

Product Safety in the United States and the European Community: a Comparative Approach

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PRODUCT SAFETY IN THE UNITED STATES AND THE EUROPEAN COMMUNITY: A COMPARATIVE APPROACH

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I. INTRODUCTION

To prepare for the unification of Europe into a single market, the European Community (EC) passed a directive on general product safety.¹ The European Community² has established on a number of oc-

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1. Council Directive 92/59 of 29 June 1992 on general product safety, 1992 O.J. (L 228) 24 [hereinafter Product Safety Directive].

2. See Treaty Establishing the European Economic Community, Mar. 25, 1957,

casions that consumer protection falls within its jurisdiction to facilitate the free flow of goods, persons, services, and capital among the Member States.³ The Product Safety Directive is but one instance of the EC's heightened awareness about consumer protection and the distortions in competition created by Member States affording different levels of protection. It follows in the wake of the Product Liability Directive,⁴ the Toy Safety Directive,⁵ and the Machinery Directive.⁶

Though complementary to these earlier initiatives, two characteristics of the Product Safety Directive distinguish it from them: its application to all consumer products and its enforcement by public authority. The Product Liability Directive, while applicable to consumer products, establishes a private cause of action for product-related harm. The Toy Safety and Machinery Directives are restricted to distinct classes of products. The Product Safety Directive declares a right of consumers throughout the EC to a minimum level of product safety and establishes the policy that infractions will be sanctioned by governmental authorities. The exact details of enforcement and punishment will be worked out, as is characteristic of directives, by the Member States.

Meanwhile, consumer product manufacturers in the United States would be well-advised to monitor the European experience with the general duty of safety standard as it emerges. Those manufacturers that export products into the EC need to be informed of the new duties it imposes on them and its impact on the cost of doing business. Furthermore, all manufacturers, whether they export to the EC or not, should track the developments in Europe as a potential harbinger of things to come in the United States. The EC followed the United States in the imposition of strict liability under the Product Liability Directive and, to some extent, the Toy Safety Directive. In a reversal of

298 U.N.T.S. 4. The twelve Member States are Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, and the United Kingdom.

3. *See, e.g.*, Council Resolution 89/C294 of 9 November 1989 on future priorities for relaunching consumer protection policy, 1989 O.J. (C 294) 1 [hereinafter Council Resolution].

4. Council Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 1985 O.J. (L 210) 1 [hereinafter Product Liability Directive].

5. Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, 1988 O.J. (L 337) 1 [hereinafter Toy Safety Directive].

6. Council Directive 89/392 of 14 June 1989 on the approximation of the laws of the Member States to machinery, 1989 O.J. (L 183) 1.

roles, the EC may now provide an example that the United States eventually follows in establishing a general duty of safety. Those companies that have tracked developments in Europe will be in the best position to anticipate and develop strategies for such an eventuality in the United States.

As a first step into the inquiry of product safety developments in the European Community, this article will describe and analyze the provisions of the Product Safety Directive. It will then review briefly the existing law in the Member States and predict the direction their harmonizing legislation might take. Finally, it contrasts the U.S. approach to product safety with that of the European Community. The comparison is drawn on two dimensions—the existence of a general duty of safety and the structural similarities and differences between federal/state relationships and EC/Member State relationships.

II. DIRECTIVE

In 1989, the European Community's Council of Ministers (Council), the legislative body of the EC, adopted a resolution on future directions for EC consumer protection policy.⁷ In that resolution, the Council reaffirmed the importance of promoting a high level of safety and better information on the quality of both products and services to ensure consumer confidence in the functioning of the market.⁸ It encouraged the implementation of a Community consumer protection and information policy to prevent obstacles to the proper functioning of the internal market and called upon the Commission of the European Community (Commission), the EC's principal policy initiator, to give priority to promoting the general safety of goods.⁹ Three years after adoption of this resolution, the Council passed the Product Safety Directive. In the Preamble, the Council identified two important policy goals that were promoted by passing the Directive. First, the Directive would operate to even the different levels of consumer protection embodied in the Member States' national product safety legislation that were "liable to create barriers to trade and distortions of competition within the internal market."¹⁰ Second, the Directive would promote a high degree of consumer protection.¹¹ The Council recognized, however, that the task of setting Community-wide standards for every

7. Council Resolution, *supra* note 3.

8. *Id.*

9. *Id.* at 2.

10. Product Safety Directive, *supra* note 1, Preamble.

11. *Id.*

product would be extremely difficult,¹² and that it could ensure a high level of consumer safety and health protection only by establishing a broadly based, horizontal framework.¹³ To be effective, this system would have to deal with both existing and yet-to-be developed products as well as cover lacunae in existing or future legislation.¹⁴ To address these concerns, the Directive created a general duty of safety.

The purpose of the Directive is, simply, "to insure that products placed on the market are safe."¹⁵ "Product" is broadly defined to mean "any product intended for consumers or likely to be used by consumers."¹⁶ A product is safe if "under normal or reasonably foreseeable conditions of use, including duration, [it] does not present any [risks] or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of [consumers]."¹⁷ If there are no more specific rules applicable, minimum risks are to be defined with regard to the state of scientific and technological knowledge, with particular reference to European or national safety standards, the information or warnings supplied with the product, accident and injury data, and the degree of safety that consumers and users in general can reasonably expect.¹⁸

The obligations of one who is involved with putting a product on the market differ depending on whether the supplier is a "producer" or a "distributor." "Producers" include manufacturers, manufacturers' representatives, importers if there is no representative in the Community, and other professionals in the supply chain if their activities may affect the safety properties of the product.¹⁹ "Producers [are] obligated to place only safe products on the market."²⁰ This responsibility in-

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.* art. 1(1).

16. *Id.* art. 2(a). Excluded from the definition are second-hand products clearly identified by the supplier as antiques or items to be repaired or reconditioned. *Id.*

17. *Id.* art. 2(b).

18. *Id.* art. 4(2). A number of circumstances are to be taken into account in determining the safety of a product. The materials used in making the product, how it is packaged, and any instructions that are provided for assembling or maintaining it must be examined. In addition, how the product is presented, its labelling, and instructions for using or disposing of it as well as any other information provided by the producer will be taken into consideration. When a product can be reasonably foreseen to interact with other products, the effect of this interaction should be considered. Finally, safety will be evaluated in light of the classes of consumers at serious risk when using the product, in particular children. *Id.* art. 2(b)(i)-(iv).

19. *Id.* art. 2(d).

20. *Id.* art. 3(1).

cludes providing consumers with information that will enable them to assess product risks where such risks are not obvious without adequate warnings.²¹ It also entails adopting measures to collect information on product risks and to take appropriate action to avoid these risks, including withdrawing the product from the market if necessary.²²

“Distributors” are professionals in the supply chain whose activity does not affect the product’s safety.²³ A distributor’s obligation is only to act with due care to assist in complying with the general safety requirement.²⁴ This means, for example, participating in monitoring activities, passing on product risk information, and cooperating in any actions taken to avoid such risks.²⁵

The general duty of safety is applicable only when there are no specific Community product safety provisions governing a particular product’s safety.²⁶ For example, the general duty would not apply to a particular safety aspect of a toy that is covered by the Toy Directive.²⁷ Under the Product Safety Directive, a product is safe when it conforms to the national law of the Member States where it is in circulation.²⁸ This provision, however, does not leave Member States free to set whatever level of safety they desire; Member States’ rules must be “in conformity with the Treaty [of Rome], in particular Articles 30 and 36.”²⁹ However, Member States may restrict the marketing of or require withdrawal from the market of any product that is dangerous to consumers even though the product conforms to Member States’ rules and/or the Directive.³⁰

Member States are obligated to adopt laws, regulations, and administrative provisions to implement the general duty of safety within two years.³¹ This necessarily includes establishing authorities with the enforcement powers required to monitor compliance.³² Appropriate enforcement powers include conducting safety inspections, mandating

21. *Id.* art. 3(2).

22. *Id.* Cited as examples of appropriate measures are marking the product so that it can be identified, sample testing, investigating complaints, and keeping distributors informed of monitoring. *Id.*

23. *Id.* art. 2(e).

24. *Id.* art. 3(3).

25. *Id.*

26. *Id.* art. 1(2).

27. Toy Safety Directive, *supra* note 5.

28. Product Safety Directive, *supra* note 1, art. 4(1).

29. *Id.*

30. *Id.* art. 4(3).

31. *Id.* art. 5.

32. *Id.*

that information be provided, testing samples, subjecting product marketing to prior conditions, requiring suitable warnings, temporarily or permanently banning the marketing of a product, and destroying dangerous products.³³ A decision restricting the marketing of a product or requiring its withdrawal does not preclude Member States from imposing criminal penalties against the producer.³⁴

The Directive provides a comprehensive system for notification and exchange of information within the Community when a Member State restricts the marketing of a product or requires that it be taken off the market.³⁵ These provisions codify the Rapid Information Exchange System (RAPEX) established in 1985 to collect and disseminate information on dangerous products.³⁶ Proprietary information may not be disclosed, unless disclosure is essential to protect health and safety.³⁷

Emergency situations are given special treatment in the Directive. A Member State must inform the Commission of any emergency measures taken to prevent or restrict product marketing or use, unless the effects of the risk of harm do not extend beyond the Member State's territory.³⁸ If there is an immediate risk of harm to consumers in more than one Member State and the Member States cannot agree on the measures to be taken, a Community-wide solution may be imposed by the Commission, assisted by a Committee on Product Safety Emergencies comprised of representatives of the Member States.³⁹ The language of the Directive implies that this power, which is carefully circumscribed,⁴⁰ is not meant to create a superagency. Rather, it is given to the Commission to prevent Member States from creating trade barriers by taking different emergency measures with respect to the same product.⁴¹ The emergency powers will seldom be invoked because most emergencies will be adequately dealt with at the local level or be so clear cut that national authorities will react in the same way.

The Directive does not affect consumers' rights under the Product Liability Directive.⁴² This assures that one who is injured by a defective product will retain his or her strict liability cause of action against

33. *Id.* art. 6.

34. *Id.* art. 14(3).

35. *Id.* art. 7 and Annex.

36. CONSUMERS IN THE EUROPEAN COMMUNITY GROUP, PRODUCT SAFETY AND 1992 10 (1992).

37. Product Safety Directive, *supra* note 1, art. 12.

38. *Id.* art. 8(1).

39. *Id.* arts. 9, 10.

40. *See id.* art. 11.

41. *Id.* Preamble.

42. *Id.* art. 13.

the product seller,⁴³ even though the product complies with the general duty of safety or specific Community or national standards.⁴⁴

With the passage of the Product Safety Directive, the European Community has taken another large step toward meeting its goal of ensuring a high level of protection for consumers in the Community. The extent to which the creation of a general duty of safety will actually result in a decrease in the marketing of unsafe products will depend in large part on how successfully and expeditiously the Member States implement the Directive's provisions.

III. MEMBER STATES' SAFETY LAWS AND REGULATIONS

Existing national law in the Member States, as expected, varies widely in its approach to product safety. Some Member States, such as France and Belgium, have extensive legislation and enforcement options to deal with unsafe products. Others, such as Ireland and Denmark, regulate specific products only. Still others, such as Spain and Portugal, have little or no existing legislation and will have to take larger steps to harmonize with the Directive.

Belgium

Safety standards are set in Belgium by one of two institutes: the Institute Belge de Normalisation (IBN) or the Comité Electrotechnique Belge (CEB). They are comprised of professional federations and have considerable power over technical standards. The standards promulgated by these institutions may be accorded quasi-legislative force by royal decree.⁴⁵

In 1977, the Belgian Parliament passed a consumer health protection law that applies to cosmetics, tobacco, detergents, foodstuffs, and food additives. The law authorizes the King to regulate or prohibit the manufacture, export, or marketing of the products covered by the statute.⁴⁶ The King also may determine what information must be disclosed to the consumer about the product and regulate advertising.⁴⁷ The law gives government authorities a right of inspection and failure

43. Product Liability Directive, *supra* note 4.

44. According to the Product Liability Directive, compliance with a mandatory standard issued by a public authority is not a defense unless the standard itself is the cause of the defect. *Id.* art. 7(d).

45. EUROPEAN PRODUCT LIABILITY 62 (Patrick Kelly & Rebecca Attree eds. 1992).

46. *Id.*

47. *Id.* at 64.

to permit access for inspection may result in criminal prosecution. Sanctions for this and other breaches of the law or the regulations implementing it include prison sentences and fines; the penalties are more severe for manufacturers and traders than for distributors.⁴⁸

“[M]achinery, machine parts, equipment, tools, apparatus, and dangerous containers” are the subject of separate legislation, as are pharmaceutical products.⁴⁹ In the case of pharmaceutical products, permission must be obtained in advance of manufacture, preparation, import, or sale.⁵⁰

Denmark

Product safety regulations are embedded in various Danish laws, including, for example, Acts on Drugs, Chemicals, and Foodstuffs.⁵¹ Explosives, fireworks, and electrical devices are also regulated. Violation of these regulations is sanctioned by fines.⁵²

France

France has a general duty of safety statute, which states that “[m]anufacturers are under an obligation to supply products which under normal conditions of use, or under conditions of use which could be reasonably expected by the manufacturer, provide a level of safety which a person can reasonably expect and will not injure the health of the individual.”⁵³ The statute creates the administrative power to regulate and prohibit the manufacture and sale of products that are not safe. The government has a wide range of powers to investigate the safety of and deal with unsafe products: inspection; testing; ordering the manufacturer to issue warnings; suspending manufacture, importation, or distribution; and requiring modification, withdrawal, or destruction of the product.⁵⁴

Non-compliance with an administrative order or request subjects the manufacturer, distributor, or seller to criminal fines, “publicity measures,” and confiscation of the profits realized from the sale of the product.⁵⁵ When personal injury or death is caused by a defective prod-

48. *Id.* at 64-65.

49. *Id.*

50. *Id.* at 65.

51. *Id.* at 90.

52. *Id.*

53. *Id.* at 114.

54. *Id.* at 115.

55. *Id.* at 114.

uct, either through gross negligence or non-compliance with regulations, a manager, the chairman of a Board of Directors, an executive director, or a member of an Executive Board is subject to a fine and imprisonment.⁵⁶

Germany

Specific safety regulations in Germany create duties for manufacturers. These duties include, for example, performing safety tests and including warnings on products. In addition, "officially approved standards and/or protective regulations exist for certain products."⁵⁷

Ireland

Ireland has some safety regulations in place. The products covered by these regulations include foodstuffs, drugs, and medicines.⁵⁸

Luxembourg

In 1953, Luxembourg passed legislation that permitted government authorities to control the manufacture, preparation, transformation, distribution, and sale of food, beverages, drugs, clothes, cosmetics, and other consumer products. A number of decrees have been issued to give effect to the 1953 legislation.⁵⁹

As in France, when personal injury or death is caused by a defective product, either through gross negligence or non-compliance with regulations, a manager, the chairman of a Board of Directors, an executive director, or a member of an Executive Board may be fined and imprisoned.⁶⁰

Netherlands

A number of laws in the Netherlands create safety standards for products. These standards may address the quality of the product itself or deal with, for example, labelling and warnings. If the standards are not met, the government may forbid the import, trade, and transport of the non-complying products. If non-compliance results in injury, the public prosecutor may bring proceedings under the Penal Code, which

56. *Id.* at 113.

57. *Id.* at 555.

58. *Id.* at 528.

59. *Id.* at 253.

60. *Id.*

permits fines and/or imprisonment.⁶¹

Portugal

Article 60(1) of the Portuguese Constitution establishes the general principle that "[a]ll consumers are entitled to [a reasonable degree of] quality of goods and services consumed, to training and information, to the protection of their health, safety and economic interests and to the recovery of damages."⁶² The Consumer Protection Law was passed in 1981 to give effect to the constitutional provision. It has been, however, an "abject failure,"⁶³ and little else was done to regulate product safety until Portugal entered the European Community in 1986. Since that time, various laws have been passed in order to implement the EC Directives on consumer protection.⁶⁴

Spain

The Spanish Constitution provides that the Spanish Central Legislature has exclusive jurisdiction to determine and coordinate economic policy, which includes consumer protection. It falls to the Regional Parliaments, however, to develop the legislation enacted by the Central Legislature by promulgating regional acts and regulations.⁶⁵ Some regional safety regulations exist for some consumer products.⁶⁶

United Kingdom

The United Kingdom passed legislation⁶⁷ in advance of the Directive creating a general duty of safety and imposing criminal liability for its breach.⁶⁸ Prior to the enactment of the Consumer Protection Act, criminal consumer safety law was piecemeal. Specific regulations covering specific products existed, but they fit together only where they touched. There was no catch-all provision to cover hazards not specifically addressed by existing laws.

According to the Act, consumer goods fail to comply with the general safety requirement if they are not "reasonably safe."⁶⁹ The lan-

61. *Id.* at 278.

62. *Id.* at 317.

63. *Id.* at 330.

64. *Id.*

65. *Id.* at 339.

66. *Id.* at 362.

67. Consumer Protection Act, 1987, ch. 43 (U.K.) [hereinafter CPA].

68. *Id.* § 10.

69. *Id.*

guage of the Act indicates, however, that the duty is not absolute.⁷⁰ The safety of goods can be judged by comparison with state of the art technology, compliance with published safety standards, and by utilizing cost-benefit analysis.⁷¹

The CPA's coverage, however, is narrower than the Directive's. The Directive applies to all consumer goods, with very narrow exceptions for antiques and goods to be repaired. The CPA's general duty of safety, on the other hand, does not apply to growing crops, food and foodstuffs, water, gas supplied by gas mains, controlled drugs, licensed medical products, tobacco, aircraft, and motor vehicles.⁷² While the excluded products are addressed through other regulatory provisions, the gap in coverage must be filled in order to effectuate true harmonization with the Directive. Additionally, the CPA specifically exempts second-hand goods.⁷³ That exclusion, too, is not compatible with the Directive and will require extension to comply with the Directive's mandates.

Enforcement of the general duty of safety in the United Kingdom falls upon local government officials (Trading Standards Officers).⁷⁴ Trading Standards Officers are empowered to charge suppliers with an offense, seize goods, apply to court for a forfeiture of goods, and carry out testing, inspections, and demand document production.⁷⁵ The Directive seems to contemplate a central authority in each of the Member States,⁷⁶ and additional legislation might be necessary to bring the United Kingdom into harmony with its provisions.

IV. COMPARISONS BETWEEN THE UNITED STATES AND EUROPE

The temptation when undertaking a comparative analysis is to search for areas of similarity as a starting point. In this case, the search is for some provision in U.S. federal law, which is structurally analogous to Community law in the European Community, that imposes a general duty of safety like that created by the Product Safety Directive. A few candidates emerge, but none has the reach or the breadth to make it truly comparable. Federal health and safety statutes, such as the Food, Drug, and Cosmetic Act,⁷⁷ the Consumer Product Safety

70. See *id.* §§ 10, 11.

71. J.R. Bradgate, *Product Safety: The EEC Follows UK Lead*, 7 *TRADING L.* 2, 4 (1990).

72. See CPA, *supra* note 67, §§ 10, 11.

73. *Id.* § 10(7).

74. Bradgate, *supra* note 71, at 8-9.

75. *Id.*

76. Product Safety Directive, *supra* note 1, art. 5.

77. 21 U.S.C. §§ 301-394 (1988).

Act,⁷⁸ and the National Traffic and Motor Vehicle Safety Act,⁷⁹ when taken together, indicate a public policy supporting consumer safety, but do not by themselves create a general duty of safety. Each one regulates in its own sphere of influence, and imposes different safety requirements.

The Consumer Product Safety Act comes the closest to the Product Safety Directive because of the range of consumer products it covers. However, even it fails to establish a general duty of safety because of the multitude of products exempted from its provisions⁸⁰ and because it fails to assert explicitly that a general duty of safety is intended.⁸¹ Combined with the other acts, the entire package of federal health and safety statutes and the federal agencies created to enforce those statutes presents the closest approximation to the EC's new general duty of safety and will form the basis of this comparison.

A. *Locus of Enforcement Power*

A general duty of safety means nothing if it cannot be enforced. Enforcement actions against unsafe products in the European Community with the adoption of the Product Safety Directive and under existing law in the United States present decidedly different strategies.

The approach taken by the European Community is to articulate the duty at the Community level and charge the individual Member States with creating local enforcement schemes. The result will certainly create differing responses to violations of the duty. For example, the United Kingdom has determined that criminal sanctions are the appropriate means to address unsafe products.⁸² The Netherlands and Germany each have an extensive administrative apparatus in place and can be expected to tailor their harmonizing legislation to fit their existing frameworks. Portugal, by contrast, has virtually no enforcement mechanism in place and will have to create a system for enforcing the general duty of safety.

By placing enforcement power at the local level, the European

78. 15 U.S.C. §§ 2051-2054 (1988 & 1992 Supp.).

79. 15 U.S.C. §§ 1381-1431 (1988).

80. Exempted from the provisions of the Consumer Product Safety Act are food, drugs, cosmetics, automobiles, tobacco, firearms, boats, and airplanes. 15 U.S.C. § 2052.

81. One of the purposes of the Consumer Product Safety Act is "to protect the public against unreasonable risks of injury associated with consumer products." 15 U.S.C. § 2051. The language provides the Consumer Product Safety Commission with a mission, but does not create a general duty of safety.

82. See CPA, *supra* note 67, § 26.

Community permits local custom and culture to dictate the response to unsafe products. The advantage is to preserve producers' expectations about the existing legal environments in which they do business, at least in those Member States that have addressed public enforcement against certain dangerous products in advance of the Directive's passage. The disadvantage is that not all Member States have existing legislation upon which to engraft the general duty of safety and therefore have no experience upon which to build. Although a blank slate permits creative thinking about how to enforce a general duty of safety, wide variation can be expected as each State fashions its response to the Product Safety Directive. The Directive provides for a Community-wide response to product hazards on an emergency basis when individual enforcement actions over a particular product are inadequate or vary too much,⁸³ but does not impose one particular enforcement structure on the Member States.

In contrast, enforcement in the United States occurs, for the most part, at the federal level. Individual states have laws and administrative agencies that regulate consumer products but, for a product that is distributed in interstate commerce, federal enforcement is the norm. It is customary in the United States for businesses to seek a uniform regulatory environment so that only one set of standards and sanctions govern the distribution of a product. Consequently, federal regulation has preempted individual state regulatory schemes except in the most local of circumstances such as local health codes. From a public policy standpoint, federal regulation provides a uniform level of safety for goods distributed in commerce and is viewed as the appropriate means of assuring safe products. Unlike the European Community, the result in the United States is that the articulation of a general duty of safety at the federal level remains elusive, although public enforcement against unsafe products, when it occurs, is centralized at the federal level.

It is not surprising that the European Community would leave Member States free to fashion their own enforcement mechanisms. It is in the nature of the directives to articulate policies and goals and permit local laws to implement them. The legal environments and cultural norms of the Member States vary significantly. The Directive approach permits Member States to give substance to those traditions. The United States does not face strong nationalistic urges from the individual states. Although each state is sovereign and the states do vary in political outlook, the notion of a central government has existed from the nation's formation and is preserved in the Constitution. The ability

83. Product Safety Directive, *supra* note 1, arts. 9, 10.

and desirability of directing and implementing public policy at the national level is more deeply embedded in the legal culture of the United States than it is in the European Community. As such, a central locus of control over the enforcement of product safety goals has emerged as the appropriate strategy to assure safe products.

It is not the purpose of this article to suggest that one approach is necessarily better than the other. Rather, we simply note that local control over enforcement with the European Community performing a monitoring function is compatible with other Community-level initiatives and is appropriate when twelve independent nations join in a confederation with shared goals, but separate traditions. Central enforcement, on the other hand, is thoroughly in keeping with the traditions and political institutions of the United States. The former respects local sovereignty and individual differences in enforcement strategy while unifying over a common goal. The latter promotes uniformity over all aspects of public policy—the articulation of the goal and its implementation.

B. Breadth of Enforcement Power

The Product Safety Directive contemplates standard setting for many products.⁸⁴ One estimate suggests that as many as 10,000 standards will be created.⁸⁵ However, the general duty of safety governs when no specific safety standards exist. Therefore, it reaches all consumer products that do not conform to safety standards or, in the absence of a standard, to “the degree of safety that consumers and users in general can reasonably expect.”⁸⁶ The Directive is all-encompassing and becomes the basis of authority for proceeding against any and all consumer products that pose a danger. Standards do not have to be set for every product for it to apply. Products that have yet to be developed will come within its jurisdiction. Most important for this comparison, no additional administrative apparatus needs to be developed at the Community level for the Directive to take effect.

In contrast, product safety regulation in the United States has been balkanized among myriad statutes and administrative agencies. There is no single central authority for the articulation of safety standards or enforcement against unsafe products. Furthermore, there is no one source for determining what constitutes an unsafe product. Using the Consumer Product Safety Act as a model because of its applicabil-

84. *Id.* Preamble.

85. Patrick Oster et al., *10,000 New EC Rules*, Bus. Wk., Sept. 7, 1992, at 48.

86. Product Safety Directive, *supra* note 1, art. 2(b).

ity to most but not all consumer products, the closest comparison can be found in section 15.⁸⁷ The section requires notification to the Consumer Product Safety Commission when a manufacturer or distributor obtains information that a product does not comply with an applicable safety rule or voluntary standard, "contains a defect which could create a substantial product hazard,"⁸⁸ or "creates an unreasonable risk of serious injury or death."⁸⁹ Failure to do so constitutes a prohibited act,⁹⁰ for which civil penalties may be assessed.⁹¹ Neither the finding of a substantial product hazard nor of an unreasonable risk of serious injury or death contains any element of consumer expectations. Furthermore, even conceding that one of the conditions exists, the obligation is to report. Public enforcement occurs for the failure to report, not for the condition of the product. Naturally, the Commission may take action based on the report, such as requiring a recall for repair or replacement,⁹² but the obligation under section 15 is to notify the Commission, not to comply with a general duty of safety. Other health and safety statutes are similar. Nowhere is there the broad articulation of a safety duty nor is there one source that covers all consumer products.

The EC's broad articulation of a general duty of safety offers at least two benefits. It relates with absolute clarity the need for a producer to establish safety as a high priority when designing, manufacturing, and distributing products. It also sets a consumer expectation standard for subsequent enforcement actions. It is doubtful that the U.S. standards of "substantial product hazard" and "unreasonable risk of serious injury or death" can do likewise effectively. "Substantial product hazard" and "unreasonable risk of serious injury or death" impose different standards on manufacturers than a general duty of safety tied to a consumer expectation test. The former allow enforcement only when significant harm caused by a product occurs and injury reports start to mount up. By contrast, the consumer expectation test allows enforcement against a producer before substantial harm has occurred.

87. 15 U.S.C. § 2064 (1988).

88. *Id.* § 2064(b)(2). A substantial product hazard is defined as:

- (1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or
- (2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

Id. § 2064(a).

89. *Id.* § 2064(b)(3).

90. *Id.* § 2068(a)(4).

91. *Id.* § 2069.

92. *Id.* § 2064(d).

Thus, the ability to prevent harm is greater and may occur earlier under the consumer expectation test than under U.S. law.

V. CONCLUSION

The foregoing analysis suggests that the United States has some of the tools available to enforce a general duty of safety, for example an extensive enforcement network, but lacks an over-arching statement that articulates the duty. On the other hand, the European Community has articulated the duty, but has yet to install the enforcement mechanisms that make it effective. Obviously differences in political structures and legal traditions prohibit exact parallels between the European Community and the United States. However, while the starting points are different, great potential exists for the evolutionary cycles of product safety occurring on the two continents to intersect. The result is a heightened concern for consumers' safety and a reduction in the monetary and social costs of product-related injuries and deaths.