Dow chemical and Occidental Chemical to help raise money.[129] In 1999, the head of a major trade association familiar with the chemical industry said, "This industry has openly said we're going to support Bush and [we are] committing to raise a huge sum of money for him."[130] Between 2000 and 2004, Bush was the top recipient of campaign contributions from the chemical industry totaling more than $900,000.[131] Using this access, the chemical industry was able to urge the Bush Administration to assist them in their opposition to REACH.[132]

The Bush Administration began to take action against REACH one month after the Administration took office in 2001.[133] The Department of Commerce and the United States Trade Representative (USTR) began to meet with the U.S chemical industry, including the ACC, to solicit their views and concerns on REACH.[134] In these meetings, the government officials advised the industry "to develop an official position and strategy as soon as possible to assist in influencing the EU's draft text."[135] An undated internal Department of Commerce document stated that two offices within the Department agreed to assist the chemical industry in developing a diplomatic protest against the REACH proposal.[136] Then in March 2002, Secretary Colin Powell sent a cable to thirty-six U.S. diplomatic posts in nations outside the European Union.[137] The

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124. *Id.* at 3-4.

125. *Id.* at 4.

126. *See* MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 4.

127. *See* DiGANGI, *supra* note 38, at 4.

128. *Id.*

129. *Id.*

130. Susan B. Glasser & John Mintz, *Bush's Capital Plan to Woo Big Business; First, He Wins Over Trade Group Chiefs*, WASH. POST, Aug. 1, 1999, at A01 (the newspaper article does not list the name of the trade association or the source who said this, presumably to maintain anonymity).

131. MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 2-3 (in that same period the chemical industry contributed more than $21 million, with the Republican Party receiving more than $16 million).

132. *Id.* at 3.

133. *Id.* at 4.

134. *Id.* (citing a Department of Commerce briefing paper).

135. *Id.*

136. *Id.* at 4-5 (stating "[the] Office of EU and Regional Affairs is working with . . . [the] Office of Chemicals on a demarche to go to EU Member States and to important third countries to get this campaign going.").

137. *Id.* at 5.

communication directed these posts to communicate to the relevant government officials and local business communities that the EU chemical policy appeared "to be a costly, burdensome, and complex regulatory system, which could prove unworkable in its implementation."[138] In support of this statement, Secretary Powell asserted that just four of the chemicals on the authorization list put $8.8 billion worth of downstream products at risk of ban or severe restrictions.[139] That dollar figure was provided by the ACC, and there is no evidence that shows an attempt by the U.S. government to verify it.[140] Other analysts concluded that the estimate could not be supported by a fair reading of the REACH proposal.[141]

After the March 2002 cable, the meetings between U.S. and chemical industry officials continued, eventually leading to a second cable by Secretary Powell.[142] An April 2003 email revealed that Catherine Novelli, the Assistant U.S. Trade Representative for Europe and the Mediterranean, had asked the chemical industry to create themes for the U.S. to use in opposing REACH.[143] The email further indicated that the U.S. government would convey all the themes to the EU.[144] The e-mail listed eleven themes the chemical industry wanted pursued.[145] Less than a month later, Secretary Powell sent another cable regarding REACH to diplomatic posts in the European Union nations.[146] The cable provided the diplomatic posts with a list of arguments to use in opposing REACH.[147] All eleven of the chemical industry's themes were reflected in Powell's cable.[148]

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138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.* at 6 (cited a presentation by the World Wildlife Fund, an environmental group, in stating, "[o]ther informed analysts concluded . . . estimate could not be supported by a fair reading of the REACH proposal.").

142. *Id.* at 6-7.

143. *Id.* at 6.

144. *Id.*

145. *Id.* at 8; *see infra* note 148 for themes.

146. *Id.* at 7.

147. *Id.*

148. *Id.* at 7-8. Some of the eleven themes as given by the chemical industry in the April, 2003 email and as worded by Powell's cable include:

Industry Theme	Powell's Cable
"Before taking unilateral action and imposing its proposals on the rest of the world, the EU Commission should use multilateral forums to discuss its proposals."	"We continue to support multilateral efforts in the OECD to promote greater international regulatory cooperation and harmonization in the area of chemicals."
"REACH will work to stifle innovation and the introduction of new safer chemicals."	"These compliance costs may negatively impact innovation and EU development of new, more effective, and safer chemicals and downstream products."

The United States government and the Bush Administration took other steps to oppose the REACH legislation. The USTR helped to organize opposition by working with the chemical industry to identify Member States that should be targeted based on their large production of chemicals.[149] The USTR even made specific assignments to industry groups to help coordinate comments for particular countries.[150] In 2002, officials from the United States EPA traveled to Europe to meet with European government officials and chemical industry representatives.[151] In conjunction with the American Chemistry Council, the EPA delivered the chemical industry's message, which called for more voluntary regulations.[152]

The U.S. Department of Commerce also got involved, adopting the chemical industry's position without even considering REACH's beneficial effect on other industries.[153] The Department developed an outreach plan which included sending staff on international outreach trips to meet with both industry and government representatives.[154] The Department planned to increase opposition to REACH by contacting countries outside the EU as well as countries planning to join the EU.[155] A Commerce Department document on a meeting of the Asia Pacific Chemical Industry Coalition, chaired by the United States, reported that action would be taken to involve the Asia-Pacific Economic Cooperation (APEC) Business Advisory Council.[156] This would help to gain industry opposition from twenty-one countries outside the EU.[157] The report also stated that the U.S.

"Suppliers might not share information about chemicals and might pull a particular chemical off the market because they don't want to go through the burden of testing and registration."	"Manufacturers of chemicals for many applications may halt production where demand does not justify registration and testing costs."
"The EU should consider fully the comments of stakeholders and their concerns and suggestions, making adjustments to the draft."	"We urge the Commission to provide all stakeholders a meaningful opportunity to provide comments on its 1200 page draft regulation, including an explanation for how such comments were considered for final proposal."

Id.

149. *Id.* at 9.

150. *Id.*

151. *Id.* at 10.

152. *Id.*

153. DIGANGI, *supra* note 38, at 11 (noting that REACH would reduce product liability concerns of other industries that use chemical industry products, such as cosmetics, toys, textiles and electronics).

154. MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 11.

155. *Id.* at 12.

156. *Id.* at 13.

157. *Id.*

industry would draft a negative economic impact paper about REACH that could be submitted by the APEC to the European Union.[158]

Public interest groups did not have the same influence as the chemical industry on the U.S. position and opposition to REACH. The USTR did hold two meetings for public interest nongovernmental groups, but their concerns seem never to have been seriously considered.[159] In November 2002 more than fifty public health professionals, labor unions, children's health advocates, environmental organizations, and community groups "wrote to President Bush to express concerns about U.S. efforts to undermine REACH."[160] Again in September 2003, more than seventy public health professionals, physicians, nurses, children's health advocates, environmental organizations, and community groups wrote to President Bush to ask the Administration to stop its efforts to oppose REACH.[161] The September letter asked the President to "stop using federal funds to undermine this important proposed legislation," and requested the Administration to "solicit public comments from the American people—including but not limited to NGOs and businesses—to formulate a forward looking position on chemicals policy . . . ."[162] The administration never responded to these letters.[163] The Department of Commerce did announce that it was planning a series of meetings to allow U.S. companies to comment on the European policy, but those meetings apparently never took place.[164] Ultimately, there was no opportunity for public comment on the REACH proposal.[165] Further, the U.S. government did not do any independent research to analyze the environmental or economic impacts of REACH.[166] In the end, the Bush Administration actively opposed EU chemical regulations based on the needs and recommendations of the chemical industry.[167] The administration did no independent research, and was unresponsive to public concern.[168]

158. *Id.*
159. *Id.* at 15.
160. *Id.* at 15-16.
161. *Id.* at 16.
162. DIGANGI, *supra* note 38, at 12-13.
163. MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 16.
164. *Id* at 16-17.
165. *Id.* at 17.
166. *Id.*
167. *Id.*
168. *Id.*

C. Effects of Chemical Industry and U.S. Opposition

Although the European Union did eventually enact REACH in 2006, the efforts of the chemical industry and U.S. government efforts were not without effect.[169] The efforts led to requests for more analysis and additional assessment of the effects on the industry by Germany, France, and Britain.[170] The EU eventually changed the proposal to increase industry confidentiality rights, to decrease comprehensive data requirements, and to decrease safety assessment requirements.[171] The American Chemistry Council noted that the "intervention by the U.S government resulted in 'significant concessions' in REACH."[172] European environmental groups felt the proposal was weakened and the balance was tipped away from environmental and public protection and towards the self interests of business.[173] Stefan Scheuer of the European Environmental Bureau commented the "United States has got 90% of what it wanted."[174] Some of the changes the U.S had advocated for included the exclusion of polymers, less regulation of intermediaries, and less stringent requirements regarding chemicals found in products.[175]

V. COST-BENEFIT ESTIMATES OF REACH

The costs of REACH have been studied, discussed and debated by the EU, independent researchers, and environmental groups. In the end, the costs of such large scale regulation are not easily quantified. Not surprisingly, the chemical industry, government agencies, and environmental groups reached different results.

The CEFIC commissioned reports which predicted extremely high costs.[176] The CEFIC initially estimated the costs of testing alone would be about eight billion euro over a ten year period.[177] Then, in response to an EU report, the CEFIC stated the costs would be between twenty to thirty billion euro when non-testing costs were taken into account.[178] Other reports estimated job losses in Germany, the EU's largest chemical manu-facturing country, between 1.7 and

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169. *Id.*

170. *Id.* at 15.

171. Corporate European Observatory, *supra* note 96, at 8 (stating the new proposal would only ensure appropriate safety assessment for about 10% of existing chemicals, and will leave most chemicals entering the EU via consumer products untouched. The new proposal will also reduce info available to the public).

172. MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, *supra* note 23, at 15.

173. *Id.*

174. Corporate European Observatory, *supra* note 96, at 8.

175. Ackerman et al., *supra* note 67.

176. Corporate European Observatory, *supra* note 96, at 4.

177. *Id.* (for comparison purposes: current exchange rate as of 2008 would equal roughly $11.7 billion).

178. *Id.* (for comparison purposes: current exchange rate as of 2008 would equal roughly $29-$44 billion).

2.3 million, with production losses of over twenty percent.[179] These numbers may seem staggering, but it must also be noted that the EU is the world's largest chemical producer, accounting for about twenty-eight percent of the world output, and directly or indirectly employing some 4.7 million people.[180]

While the chemical industry was looking at costs, environmental groups were trying to find benefits. The World Wildlife Fund (WWF) estimated that REACH could save as much as $180 billion in public health costs even after the implementation costs are subtracted.[181] Even at $180 billion, the WWF study authors felt this was an underestimate because it did not account for environmental benefits.[182]

The chemical industry and the environmental group studies represent extreme costs or extreme benefits, but the EU estimates were more moderate.[183] The EU conducted an impact assessment that estimated the direct costs of REACH to be $4 billion which comes to less than one tenth of one percent of annual EU chemical sales.[184] The EU study also estimated that REACH could prevent as many as 4,500 occupational cancer cases each year.[185] Additionally, the study revealed that REACH could reduce chemical exposure related health care costs by as much as $69 billion over the next thirty years.[186]

Because REACH applies to all manufacturers who supply chemicals to the EU, the U.S. manufacturers will also incur costs.[187] U.S. exports subject to REACH amount to about $13.7 billion and are directly or indirectly responsible for 54,000 jobs.[188]

While these numbers are not insignificant, the additional costs of complying with REACH have been estimated to only $14 million annually, roughly one tenth of one percent of the export total.[189] Unfortunately, the health benefits estimated to the EU would not be the same in the U.S. unless and until the U.S. adopts stricter regulations of its own.

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179. *Id.*

180. Elizabeth Becker & Jennifer Lee, *Europe Plan on Chemicals Seen as Threat to U.S. Exports*, N.Y. TIMES, C8 (May 8, 2003).

181. DiGANGI, *supra* note 38, at 2.

182. *Id.*

183. *See id.*

184. *Id.*

185. Shapiro, *supra* note 12, at 81.

186. *Id.*

187. Ackerman et al., *supra* note 67.

188. *Id.*

189. *Id.*

VI. KID SAFE CHEMICALS ACT: UPDATING THE TSCA

In the midst of the Bush Administration's fight against the passage of REACH in the European Union, the United States Congress was attempting to pass legislation that would fill some of the gaps of the TSCA.[190] The "Child, Worker, and Consumer-Safe Chemicals Act of 2005" or the "Kid Safe Chemicals Act" (KSCA) was introduced in the United States Senate by Senator Frank Lautenberg on July 13, 2005.[191] Perhaps inspired by REACH, the bill was introduced as an amendment to the TSCA, for the purpose of reducing the exposure of toxic chemical substances to children, workers, and consumers.[192]

Because reform of the TSCA would not be easy, Senator Lautenberg (D-NJ), along with co-sponsor James Jeffords (I-VT), requested a report from the Government Accountability Office (GAO) on the TSCA in early 2004.[193] The GAO report, released in June of 2005, assessed the weaknesses of the TSCA and listed several areas where reform was needed.[194] A month after the report was released, Senator Lautenberg introduced the KSCA on the Senate floor.[195] Then in November of 2005, Congressman Henry Waxman (D-CA) introduced an identical bill in the House of Representatives.[196]

The KSCA would make several changes to the existing framework of the TSCA. The stated goal of the amendment was "to eliminate the exposure of all children, workers, consumers, and sensitive subgroups to harmful chemicals distributed in commerce by 2020."[197] The amendment would accomplish this goal by creating a priority list of chemicals, a new safety standard, new reporting requirements, better enforcement capabilities, and by requiring more access to confidential information.[198] The bill also included a provision for the creation of market incentives to develop safer chemicals.[199]

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190. Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005); *see also* Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005).

191. S. 1391; *see also* H.R. 4308 (House version of bill introduced by Rep. Waxman on Dec. 2, 2005).

192. Euractiv.com, *supra* note 10; *see also* S. 1391.

193. Beveridge & Diamond PC, *The Kid Safe Chemicals Act: A Significant Potential Change to the Toxic Substances Control Act*, 1 (Jan. 27, 2006) *available at* http://www.bdlaw.com/assets/attachments/115.pdf; *see also* USGAO, GAO-05-458, *supra* note 22.

194. *See* USGAO, GAO-05-458, *supra* note 22, at 37 (recommending that Congress give more authority to the EPA to require testing as well as data sharing of chemical substances).

195. S. 1391.

196. H.R. 4308

197. S. 1391, § 2(c).

198. S. 1391, § 2(c); *see also* Beveridge & Diamond PC, *supra* note 193, at 3-7.

199. S. 1391, § 506.

A. The Priority List and Safety Standard Under KSCA

The KSCA provides for a new safety standard with a higher threshold than under the TSCA.[200] While the TSCA requires that the EPA find that a chemical presents an "unreasonable risk" to human health or the Environment,[201] the KSCA requires a "reasonable certainty" that no harm will be caused by the aggregate exposure of a fetus, infant, child, worker or member of other sensitive subgroup.[202]

The bill also requires that the EPA develop a priority list of at least three hundred chemicals within eighteen months of the enactment of the legislation.[203] The EPA would determine the chemicals to go on the list by looking at five factors: whether the chemical substance (1) is found in human blood, fluids or tissue; (2) is found in food or drinking water; (3) is manufactured or discharged into the environment at a volume of more than 1 million pounds annually; (4) is known or suspected reproductive, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or causes negative developmental effects; or (5) is persistent or bioaccumulative (a chemical that builds up in an organism, in that the substance is absorbed faster than it can be dissipated).[204] The EPA would also be required to update the list at least annually until all chemical substances which meet the above criteria have been added.[205]

The priority list is of significance because these chemicals will be the first chemicals for which a safety determination would be made under the new safety standard.[206] The EPA must determine whether the manufacturer has established the chemical meets the safety standard within three years of being placed on the list.[207] If the EPA has made no determination within five years of the chemical's placement on the priority list, the chemical cannot be distributed.[208] The EPA has fifteen years from the date of enactment of the legislation for all other existing chemicals.[209] New Chemicals (chemicals not manufactured within 90 days of enactment) cannot be distributed in commerce until the EPA has determined that the chemical has met the new safety standard.[210]

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200. *Compare* S. 1391, § 503(a)(1) (the safety standard is a "reasonable certainty") *with* 15 U.S.C. § 2605 (2006) (the safety standard is no "unreasonable risk").

201. 15 U.S.C. § 2605(a).

202. S. 1391, § 503(a)(1).

203. *Id.*

204. *Id.* § 502(b).

205. *Id.* § 502(a)(2).

206. *Id.* § 502(a)(1).

207. *Id.* § 503(c)(1)(A).

208. *Id.* § 503(c)(1)(B).

209. *Id.* § 503(c)(2).

210. *Id.* § 503(c)(3).

B. Reporting Requirements Under KSCA

The KSCA also provides for updated reporting requirements from Chemical Manufacturers. Every manufacturer of existing chemicals would be required to submit a statement signed by the chief executive officer certifying the chemical has met the new safety standard within a year of the enactment of the amendment.[211] The chemical manufacturer must also submit all reasonably available information in the company's possession or control.[212] The KSCA would also require the manufacturers to update the information at least every three years.[213] The manufacturers would be required to submit significant new information as soon as it becomes available.[214]

The KSCA would also require chemical manufacturers to provide the EPA with a biomonitoring study for some chemicals.[215] The biomonitoring study would determine the chemical's presence in human blood, fluids, or tissues to determine exposure to the chemicals.[216] The chemical companies would be required to submit these studies only for chemicals manufactured in quantities greater than one million pounds per year, or chemicals to which there is cause for concern regarding human exposure.[217]

C. Enforcement Provisions Under KSCA

The KSCA also provides for much stronger enforcement provisions than the current TSCA.[218] As discussed above, the TSCA does not allow a ban on a substance until the EPA can determine the chemical poses an "unreasonable risk" to human health or the environment, and a ban can only be the chosen regulatory tool if it is the "least burdensome." Under the KSCA, manufacture would be prohibited if the EPA determines a chemical has not met the safety standard.[219] Manufacture would also be prohibited if the chemical manufacturer has not followed procedures regarding reporting requirements, or safety standard determinations.[220] The prohibition would also apply if the EPA failed to make a determination within the timeline required which could be as little as five years for chemicals on the priority list.[221]

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211. *Id.* § 501(a)(1).

212. *Id.* § 501(a)(2).

213. *Id.* § 501(b)(1).

214. *Id.* § 501(b)(2).

215. *Id.* § 503(d).

216. *Id.* § 503(d)(1) (stating the EPA will establish the standard for biomonitoring studies, the sample size and detection levels).

217. *Id.* § 503(d)(1).

218. *Compare Id.* § 504 *with* 15 U.S.C. § 2605.

219. S. 1391, § 504(a)(2).

220. *Id.* § 504(a)(1).

221. *Id.* § 504(a)(3) (although the EPA is required to make a determination of the safety of a chemical

D. Access to Information Under KSCA

The KSCA also provides for greater information accessibility and reliability. The amendment would require all federal agencies and institutions to provide the EPA with all information they possess relating to the hazard or risk of exposure of a chemical substance.[222] The EPA would also be required to establish an electronic database sharing information relating to toxicity use of, or exposure to, chemical substances.[223] The EPA would also make this information available to the public unless it is regarded as confidential.[224] The KSCA would attempt to limit the amount of confidential information by requiring the manufacturer's chief executive officer to provide the EPA with written justification for confidentiality.[225] Even with written justification, the EPA will not consider information regarding the effects on human health or the environment as confidential.[226]

E. Safer Alternatives Incentives

The KSCA would require the EPA to establish a program to create market incentives for the development of safer alternatives to existing chemicals.[227] The act would require the EPA to expedite the review process when a manufacturer submits test data that shows a new chemical substance is the safer alternative for a particular use than existing chemical substances used for the same purpose.[228] The amendment would also provide for public awards and other incentives the EPA finds to be appropriate for the development of safer chemical alternatives.[229] The EPA would also be required to establish a network of green chemistry and research clearinghouse centers.[230] These centers would support the development of safer alternatives, particularly chemical substances on the priority list.[231] The research centers would provide technical assistance, technical training, conduct analysis, and provide grants to promote the development and adoption of alternative chemicals.[232]

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placed on the priority list within three years under 503(c)(1)(A), failure to make a determination within five years will result a ban on manufacture under § 504(a)(3)).

222. *Id.* § 509(a).
223. *Id.* § 509(b).
224. *Id.* § 509(c).
225. *Id.* § 510(a)(1).
226. *Id.* § 510(c).
227. *Id.* § 506(a).
228. *Id.* § 506(a)(1).
229. *Id.* § 506(a).
230. *Id.* § 506(b)(1).
231. *Id.*
232. *Id.* § 506(b)(2).

The KSCA had the potential to make several important changes to the TSCA. Although the amendment did not include the extensive testing requirements of REACH, the improvements would bring the TSCA closer to the EU regulations.[233] Unfortunately, the KSCA never made it out of committee.[234] The TSCA remains intact as passed in 1976, and the EPA remains limited in its ability to control the manufacture of chemical substances in the U.S.

VII. REACH: IMPACT ON U.S. CHEMICAL REGULATIONS

Although the toxic substance regulation problem persists in the U.S., the EU regulations may pave the way for reform. Because REACH regulates substances whether manufactured or imported into the EU, the impact will be global. REACH may have a positive impact on U.S. regulations in three ways. First, REACH could decrease the resistance to new U.S. regulations such as the KSCA. Second, REACH may impact the future of state chemical regulations; and finally, REACH may positively impact the administration of the TSCA.

REACH could decrease resistance to new regulations by lessening the resistance of the U.S. chemical companies. Once the U.S. chemical companies spend the money to comply with REACH, they may be less resistant to U.S. reform. The U.S. companies will likely comply with REACH due to the nearly $14 billion in annual chemical exports to the EU.[235] Past failures to comply with foreign standards have come at high costs the chemical industry is not likely to repeat.

Past examples of U.S. export losses can be seen in the corn and beef industries.[236] "Bt corn," a variety of genetically modified corn came onto the U.S. market in the early 1990s.[237] Bt corn rose from one point four percent of planted area in 1996 to thirty-two percent in 2004.[238] The exporters could not separate the traditional corn from the genetically modified variety, and European consumers strongly rejected genetically modified foods.[239] U.S. corn exports to the EU were over $100 million per year in the early 1990s, but from 1999 to the present, they have been less than $8 million per year.[240]

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233. *See* Pat Phibbs, *Report Lists Actions Congress Could Take To Improve EPA Assessments Under TSCA*, 29 No. 29 CHEM. REG. REP. (July 18, 2005), *available at* http://ehscenter.bna.com/pic2/ehs.nsf/id/BNAP-6EEFVN?OpenDocument (quoting Lautenberg, "Europe gave us the inspiration to look hard at our own chemical law and ways to improve it.").

234. S. 1391 (last known status, introduced July 13, 2005).

235. Ackerman et al., *supra* note 67.

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id*

240. *Id.*

A similar loss occurred in beef exports. U.S. beef exports were roughly $3 billion per year from 2000 to 2003.[241] Following the detection of two cases of mad cow disease in North America in 2003, the United States Department of Agriculture (USDA) introduced new testing procedures.[242] Although the USDA was testing record levels of cattle in the U.S., it was still only testing about one percent of the cattle slaughtered annually.[243] At the same time, the EU was testing forty-eight percent and Japan was testing one hundred percent.[244] Not surprisingly, the U.S. beef exports dropped to only $554 million in 2004 and remained below $1 billion in 2005.[245] One key difference between these examples and chemical exports is that REACH will completely block the import of chemicals that fail to meet its standards.[246]

Because of the significant losses that U.S. companies could incur, many of them are already working on compliance. Large manufacturers such as Dow Chemical Company are hiring in-house employees to help work on REACH.[247] The U.S. Department of Commerce is reaching out to small and medium sized firms to make sure they can stay in the market.[248] The Department of Commerce wants to make sure they understand what is needed to comply with REACH.[249] Although the intensive data requirements of REACH may cause some chemicals to drop out of the EU market, most will comply to avoid the loss of such a large market.[250]

Once manufacturers make these changes, reform of the TSCA or even additional U.S. regulations might be more easily implemented. Senator Lautenberg indicated an intention to reintroduce a version of the KSCA.[251] Although the bill failed to gain support last time, perhaps next time would be more successful. Since the chemical industry would already be paying for increased testing costs, and would also have additional data for chemicals exported to the EU, there may be less resistance. The KSCA could even be viewed as a compromise between the TSCA and REACH.

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241. *Id.*

242. *Id.*

243. *Id.*

244. *Id.*

245. *Id.*

246. Europa, Regulatory Framework, *supra* note 19 (if a substance is not registered, it cannot be placed on market in EU).

247. Harvey Black, *Chemical Reaction: The U.S. Response to REACH*, 116 No. 3 ENVTL. HEALTH PERSP. A125, A125 (Mar. 2008), *available at* http://www.ehponline.org/members/2008/116-3/EHP116pa124PDF.PDF (quoting Spencer Williams, a toxicologist at Chemrisk, a consulting firm "Dow [Chemical Company] has a number of people in-house, at least eighteen that I'm aware of, who are hired to work on REACH.").

248. *Id.* at A126.

249. *Id.*

250. *See id.* (surveying several chemical companies and finding the companies plan to remain in the European market after REACH).

251. Children's Environmental Health Network, A Child Safe U.S. Chemicals Policy, http://www.cehn.org/Child_Safe_Chemicals_Policy_may_2007.htm (last visited, Nov. 5, 2008).

Even if Congress is not able to reform the TSCA, states could be influenced by REACH to make changes. Both California and Maine appear to be looking at REACH in reform efforts.[252]

In February 2006 Maine's governor established a task force to develop a policy offering incentives to use safe chemicals in consumer products.[253] In California, Governor Arnold Schwarzenegger is taking recommendations for changes to the state's toxic substances regulations.[254]

California lawmakers are expected to use a recent report commissioned by the California EPA in their push for tighter regulations.[255] The report found that more than 200,000 workers were diagnosed with deadly diseases attributable to workplace chemical exposure.[256] It also attributed 240,000 cases of preventable childhood diseases to environmental exposure to chemical substances.[257] The report estimated the state's total costs at $2.6 billion.[258] With the help of this report, California could be the first state to adopt a framework similar to REACH.[259]

Another possible side effect of REACH is that it may assist the EPA in the administration of the TSCA. One of the faults of the TSCA has been the lack of available information. Under REACH, chemical manufacturers are required to develop more data relating to the environmental and human health impacts.[260] The EPA would be able to use this data developed by chemical manufacturers, and it may also gain access to confidential business information submitted under REACH.[261] Although the EPA would still be forced to work within the TSCA framework, additional information could be valuable in controlling the most harmful substances.

VIII. CONCLUSION

Whether or not U.S. firms comply, tougher regulations have arrived and the U.S. is not the one leading the way. REACH shifts the burden of testing chemicals for safety from the government to the manufacturers.[262] REACH requires this information to be spread throughout the supply chain so all users can minimize

252. Black, *supra* note 247, at A127 ("Maine's search for more comprehensive ways to regulate chemicals . . . was influenced by REACH . . . [i]n California, REACH is 'definitely being considered as a model.'").

253. *Id.*

254. Kara Sissell, *Energy and Security Top ACC's 2008 Priorities*, CHEMICAL WEEK, Dec. 19, 2007, at 7.

255. Kara Sissell, *California Tallies the Health Cost of Chemical Exposure,* CHEMICAL WEEK, Feb. 4, 2008, at 28.

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.*

260. Europa, Regulatory Framework, *supra* note 19.

261. Black, *supra* note 247, at A126.

262. Europa, Regulatory Framework, *supra* note 19.

risk.[263] REACH allows for governmental restrictions when manufacturers do not comply or cannot show the safety of chemicals.[264] The TSCA does not do any of these things. The TSCA puts the burden of testing on the EPA, unless specific requirements are met.[265] More importantly, the TSCA does not allow enforcement of bans or restrictions until the EPA can show that a chemical poses an unreasonable risk.[266] Even after meeting this high burden, the EPA can only apply the least burdensome regulations on a substance.[267]

The KSCA attempted to bring the TSCA more in line with REACH requirements.[268] While the KSCA would not shift the burden of testing to chemical manufacturers completely, it would require chemical manufacturers to prove the safety of chemicals placed on the priority list.[269] The KSCA would also change the standard for restrictions on chemical manufacture and it would increase reporting requirements.[270] In the end, the EU passed REACH in 2006, but the KSCA never made it out of committee.[271]

The United States now stands a step behind in regulation of toxic substances. REACH provides a roadmap for reform, but U.S. lawmakers will still need to overcome some obstacles before they can legislate change.The ACC and the U.S. Government collaborated to oppose the passage of REACH from the beginning. REACH did eventually pass, but not without some modifications. During this same time, the KSCA was introduced in Congress but never made it out of committee. Although this cannot be directly attributed to the ACC or the Bush Administration, it seems not too great a stretch to think both had some influence on the KSCA.

The ACC and chemical manufacturers also continue to resist change. Even though many chemical manufacturers will be forced to conduct additional testing and release more information to comply with REACH, they oppose an update of the TSCA. While national-level change does not seem imminent, state reforms are a greater possibility. Because the states are looking at REACH as a model, the ACC has said one of its top priorities will be working against those efforts.[272]

Even given these obstacles, it seems likely that REACH will have some impact on U.S. regulations. Congress will be able to assess the strengths and weaknesses of REACH as it goes into effect, and possibly make reforms of the TSCA. It makes sense that a chemical manufacturer should be required to prove the safety of a chemical before it is put on the market. It makes sense that the EPA would have the

263. *Id.*

264. *Id.*

265. USGAO, GAO-06-217R, *supra* note 34, at 4.

266. *Id.* at 5.

267. *Id.* at at 2.

268. Phibbs, *supra* note 223, at 3.

269. Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. § 503(c)(1)(B) (2005).

270. *Id.*

271. *Id.*

272. Sissell, *supra* note 255.

authority to request all data in the chemical manufacturers' possession. It makes sense for the EPA to have the authority and ability to suspend the production and sale of chemicals when manufacturers do not comply with these requirements. With the guidance of the EU, these common-sense changes may not be out of reach.