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# Do Chemicals Found in Plastic Toys Pose a Threat to the Children Who Play with Them? The European Community's Attempt to Regulate the Use of Chemical Plasticizers

## I. Introduction

Recently, several European countries including Austria, Denmark, Norway, and Sweden have taken steps to ban the use of certain chemical plasticizers in children's toys.<sup>1</sup> The bans follow closely on the heels of the results of several tests conducted by various European countries, as well as the environmental group Greenpeace. These tests have indicated that phthalate<sup>2</sup> plasticizers in PVC (polyvinyl chloride or vinyl) plastic toys pose a health risk to small children.<sup>3</sup>

The evidence, however, is not wholly conclusive as to what health effects, if any, such phthalates actually pose to children coming into contact with the PVC toys.<sup>4</sup> The plastics industry and many international toy manufacturers maintain that the use of PVC and its phthalate softeners is do not create a safety risk.<sup>5</sup> Environmental groups like Greenpeace, however, claim that PVC softening phthalates are unsafe for children.<sup>6</sup> These groups cite experiments demonstrating that certain PVC softening phthalates pose serious threats to the health of small children.<sup>7</sup>

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1. *Consumer Affairs: Eagerly-Awaited Phthalates Study Appears*, Eur. Rep., Sept. 30, 1998, available in Westlaw INTNEWS database.

2. Phthalates (pronounced thay-lates) are chemicals used to soften the plastic used in a variety of plastic compounds around the world. *Id.*

3. Michael Lauzon, *EC Members to Check Phthalates in PVC Toys*, PLASTIC NEWS, July 6, 1998 at 24.

4. *Consumer Affairs supra* note 1, at 33.

5. *Id.*

6. *PVC Study Rejected*, CHEMICAL WK., Oct. 1, 1997, at 41.

7. *Determination Of The Composition And Quantities Of Phthalate Ester Additives In PVC Children's Toys*, (visited Sept. 26, 1998) <<http://www.greenpeace.org/~comms/97/pvctoys/documents/summary.html>>.

There is little that is certain in this controversy as even scientific researchers have been unable to devise an experimentation method that definitively duplicates the actions that children take when they chew on and play with PVC toys.<sup>8</sup> In addition, researchers have also been unable to determine an effective way to accurately measure the amount of phthalate chemicals that might leach out of those toys and be ingested by children when they play with these toys.<sup>9</sup>

Taking into account the conflicting views and evidence that exists regarding the dangers associated with the use of chemical phthalates, the European Community (hereinafter, the "EC") chose not to implement an outright ban on the use of phthalates in children's toys when it considered the issue in July 1998.<sup>10</sup> Instead, the EC chose to leave the decision up to its member states as whether or not to take action to take action regarding the regulation or banning of PVC toys until further scientific research could be conducted in order to evaluate the health risks associated with chemical phthalates.<sup>11</sup>

Many environmentalists and EC government officials consider the EC's non-committal directive disturbing and ineffective.<sup>12</sup> Both sides claim that the EC should have taken a stance on the issue one way or the other.<sup>13</sup> They assert that the EC should have either developed and implemented some standard by which to regulate the use of phthalates in children's plastic toys or declared that the use of the PVC softening chemicals in toys poses no safety threat to small children.<sup>14</sup>

This comment will demonstrate that the current state of the law governing the use of phthalates in children's plastic toys, as promulgated by the EU, is inadequate given the potentially dangerous consequences that phthalates could pose to small children. The scientific evidence currently available suggests that the EC needs to do more than just recommend that member nations conduct their own phthalate tests and take actions based

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8. *PVC Toys Are Declared Safe by the European Commission*, MODERN PLASTICS, Aug. 1, 1998, at 14.

9. *Id.*

10. 1998 OJ (L 217) 35.

11. *Id.*

12. Julie Wolf and Jennie James, *A Special Background Report on European Union Business and Politics*, WALL ST. J. EUR., July 2, 1998, at Eur.1.

13. *Soft PVC Infant's Toys: Commission Recommends Vigilant Approach From Member States*, EURO. REP., July 4, 1998, available in Westlaw INTNEWS database.

14. *Id.*

on the result of those tests. The EC needs to continue to conduct tests of its own in an attempt to reach some conclusion that would enable the organization to implement universal guidelines regarding what amount of phthalates, if any, can be safely used in children's toys. And once the EC reaches a conclusion, they should subsequently legislate accordingly in order to create uniform guidelines that would benefit EC consumers as well as EC companies engaged in the sale or manufacture of plastics products and children's toys.

Part II of this comment will discuss the intricate background behind the present controversy over the use of phthalates in children's toys. The section will begin by explaining what a phthalate is and will examine why they are used in children's toys. Second, this comment will present the relevant scientific data emanating from various EC member nations concerning the study of the safety issues surrounding the use of phthalates in children's toys. Additionally, it will look at how various EC member nations have chosen to respond to this data. Third, it will examine the EU's attempt to take legal action and the effects of that legislation on the present controversy.

Part III will analyze what steps the EC should take next as well as how it should go about implementing any potential future legislation. Finally, Part IV will present a brief conclusion that will restate the issue and summarize how the EC could deal with this issue.

## II. Background

Polyvinyl chloride (hereinafter, "PVC"), or vinyl is a stiff, amber-colored material that becomes more pliable and flexible when chemical plasticizers are added to it.<sup>15</sup> The primary chemical plasticizers used in children's toys are phthalate esters.<sup>16</sup> Phthalates (pronounced thay-lates) are frequently added to PVC toys in order to make certain products like teething rings softer and more flexible for young children.<sup>17</sup>

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15. EC Scientific Committee on Toxicity, *Ecotoxicity and the Environment (CSTEE): Phthalate Migrations From Soft PVC Toys and Child-care Articles*, Apr. 24, 1998, at 5.

16. Charlie Gray, *Experimenting on Children*, RACHEL'S ENVIR'T HEALTH WKLY., June 18, 1998, at 1.

17. James Gerstenzang, *U.S. Lobbies on Toy Restrictions Trade: Efforts to Ban Controversial Chemicals Used In Many Items Spur Outcry From Makers*, L.A. TIMES, May 28, 1998, at A16.

Phthalate esters have been used as plasticizers since the 1930's.<sup>18</sup> PVC is commonly used in a variety of household items including cables, packaging adhesives, vinyl flooring, paint, food packaging, ink and children's toys.<sup>19</sup> In addition, phthalates are also present in baby formulas, margarines, cheeses, and chips.<sup>20</sup> These chemicals are no longer used in cling wraps and other kinds of plastics that frequently come into contact with food.<sup>21</sup> Finally, phthalates are also used to enhance the flexible vinyl compounds necessary to make blood bags, IV bags, IV tubing and other products for the medical industry.<sup>22</sup>

The most frequently used phthalates include: diethylhexylphthalate (DEHP), monoethylhexylphthalate (MEHP), dimethylphthalate (DMP), butylbenzylphthalate (BBP), dibutylphthalate (DBP), dicetylphthalate (DOP), diisononyl phthalate (DNOP), and diisononylphthalate (DINP).<sup>23</sup>

#### A. *How a Phthalate Works*

Researchers have concluded that phthalates do not actually bond with the PVC chemical compound when they are added to it.<sup>24</sup> Instead, phthalates have been shown to move around freely within the PVC compound.<sup>25</sup> Such freedom of movement within the plastic compound means that the phthalates could potentially leach out of the plastic over a period of time.<sup>26</sup> Thus, the plastic compound could continuously lose phthalates during its lifetime.<sup>27</sup> Furthermore, some isolated research has demonstrated that the potential exists for the phthalates to leach out of the plastic compound at an accelerated rate when the plastic compound is continuously sucked on or played with by small children.<sup>28</sup> This

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18. Food Surveillance Information: Phthalates in Food. UK Ministry of Agriculture, Fisheries and Food, MAFF 1996a, at Sheet Number 82.

19. *Id.*

20. *Id.*

21. *Id.*

22. Vinyl Council of Canada, *Phthalate Plasticizers: Safely Used in Vinyl Products for Over 40 Years*, 1998, at 1.

23. Food Surveillance Information: Phthalates in Food, UK Ministry of Agriculture, Fisheries and Food, MAFF 1996a, at Sheet Number 82.

24. *Background on PVC Toys*, (visited Sept. 26, 1998) <<http://www.greenpeace.org/~comms/97/pvctoys/documents/background.html>>.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

research has sparked a global debate concerning the safety of these chemicals in toys designed for children.

### *B. The Debate Over the Safety of Phthalates*

In May 1997, the flexible vinyl industry first began examining whether phthalate esters could disrupt the human endocrine system at an environmental seminar sponsored by the Chemical Fabrics and Film Association in Cleveland.<sup>29</sup> Endocrine disruptions broadly cover abnormalities in the human and animal reproductive systems.<sup>30</sup> A product regulation supervisor for the Pittsburgh, Pennsylvania based Aristech Chemical Corporation, explained that the industry would continue to study phthalates in response to the claims being made by Greenpeace and other environmental groups.<sup>31</sup> He also pointed out that it is one thing to make statements and quite another thing to be able to support those statements with sound information.<sup>32</sup>

In addition, an Eastman Chemical Company executive, downplayed a study done by a group of environmentalists that showed that phthalate esters disrupted the endocrine systems of animals.<sup>33</sup> He claimed that the study was part science and part "leap of faith" because the evidence presented by the three authors did not adequately support their contention that phthalate esters cause disruption of the endocrine system.<sup>34</sup> This study was just the beginning of a series of controversial reports that the major plastics companies were forced to contend with.

1. *The Danish EPA Reports that Phthalates Migrate Out of Children's Toys at a Harmful Level.*—Denmark was the first European country to conduct a study to determine if phthalates were capable of leaching out of children's toys.<sup>35</sup> The Danish Environmental Protection Agency studied 11 kinds of children's teething rings in an attempt to discern whether phthalates were escaping.<sup>36</sup> The study concluded that large amounts of toxic

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29. See Craig Urey, *Flexible Vinyl Industry Faces Four-Pronged Dioxin Assault*, PLASTICS NEWS, May 12, 1997, at 12.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. See Urey *supra* note 29.

35. *Alarm Sounds Over Toxic Teething Rings. Stores in European Union Remove Plastic Baby Toys after Study Show They Release Large Amounts of Toxins Called Phthalates*, NEW SCIENTIST, June 14, 1997 at 10 [hereafter *Alarm Sounds*].

36. *Id.*

phthalates were leaching out of the teething rings.<sup>37</sup> It revealed that three children's teething rings made by one of the world's largest toy makers, Chicco, leached large amounts of phthalates when they were shaken in artificial saliva.<sup>38</sup> The head of the Danish Environmental Protection Agency's chemicals division claimed that a child would consume 2,219 micrograms of phthalates per kilogram of body weight if he or she sucked on a Chicco teething ring for three hours.<sup>39</sup> Additionally, he stated that that amount of phthalates per kilogram of body weight is 44 times the maximum allowed pursuant to EU law.<sup>40</sup>

In view of these findings, Denmark's EPA decided that items containing phthalates posed a danger to the health of humans and should be labeled and taxed accordingly.<sup>41</sup> The European Council for Plasticizers and Intermediaries, however, questioned the science supporting the Danish government's findings.<sup>42</sup> The Council claimed that the Danish EPA study ran "completely against all available scientific evidence and the careful research that has been undertaken in this area."<sup>43</sup> Danish authorities, however, refused to back down from their initial comments.

Despite the statement by the European Council for Plasticizers and Intermediaries, Denmark demanded that the EC set limits on the inclusion of chemicals in children's toys.<sup>44</sup> Denmark's demand was made pursuant to the emergency notification requirements regulating consumer products that present a serious risk to health and safety contained in Article 8 of Directive 92/59/EEC on General Product Safety.<sup>45</sup>

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37. *Sweden Reviews PVC Toys*, CHEMICAL WK., June 4, 1997, at 6 [hereafter *Sweden Reviews*].

38. See *Alarm Sounds supra* note 35.

39. *Id.*

40. *Id.*

41. Alex Scott, *Environment: Denmark Considers Phthalate Tax*, CHEMICAL WEEK, June 25, 1997, at 21.

42. *Id.*

43. *Id.*

44. See *Alarm Sounds supra* note 35.

45. OJ L No. 228 of 11.08.92, p.24. Article 8, paragraph 1, states: "Where a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of a product or product batch by reason of a serious and immediate risk presented by the said product or product batch to the health and safety of consumers, it shall forthwith inform the Commission thereof, unless provision is made for this obligation in procedures of a similar nature in the context of other Community instruments." *Id.*

In response to the Danish EPA experiment, KF, Sweden's largest retailer of toys, pulled 75 PVC items from the marketplace until they could evaluate whether those items contained chemical additives that could cause endocrine disruption.<sup>46</sup> Additionally, retailers in Italy, Spain, and Sweden also chose to remove some plastic toys from their shelves based on the findings of the Danish study.<sup>47</sup> The widespread reaction from many European countries quickly prompted the EC to become involved in the continuing controversy.

2. *The European Commission's First Response to Questions Concerning the Safety of Phthalates in Children's Toys.*—In response to the actions taken by retailers in Italy, Spain, and Sweden, a number of queries were submitted to the European Commission regarding the findings of the Danish EPA study and how the Commission intended to address the findings of the study.<sup>48</sup> Several months later the Commission responded to the questions by acknowledging its awareness of the endocrine disruption issue and announcing that it was taking steps to acquire more information regarding any dangers PVC toys might present to the health of children.<sup>49</sup>

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46. See Sweden Reviews *supra* note 37.

47. See Alarm Sounds *supra* note 35.

48. 1997 OJ (C 158) 8. The questions were: "1. What action does the Commission intend to take, in conjunction with the toy industry, following the withdrawal from the market of PVC plastic baby toys in Denmark, Italy and Spain after evidence from the Danish Environmental Protection Agency of dangers to babies from the leaking of plastics into their mouths when sucking on these products? 2. Will the Commission participate in the international working group set up by the toy industry to investigate this problem and will it ensure it is informed of the results of their investigations? 3. Has the Commission already discussed with industry the options for working towards the substitution of known endocrine-disrupting chemicals in their products with benign substances? If not, when will it do so and would it make Community funds available for this? 4. Does the Commission agree that industry should take responsible care for its products and respond promptly to concerns over potential dangers for end-users? 5. Does the commission condone the categorical statements by certain industry associations that plasticizers such as phthalate and bisphenol A are not hormone-disrupting chemicals, despite growing scientific evidence that these products do have hormone-disrupting effects? 6. The chemical industry has responded to independent scientific concerns over hormone disrupting chemicals by commissioning its own research into the suspected products. Does the Commission see all the results of research undertaken by industry into suspected endocrine-disrupting chemicals and will it make these available to MEPs? 7. Is the Commission concerned by the possible withholding of research, funded by industry, which produces results contrary to industry's interests?" *Id.*

49. *Id.*



The Commission explained that it had formed the European Committee for Standardization (CEN). This committee would act as a working group pursuant to technical committee 52 (toys) in order to investigate the “organic chemical compounds in toys, in compliance with Article 2.1 and Annex III, point II.3 of Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (OJL 187, 16.7.1988).”<sup>50</sup> The Commission also added that the working group would include Commission members, representatives from the toy industry, as well as European consumer groups and national “standardisation bodies.”<sup>51</sup>

Article 2.1 states that “toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behavior of children.” Furthermore, Annex III, point II.3 says that “toys must be so designed and constructed that, when used as specified in Article 2(1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.”

The Commission also stated that it would work closely with the toy industry on this issue and keep itself informed of the outcomes of research performed by the International Council of Toy Industries (ICTI).<sup>52</sup> The Commission went on to explain that it supported a number of different experiments pertaining to the identification of substances possessing the ability to disrupt the endocrine system.<sup>53</sup> In addition, the Committee recognized that the toy industry as a whole should be responsible for the products it places on the market and react quickly to concerns regarding any dangers associated with those products.<sup>54</sup>

Finally, the Commission concluded that it would act pursuant to Council Regulation No. 793/93 in an effort to evaluate and control the risks posed by certain substances.<sup>55</sup> Under Council Regulation No. 793/93, the Commission, with input from the Member States, selected a group of about 100 chemicals that were

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50. *Id.*

51. *Id.*

52. *Id.*

53. 1997 OJ (C 158) 8. The Commission added that these experiments were selected based on open requests for proposals and “independent scientific evaluation.”

54. 1997 OJ (C 158) 8.

55. *Id.*

compiled into three lists of "priority substances".<sup>56</sup> Subsequently, each Member State was called upon to study a different "priority substance" by analyzing industry data concerning that substance and then were required to report their findings in the form of a "risk assessment report" that would be passed on to the Member States.<sup>57</sup> If a Member State's "risk assessment report" found that one of the substances posed a risk to humans or the environment, it could recommend ways to minimize that risk.<sup>58</sup> Then the Commission would publish the "risk assessment report" as well as the proposed steps to combat any potential risk; these steps would then be adopted at the Community level.<sup>59</sup> Finally, the Commission could decide to propose Community action pursuant to relevant legislation.<sup>60</sup>

After further inquiry, the Commission declared that three phthalates (Di-n-butylphthalate (DBP), Bis (2-ethylhexyl) phthalate (DEHP), and Benzylbutylphthalate (BBP)) thought to cause endocrine disruption were in fact on the list of "priority substances" identified by Council Regulation No. 793/93.<sup>61</sup> The inquiry also revealed that the risk assessment reports for each of those three phthalates had yet to be submitted to the Commission.<sup>62</sup>

Denmark, unwilling to wait for the European Commission to act, chose to go ahead with plans to draft legislation banning hazardous substances in children's toys and pacifiers.<sup>63</sup> The proposed ban also included phthalate plasticizers that are often used to soften PVC.<sup>64</sup> Denmark's decision to enact a ban on phthalates was based on evidence previously collected by the Danish EPA that showed that children's pacifiers contained high levels of dangerous phthalates that could disrupt the endocrine system.<sup>65</sup> The Danish, however, were not the only people concerned about the safety of phthalates.

3. *The Greenpeace Report Fuels the Controversy Over the Safety of Phthalates in Children's Toys.*—Shortly after the release

56. *Id.*

57. 1997 OJ (C 158) 8.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Denmark Moves to Ban PVC in Toys*, CHEMICAL WK., Dec. 10, 1997, at 6.

64. *Id.*

65. *Id.*

of the Danish EPA study, the environmental group Greenpeace released the results of its own study in October 1997 in which it urged consumers not to buy PVC toys.<sup>66</sup> Greenpeace claimed that chemical phthalates used to soften children's toys made out of PVC are dangerous.<sup>67</sup> Although the Greenpeace study did not ascertain the rates at which chemical phthalates leach out of PVC toys, it nevertheless concluded that the mere fact that phthalates like DINP and DEHP are used "abundantly" in children's toys and represent a serious health hazard to young children.<sup>68</sup>

The report stated that a child's exposure to chemical phthalates is unacceptable, despite the fact that the study admitted that it is nearly impossible to accurately quantify the amount of chemicals that could actually be ingested.<sup>69</sup> It relied primarily on previous studies performed on laboratory animals using the phthalate DINP.<sup>70</sup> Those studies suggested that DINP caused liver and kidney disorders, reproductive abnormalities including testicular atrophy, and higher rates of certain kinds of cancers including cancers of the liver, kidney, and mononuclear cell leukemia.<sup>71</sup> Furthermore, the report stated that children may be more prone to these risks because in biological traits characteristic of young children.<sup>72</sup>

Additionally, the study explained that recent research shows that some phthalates including DINP "mimic the hormone estrogen in human cells."<sup>73</sup> Finally, it also revealed that when DINP is bought for use in a laboratory it comes with several warnings including "harmful by inhalation, in contact with skin and if swallowed," "possible risk of irreversible effects," and "may cause cancer."<sup>74</sup> Despite these warnings, toys that contain as much as 40% DINP are often labeled non-toxic.<sup>75</sup> The European

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66. *PVC Study Rejected*, CHEMICAL WK., Oct. 1, 1997, at 41.

67. *Id.*

68. *Determination of the Composition and Quantities of Phthalate Ester Additives in PVC Children's Toys*, (visited Sept. 26, 1998) <<http://www.greenpeace.org/~comms/97/pvctoys/documents/summary.html>>.

69. *Id.*

70. *Id.*

71. *Background on PVC Toys*, (visited September 26, 1998) <<http://www.greenpeace.org/~comms/97/pvctoys/documents/background.html>>.

72. *Id.*

73. *Determination of the Composition and Quantities of Phthalate Ester Additives in PVC Children's Toys*, (visited September 26, 1998) <<http://www.greenpeace.org/~comms/97/pvctoys/documents/summary.html>>.

74. *Id.*

75. *Id.*

Council of Vinyl Manufacturers (ECVM) has attempted to discredit the Greenpeace study by asserting that the environmental group had ignored certain scientific data and had manipulated the results of their study.<sup>76</sup>

During the Christmas holiday season, Greenpeace released another study claiming that migration tests found unacceptably high levels of potentially hazardous phthalate plasticizers in 12 of 23 plastic toys.<sup>77</sup> It alleged that children sucking on these toys would absorb potentially carcinogenic phthalates like DINP and DEHP.<sup>78</sup> Greenpeace also asserted that PVC toys with DEHP have been banned in Switzerland and that the International Agency for Research on Cancer (IARC) lists DEHP as a possible carcinogen.<sup>79</sup> At the end of November, Karstadt-Hertie and Metro Konzern, two large German retailers, pulled all PVC toys from their shelves following similar actions by other European stores in response to the most recent Greenpeace study and pressure from other consumer advocacy groups.<sup>80</sup>

The second Greenpeace study also met stiff resistance from companies in the PVC business and toy manufacturers.<sup>81</sup> Both groups responded by pointing to the fact that numerous regulatory agencies and other research groups have been unable to establish a nexus between PVC toys and health risks despite an abundance of extensive experiments.<sup>82</sup> Both the U.S. Consumer Product Safety Commission and Health Canada have concluded that PVC toys are not dangerous when used or handled in a reasonably foreseeable manner.<sup>83</sup> Furthermore, the toy industry itself refused to acknowledge the validity of the Greenpeace report.

The trade association Toy Industries of Europe (TIE) lobbied strongly against an EC ban on the use of soft PVC toys.<sup>84</sup> Instead, it argued that experts should come up with a standardized way to test the use of PVC in toys that could be used by the entire European Community.<sup>85</sup> In addition, the head of marketing for plasticizers at BASF, said that the IARC decision was the result of

76. *Id.*

77. Peter Mapleston, *German Stores Pull PVC Toys on Greenpeace Health Claims*, MODERN PLASTICS, January, 1997, at 35.

78. *Id.*

79. *Id.*

80. Mapleston, *supra* note 77.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. Mapleston, *supra* note 77.

bad science.<sup>86</sup> An officer of Teknor Apex Co. added that there is some doubt concerning whether or not the Greenpeace study relied on phthalates that are not available commercially.<sup>87</sup> The plastics industry was forced to result to the courts to resolve the problems created by the phthalate controversy.

And at the end of 1997, Solvay and European Vinyls Corporation (EVC) filed a \$27 million lawsuit in Italy against Greenpeace claiming slander and economic damages that allegedly resulted from Greenpeace's campaign against the use of PVC in children's toys.<sup>88</sup> A number of Italian toy retailers pulled toys off of the shelves as a result of the Greenpeace campaign against PVC.<sup>89</sup> Thus, the controversy continued unabated.

Early in February of 1998 a report, by the Swedish Medical Centre found that men exposed to PVC have a heightened chance of developing testicular cancer.<sup>90</sup> The study hypothesized that phthalates used to soften the PVC could be the cause of the problems.<sup>91</sup> It concluded that workers in PVC plants were seven times more likely to develop testicular cancer.<sup>92</sup> The report speculated that, "the study is expected to fuel the growing debate over the safety of PVC, particularly for pliable toys."<sup>93</sup>

Later in February, the EU's Scientific Committee for Toxicity, Ecotoxicity and the Environment reported that some phthalates do leach out of children's toys when they are mixed with saliva.<sup>94</sup> Although the committee admitted that the results of its research were hampered by several uncertainties regarding exposure values, it did find that three phthalates, DINP, DNOP, and DEHP, posed enough of a danger to small children to warrant some concern.<sup>95</sup> It also reported that new phthalate extraction methods should be considered in order to better replicate the

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86. *Id.* Gans claimed that rodents used in the IARC tests responded in ways that humans would not and that recent studies done on "genetically modified" mice indicate that phthalates do not cause cancer.

87. *Id.*

88. *Solvay, EVC Sue Greenpeace in Italy*, CHEMICAL WK., Dec. 24, 1997, at 4.

89. *Id.*

90. William MacDonald, *PVC Linked to Testicular Cancer*, CHEMICAL ENGINEERING, Feb. 1998, at 52.

91. *Id.*

92. *Id.*

93. *Id.*

94. *EU Reviews PVC Toys*, CHEMICAL WK., Feb. 25, 1998, at 48.

95. CSTEE, *Opinion on Phthalate Migration From Soft PVC Toys and Child-Care Articles*, Sept. 26, 1998.

process through which children would likely chew on these toys.<sup>96</sup> Despite these shortcomings, the committee recommended that limits should be imposed on the amounts of phthalates that a toy should be permitted to release.<sup>97</sup> They added that additional risk assessment studies should be conducted in accordance with the original process the committee followed prior to the addition of plasticizers.<sup>98</sup> Following its research, the committee was unable to definitively state whether an actual danger exists.

In response to the EC's preliminary report, the European Council for Plasticizers and Intermediaries (ECPI) and the Toy Industries of Europe (TIE) stated that they agreed that the EC should adopt a set of standardized tests to measure the migration of phthalates in children's items made from flexible PVC.<sup>99</sup> An ECPI spokesperson explained that the Council was "[p]leased that the committee has confirmed that phthalates can be safely used in PVC toys by setting extraction levels based on sound toxicological studies."<sup>100</sup> In addition, he admitted that any viable studies need to accurately reflect the ways in which the toys are actually used.<sup>101</sup> The spokesperson claimed that it was unrealistic to think that any child has a toy in his or her mouth for 12 hours straight.<sup>102</sup> The European Council for Vinyl Manufacturers asserted that the EC should reach a decision on whether or not to ban the use of phthalates in children's toys only after enough research has been conducted to make a scientifically sound determination.<sup>103</sup>

In the aftermath of the EC's initial study regarding the potential dangers of phthalates, Spain formally requested that the European Commission use its power to enact a ban on PVC toys in the EC.<sup>104</sup> The Commission refused to respond to Spain's request until after the commission completed its study of the use

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96. *Id.*

97. *Id.*

98. *Id.*

99. *Plasticizer Makers Urge EU Standard for Soft Toys*, MODERN PLASTICS, Apr. 1, 1998, at 14.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* "Should the authorities make well-researched, scientific judgments that specific plasticizers should not be used for a particular baby application, we would obviously encourage our customers to use alternatives," stated John Svalander, the director of ECVI. *Id.*

104. Alex Scott, *Spain Calls for EC Ban on Soft PVC Toys*, CHEMICAL WEEK, April 18, 1998, at 21.

of phthalates in plastic toys.<sup>105</sup> Both the ECVI and the TIE publicly questioned Spain's request for a ban before the committee had completed its investigation into the potential migration of phthalates from PVC.<sup>106</sup> Maurits Bruggink, the Secretary General of TIE exclaimed, "It's extremely unfortunate that the Spanish authorities could not have waited for proper test methods and scientific data before reacting."<sup>107</sup> Given the potential consequences of the intensifying phthalate debate, it was only a matter of time before the United States brought its weight to bear on the controversy.

4. *The Initial Reaction of the United States to the International Phthalate Controversy.*—The Federal government, acting on behalf of American toy makers like Hasbro and Mattel, began urging the EC not to restrict the use of phthalates in toys made from PVC.<sup>108</sup> The Toy Manufacturers of America (TMA), claimed that if any of the Greenpeace studies were based on legitimate scientific findings, then the TMA would promptly take appropriate measures to remedy the situation.<sup>109</sup>

In late February 1998, the United States ambassador to the EC stated that the "[s]udden ban on products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the United States and the European Union."<sup>110</sup> The United States wanted the EC to wait until the U.S. Consumer Product Safety Commission conducted its own study on the migration of phthalates in PVC toys before the EC decided whether or not to ban the chemicals.<sup>111</sup> Greenpeace, however, accused the United States of acting only to protect the interests of the country's toy industry.<sup>112</sup>

Domestic toy manufacturers were worried that a ban could negatively effect their sales in Europe as well as their sales within the United States.<sup>113</sup> Their worries centered around the fact that

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105. *Id.*

106. *Id.*

107. *Id.*

108. Steve Toloken, *Feds Defend Toy Makers Against EU Restrictions*, PLASTICS NEWS, May 18, 1998, at 4.

109. *Id.*

110. *Id.*

111. Toloken, *supra* note 108.

112. *Id.*

113. James Gerstenzang, *U.S. Lobbies EU on Toy Restrictions Trade: Efforts to Ban Controversial Chemicals Used in Many Items Spur Outcry from Makers. Studies Suggest They May Cause Medical Problems*, L.A. TIMES, May 28, 1998, at

some phthalates are essential to the production of toys and other plastic items in this country.<sup>114</sup> A public health doctor and professor of medicine at Mt. Sinai Medical School, stated, "There's not the definitive study that says we've got to stop manufacturing these things, but there's growing evidence and growing concern that we're doing a global experiment on children by dramatically altering the chemical environment."<sup>115</sup> Additionally, a United States Commerce Department official in the European affairs office said that any decisions regarding a ban should be premised on scientifically quantifiable evidence.<sup>116</sup> The Europeans, however, refused to succumb to pressures from the United States.

5. *The Second CSTEE Study and the Proposal of a Ban on Phthalates by the European Commission's Consumer Policy Group.*—A second on the potential dangers of certain phthalates in PVC toys was released in April 1998. Following the report's release, Emma Bonino, the European Consumer Policy Commissioner, proposed a ban on the use of two phthalates commonly found in children's toys made from soft PVC.<sup>117</sup> This report by the EC Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) found that two (DINP and DEHP) of the six phthalates it studied posed a danger to humans.<sup>118</sup> This study was again hampered by the scientific community's inability to devise a method to accurately replicate the conditions that a PVC toy is subjected to when sucked on by a child<sup>119</sup>.

Despite this fact, the CSTEE concluded that its findings justified some concern on the part of the EC regarding risks to children coming in contact with the two chemicals.<sup>120</sup> The consumer policy group was divided over whether or not to immediately withdraw products containing these substances from the marketplace prior to the enactment of an official directive. The group nevertheless decided to push for a ban in lieu of action

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A16.

114. *Id.*

115. *Id.*

116. *Id.*

117. *Proposal On Babies' Toys Made of PVC*, European Information Service: EUR. REP., May 30, 1998, at 2319.

118. *Id.*

119. EC Scientific Committee on Toxicity, Ecotoxicity and the Environment, *Phthalate Migration From Soft PVC Toys and Child-Care Articles*, April 24, 1998, at Section 7.

120. *Id.*



taken by several countries including Austria, Belgium, Germany, and the Netherlands.<sup>121</sup>

After several weeks of lobbying by Bonino, the EC held a meeting in early June 1998 to decide the fate of phthalates in PVC toys.<sup>122</sup> The EC faced three different options. The first option involved a comprehensive ban on the sale of PVC toys containing the dangerous phthalates in addition to a recall of all existing products already on the market.<sup>123</sup> The second option involved a ban on the sale of such products.<sup>124</sup> The third option would have set limits on the amount of phthalates that could be used in the offending toys.<sup>125</sup>

*C. The EC Initially Declines to Support a Comprehensive Phthalate Ban on Children's Toys*

At the conclusion of a special meeting on June 10, 1998, the EC chose not to implement a ban on phthalates in PVC toys as Bonino was unable to convince other EC departments to support such a proposed ban.<sup>126</sup> The EC did not choose to take any other action regarding the use of phthalates in children's toys and their initial decision failed to end the debate over whether or not to impose a ban.<sup>127</sup> As a result of the impasse, Bonino began initiating new legislation to limit the use of phthalates in PVC toys meant for children under the age of three.<sup>128</sup> At this juncture the United States government predicted that the EC would most likely opt for the adoption of phthalate migration standards.<sup>129</sup> The Commerce Department admitted that it could not accurately predict how the EC would eventually act since during the original vote the College of Commissioners was only one vote short of a ban and recall of all PVC toys.<sup>130</sup>

*1. The CSTEE Addresses Four New Questions Regarding the Migration of Phthalates in Children's Toys.*—Following the

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121. European Information Service, *supra* note 119, at 40.

122. *Commission to Decide Fate of Babies' Toys Made of Soft PVC*, Europe Information Service: EUR. REP., June 10, 1998.

123. *Id.*

124. *Id.*

125. *Id.*

126. Steve Toloken, *EU Nixes Ban on PVC in Toys, But Restrictions Are Possible*, PLASTICS NEWS, June 15, 1998, at 45.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

EC's inability to arrive at any consensus on the issue of phthalates in children's toys, the CSTEE dealt four new questions regarding the potential safety risks posed by certain chemical phthalates in those toys.<sup>131</sup> Initially, the committee explained that the question of whether or not phthalates in PVC toys pose a serious or immediate risk to children who play with those toys, depends on the EC's definition of "immediate" and "serious."<sup>132</sup> The CSTEE responded that its April 1998 study did not consider the risk of phthalate migration to be life threatening, but it did admit that it was concerned about potentially long term toxic effects on the liver and kidneys.<sup>133</sup> Given the scientific community's continuing inability to accurately measure the levels of exposure to the chemical phthalates, the committee urged the EC to await a Dutch study utilizing human volunteers, prior to settling on a standardized method of testing for phthalate migration or taking any legislative action.<sup>134</sup>

In addition, the CSTEE admitted that no "standardized" or "validated" way exists to determine the greatest amount of phthalates that could be extracted out of PVC toys.<sup>135</sup> The committee explained that a number of different testing methods exist, but the reliability of those methods is questionable.<sup>136</sup> Furthermore, it stated that any recommendation it could make would involve merely "scientific judgment[s] and assessments."<sup>137</sup>

2. *The EC Issues a Decision that Leaves the Individual Member Countries Responsible for Testing and Implementing Standards Regarding Phthalates in Children's Toys.*—The CSTEE's response to these new questions led the EC to once

131. CSTEE, *Opinion on Phthalate Migration From Soft PVC Toys and Child-Care Articles*, June 16, 1998 (visited October 29, 1998) <<http://www.europa.eu.int>>. The committee was asked: 1. On the basis of the Scientific Opinion of 24 April on phthalates in toys, is it possible to say that there is serious and immediate risk? 2. Does it exist at present a standardised, validated method to measure the maximum extracted amounts of phthalates in toys? 3. If such method does not exist, how is it possible to implement the CSTEE recommendations on the guideline values for extractable amounts of phthalates in toys? 4. How many methods to measure the maximum extracted amounts of phthalates in toys exist at present and how reliable are they? Which of the existing methods does give the greatest guaranties of reliability? *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. CSTEE, *Opinion on Phthalate Migration From Soft PVC Toys and Child-Care Articles*, June 16, 1998 (visited Oct. 29, 1998) <<http://www.europa.eu.int>>.

137. *Id.*

again postpone their decision on what to do about PVC toys.<sup>138</sup> And after months of deliberation, the EC finally acted on July 1, 1998. The Commission chose not to take any continent wide emergency action pursuant to Directive 92/59.<sup>139</sup> Instead, it stated that the 15 member countries should each assess the rate at which phthalates migrate out of children's PVC toys and take the requisite action if those rates surpass the levels promulgated by the CSTEE.<sup>140</sup> The EC's non-binding recommendation encourages member countries to regulate the amounts of six phthalates, particularly DINP and DEHP, that are used in manufacturing children's PVC toys.<sup>141</sup>

If any of the EC countries choose to impose restrictions on the use of phthalates in children's PVC toys they are required to notify the Commission.<sup>142</sup> In addition, countries are asked to help the EC establish standardized methods to accurately determine the amounts of phthalates that migrate from PVC items.<sup>143</sup> Following the CSTEE's examination of the Dutch study, the

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138. *Europe Again Postponing PVC Decision*, PLASTICS NEWS, June 22, 1998, at 7.

139. *Soft PVC Infant's Toys: Commission Recommends Vigilant Approach From Member States*, EUR. REP., July 4, 1998, available in Westlaw INTNEWS database.

140. Article 1(1) of 1998 OJ (L217)35 says that:

"Member States shall adopt the measures required to ensure a high level of child health protection in regard to phthalate-containing soft PVC childcare articles and toys intended to be placed in the mouth of less three years of age, and notably the substances. . . . Particular attention should be paid to the substances DINP and DEHP." Article 1(2) states that, ". . . Member States shall monitor the levels of migration of these substances in the context of appropriate checks, taking into account the opinion on phthalates in toys delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on 24 April 1998 and notably the migration limit values for phthalates released by these products recommended by the Committee and reproduced in the Annex." And Article 1(3) says, "Member States shall regularly inform the Commission of the test methods and measurement methods used to determine the levels of migration in question, the results of the checks, and the conclusions they have reached; Member States are invited to furnish initial information before the end of August 1998." 1998 OJ (L 217) 35.

141. *Soft PVC Infant's Toys: Commission Recommends Vigilant Approach From Member States*, EUR. REP., July 4, 1998, available in Westlaw INTNEWS database.

142. *Id.*

143. *Soft PVC Infant's Toys*, *supra* note 141.

Commission reserved the ability to amend its recommendation.<sup>144</sup> Thus, when the EC countries establish a standardized testing method that accurately measures the amount of phthalates that leach out of children's PVC toys, the EC will initiate legislation to address the problem accordingly.

While members of the European toy industry and PVC producers announced that they supported the EC's decision to adopt standardized phthalate migration tests, consumer groups were quick to criticize the plan.<sup>145</sup> By not proposing European-wide legislation, the EC failed to garner the support of either side of the phthalates in children's toy controversy. Toy manufacturers pointed to the detrimental effect that the proposal could have on the uniformity of the marketplace and consumer advocates claimed that the EC backed down due to commercial and political pressure from the toy and plastic industries as well as the United States.<sup>146</sup>

3. *Several European Countries Announce National Bans on Phthalates in Children's Toys Despite a Lack of Conclusive Evidence.*—In response to the EC Commission's recommendations, a number of EC member nations decided to impose bans on the use of all phthalates in toys. Denmark informed the EC that it planned to implement a national ban on all phthalates in toys and other items intended for use by children under the age of three that would take effect in November 1998.<sup>147</sup> Additionally, Austria announced that it would also ban the use of phthalates in toys for children under the age of three.<sup>148</sup> Austria's ban would also include toys that could foreseeably end up in the mouths of children under three.<sup>149</sup> In opposition to this ban, a spokesman for the European Council for Plasticizers and Intermediaries (ECPI), stated that an outright ban on the use of phthalates was unnecessary and in direct opposition to the EC Commission's most recent recommendations.<sup>150</sup>

144. *Id.*

145. *Id.*

146. Julie Wolf and Jennie James, *A Special Background Report on European Union Business and Politics: Softened Stance: Commission Draws Flak For Toys Ruling*, WALL ST. J. EUR., July 2, 1998, at Eur. 1.

147. Danish EPA, *Phthalates in Toys Now to be Banned*, Aug. 4, 1998, (visited Sept. 26, 1998) <<http://europa.eu.int/comm/dg24>>

148. *Austria and Denmark Ban Phthalates in Toys*, CHEMICAL MARKET REP., Aug. 31, 1998, at 6.

149. *Id.*

150. *Id.*

In September, Sweden notified the EC that it was also examining the possibilities of banning phthalates in toys intended for children under the age of three.<sup>151</sup> Furthermore, Sweden explained that it was also considering whether or not to prevent certain other chemical additives from replacing phthalates.<sup>152</sup> Norway also has intentions to propose a similar ban.<sup>153</sup>

4. *Several Members of the Toy Industry Prematurely Respond to the Phthalate Scare.*—In late September, Mattel Inc. announced that it would phase out the use of phthalates in teething rings produced for children under the age of three.<sup>154</sup> At the same time, however, Mattel emphatically denied that phthalates were unsafe.<sup>155</sup> The company stated that it would not recall products already on the market, but it would start producing phthalate free teething rings early in 1999.<sup>156</sup> Mattel's move to stop using phthalates prompted a division of Rubbermaid Inc. to also stop using phthalates in products designed for use by children under the age of three.<sup>157</sup>

5. *The Highly Anticipated Dutch Study Shows That Children Face A Very Minimal Chance Of Ingesting Harmful Amounts of Phthalates Present In Children's Toys.*—Much to the chagrin of the EC, the highly anticipated Dutch experiment conducted by the Netherlands National Institute of Public Health and the Environment failed to put an end to the phthalate debate.<sup>158</sup> This study, the first to use human volunteers, showed that children actually face a very minimal risk of ingesting harmful amounts of the phthalates used to soften PVC toys.<sup>159</sup> The experiment found that the risk posed to children was much less than that published by the CSTEE in April 1998.<sup>160</sup> While

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151. Steve Toloken, *Sweden Eyes Phthalate Ban in Vinyl Toys*, PLASTICS NEWS, Sept. 21, 1998, at 6.

152. *Id.*

153. *European Chemical News: Sweden and Norway to Join Phthalate Ban?*, CHEMICAL BUSINESS NEWSBASE, Oct. 5, 1998, available at Lexis-Nexis CHEMICAL BUSINESS NEWSBASE.

154. *Mattel to Phase Out Chemicals in Teethers*, L.A. TIMES, Sept. 24, 1998, at D2.

155. *Id.*

156. Stacy Kravetz, *Decision Anticipates a Possible Ban*, WALL ST. J. EUR., Sept. 24, 1998, at UK9A.

157. *Id.*

158. *Dutch Study Fails to End European Phthalate War*, EUR. CHEMICAL NEWS, Sept. 28, 1998, at 23.

159. Michael Luzon, *Mattel, Little Tikes Alter Teething Toys: Actions Deal Blows to Vinyl, Phthalates*, PLASTICS NEWS, Sept. 28, 1998, at 1.

160. *Consumer Affairs: Eagerly-Awaited Phthalates Study Appears*, EUR.

Greenpeace was quick to criticize the study, plastics producers and toy manufacturers alike announced that the experiment had finally established a uniform testing method that could be used throughout the EC.<sup>161</sup>

6. The EC Responds to the Findings of the Dutch Study.— In light of the evidence produced by the Dutch study which concluded that phthalates could be safely used in children's plastic products, the EC may not allow member nations to ban the use of phthalates in toys.<sup>162</sup> Instead, it might allow them to simply limit the permissible levels of phthalates in those items.<sup>163</sup>

### III. Analysis

Despite the fact that the EC chose not to take any continent-wide action regarding the phthalate scare, the EC does have the authority to legislate the production of children's toys based upon several existing EC directives. Initially, Article 2(1) of Council Directive 88/378/EEC of May 3, 1988 says that only toys that do not jeopardize the health or safety of children may be placed on the market.<sup>164</sup> Subsection 2 of Article 2 explains that any toys placed on the market must comply with certain health and safety requirements.<sup>165</sup> Additionally, Annex II of the directive states that toys must not, "present health hazards or risks of physical injury by ingestion..." and that toys "nor should toys "...contain

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REP., Sept. 30, 1998, available at Westlaw INTNEWS database. "The findings conclude that children over 12 months are in no danger and that in certain extreme cases, those under 12 might be exposed to levels exceeding safety standards. The level of risk is clearly lower than stated last April by Commission scientific experts." *Id.*

161. *Id.* "There is clearly no health risk to children, but we believe that agreed safety limits should not be exceeded - even in cases like the when they have extremely high safety margins built into them," stated Maurits Bruggink, of Toys Industries of Europe. Furthermore, he added that a "test method will ensure that migration levels can be properly measured, and we will be urging the European Commission to move quickly in order for it to be adopted on a European basis. In the meantime, toy manufacturers will take immediate steps to ensure that toys intended to go into the mouth for children under three years old will be manufactured to conform to phthalate migration levels as determined by the proposed Dutch method."

162. *Chemical Market Report: EC May Back Down on Phthalates*, CHEMICAL BUSINESS NEWSBASE, Oct. 7, 1998, available at Lexis-Nexis CHEMICAL BUSINESS NEWSBASE.

163. *Id.*

164. 1988 OJ (L 187) 3.

165. *Id.*

dangerous substances or preparation . . . in amounts which may harm the health of children using them.”<sup>166</sup>

Article 3 of Directive 88/379/EEC says that EC member nations are responsible for ensuring that any toys placed on the market meet these safety criteria.<sup>167</sup> If it is decided that any action should take place regarding toys, the member nation must promptly inform the EC of the action that has been taken and the nation must state their reason for doing so.<sup>168</sup> The directive also requires the EC to consult with the parties involved prior to taking any action of its own.<sup>169</sup>

The EC should not take any comprehensive action in this controversy until science shows that children's toys containing phthalates are dangerous. Until a definitive study emerges regarding the safety of phthalates in children's toys, the EC should continue to investigate on its own. For the time being, the latest studies indicate that phthalates present in toys pose no substantial risk to small children.

Although the highly-anticipated Dutch study claimed that phthalates posed no actual risk to small children who suck on toys containing the PVC softening compound, the EC has done nothing on the legislative front to reassure consumers or plastic manufacturers and toy makers. By leaving the individual member nations the authority to test and take action as they see fit, the EC seems to have forgotten one of the primary purposes for its formation, namely continent-wide safety and economic regulations that make it easier for consumers and manufacturers to interact on a cost effective uniform basis.

The EC's recommendation was met by skepticism from both consumer groups as well as industry officials. Members of the toy and plastic industries claimed that the recommendation usurped the EC's "single-market" goal and would cause confusion in the market place. At the same time, consumer groups have asserted that the EC's recommendation ignored its responsibilities by putting economic and industrial motives ahead of children's safety.<sup>170</sup>

With those statements in mind, the EC needs to reconsider its July 1, 1998 recommendation regarding the use of phthalates in children's toys and take a proactive stance in this controversy. If

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166. *Id.*

167. 1988 OJ (L 187) 3.

168. *Id.*

169. *Id.*

170. Wolf and James, *supra* note 146.

the EC could not reach a collective conclusion on its own after considering the findings of the CSTEE, how can it expect the various member nations do any better individually. By conducting further studies the EC should attempt to gain greater knowledge with regards to the potential dangers that phthalates may or may not pose to small children. Thereafter, the EC should use that newly acquired knowledge to draft legislation pursuant to the existing relevant laws of the EC. In doing so it should rely on definitive science and sound judgment, not the politically charged claims made by environmentalists and plastic industry insiders.

If the EU's research demonstrates that phthalates are in fact hazardous to the health of small children, the EC presently has legislation in place that would allow it to act quickly to alleviate the problem while it considered further and more comprehensive long term measures. Section 1 of Article 3 of Council Directive 92/59/EEC of 29 June 1992 clearly states that only safe products shall be placed on the market.<sup>171</sup> And manufacturers must use due care to comply with the requirement of safety set out in section 1 of Article 3.<sup>172</sup>

Additionally, section 3 of the directive says that manufacturers should not supply products that they know, or should know based on their professional knowledge, do not comply with the safety requirements set out in the rest of the Article.<sup>173</sup> Section 3 also says that manufacturers should continuously monitor the safety of the products they put on the market, inform consumers of potential product risks, and cooperate to avoid any of these potential risks.<sup>174</sup> Again, however, reliable evidence must demonstrate that phthalates are actually unsafe in children's toys before the EC can rely on the requirements of this Directive.

Either way, the EC should not allow the member states to enact their own regulations regarding the use of phthalates in toys based on their own scientific research and regional political pressures. Alternatively, the EC cannot allow the plastics industry or radical environmental groups to make the ultimate of decision regarding whether or not phthalates pose a danger to small children in the EC as a whole. While scientific input from the various concerned member nations and interested industrial

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171. 1992 OJ (L 228) 24.

172. *Id.*

173. *Id.*

174. *Id.*



groups may prove beneficial to the EC, the EC should not rely wholly on what may be biased information.

If further studies conducted on behalf of the EC show that toys containing phthalates represent a risk to small children, then the EC should act to restrict and eventually curtail their availability on the market pursuant to this directive. However, if additional experiments find that phthalates do not pose any sort of quantifiable risk to children, then the EC should publicly announce its findings and prevent other nations from legislating bans on their use.

The fact that some American toymakers (Mattel) have already decided to voluntarily stop using phthalates in some should send a wake-up call to the EC to reach a viable conclusion supported by objective and quantifiable evidence.<sup>175</sup> Mattel's announcement should prompt the EC to conduct more tests in order to insure that the policy they choose to promulgate is soundly rooted in scientifically verifiable facts. Only that type of impartially drafted legislation will maximize the benefits and protections available to consumers as well as manufacturers. The EC cannot allow the various member nations to decide the fate of PVC toys in Europe based on the claims that have already prompted Austria, Denmark, and Sweden to propose banning the use of all phthalates in toys. This type of ban would be contrary to a substantial portion of the existing evidence available.

The EC has been put in a difficult position due to its own inaction as several EC member nations have chosen to ban phthalates as suggested by the Community's July 1, 1998 recommendation. The EC wants to prohibit countries from banning phthalates despite the fact that the commission's 1998 recommendation initially encouraged those same member nations to "adopt the measures required to ensure a high level of child health protection in regard to phthalate-containing soft PVC child care articles and toys intended to be placed in the mouth of [children]less than three years of age,. . . ."<sup>176</sup>

EC member nations clearly have the ability to take the actions described in the 1998 recommendation pursuant to Article 7 of Directive 88/378/ECC.<sup>177</sup> Article 7 says that member nations may take any action necessary to take toys off of the market or

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175. *Mattel to Phase Out Chemicals in Teethers*, L.A. TIMES, Sept. 24, 1998, at D2.

176. 1998 OJ (L 217) 35.

177. 1988 OJ (L 187) 3.

curtail their placement on the market if those nations decide that those toys pose a "...safety and/or health..." threat "...to consumers and/or third parties..." when used as intended or pursuant to Article 2.<sup>178</sup>

But Article 7 provisions also limit the power of member nations to act by subjecting any such action to EC review.<sup>179</sup> Article 7 states that any member nation which chooses to take products off of the market or restrict their presence on the market pursuant to Article 7 must immediately inform the EC of their decision.<sup>180</sup> Subsequently, the country must also explain and justify its action to the EC.<sup>181</sup> And after the EC has consulted with the parties in question and studied the member's submissions it may agree with the nation's action or it may disagree with the action taken.<sup>182</sup>

If the EC believes that the nation acted in a justifiable manner then it will inform that country and the other member nations of its conclusions.<sup>183</sup> However, if the EC disagrees with the action in question, the country that initiated the plan may refer it to the Standing Committee. Once the committee has submitted its opinion, the EC will inform the country whether or not the action meets the requirements of the directive.<sup>184</sup>

This system puts the EC in quandary. Given the provisions of Articles 6 and 7 of Directive 88/378/EEC, it seems unlikely that the EC could successfully defeat a proposed ban because of the uncertain character of the evidence necessary to refute a proposed ban. And the EU's mandates in the 1998 recommendation would make it even more difficult for the EC to oppose a ban and obtain a favorable standing committee decision. Thus, the EC needs to formulate continent-wide standards or legislation with regard to the use of phthalates in children's toys as soon as possible.

This legislation needs to balance the relative merits of the use of phthalates with the potential consequences of continuing to use the chemical in toys that often find their way into the mouths of children. Furthermore, any legislation needs to be soundly rooted in verifiable scientific evidence. Initially, the EC needs to formulate and adopt standardized phthalate migration testing

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178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. 1988 OJ (L 187) 3.

183. 1988 OJ (L 187) 3.

184. *Id.*

methods so that all member nations apply the standards adopted by the EC identically.

Then it must use that method to determine whether phthalates are in fact dangerous, or alternatively, at what level they become dangerous. If the EC decides that they pose no threat to the member nations, then they need to announce that to the public. If it is determined that phthalates are dangerous, member nations must be immediately informed. This would allow individual countries to react swiftly pursuant to Directive 88/378, while allowing the EC to take formalized action of its own.

#### IV. Conclusion

Although the debate surrounding the use of phthalates in children's toys is scientifically and politically complex. It is an issue that is motivated largely by the divergent agendas of the participants. The EC must resolve the issue by taking action to alleviate the fears of the public at large. In light of the evidence presently available, the EC must continue to examine the scientific data in an effort to establish a standardized way to measure phthalate migration. This process is the key to developing uniform regulations governing the use of phthalates in children's toys.

Upon adoption of a standardized phthalate migration test the EC must draft legislation that says one of three things depending on the results of those tests. First, if the EC finds that phthalates are not dangerous it must come out and say so. Second, if it finds that they are dangerous only at certain levels, it needs to set uniform and standardized limits on the use of phthalates. Lastly, if the EC determines that phthalates pose a severe threat to the safety of children, it must impose an outright ban on them pursuant to existing legislation.

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