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## The Roles of Precaution and Political Accountability in the Regulation of Polybrominated Diphenyl Ethers

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# NOTES

## The Roles of Precaution and Political Accountability in the Regulation of Polybrominated Diphenyl Ethers

### ABSTRACT

*The differing approaches used in the United States and the European Union to regulate toxic chemicals have been highlighted by debates about a group of chemicals called polybrominated diphenyl ethers, or PBDEs. PBDEs act as flame-retardants and are added to consumer products to increase their safety. Questions about the continued use of PBDEs have been raised, however, because of concerns that PBDEs may be dangerous to human health and the environment. The European Union has decided to ban two types of PBDEs, while the United States has not issued similar restrictions. In this Note, the Author argues that neither decision is inherently correct or incorrect because deciding how much risk is acceptable is a policy decision. Consequently, the "right" decision is the one that reflects the will of the people who will benefit from, or bear the costs of, acting now versus waiting until later. This Note argues, however, that the United States should align its policy with that of the international community by taking a more precautionary approach because PBDEs used in the United States cause harm outside its borders.*

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## I. INTRODUCTION

The use of chemicals in the modern industrial world is widespread. Ethyl vinyl acetate, octyl metnoxycinnamate, thiosulfate—attempting to pronounce the components of most products is a tongue twister in any language. Often these chemicals make the products consumers use better and their lives easier. Ethyl vinyl acetate absorbs shock in running shoes, octyl metnoxycinnamate is an active ingredient in sunscreen, and

thiosulfate is used to develop photos.<sup>1</sup> Occasionally, however, the use of these chemicals has unanticipated consequences and creates dangers for human health and the environment. Unfortunately, questions about the safety of these chemicals generally are not raised until they have been in use for many years, and by that time the benefits of continued use must be weighed against the costs of potential harm.

The difficulties posed by these questions are exemplified by recent debates over a group of chemicals called polybrominated diphenyl ethers (PBDEs). PBDEs have been used for several years and benefit the public by reducing the risk of fire.<sup>2</sup> Recent studies indicate that PBDEs are appearing at increasingly high concentrations in humans and might have the potential to cause serious harm.<sup>3</sup> As is often the case, however, there are more questions about PBDEs than there are definitive answers. The European Union has decided to ban two forms of PBDEs and restrict the use of a third, but the United States has not taken similar action at a national level.<sup>4</sup> This divergence has led to much debate over who is right—the EU for acting in a precautionary manner or the United States for requiring more scientific evidence before taking formal action.<sup>5</sup>

Deciding what action to take in this type of situation, where so much is unknown, requires a determination of how much risk is acceptable. Every day, people evaluate risks and adjust their behavior accordingly. Some drivers meticulously follow the speed limit while others are willing to drive faster and risk getting a speeding ticket. Some investors are willing to invest in high-risk stocks that have the potential for a substantial return while others prefer the security of low-risk mutual funds. Any one of these decisions is not right or wrong *per se*, but rather a personal decision based on how much risk a person is willing to tolerate in consideration of the anticipated costs and benefits. Similarly, at the national regulatory level deciding how much risk is acceptable is a policy judgment, and there is no intrinsically correct answer. With respect to PBDEs, the “right” approach is the one that reflects the will of the people who will benefit from, or bear the costs of, acting now or waiting until later.

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1. The Chemical Industry, *Chemicals in Sport and Leisure*, available at <http://www.chemical-industry.org.uk> (last visited Feb. 8, 2005).

2. U.S. Department of Health and Human Services: Agency For Toxic Substances and Disease Registry, *ToxFAQs: Polybrominated Biphenyls and Polybrominated Diphenyl Ethers*, available at <http://atsdr.cdc.gov/tfacts08.html> (last visited Feb. 28, 2005) [hereinafter DHHS].

3. See, e.g., Frank Rahman et al., *Polybrominated Diphenyl Ether (PBDE) Flame Retardants*, SCI. TOTAL ENV'T., July 25, 2001, at 3.

4. See *infra* Part II.C.

5. See *infra* Part II.A.

Risk taking in driving and making investments affects, almost exclusively, the person who makes that decision. In contrast, decisions made by the European Union and the United States about PBDEs have a significant effect on people outside their respective borders. PBDEs belong to a category of pollutants called persistent organic pollutants (POPs), a defining characteristic of which is the ability to travel long distances.<sup>6</sup> As a result, the costs of PBDEs produced or used in the EU and the United States will be borne, at least in part, by people in other countries who were not involved in the decision-making process. Many countries, following the lead of the EU, are enacting formal restrictions and bans on various forms of PBDEs.<sup>7</sup> This Note will argue that, given the global trend toward restrictions on PBDEs and the externalities caused by the continued use of PBDEs in the United States, the United States should respect the will of the international community and take a more precautionary approach to PBDEs. The United States will be unable to do so effectively, however, unless it amends its domestic legislation governing the regulation of toxic chemicals, the Toxic Substances Control Act, and ratifies and implements the Stockholm Convention on Persistent Organic Pollutants in its entirety. Part II of this Note discusses the history of PBDEs. Part III outlines the use of precaution as a basis for action in international agreements. Part IV compares the different approaches used by the European Union and the United States to regulate toxic chemicals. Part V analyzes the consequences of those approaches on PBDEs in light of evidence of PBDE exposure levels in the EU and United States and the possible effects of PBDEs. Finally, Part VI suggests a course of action for the United States based on principles of public choice and political accountability.

## II. OVERVIEW: HISTORY OF PBDES

Polybrominated diphenyl ethers (PBDEs) belong to a group of chemicals known as brominated flame retardants.<sup>8</sup> PBDEs are used in industrial manufacturing processes because of their flame-retardant qualities, increasing the safety of the products to which

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6. Kim Hooper & Jianwen She, *Lessons from the Polybrominated Diphenyl Ethers (PBDEs)*, 111 ENVTL. HEALTH PERSP. 109, 110 (2003); U.S. Environmental Protection Agency, *Persistent Organic Pollutants: A Global Issue, A Global Response* (Apr. 2002), available at <http://www.epa.gov/international/toxics/pop.pdf> (last visited Feb. 28, 2005) [hereinafter EPA, POPs].

7. SONYA LUNDER & RENEE SHARP, *Mothers' Milk*, ENVTL. WORKING GROUP, at 12 (2002).

8. U.S. Environmental Protection Agency, *Polybrominated Diphenyl Ethers (PBDEs)*, available at <http://www.epa.gov/opptintr/dfe/projects/flameret/pbde.htm> (last updated Dec. 1, 2004) [hereinafter EPA, PBDEs].

they are added.<sup>9</sup> There are numerous different congeners, or forms, of PBDEs that differ based on the number and position of bromine atoms in each molecule.<sup>10</sup> The three congeners most commonly used in industrial processes are penta-BDE (hereinafter, Penta), octa-BDE (hereinafter, Octa), and deca-BDE (hereinafter, Deca), containing five, eight, or ten bromine atoms, respectively.<sup>11</sup> The production and use of PBDEs has increased exponentially since the 1970s, and the production of Penta nearly doubled during the 1990s.<sup>12</sup> By the mid-1990s it was estimated that approximately 40,000 tons of PBDEs were used globally each year.<sup>13</sup> Deca is used in the greatest quantity, followed by Octa, and lastly Penta.<sup>14</sup> As of 2001, the United States was responsible for almost fifty percent of the PBDE use worldwide, while Europe was responsible for approximately twelve percent.<sup>15</sup>

PBDEs are used in a variety of materials including plastics, textiles, and polyurethane foam.<sup>16</sup> These materials are then incorporated into numerous consumer products that are found in the majority of U.S. homes, such as home furniture, carpeting, computers, televisions, carpets, hair dryers, copy machines, and smoke detectors.<sup>17</sup> The amount of PBDEs added to these products varies but can reach as much as thirty percent of the product's weight.<sup>18</sup>

Of increasing concern to many is not only the quantity of PBDEs used in these products but also *how* the chemicals are used. Flame retardants used in commercial products can be placed in two broad categories: reactive chemicals and additive chemicals.<sup>19</sup> The important difference between these two categories is the stability of the chemical flame retardant in the finished product. When reactive chemicals are used as flame retardants, chemical bonds form between the flame retardant and the consumer good during the manufacturing process, and the finished product is relatively stable.<sup>20</sup> In contrast, when additive chemicals are used as flame retardants they are simply

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9. *Id.*

10. Rahman et al., *supra* note 3, at 2.

11. *Id.* at 3.

12. LUNDER & SHARP, *supra* note 7, at 9.

13. Rahman et al., *supra* note 3, at 3.

14. *Id.* Of the estimated 40,000 tons used annually by the mid-1990s, 30,000 tons were Deca, 6000 tons were Octa, and 4000 tons were Penta. *Id.*

15. Linda S. Birnbaum & Daniele F. Staskai, *Brominated Flame Retardants: Cause for Concern?*, 112 ENVTL. HEALTH PERSP. 10 (2004). According to the numbers provided in Table 1, 67,440 metric tons of PBDEs were used worldwide. The Americas used 33,100 metric tons (or 49.08%) while Europe used 8,360 metric tons (or 12.40%). *Id.*

16. EPA, PBDEs, *supra* note 6.

17. LUNDER & SHARP, *supra* note 7, at 10.

18. *Id.* at 9.

19. Rahman et al., *supra* note 3, at 2.

20. *Id.*

mixed into the product; chemical bonds are not formed between the flame retardant and the finished product.<sup>21</sup> Because additive flame retardants such as PBDEs are not chemically bound to the final product, they are less stable than reactive flame retardants and more likely to leach into the surrounding environment.<sup>22</sup>

#### A. A Necessary Risk?

It would be easy to argue that PBDEs should be eliminated completely and immediately if they did not provide a significant public benefit. PBDEs create a difficult regulatory issue because although they are potentially harmful to human health and the environment, they also benefit the public by reducing the risk of fire in the products to which they are added.<sup>23</sup> Reducing the number of fires that occur not only saves lives but also creates indirect benefits to human health and the environment by reducing the amount of toxic chemicals released during fires.<sup>24</sup> Companies that use PBDEs in the manufacturing process are, of course, quick to point out the benefits of using these chemicals and argue that the benefits outweigh the risks.<sup>25</sup> Concerned activists agree that fire prevention is an important social goal, but argue it can be achieved without the use of potentially dangerous chemicals.<sup>26</sup> For example, the Environmental Working Group (EWG), a U.S.-based public interest group composed of scientists, engineers, policy analysts, and lawyers, advocates numerous alternatives to PBDEs. Such alternatives include the use of less toxic flame retardants, changes in product design to make goods inherently less flammable, and even simple changes in the production of cigarettes, which are responsible for starting many fires.<sup>27</sup> Moreover, the U.S. Consumer Products Safety Commission has reported that the safety standards required of furniture sold in California (which are among the most stringent in the world) can be achieved without the addition of chemical flame retardants, and activists argue that protection from fire does not require exposure to persistent organic pollutants such as PBDEs.<sup>28</sup>

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21. *Id.*

22. *Id.*

23. *See* Birnbaum & Staskai, *supra* note 15, at 9.

24. *Id.*

25. *See, e.g.*, Statement of European Brominated Flame Retardant Industry Panel (June 7, 2002), available at <http://www.ebfrip.org/mission.html> (last visited Feb. 8, 2005).

26. *See, e.g.*, LUNDER & SHARP, *supra* note 7, at 6.

27. *Id.* at 37-39.

28. *Id.* at 12.

### B. *The Dangers of Persistent Organic Pollutants (POPs)*

PBDEs belong to a category of chemicals called Persistent Organic Pollutants (POPs).<sup>29</sup> POPs are problematic because of four shared characteristics.<sup>30</sup> First, studies have shown POPs to be highly toxic, linking them to a wide range of adverse effects on health and the environment.<sup>31</sup> In humans, exposure to POPs has been linked to a range of reproductive, developmental, and behavioral problems as well as impaired functioning of the nervous, endocrine, and immune systems.<sup>32</sup> Second, POPs are persistent, meaning that they remain in the environment for a long time once they are introduced and thus break down very slowly.<sup>33</sup> Third, POPs are easily absorbed by the fatty tissue of living beings.<sup>34</sup> As a result POPs bioaccumulate, becoming more concentrated in organisms at the top of the food chain, such as humans.<sup>35</sup> Finally, POPs are capable of long-range transport within and across national boundaries by air, water, and migratory species.<sup>36</sup> As a result, POPs generated in one country have the potential to affect the citizens and environments of foreign countries adversely, and are thus considered a global problem.<sup>37</sup>

Global concern over POPs led to the passage of the Stockholm Convention on Persistent Organic Pollutants in May 2001.<sup>38</sup> By May 2002, only one year later, there were 151 signatories to the treaty.<sup>39</sup> On February 17, 2004, France became the fiftieth participant to ratify the Stockholm Convention.<sup>40</sup> As provided for by Article 26 of the Stockholm Convention, the treaty entered into force on May 17, 2004, ninety days after ratification by the fiftieth participant.<sup>41</sup> An additional forty-four countries ratified or accepted the Stockholm Convention in the year following France's ratification, raising the total number of parties to ninety-four, nearly two-thirds of the

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29. Hooper & She, *supra* note 6, at 109.

30. *Id.* at 5.

31. *Id.*

32. EPA, POPs, *supra* note 6, at 6.

33. *Id.* at 3.

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. Stockholm Convention on Persistent Organic Pollutants, May 17, 2004, 40 I.L.M. 532 [hereinafter Stockholm Convention]

39. Stockholm Convention Participant List, *available at* <http://www.pops.int/documents/signature/signstatus.htm> (last visited Feb. 8, 2005).

40. *Id.*

41. Stockholm Convention, *supra* note 38, at art. 26 § 1 ("This Convention shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification acceptance, approval, or accession.").

signatories.<sup>42</sup> The United States has not yet ratified the Stockholm Convention and is therefore not obligated to comply with its provisions.<sup>43</sup>

Parties to the Stockholm Convention have agreed to reduce or eliminate the production, use, and release of the twelve most concerning POPs, known as the "Dirty Dozen."<sup>44</sup> Many of the chemicals listed in the Dirty Dozen are no longer produced in the United States and have not been for several years.<sup>45</sup> Two of these chemicals, polychlorinated biphenyls (PCBs) and dichlorodiphenyl trichloroethane (DDT), have been banned altogether in the United States since the 1970s; Congress statutorily banned the use of PCBs in 1976 through the enactment of the Toxic Substances Control Act (TSCA), while the United States Environmental Protection Agency (EPA) banned the use of DDT, a pesticide, in 1972 when it cancelled its registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>46</sup> The International Agency for Research on Cancer has classified PCBs as a probable human carcinogen and DDT as a possible human carcinogen.<sup>47</sup> What concerns many researchers is that the chemical structure of PBDEs is similar to that of PCBs and DDT.<sup>48</sup> Because PBDEs are structurally similar to these banned chemicals, their chemical properties and distribution in the environment also show similarities.<sup>49</sup>

The goals of the Stockholm Convention are not limited to the restriction or elimination of the Dirty Dozen chemicals, as an additional purpose is to identify and target additional POPs for action.<sup>50</sup> The Stockholm Convention establishes a POPs Review Committee whose functions include reviewing proposals by parties to list additional POPs in the form of an amendment.<sup>51</sup> Given the

42. Stockholm Convention Participant List, *supra* note 39 (as of February 2005, the list has 94 Parties).

43. *Id.*

44. Stockholm Convention, *supra* note 38, at Annexes A-B. The "Dirty Dozen" consists of the following chemicals: aldrin, chlordane, dichlorodiphenyl trichloroethane (DDT), dieldrin, endrin, heptachlor, hexachlorobenze, mirex, polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (dioxins), and polychlorinated dibenzofurans (furans). EPA, POPs, *supra* note 6, at 18-19.

45. EPA, POPs, *supra* note 6, at 3.

46. See 15 USC. § 2605(e) 2005 (provision banning PCBs). Information on EPA's cancellation of DDT's pesticide registration under FIFRA is available at <http://www.epa.gov/opptintr/pbt/ddt.htm#8> (last visited Feb. 28, 2005).

47. UNITED NATIONS ENVIRONMENT PROGRAMME, RIDDING THE WORLD OF POPs: A GUIDE TO THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS 14 (Aug. 2002), available at <http://www.pops.int/documents/guidance/Default.htm> [hereinafter GUIDE TO THE STOCKHOLM CONVENTION].

48. Rahman et al., *supra* note 3, at Abstract (stating that PBDEs are "structurally similar to PCBs and DDT").

49. *Id.*

50. GUIDE TO THE STOCKHOLM CONVENTION, *supra* note 47, at 13.

51. *Id.* at 12.

similarities between PBDEs and chemicals already listed in the Dirty Dozen, many believe PBDEs will be included in the Stockholm Convention in the near future.<sup>52</sup>

### C. Restrictions and Bans on PBDEs

PBDEs have only started receiving coverage from major media outlets in the United States during the past few years. For example, PBDEs were first mentioned in the *New York Times* in 2001, *USA Today* in 2002, and the *Washington Post* in 2003.<sup>53</sup> This might lead many in the United States to reasonably conclude that concerns over PBDEs are a fairly recent development. That is not the case, however. To the contrary, concerns over PBDEs have existed for long enough that bans were proposed in three European countries—Germany, Sweden, and the Netherlands—as early as the mid-1980s.<sup>54</sup> In 1986 industries in Germany agreed to voluntarily phase PBDEs out of use, and industries in Sweden and the Netherlands soon did the same.<sup>55</sup> Germany officially restricted the use of PBDEs in its 1993 Dioxin Ordinance.<sup>56</sup>

The current legal status of PBDEs varies greatly. In early 2003 the European Union announced its decision to ban two forms of PBDEs, Penta and Octa.<sup>57</sup> According to the EU's directive, "In order to protect health and the environment the placing on the market and the use of pentaBDE and octaBDE and the placing on the market of articles containing one or both of these substances should be prohibited."<sup>58</sup> Member States are directed to adopt and implement the laws, regulations, and provisions necessary to comply with the ban by August 2004.<sup>59</sup> The European Union's general ban does not apply to Deca, but a second directive passed in early 2003 becomes effective July 1, 2006 and prohibits the use of all PBDEs, including

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52. See *infra* note 90 and accompanying text.

53. Based on Lexis searches of *The New York Times*, *USA Today*, and *The Washington Post* using the term "PBDE" and finding the earliest article in which that term appeared. See Laurie Tarkan, *Research is Urged for Healthier Breast Milk*, N.Y. TIMES, Oct. 16, 2001, at F6; see also Charisse Jones, *Anxieties Raise over Toxins at Ground Zero*, USA TODAY, Feb. 7, 2002, at 1; see also Associated Press, *California Becomes First State to Ban Flame Retardants*, WASH. POST, Aug. 11, 2003, at A02.

54. LUNDER & SHARP, *supra* note 7, at 33.

55. *Id.*

56. *Id.*

57. Council Directive 2003/11/EC of 6 Feb. 2003, Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (pentabromodiphenyl ether, octabromodiphenyl ether), 2003 O.J. (L 42) 45 [hereinafter Council Directive 2003/11/EC].

58. *Id.*

59. *Id.*

Deca, in the majority of electronic equipment.<sup>60</sup> China recently decided to adopt the same policy, announcing a ban on the use of all PBDEs in electronic equipment effective July 1, 2006.<sup>61</sup> The types of products included in the EU and Chinese measures include electronic communication products, television products, computers, and home electronic products.<sup>62</sup>

In sharp contrast to the European Union bans, federal regulation of PBDEs in the United States is minimal. Companies that use or produce large quantities of Deca must file a Toxics Release Inventory (TRI) Report.<sup>63</sup> A TRI report is only required if a company uses more than 10,000 pounds or produces more than 25,000 pounds of Deca annually.<sup>64</sup> An obligation to file a TRI report is strictly a reporting requirement, however; it does not impose a ceiling on the quantity of a toxic chemical an industrial firm can use or produce.<sup>65</sup> There are no other federal regulations relating to PBDEs.<sup>66</sup> As a result, not only are PBDEs not banned in the United States, but there are no restrictions on the amount used or produced.

Despite this absence of regulation, concern over PBDEs has been expressed at the federal level. In the fall of 2003, members of the Committee on Energy and Commerce wrote a letter to the EPA expressing their concern.<sup>67</sup> The letter also requested the provision of more information including:

- What steps the EPA has taken to better understand how PBDEs effect human health and the environment;
- Whether the EPA is taking steps to expedite the evaluation of information on PBDEs voluntarily submitted by industries as part of the Voluntary Children's Chemical Evaluation Program;
- Information that the EPA received from several roundtable discussions on brominated flame retardants in late 2002 and early 2003;

60. Council Directive 2002/95/EC of 27 Jan. 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, 2003 O.J. (L 37) 19.

61. SinoCast China Business Daily News, *MII Announces Electronic Pollution Act* (Jan. 15, 2004), available on Global News Wire (accessible through Lexis).

62. *See id.*

63. US ENVIRONMENTAL PROTECTION AGENCY, EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW SECTION 313 LIST OF TOXIC CHEMICALS (Mar. 2001), available at <http://www.epa.gov/tri>. This document lists all chemicals that trigger the TRI reporting requirement of EPCRA § 313. Deca can be found on the list according to its CAS registry number (1163-19-5). Penta (CAS no. 32534-81-9) and Octa (CAS no. 32536-52-0) are not on the list. *Id.*

64. 42 U.S.C. § 11023(f) (2002).

65. *Id.*

66. *See* LUNDER & SHARP, *supra* note 7, at 34.

67. *See* John D. Dingell, et al., *Letter to EPA re: PBDEs* (Oct. 21, 2003), available at [http://www.house.gov/commerce\\_democrats/press/108ltr64.htm](http://www.house.gov/commerce_democrats/press/108ltr64.htm).

- Copies of a letter sent from the EPA to the Centers for Disease Control recommending PBDEs as a potentially harmful substance that should be biomonitoried.<sup>68</sup>

The letter concluded with the statement that “[i]n light of the scientific evidence that shows PBDEs are doubling in our population every two to five years, the urgent need for EPA to take immediate further action to address the potential threat is clear.”<sup>69</sup>

Several states have acted at the local level to restrict PBDEs. In August 2003, California became the first state to enact legislation banning the manufacture and distribution of Penta and Octa.<sup>70</sup> As passed, the ban was not scheduled to go into effect until January 1, 2008, but the legislature passed an amendment advancing the effective date to June 1, 2006.<sup>71</sup> Not long thereafter, Maine and New York both enacted legislation banning the sale of products containing Penta and Octa, but those bans become effective on January 1, 2006, almost six months earlier than the California ban.<sup>72</sup> Finally, the Michigan legislature considered bills banning the use of PBDEs in both the 2002 and 2003 sessions, but the bills have not yet passed.<sup>73</sup>

### III. PRECAUTION AS A BASIS FOR ACTION

The PBDE ban in the European Union and the contrasting lack of regulation in the United States can be explained in part by their differing views of the precautionary principle, and by how those views affect the approaches taken by each to the regulation of toxic chemicals. While the European Union has expressly adopted the principle and incorporated it into its regulatory approach, the United States has not. This influences two aspects of chemical regulation in the EU and the United States: participation in international agreements governing toxic chemicals and domestic regulation governing toxic chemicals within their respective borders.

#### A. *The Precautionary Principle*

Debates over whether it is preferable to have a regulatory system that takes preventive and precautionary action or one that requires scientific evidence of harm before action have been

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68. *Id.*

69. *Id.*

70. Marla Cone, *Davis Signs Bill to Ban Flame Retardants*, L.A. TIMES, Aug. 10, 2003, at pt. 2, p. 6.

71. CAL. HEALTH & SAFETY CODE § 108922 (2004).

72. ME. REV. STAT. ANN. tit. 38, § 1609 (2004); N.Y. ENVTL. CONSERV. LAW § 37-0111 (2004).

73. Lunder & Sharp, *supra* note 7, at 34.

longstanding in both Europe and the United States.<sup>74</sup> There is no environmental legislation in the United States that expressly adopts the precautionary principle as a basis for regulation.<sup>75</sup> In contrast, the treaties that establish the European Union expressly state that the precautionary principle is to be used as the basis for environmental policy.<sup>76</sup>

The precautionary principle developed out of concerns that all too often, scientific certainty about cause and effect cannot be established until it is too late to prevent harm to human health or the environment.<sup>77</sup> Supporters of the precautionary principle argue that precaution is particularly important in the environmental context because the harm that results is often irreversible.<sup>78</sup> The most widely accepted tenet of the precautionary principle is that in Principle 15 of the Rio Declaration on Environment and Development, which states:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.<sup>79</sup>

Critics of the principle argue that it is “unscientific and protectionist” and allows governments to unreasonably restrict trade when no risk is present.<sup>80</sup> The European Commission’s official statement on the principle states, however, that “[r]ecourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product, or process have been

74. See, e.g., Jonathan B. Weiner, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 13 DUKE J. COMP. & INT’L L. 207, 214-15 (2003). According to Professor Weiner:

Normative evaluations of this situation vary. Some observers see a civilized, safe, careful Europe confronting a risky, reckless, and violent America. To this group, the Precautionary Principle is an antidote to industrialization, globalization, and American risk-taking. On the other hand, other observers see a fearful, statist, protectionist Europe trying to rise in the post Cold-War era to challenge a market-based, scientific, entrepreneurial United States. To this group, the Precautionary Principle is an obstacle to science, trade and progress.

*Id.*

75. *Id.* at 212.

76. *Id.*; see also European Union: Consolidated Version of the Treaty on European Union and Consolidated Version of the Treaty Establishing the European Community, Jan. 1998, 37 I.L.M. 56, 116-17 (1998).

77. DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 405 (2d ed. 2002).

78. *Id.* at 409.

79. *Id.* at 406; Rio Declaration on Environment and Development, June 14, 1992, princ. 15, 31 I.L.M. 874.

80. See, e.g., Scientific Alliance, *The Debate over Chemicals*, available at [http://www.scientific-alliance.org/the\\_debate\\_chemicals.htm](http://www.scientific-alliance.org/the_debate_chemicals.htm) (last visited Feb. 22, 2005) [hereinafter Scientific Alliance].

identified.”<sup>81</sup> That is, as interpreted by the European Commission, the principle does not justify action in the complete absence of evidence establishing risk. In addition, the European Commission also takes the position that action based on the precautionary principle should be “subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.”<sup>82</sup> It appears, therefore, that the European Commission does not intend for regulatory action based on the precautionary principle to be permanent or unsupported by science. Instead, the purpose of the precautionary principle is to maintain the status quo until further information is available and before irreversible damage occurs.

### B. *The Use of Precaution in International Agreements*

The Rio Declaration is not the only international agreement that emphasizes the importance of precaution in risk regulation. To the contrary, precaution is a theme emphasized in numerous international environmental agreements, many of which specifically refer to the precautionary principle.<sup>83</sup> Most recently, the international community affirmed its commitment to the precautionary principle in Article 1 of the Stockholm Convention, which states:

Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this convention is to protect human health and the environment from persistent organic pollutants.<sup>84</sup>

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81. European Commission, *Communication from the Commission on the Precautionary Principle*, reprinted in HUNTER ET AL., *supra* note 77, at 407.

82. *Id.*

83. See, e.g., Framework Convention on Climate Change, May 9, 1992, art. 3, 31 I.L.M. 849 (“The [p]arties should take precautionary measures to anticipate, prevent, or minimize the causes of climate change and mitigate its adverse effects.”); Convention on the Protection and Use of Transboundary Watercourses and International Lakes, Mar. 17, 1992, art. 2, 31 I.L.M. 1312 (Parties are to be guided by a number of principles, including the “precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link . . . .”); Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa, Jan. 29, 1991, art. 4, 30 I.L.M. 773 (“Each [p]arty shall strive to adopt and implement the preventive, precautionary approach to pollution problems . . . .”); Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, 26 ILM 1541 (“Parties to this protocol . . . [d]etermined to protect the ozone layer by taking precautionary measures . . . .”); see also Carolyn Raffernsperger, *Uses of the Precautionary Principle in International Treaties and Agreements*, Oct. 1999, available at [http://www.biotech-info.net/treaties\\_and\\_agreements.html](http://www.biotech-info.net/treaties_and_agreements.html).

84. Stockholm Convention, *supra* note 38, at art. 1.

Recent debates in this country indicate that the failure of the United States to ratify the Stockholm Convention has been a result of the Convention's precautionary approach and how that approach governs the addition of new chemicals to the Convention.<sup>85</sup>

As noted earlier, one goal of the Stockholm Convention is to target additional POPs that require action, and the Convention establishes a process for adding those new chemicals to the agreement.<sup>86</sup> Any party to the Convention can propose the addition of a new chemical by submitting a report that details evidence of the chemical's persistence, bio-accumulation, potential for long-range environmental transport, and adverse effects to human health or the environment.<sup>87</sup> The report also must include a statement indicating the need for global control of the chemical.<sup>88</sup> Finland has already prepared such a report for Penta and appears ready to propose its addition to the Convention.<sup>89</sup>

Once a proposal is submitted, a scientific review committee established by the Convention evaluates the proposal and creates a risk profile for the chemical.<sup>90</sup> The proposal proceeds if the committee determines the chemical "is likely . . . to lead to significant adverse human health and/or environmental effects such that global action is warranted."<sup>91</sup> The importance of precaution and preventive action in this process is clear; as the Convention states, "[l]ack of full scientific certainty shall not prevent the proposal from proceeding."<sup>92</sup> If the committee determines that the process should proceed, the proposal is submitted for consideration to the Conference of Parties (COP), which is composed of representatives from each country that has ratified the Convention.<sup>93</sup> The precautionary nature of the Convention is again evident, as the parties are directed to "decide, in a precautionary manner, whether to list the chemical."<sup>94</sup>

The importance of scientific evidence in this process is also clear, however. To recommend the addition of a chemical to the Convention,

85. See, e.g., Pep Fuller & Thomas O. McGarity, *Beyond the Dirty Dozen: The Bush Administration's Cautious Approach to Listing New Persistent Organic Pollutants and the Future of the Stockholm Convention*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 1 (Fall 2003).

86. Stockholm Convention, *supra* note 38, at art. 8.

87. *Id.* art. 8, annex D.

88. *Id.* at annex D.

89. See JOHANNA PELTOLA & LEENA YLA-MONONEN, FINNISH ENV'T INST., PENTABROMODIPHENYL ETHER AS A GLOBAL POP 8-9, available at [http://www.greenstart.org/efc9/bfrs/bfr\\_pdfs/BFR\\_16\\_PE.pdf](http://www.greenstart.org/efc9/bfrs/bfr_pdfs/BFR_16_PE.pdf) (last visited Feb. 25, 2005).

90. Stockholm Convention, *supra* note 38, at art. 8.

91. *Id.* art. 8(7).

92. *Id.*

93. Stockholm Convention, *supra* note 38, at art. 8(4)(a); EPA, POPs, *supra* note 6, at 13.

94. Stockholm Convention, *supra* note 38, at art. 8(9).

the committee must find, based on a report detailing its adverse effects, that significant adverse effects are likely.<sup>95</sup> The scientific report requirement and the inclusion of the words *significant* and *likely* preclude the committee from recommending the addition of a chemical that merely poses a negligible risk. It is evident that this process attempts to strike a balance between not acting absent scientific support and acting before significant irreversible harm occurs.

This precautionary approach for the listing of additional chemicals to the Convention has been met with significant resistance in the United States. For example, although President Bush submitted proposed legislation for the implementation of the Stockholm Convention in April 2002, the proposal did not address the addition of new POPs to the Convention.<sup>96</sup> According to Pep Fuller, chief EPA negotiator for the Stockholm Convention, and Professor Thomas McGarity, this omission would have severely limited U.S. participation in the Stockholm Convention because the legislation proposed by President Bush required the United States not only to ratify a Convention amendment but also to amend one of two U.S. statutes, the Toxic Substances Control Act (TSCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), every time the international community decided to list a new POP in the Convention.<sup>97</sup> Fuller and McGarity conclude that the Bush Administration appears unwilling to accept recommendations made by the COP on whether a new chemical should be added, and instead has taken the position that the United States should not add a chemical to the Convention unless the proposal passes a quantitative cost-benefit analysis.<sup>98</sup> The cost-benefit analysis endorsed by the administration, however, has previously led to significant delays whenever the EPA has attempted to cancel the registration of pesticides that are POPs.<sup>99</sup> Consequently, it appears that had the Senate approved the proposed legislation, the practical effect would have been to limit U.S. participation in the Stockholm Convention to the original Dirty Dozen.

The precautionary approach for the listing of new chemicals contained in the Stockholm Convention has, however, received support in the United States from others outside the Bush Administration. A competing bill to implement the Convention was introduced by Senator James M. Jeffords (hereinafter, the Jeffords

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95. *Id.* art. 8(7).

96. Fuller & McGarity, *supra* note 85, at 10-11.

97. *Id.* at 11.

98. *Id.* at 3-4.

99. *Id.* at 4; *see also* 7 U.S.C. § 136d(b) (2005) (requiring the EPA to establish that use of a pesticide results in unreasonable adverse effects before cancellation is possible).

Bill) at the same time that President Bush submitted his proposed legislation.<sup>100</sup> The Jeffords Bill did not affect the Convention's requirement that a party ratify an amendment in order to be bound by it, and it also preserved the ability of the United States to "opt-out" of any such amendment.<sup>101</sup> The Jeffords Bill eliminated the need in the President's Bill to amend TSCA or FIFRA if the United States decided to ratify an amendment to the Convention.<sup>102</sup> That is, under the President's Bill two legislative acts were needed to list a new POP—ratification of the Convention amendment *and* an amendment to either TSCA or FIFRA. In contrast, under the Jeffords Bill only the former was needed.

Ultimately, neither bill was passed.<sup>103</sup> Efforts to ratify and implement the Stockholm Convention were renewed in light of the Convention's recent entry-into-force date of May 17, 2004. On February 25, 2004, proposed legislation was introduced to help the United States meet its pesticide-related obligations under the Stockholm Convention and two other international environmental agreements.<sup>104</sup> The most recent proposal evidences a continued unwillingness to defer to a decision made by the COP, as the proposal instructs the EPA to consider the recommendation of the COP, but the procedure that must be followed to cancel the registration of a pesticide is otherwise unaltered.<sup>105</sup> Requiring the EPA to conduct a full cancellation process under FIFRA to implement an amendment to the Convention is problematic because the cancellation process is considered burdensome and inefficient and is, therefore, rarely used.<sup>106</sup> The 2002 Jeffords Bill also would have required the EPA to conduct a cancellation hearing, but it gave the EPA the authority to do so without first establishing that the pesticide posed an unreasonable risk.<sup>107</sup> "In effect, the Jeffords Bill would have permitted, but not required, the EPA to effectuate a rebuttable

100. Fuller & McGarity, *supra* note 85, at 12.

101. *Id.*

102. *Id.*

103. See S.2507, 107th Cong. Bill Summary & Status (May 31, 2002), available at <http://thomas.loc.gov/bss/d107query.html> [hereinafter S.2507 Bill Summary & Status]; S.211B, 107th Cong. Bill Summary & Status (Apr. 11, 2002), available at <http://thomas.loc.gov/bss/d107query.html> [hereinafter S.211B Bill Summary & Status].

104. PIC and POPs Convention and the LRTAP POPs Protocol Implementation Act (Feb. 25, 2004) available at <http://www.epa.gov/opptintr/fifrafeb25.pdf>. [hereinafter Proposed Legislation]. The proposed legislation affects not only U.S. participation in the Stockholm Convention, but also the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention) and the Protocol on Persistent Organic Pollutants to the 1979 Convention on Long-Range Transboundary Air Pollution (LRTAP POPs Protocol). *Id.*

105. See *id.* at 18 (proposed new FIFRA § 17(7)).

106. See *supra* note 99 and accompanying text.

107. Fuller & McGarity, *supra* note 85, at 12.

presumption that a newly listed POP should be regulated.”<sup>108</sup> As a result, the Jeffords Bill would have given weight and deference to a listing decision made by the scientific review committee that is supported by scientific evidence, but it still would have allowed the United States to “opt out’ of a ‘crazy COP’ decision.”<sup>109</sup>

In addition, it is important to note that the scope of the most recent proposal is limited to FIFRA, the statute governing pesticides.<sup>110</sup> The introduction to the Bill states that its purpose is “to implement *pesticide-related obligations* of the United States under the international conventions or protocols known as the PIC Convention, the POPs Convention, and the LRTAP POPs Protocol.”<sup>111</sup> Because the Bill does not propose any amendments to TSCA, the statute governing toxic chemicals such as PBDEs, it would not enable the country to meet all of its obligations under these international agreements. Instead, it would only enable the country to act in conjunction with the international community if a pesticide is at issue. No action has been taken on this proposal, but it demonstrates that the government apparently remains unwilling to consent to decisions made by the COP and is unlikely to endorse any amendment expanding the Convention’s scope beyond the Dirty Dozen, including a potential amendment to list PBDEs.<sup>112</sup> Unfortunately, the risks posed by PBDEs are also unlikely to be adequately reduced or eliminated by the U.S.’s toxic chemical regulatory system.

#### IV. APPROACHES TO THE REGULATION OF TOXIC CHEMICALS

The divergence of European Union and United States environmental policy with respect to the precautionary principle is also evident in their respective approaches to the regulation of toxic chemicals within their borders. The chemical regulatory systems in the EU and the United States share both similarities and differences. For example, although both systems establish separate frameworks for new chemicals and for existing chemicals, they differ in precisely how they regulate these two classes.<sup>113</sup> For new chemicals, the primary difference between the EU and U.S. systems lies in what the regimes require of new chemicals before they can be introduced into

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108. *Id.*

109. *Id.* at 13.

110. Proposed Legislation, *supra* note 104.

111. *Id.* at 1 (emphasis added).

112. See S.2507 Bill Summary & Status, *supra* note 103; see S.2118 Bill Summary & Status, *supra* note 103; see Fuller & McGarity, *supra* note 85.

113. See *infra* Parts IV.A-B.

the market.<sup>114</sup> For existing chemicals, the primary difference regards the circumstances under which a ban or restriction on use is considered justified.<sup>115</sup>

### A. Regulation of New Chemicals

The EU and U.S. systems both require more of new chemicals than existing chemicals.<sup>116</sup> The major components of new chemical regulation in both systems are notification and risk assessment.<sup>117</sup> The EU's risk assessment requirement, however, is more extensive than its counterpart in the United States.<sup>118</sup>

#### 1. Regulation of New Chemicals in the European Union

In the EU, any chemical first marketed after September 18, 1981, and therefore not listed in the European Inventory of Existing Chemical Substances (EINECS), is classified as a new chemical.<sup>119</sup> Uniform regulation of new chemicals among European countries was first required with the passage of Directive 79/831/ECC in 1979.<sup>120</sup> Although the directive encouraged the testing of new chemicals before their introduction to the market, it did not impose a mandatory testing requirement.<sup>121</sup> Instead, the mandatory requirements were related to notification and labeling.<sup>122</sup> Under the directive, chemical manufacturers and importers are required to notify the appropriate government before placing a new chemical on the market and to label the chemical if they determine it is "dangerous" as defined by the directive.<sup>123</sup> Even though the directive does not require testing, the precautionary nature of the European approach is still evident. For

114. See *infra* Part IV.A.

115. See *infra* Part IV.B.

116. Compare *infra* Part IV.A, with *infra* Part IV.B.

117. See *infra* Parts IV.A.1-2.

118. Compare *infra* Part IV.A.1, with *infra* Part IV.A.2.

119. European Chemical Bureau, *Existing Chemicals*, overview § 2 n.2, available at <http://ecb.jrc.it/existing-chemicals> (last visited Feb. 27, 2005).

120. Council Directive 79/831/EEC of 18 September 1979 Amending for the Sixth Time Directive 67/548/EEC, 1979 O.J. (L 259) 10 [hereinafter Council Directive 79/831/EEC]. Council Directive 67/548/EEC was passed on June 27, 1967 and consists of laws, regulations, and provisions relating to the classification, packaging, and labeling of dangerous substances. 1967-68 O.J. SPEC. ED. at 234.

121. Council Directive 79/831/EEC, *supra* note 120, at 1 ("In order to control the effects on man and the environment it is *advisable* that any new substance placed on the market be subjected to a prior study by the manufacturer or importer.") (emphasis added).

122. *Id.*

123. *Id.* arts. 2(2)(a)-(n), 6(1), 16(1) (Substances are considered "dangerous," and must be labeled accordingly, if they are explosive, oxidizing, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, dangerous for the environment, carcinogenic, teratogenic, or mutagenic). *Id.*

example, the directive classifies a chemical as “dangerous for the environment” if it “presents *or may present* immediate or delayed risk.”<sup>124</sup> Similarly, a chemical is classified as “harmful” if it “*may involve* limited health risks” when inhaled or ingested.<sup>125</sup>

In the early 1990s the European Community increased the burden on parties wanting to manufacture or import new chemicals by requiring, instead of merely encouraging, a risk assessment to be performed.<sup>126</sup> The language of the new directive places even greater emphasis on the value of precaution with respect to toxic chemicals. For example, the introductory language states that a goal of the new directive is to “protect man and the environment from *potential risks which could arise* from the placing on the market of new substances.”<sup>127</sup>

## 2. Regulation of New Chemicals in the United States

In the United States, a new chemical is classified as one not listed in the Toxic Substances Control Act Inventory (hereinafter, TSCA Inventory).<sup>128</sup> Testing is not mandatory if a party wants to add a new substance to the TSCA Inventory, but the EPA can require the manufacturer to submit test data on the substance’s effect on human health and the environment if certain conditions are established.<sup>129</sup> To require testing, the EPA must first find that the substance “may present an unreasonable risk of injury to health or the environment” or that it is produced in substantial quantities that may result in significant environmental release or human exposure.<sup>130</sup>

At first glance, TSCA and Directive 79/831/EEC appear to embody a similarly precautionary approach, as both contain the phrase “may present.” However, although the EU directive qualifies “may present” with the word “risk,” TSCA qualifies “may present” with the phrase “*unreasonable risk*,” suggesting it is more stringent than its EU counterpart.<sup>131</sup> If the EPA does not make the findings necessary to establish that a chemical poses an unreasonable risk, or

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124. *Id.* art. 2(2)(k) (emphasis added).

125. *Id.* art. 2(2)(h) (emphasis added).

126. Council Directive 92/32/EEC of 30 April 1992 Amending for the Seventh Time 67/548/EEC, art. 3(2), 1992 O.J. (L 154) 1, 4 (effective Nov. 1993) (imposing a mandatory testing requirement on new chemical substances to assess real or potential risks).

127. *Id.* at 1 (emphasis added).

128. See U.S. Environmental Protection Agency, *New Chemicals and Existing Chemicals*, available at <http://www.epa.gov/oppt/newchems/newvexist.htm> (last updated Feb. 21, 2005) [hereinafter EPA, *New Chemicals*] (“Once on the Inventory, a substance is considered an ‘existing’ chemical. . .”).

129. 15 U.S.C. § 2604(b) (2005).

130. *Id.* § 2603(a)(1)(A)(i), (B)(i).

131. See, e.g., *id.*; Council Directive 79/831/EEC, *supra* note 120, art. 2(2)(k), at 12.

the findings are not upheld by the courts, the manufacturer of a new chemical substance is free to use, sell, and market a substance without the submission of any data regarding its potential effects on human health and the environment.<sup>132</sup> That is, not only does the U.S. system lack a mandatory testing requirement, it also places the initial burden of proof on the EPA—not the industry that stands to profit from the introduction and use of a new chemical.

### B. Regulation of Existing Chemicals

Chemical substances that are listed in either EINECS or the TSCA Inventory are classified as existing chemicals.<sup>134</sup> With respect to PBDEs, the most important differences between these systems are the hurdles that each government must overcome before it can restrict or ban the use of an existing chemical. These “hurdles” are significantly greater in the United States than in the EU.<sup>135</sup>

#### 1. Regulation of Existing Chemicals in the European Union

The current system for regulating existing chemicals within the EU was established in 1993 when the Council of the European Communities adopted the Existing Substances Regulation.<sup>136</sup> As with the directive governing new chemicals, the influence of the precautionary principle can be seen in this regulation. For example, the Commission is directed to “regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their *potential effects* on man or the environment.”<sup>137</sup> The directive does not require the Commission to have conclusive evidence showing that a substance causes harm before it can be placed on a priority list.<sup>138</sup> To the contrary, a lack of data on the effects of the substance is a factor that supports placing a substance on a priority list.<sup>139</sup>

Once a substance is placed on a priority list, a Member State then bears the responsibility to oversee an extensive risk assessment.<sup>140</sup> The Member State’s delegated rapporteur has the

132. See 15 U.S.C. § 2603 (2005) (setting forth the limited situations in which EPA can require testing of a chemical substance before it is introduced to the market).

134. See *infra* Part IV.B.1-2.

135. Compare *infra* Part IV.B.1, with *infra* Part IV.B.2.

136. Council Directive 793/93/EEC of 23 March 1993 Evaluation and Control of the Risks of Existing Substances, 1993 O.J. (L 84) 1 [hereinafter Council Directive 793/93/EEC].

137 *Id.* art. 8, at 4 (emphasis added).

138 *Id.*

139. *Id.*

140. *Id.* art. 10, at 5.

authority to require manufacturers and importers of the substance under investigation to submit further data, conduct additional testing, or both.<sup>141</sup> The rapporteur may not limit the risk assessment to the known effects of the substance, as he or she is directed to evaluate the evidence with respect to "the real or potential risk to man and the environment."<sup>142</sup> After the data has been collected and evaluated, and any lack of data has been taken into consideration, the rapporteur must characterize the risk by placing the chemical in one of three categories.<sup>143</sup> The rapporteur's risk assessment is then submitted to the Commission and a vote is taken on whether to adopt the rapporteur's recommended risk reduction strategy.<sup>144</sup> If the Commission approves a strategy that includes a restriction or ban, the Commission will generally incorporate that restriction as an amendment to Directive 76/769/EEC, which establishes restrictions on the marketing and use of dangerous substances within the European Community.<sup>145</sup>

## 2. Regulation of Existing Chemicals in the United States

The authority of the EPA to restrict or ban the use of an existing chemical in the United States is rooted in § 6 of the Toxic Substances Control Act (TSCA).<sup>146</sup> The EPA cannot restrict or ban an existing chemical unless it can show that it "presents or will present an unreasonable risk of injury to health or the environment."<sup>147</sup> The absence of the word "potential" from § 6 of TSCA, and the inclusion of the phrase "presents or will present" and the word "unreasonable," restrain the United States from taking preventive or precautionary action to the degree that the EU system allows.

Because the authority of the EPA is constrained by a statutory requirement of unreasonable risk, any attempt to issue a rule under § 6 of TSCA must comply with the Administrative Procedure Act and is subject to judicial review.<sup>148</sup> The availability of judicial review provides ample opportunity for well-financed industrial groups to challenge any EPA rule, and the unreasonable risk standard as

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141. *Id.*

142. *Id.* (emphasis added).

143. European Chemical Bureau, *Existing Chemicals*, *supra* note 119, at priority setting § 5. One possible designation is "substance of concern, further risk reduction measures, beyond those already in place, are required." *Id.*

144. Council Directive 793/93/EEC, *supra* note 135, art. 11, at 5.

145. See *id.* art. 11 (referring to Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, 1976 O.J. (L 262) 201).

146. 15 U.S.C. § 2605.

147. *Id.* § 2605(a).

148. *Id.*; 5 U.S.C. § 704.

interpreted by the courts has proved to be exceedingly difficult to meet.<sup>149</sup> Despite efforts to do so, the EPA has not successfully banned a chemical using its § 6 authority in the more than twenty-five years since TSCA was enacted.<sup>150</sup>

The burden faced by the EPA under this system is exemplified by *Corrosion Proof Fittings v. EPA*.<sup>151</sup> In *Corrosion Proof Fittings*, industry groups successfully challenged an EPA rule banning the manufacture, import, and processing of nearly all products that contained asbestos.<sup>152</sup> The Fifth Circuit held that the EPA did not adequately consider alternatives to a ban, and that it was required to calculate the costs and benefits of less burdensome alternatives.<sup>153</sup> *Corrosion Proof Fittings* has been described as “the demise of section 6 of TSCA.”<sup>154</sup> The EPA had proposed a § 6 ban on acrylamide and N-methylacrylamide grouts before *Corrosion Proof Fittings* was decided, but the agency has taken no action on the proposal since the Fifth Circuit’s decision.<sup>155</sup> In fact, the EPA has not initiated any action under § 6 since *Corrosion Proof Fittings*.<sup>156</sup> Fuller and McGarity describe the EPA’s response as “entirely rational, if not courageous” given the probability that industry groups will challenge any attempt by the EPA to restrict or ban a chemical.<sup>157</sup> They further conclude that “given the fact that the court was unwilling to allow the agency to regulate even such a notorious bad actor as asbestos . . . the agency cannot be faulted for deciding that its limited resources are better devoted to other activities.”<sup>158</sup>

### C. Addressing the Problem of “Grandfathered” Chemicals

The differing procedural requirements for restricting or banning the use of an existing chemical are particularly important for a major problem faced by both the EU and U.S. systems: how to act with regard to the so-called “grandfathered” chemicals.<sup>159</sup> The use of chemicals in industrial processes was already widespread by the time EINECS and the TSCA Inventory were established.<sup>160</sup> To accommodate those industries, chemicals that were already in use were placed into EINECS or the TSCA Inventory without being the

149. See *infra* notes 151-56 and accompanying text on *Corrosion Proof Fittings*.

150. LYNN L. BERGESON, TSCA: TOXIC SUBSTANCES CONTROL ACT 49 (2000).

151. 947 F.2d 1201 (5th Cir. 1991).

152. *Id.* at 1229-30.

153. *Id.* at 1229; see Fuller & McGarity, *supra* note 85, at 27.

154. See Fuller & McGarity, *supra* note 85, at 26.

155. BERGESON, *supra* note 150, at 50.

156. Fuller & McGarity, *supra* note 85, at 28.

157. *Id.*

158. *Id.*

159. *Id.* at 39.

160. See LUNDER & SHARP, *supra* note 7, at 38.

subject to the regulatory requirements applicable to new chemicals.<sup>161</sup>

It is estimated that more than 150,000 chemicals, including brominated flame retardants, were in use when the TSCA Inventory and EINECS were created, and these chemicals were subsequently left on the market without any consideration of their potential hazards.<sup>162</sup> In the EU, approximately 100,000 chemicals used between January 1, 1971 and September 18, 1981 were grandfathered into EINECS.<sup>163</sup> In the United States, approximately 63,000 chemicals used between 1975 and 1977, the years immediately surrounding TSCA's 1976 enactment, were grandfathered into the TSCA Inventory.<sup>164</sup> Given the sheer volume of chemicals that were grandfathered into the two systems, the state of knowledge about the potential risks posed by a significant number of industrial chemicals has been described as "profoundly ignorant."<sup>165</sup>

The EPA acknowledges that this has led to situations in which an existing chemical is not subject to any testing requirements even though it may be of similar or greater toxicity than a new chemical that would be subject to testing requirements if it were introduced for the first time today.<sup>166</sup> The EPA also notes that the "lack of controls on the older chemicals may cause a misunderstanding that, because there are fewer (or no) requirements, they are considered safer than the new, regulated chemicals."<sup>167</sup> The EPA is, however, working to reduce this disparate treatment for existing chemicals.<sup>168</sup> Recognizing that formal regulation of existing chemicals under TSCA has been inefficient and difficult to implement, EPA's Existing Chemicals Program is increasingly relying on the voluntary cooperation of industries to implement risk-reducing measures.<sup>169</sup>

EU Member States have expressed concern that, despite the explicit incorporation of the precautionary principle into its toxic chemical regulatory system, banning or restricting the use of existing chemicals remains quite difficult.<sup>170</sup> The EU is addressing these concerns and the problems of grandfathered chemicals with a

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161. *Id.*

162. European Chemical Bureau, *Existing Chemicals*, *supra* note 119; LUNDER & SHARP, *supra* note 7, at 38.

163. European Chemical Bureau, *Existing Chemicals*, *supra* note 119.

164. EPA, *New Chemicals*, *supra* note 128.

165. WWF, *EU Toxics Briefing: An Introduction to REACH - a New Regulatory System for Chemicals in Europe*, available at [http://www.worldwildlife.org/toxics/pubres/eu\\_toxics\\_briefing.pdf](http://www.worldwildlife.org/toxics/pubres/eu_toxics_briefing.pdf) (Sept. 2003) [hereinafter WWF, *EU Toxics Briefing*].

166. EPA, *New Chemicals*, *supra* note 128.

167. *Id.*

168. *Id.*

169. U.S. Environmental Protection Agency, *TSCA Existing Chemicals Program Overview*, available at <http://www.epa.gov/opptintr/chemtest/mtlappx1.htm> (last updated Oct. 6, 2004).

170. WWF, *EU Toxics Briefing*, *supra* note 165, at 1.

proposed new regulatory system called REACH.<sup>171</sup> The European Commission outlined the key components of REACH—registration, evaluation, and authorization—in a paper released in early 2001.<sup>172</sup> The REACH proposal continues the EU trends of emphasizing the importance of precaution and increasing the burden on industries that want to use chemicals and stand to profit from them. Under REACH, industries are required to submit safety data for all chemicals that they use to the government, and if the government determines that the chemical is of “very high concern,” it will be phased out of use unless the industry can show its use presents negligible risk.<sup>173</sup> REACH would retain the mandatory testing requirement for new chemicals. In an attempt to address the problem of grandfathered chemicals, it would also create a database containing information on chemicals for which little to no data is currently available.<sup>174</sup> All chemicals that meet the standards in the Stockholm Convention for persistence, bioaccumulation, toxicity, and long-range transport would automatically be characterized as chemicals of very high concern and would be subject to a presumptive phase-out unless the members of the industry wishing to use the chemical satisfy a very high burden of proof.<sup>175</sup>

If REACH is approved and implemented as planned, the chemical regulatory systems in the EU and United States will become even more polar. In the United States, the government will continue to bear the burden of proving that a worrisome chemical poses an unreasonable risk before its use or production can be restricted. In contrast, industries in the EU will bear the burden of showing that a worrisome chemical presents a negligible risk before its introduction (for new chemicals) or continued use (for existing chemicals) is authorized. The disparity between EU and U.S. environmental policy appears to be increasing, as the U.S. government recently sent a letter to the World Trade Organization outlining its opposition to REACH.<sup>176</sup> The U.S. letter characterizes REACH as “particularly costly, burdensome, and complex” and expresses concerns that it will “prove unworkable in its implementation, disrupt global trade, and adversely impact innovation.”<sup>177</sup>

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171. *Id.*

172. European Commission, *White Paper: Strategy for a Future Chemicals Policy*, Feb. 2001, available at <http://www.europa.eu.int/comm/environment/chemicals/whitepaper.htm>.

173. WWF, *EU Toxics Briefing*, *supra* note 165, at 2.

174. *Id.*

175. *Id.*

176. U.S. Department of State, *U.S. Voices Concerns over Latest EC Chemicals Proposal*, available at <http://usinfo.state.gov> (last visited June 21, 2004).

177. *Id.* pts. 4, 7.

## V. THE EFFECT OF EU AND U.S. ENVIRONMENTAL POLICY ON PBDES

Under both the EU and U.S. systems, PBDEs are classified as existing chemicals and are among the chemicals that were grandfathered into the two systems. While it is highly possible that PBDEs will be added to the Stockholm Convention in the foreseeable future, they are not currently covered by any international agreement. Because no international agreement addresses the use of PBDEs, any official restriction on their production or use must originate domestically. While the European Union chose to issue official restrictions, the United States has yet to do so at the federal level.

### A. Evidence of Effects

Research into the toxicity of potentially harmful chemicals is necessarily limited by one obvious fact—it is impossible to systematically study their effects without purposeful exposure. Clearly no one would advocate purposeful human exposure to toxins simply to gain a better understanding of them. As a result, the evidence of the effects of a chemical is typically based on controlled animal studies or accidental human exposure.<sup>178</sup> The validity of using animal studies to draw conclusions about potential effects in humans is widely accepted.<sup>179</sup> Because there is disagreement about precisely how to relate animal findings to humans, however, researchers often draw different conclusions about the magnitude of the threat to human health.<sup>180</sup> As with most environmental toxins, research on the health effects of PBDEs is primarily based on laboratory studies involving animals. There is no direct evidence linking PBDEs to adverse health effects in humans, but PBDE exposure in animals has been linked to numerous adverse health effects.<sup>181</sup> In addition, there is direct evidence linking a chemically similar group of fire retardants, polybrominated biphenyls (PBBs), to human health problems.<sup>182</sup>

Like PBDEs, PBBs are manmade chemicals with flame-retardant qualities that can be added to consumer products to make them more difficult to burn.<sup>183</sup> Unlike PBDEs, however, there is direct evidence linking PBBs to human health problems as a result of accidental exposure. In 1973, approximately one thousand pounds of

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178. ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 383 (4th ed. 2003).

179. *Id.*

180. *Id.*

181. LUNDER & SHARP, *supra* note 7, at 27.

182. Rahman et al., *supra* note 3, at 11.

183. DHHS, *supra* note 2.

a brominated flame retardant named Firemaster, which consisted of a mixture of PBBs, was accidentally mixed into the feed of dairy, livestock, and poultry in Michigan.<sup>184</sup> By the time the contamination was discovered, approximately 10,000 people had been eating contaminated animal products for several months.<sup>185</sup> Numerous physical health problems were reported in association with the exposure, including nausea, abdominal pain, loss of appetite, joint pain, fatigue, and weakness.<sup>186</sup> Many people also reported episodes of amnesia and confusion.<sup>187</sup> Children born to mothers exposed to Firemaster in 1973–74 are reported to have decreased birth weights, increased respiratory illnesses, and lower IQs.<sup>188</sup> The monitoring of people directly exposed to Firemaster, and their children, has continued over the last thirty years in order to evaluate the relationship between the accidental exposure and various health problems, including breast cancer.<sup>189</sup> The people affected by the Firemaster contamination were obviously exposed to a very large quantity of PBBs, much more so than average citizens who had products in their homes containing PBBs. Nonetheless, concern over PBBs was great enough that their use was discontinued in the United States soon after the Michigan accident.<sup>190</sup> It was after PBBs were removed from the fire retardant market that the manufacture and use of PBDEs in fire retardants grew exponentially.<sup>191</sup> Fortunately, there is no evidence linking PBDEs to adverse human health effects because there has been no accidental exposure that parallels the exposure of Michigan residents to PBBs. Unfortunately, some of the laboratory studies conducted on PBDEs using animals indicate a cause for concern.

Laboratory research into the possible toxic effects of brominated flame retardants, and specifically PBDEs, began as a result of the PBB accident in Michigan.<sup>192</sup> A recent review of the toxicology of brominated flame retardants concluded that although the current data are limited and sometimes contradictory, they do raise concern over the safety of the continued use of some brominated flame

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184. Daniel W. Nebert & Howard G. Shertzer, *Toxic Effects of Polyhalogenated Biphenyls*, INTERFACE: GENES AND THE ENVIRONMENT 2, available at <http://www.eh.uc.edu/ceg/wwInte14.pdf>. (Spring 1998).

185. *Id.*; DHHS, *supra* note 2.

186. DHHS, *supra* note 2.

187. Nebert & Shertzer, *supra* note 184, at 2.

188. *Id.*

189. See U.S. Environmental Protection Agency, *EDRI Federal Project Inventory: Study of the Human Health Consequences of Polybrominated Biphenyls (PBB) Contamination in Michigan*, available at <http://www.epa.gov/endocrine/inventory/CDC-RUB1.html> (last updated Apr. 1, 2003).

190. The manufacture of PBBs was discontinued in the U.S. in 1976. See DHHS, *supra* note 2.

191. LUNDER & SHARP, *supra* note 7, at 9.

192. Rahman et al., *supra* note 3, at 11.

retardants.<sup>193</sup> PBDE exposure in laboratory animals is linked to various adverse health effects including behavioral changes and learning, memory, and hearing problems, but most of the concern is based on the potential effect of PBDEs on the thyroid gland and the nervous system.<sup>194</sup>

PBDEs have been shown to alter the levels of thyroid hormones and harm the developing nervous system in animals.<sup>195</sup> In humans, low levels of thyroid hormones (hypothyroidism) are associated with a variety of health problems ranging from anxiety and depression to fatigue and hair loss.<sup>196</sup> Pregnant women with particularly low levels of one thyroid hormone have been reported to have children with lower IQs.<sup>197</sup> Because pregnancy itself puts stress on the thyroid gland, researchers are concerned that pregnant women (and their unborn children) could be particularly vulnerable if PBDEs are capable of lowering thyroid hormone levels in humans.<sup>198</sup> The data on human exposure to brominated flame retardants is very limited, but one study did find higher rates of hypothyroidism among people who were exposed to brominated flame retardants while at work.<sup>199</sup>

Based on the current research it is unclear whether PBDEs have the ability to cause cancer. The EPA has classified one category of PBDEs, Deca, as a possible human carcinogen.<sup>200</sup> This classification of Deca is based on a 1986 study in which mice exposed to Deca developed tumors of the liver, thyroid, and pancreas.<sup>201</sup> That study, however, is the only one that has tested the PBDE mixtures used in consumer products for their potential to cause cancer.<sup>202</sup> As a result, the fact that only Deca has been classified as a possible human carcinogen does not mean Penta and Octa are less worrisome than Deca. Instead, it is quite possible that the lack of a carcinogen classification is based on a lack of research. Future research could theoretically show Penta and Octa are not carcinogens, but that appears unlikely. To the contrary, some researchers believe Penta and Octa are more likely to cause cancer than Deca based on an analysis of the differences in their chemical structures.<sup>203</sup>

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193. Birnbaum & Staskai, *supra* note 15.

194. LUNDER & SHARP, *supra* note 7, at 27.

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.* at 28.

199. *Id.*

200. DHHS, *supra* note 2.

201. LUNDER & SHARP, *supra* note 7, at 30.

202. *Id.*

203. T. McDonald, *A Perspective in the Potential Health Risks of PBDEs*, 46 CHEMOSPHERE 745, 755 (2002).

### B. Evidence of Exposure

Although evidence of the effects of PBDEs is very limited, there is more evidence tracking exposure levels in the EU than in the United States. Studies evaluating human exposure to PBDEs usually do so by measuring the levels of the chemicals in the breast milk of mothers, and these studies have been conducted more frequently in the EU.<sup>204</sup> Despite this evidential discrepancy, three trends have been identified: exposure levels in the EU and United States both rose quickly throughout the end of the twentieth century, levels in the United States are much higher than in the EU, and levels in the EU have begun to decline while levels in the United States continue to rise.<sup>205</sup>

In the most extensive long-term monitoring of human exposure to PBDEs, Swedish researchers reported that the concentration of PBDEs in breast milk increased by sixty times between 1972 and 1999.<sup>206</sup> That rise corresponds to a doubling of PBDE concentration every five years.<sup>207</sup> Similarly, Canadian researchers also reported that PBDE levels increased by a high multiple between 1992 and 2002, but they found that the concentrations doubled in an even shorter time span—2.6 years as compared to five years.<sup>208</sup> Comparable long-term, nationwide data about exposure in the United States are not available, but measurements of women living in the San Francisco area have shown a three-fold increase in PBDE levels over the past thirty years.<sup>209</sup>

PBDE exposure has seen an upward trend worldwide, but the levels reported in the United States are by far the highest. For example, the sixty-fold increase reported in Sweden represented a rise in median PBDE concentration from 0.072 parts per billion (ppb) to 4.01 ppb.<sup>210</sup> Similarly, the ten-fold increase reported in Canada represented a median rise from 2 ppb to 25 ppb.<sup>211</sup> In contrast, three recent studies in the United States have reported median PBDE concentration levels of 34 ppb, 37 ppb, and 58 ppb.<sup>212</sup> Similar

204. LUNDER & SHARP, *supra* note 7, at 15-21.

205. *See infra* notes 205-14 and accompanying text.

206. LUNDER & SHARP, *supra* note 7, at 18-19.

207. *Id.*

208. *Id.*

209. *Id.*

210. *See id.* at 19 (Table: Dramatic increase in levels of fire retardants in Swedish women's bodies, 1972 to 1997). These statistics are based on the median (or midpoint) value reported in each study. For each group of women monitored, 50% of the levels reported are below the median and 50% of the levels reported are above the median. *Id.*

211. *Id.* at 18 (Table: Studies of blood and breast milk show U.S. women have the highest levels of brominated fire retardants in the world).

212. *Id.*

differences among the countries are seen in the highest concentration levels recorded: 7.7 ppb in Sweden, 590 ppb in Canada, and 1078 ppb in the United States.<sup>213</sup>

While levels in the United States have been on the rise, levels in the EU have recently begun to decline, likely because of the voluntary reductions that were already in place before the formal bans on Penta and Octa were passed.<sup>214</sup> For example, Sweden reported mean PBDE levels of approximately 4 ppb in the late 1990s, but that value had decreased to 2 ppb by 2001.<sup>215</sup>

### C. Making the Decision

Equipped with the same laboratory evidence regarding the possible dangers of PBDEs and the widespread exposure to humans (albeit at different levels), the governments of the European Union and United States had to address the same issue—whether formal restrictions on the production and use of PBDEs were necessary or justified. Even though exposure levels in the EU were much lower than in the United States, the EU answered that question in the affirmative while the United States did not. Those differing answers have led to much public debate about who is “right” and who is “wrong.”

## VI. RESOLUTION: A MATTER OF CHOICE, WITH LIMITS

The debate over whether or not PBDEs should be restricted or banned is relatively new. Central to that debate, however, is an older debate—the debate over the appropriate role of precaution in the face of uncertainty. Scholars, politicians, and concerned citizens have debated for years about what type of system is better: one that permits action based on precaution or one that requires proof of identifiable risk before action is taken.<sup>216</sup>

Supporters of a more precautionary approach argue vigorously that the world should not wait until human health or the environment actually suffer harm, much of which is irreversible, before acting to minimize risk.<sup>217</sup> Supporters of a wait-and-see approach, on the other hand, argue just as vigorously that action unsupported by science is unjustified and causes the public to overestimate risks from some sources and underestimate risk from

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213. *Id.* at 16-18.

214. *Id.* at 18-19.

215. *Id.*

216. *See, e.g., supra* note 74 and accompanying text.

217. *See, e.g., supra* notes 77-82 and accompanying text.

others.<sup>218</sup> It seems probable that one approach is not inherently better than the other. Instead, there are advantages and disadvantages to each. Frequently, an ounce of prevention really will be worth a pound, and perhaps much more, of cure. Sometimes, however, fears about the unknown may be reduced upon learning, after further investigation, that the unknown is not as dangerous as initially feared. As a result, it seems that the better question is not which approach is per se better than the other, but rather which approach reflects the concerns and values of the people who must decide whether to act now or wait until more is known, and who will benefit from or bear the costs of that decision.

#### A. Choice and Political Accountability

In general, decisions regarding whether to endorse the precautionary principle and take protective action or wait before there is a clearer understanding of precisely what a given risk entails should be left to the citizens and government of each independent, sovereign country. In the end, deciding when precaution is worthwhile and when to take restrictive action is a policy decision. These decisions are typically made by elected government officials who are directly accountable to their constituents or by government representatives who, although not directly elected, remain politically accountable through elected government officials. These officials can be voted out by the citizens if they disagree with the approach the officials have taken. Presumably, EU environmental policy endorses the precautionary principle because that approach reflects the concerns, priorities, and will of the majority voting population. If concerned citizens in the United States decide that their government is unnecessarily exposing them to risk by not acting early enough, they can voice that disagreement on election day. If those concerns become dominant, U.S. environmental policy will become more precautionary to appropriately reflect the will of the majority.

The power of each country to make these policy-based decisions should not be unlimited, however. This power should be limited in situations in which postponing restrictive action allows a country to internalize the benefits of delay but externalize some of the costs to the citizens and the environments of foreign countries. That is the situation created by the use of POPs, including PBDEs. One of the four defining characteristics of POPs is their susceptibility to long-range transport.<sup>219</sup> As a result, far less than 100 percent of the PBDEs released in the United States will remain within the United

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218. See, e.g., Scientific Alliance, *supra* note 80.

219. EPA, POPs, *supra* note 6, at 5.

States.<sup>220</sup> This situation creates the same cost-benefit problem observed in numerous aspects of human behavior: the United States is able to internalize all of the benefits associated with the continued use of a chemical (typically increased revenue from industry), but externalize some of the costs (in the form of harm to the environment and public health of foreign countries). Citizens of the EU, Canada, or Mexico who are harmed by the U.S.'s release of POPs, including PBDEs, have no political recourse against the U.S. government.

Because of the unusual characteristics of this situation, the United States should align its environmental policy with the prevalent standards of the international community by explicitly incorporating the precautionary principle into its regulation of POPs. In other areas of environmental policy, the United States internalizes all of the costs of its decision-making. For example, citizens in Europe would have difficulty making a compelling argument that they are harmed by the level of pollution in an isolated lake in the Midwest. In that situation, the United States should have full autonomy to act cautiously and reduce the pollution, or defer acting until more is known about whether the pollution level is harmful to human health or the environment. If local residents believe action should be taken to reduce pollution, they can voice their disapproval and, if necessary, elect new representatives.

#### B. POPs: Aligning U.S. Policy with the International Community

The United States cannot effectively align its POPs policy with the rest of the international community without revising TSCA and ratifying and implementing the Stockholm Convention in its entirety. The difficult burden created by § 6 of TSCA, which requires the EPA to prove that a chemical poses an "unreasonable risk" before restrictive action can be taken, has been routinely criticized.<sup>221</sup> The *Corrosion Proof Fittings* court did not interpret TSCA as requiring undisputed proof of inevitable harm, but the numerous findings required by the court nonetheless are much more burdensome than any test envisioned by the articulation of the precautionary principle in the Rio Declaration.<sup>222</sup> The EPA has effectively used tools besides TSCA to protect human health and the environment from toxic chemicals, as demonstrated by its recent negotiations with Great Lakes Chemical for the voluntarily stoppage of the production of

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220. See *id.* Contamination from Persistent Organic Pollutants has even been found in distant Arctic regions that are located thousands of miles away from any known source of chemical production or use. *Id.*

221. See, e.g., Fuller & McGarity, *supra* note 85, at 25-28.

222. See *supra* notes 79-80, 83, 150-56 and accompanying text.

Penta and Octa.<sup>223</sup> The risks posed by PBDEs, however, are far from eliminated. The EU ban prohibits not only the production of Penta and Octa but also the sale of any products containing those chemicals.<sup>224</sup> In contrast, although Great Lakes has agreed to stop producing Penta and Octa, there is no federal law prohibiting the use of Penta and Octa or the sale of goods containing them.<sup>225</sup> As a result, U.S. manufacturers remain free to import Penta and Octa for use in their production processes or import goods that already contain Penta and Octa and sell them to the public, subject to the bans in California, Maine, and New York.

In addition, Great Lakes Chemical also manufactures Deca, which is not included in the voluntary phaseout.<sup>226</sup> This omission is disconcerting for two reasons. First, Deca is by far the most widely used of the PBDEs, comprising eighty-three percent of the global market by weight.<sup>227</sup> Second, recent studies indicate Deca breaks down in the environment into the smaller congeners that are "the very chemicals being banned in Europe and California."<sup>228</sup> The EPA could theoretically negotiate a similar agreement with Great Lakes Chemical in the future to stop its production of Deca. The negotiating position of the EPA, however, is significantly weakened by the common knowledge within industry that "unless Congress amends TSCA . . . it can safely be predicted that EPA will never take another action under section 6 (Regulation of hazardous chemical substances) over the objection of the affected industry."<sup>229</sup> Consequently, unless TSCA is amended to give the EPA the realistic option of using its § 6 authority to ban an existing chemical, the United States will be unable to take precautionary action unless the affected industry supports the change. Presumably, any industries involved would strongly resist such changes as businesses would not be using a particular chemical in the first place unless it was profitable.

In order to respect the decision of the international community to regulate POPs on a more precautionary basis, the United States also needs to ratify and implement the Stockholm Convention in its entirety. As noted earlier, the most recent proposed legislation only addresses U.S. regulation of pesticides, not industrial chemicals such as brominated flame retardants that may be added to the

223. Mary Beth Polley, *Great Lakes to Phaseout Pent- and Octa- PBDE Production by 2005*, PESTICIDE AND TOXIC CHEMICAL NEWS, Nov. 10, 2003, at 20.

224. See Council Directive 2003/11/EC, *supra* note 57, ¶ 4 (stating that "In order to protect health and the environment the placing on the market and the use of pentaBDE and octaBDE and the placing on the market of articles containing one or both of these substances should be prohibited.") (emphasis added).

225. See *supra* notes 63-66 and accompanying text.

226. See Polley, *supra* note 223.

227. LUNDER & SHARP, *supra* note 7, at 9.

228. LUNDER & SHARP, *supra* note 7, at 36-37.

229. Fuller & McGarity, *supra* note 85, at 28.

Convention.<sup>230</sup> The Stockholm Convention, although precautionary in nature, contains numerous procedural safeguards to ensure that any decision to list a new substance is supported by scientific evidence.<sup>231</sup> Canada and Mexico have both ratified the Convention and are therefore bound by its terms.<sup>232</sup> Part of the costs to human health and the environment that will result from the U.S.'s ongoing delay to ratify the Stockholm Convention will be borne by Canada and Mexico because of their proximity to the United States. As such it will not be surprising if those two nations pressure the United States to ratify the Convention and commit to a precautionary approach to the regulation of POPs.

## VII. CONCLUSION

The recent action by the European Union to ban formally the use of PBDEs, and the lack of similar action in the United States, has renewed the debate over the appropriate course of action in the face of scientific uncertainty. Arguments in favor of a precautionary approach and arguments in favor of waiting until more is understood both have merit. These decisions require the evaluation and prioritization of numerous factors. With regard to PBDEs, those factors include weighing the benefits of fire protection against the potential harm to human health and the environment that may result from their continued use.

There is no universal and inherent "right" answer to these questions. Instead, these difficult decisions should be made by each country in response to the will of the people who will share the benefits of, and bear the costs of, these decisions. But when a portion of these costs will be borne by large groups of individuals who have no say in the decision-making process, governments should also be responsive to those individuals' concerns.

Large sections of the international community have indicated their commitment to the precautionary principle in the regulation of POPs through formal restrictions on PBDEs and ratification of the Stockholm Convention. Because of the externalities caused by the production and use of PBDEs, foreign citizens and environments bear part of the costs of continued production and use of PBDEs by the United States. Consequently, the United States should respect the will of the international community by expressly incorporating the precautionary principle into its policy regarding POPs, including PBDEs. In order to do so, however, the United States needs to

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230. See *supra* notes 104-12 and accompanying text.

231. See *supra* notes 86-95 and accompanying text.

232. Stockholm Convention Participant List, *supra* note 39.

decrease the hurdles created by § 6 of TSCA in the regulation of existing chemicals and ratify and implement the Stockholm Convention in its entirety.

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