

PRODUCT LIABILITY: ADVANCEMENTS IN EUROPEAN UNION PRODUCT LIABILITY LAW AND A COMPARISON BETWEEN THE EU AND U.S. REGIME

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INTRODUCTION

In recent years, the product safety regime in the European Union (“EU”) has been amended to provide increased stability for producers and more protection for consumers. The framework seeks to balance the interest of consumers in having access to safe products with the interest of producers in avoiding costly litigation due to differing national standards. There are currently three prominent EU directives designed to protect the health and safety of consumers. These three directives are the Product Liability Directive (the “Directive”), the European General Product Safety Directive (the “GPSD”), and the Product Warranty Directive.¹ This paper will focus on the impact of the Directive and the

1. *The European General Product Safety, Product Liability & Product Warranty Directives*, Emergo Grp., <http://www.emergogroup.com/resources/articles/other-european-directives> (last visited

GPSD in the EU and will compare these two directives with product liability law in the United States (“U.S.”). This paper will also explore the newly proposed Product Safety and Market Surveillance Package (the “Package”), expected to replace the GPSD as soon as 2015, and the impact that the Package will have on product liability law in the EU.²

The combination of the Directive and the GPSD provide a comprehensive scheme for product liability law in the EU. When compared with U.S. product liability law, these two directives achieve greater harmonization across member states than the current U.S. product liability regime. Although both the EU and the U.S. have similar product liability laws, the current EU regime often affords consumers greater access to redress and maintains strict requirements in regards to product labeling. The proposed Package will introduce even more harmonization into the EU, making it harder on economic operators who sell or produce defective products to escape liability. However, the EU product liability regime is not without problems and there are multiple areas in which the U.S. product liability framework offers better alternatives and provides less confusion for manufacturers and consumers.

I. THE PRODUCT LIABILITY DIRECTIVE (85/374/EEC)

Prior to the implementation of the Directive, countries adopted differing product liability systems. Some countries adopted a fault based system for defective products, whereas others had in place a strict liability regime.³ These differing interpretations were the impetus for a new directive that would harmonize product liability law across all EU member states. Specifically, the Council of the European Union (the

Feb. 11, 2014) [hereinafter Emergo Group].

2. See *Product Safety and Market Surveillance Package: Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - More Product Safety and Better Market Surveillance in the Single Market for Product*, COM (2013) 74 final (Feb. 13, 2013) [hereinafter *Communication on More Product Safety*].

3. Council Directive 85/374/EEC, 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) 29, 30 [hereinafter *Product Liability Directive*].

“Council”) believed that “existing divergences [in the laws] may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damages caused by a defective product to his health or property.”⁴ Therefore, in September 1976, the European Commission (the “Commission”) began the legislative process of implementing the Directive.⁵

On July 25, 1985, the Council issued the Product Liability Directive.⁶ The Directive was eventually amended in 1999 to expand the scope of products covered to include agricultural products.⁷ This was the first piece of legislation introduced in the EU concerning a producer’s liability for harm caused by defective products. The Directive’s purpose was to impose liability without fault on all economic operators involved in manufacturing defective products.⁸ Article 1 of the Directive, which states, “[t]he producer shall be liable for damage caused by a defect in his product” encompasses the idea of strict liability.⁹ “Producer” also has an expansive definition and encompasses the manufacturer of finished products or components, producers of raw materials, individuals who place their name or trademark on products, individuals who import products into the EU for distribution, and product suppliers unless they can provide the injured consumer with the name of the producer.¹⁰ The Directive also requires the Commission to present reports on

4. *Id.* at 29.

5. Commission Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, O.J. (C 241) 9 (1976).

6. Product Liability Directive, *supra* note 3, at 29.

7. *See* Council Directive 1999/34/EC, of the European Parliament and of the Council of 10 May 1999 Amending Council Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1999 O.J. (L 141) 20 [hereinafter 1999 Amendment].

8. Product Liability Directive, *supra* note 3, at 29.

9. *Id.* art. 1, at 30.

10. *Id.* art. 3, at 30-31.

implementation of the Directive every five years and make recommendations as to whether the Directive should be amended.¹¹

The Commission's first report regarding implementation of the Directive was published on December 13, 1995.¹² The report concluded that the Directive was generally well received and "has contributed towards an increased awareness of and emphasis on product safety."¹³ However, experience with the Directive was limited and the European Court had yet to hear a case concerning interpretation of the Directive.¹⁴ To determine how the Directive worked in practice, the Commission carried out a study in the form of a Green Paper,¹⁵ which surveyed economic operators, consumers, insurance companies, and public administrators.¹⁶ The results of the Green Paper formed the basis for the Commission's second report on implementation of the Directive and led to the 1999 Amendment.¹⁷

The Commission's second report on the Directive's implementation was published on January 1, 2001 and examined the practical effects of the Directive as well as possible reform.¹⁸ The Commission found that the Directive worked well in practice and that member states generally implemented the Directive alongside other liability regimes, such as

11. *Id.* art. 21, at 33.

12. *See Commission First Report on the Application of Council Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products (85/374/EEC)*, COM (1995) 617 final (Dec. 13, 1995).

13. *Id.* at 2.

14. *Id.*

15. Green Papers are "documents published by the European Commission to stimulate discussion on given topics at European level. They invite the relevant parties (bodies or individuals) to participate in a consultation process and debate on the basis of the proposals they put forward." *Glossary - Green Paper*, EUROPA, http://europa.eu/legislation_summaries/glossary/green_paper_en.htm (last visited Apr. 17, 2015).

16. *See Commission Green Paper on Liability for Defective Products*, COM (1999) 396 final (July 28, 1999).

17. *Commission Report on the Application of Directive 85/374 on Liability for Defective Products*, at 6-7, COM (2000) 893 final (Jan. 31, 2001) [hereinafter *Second Report*].

18. *Id.* at 12-27.

contract or tort law.¹⁹ The second report also considered how the Directive affected European businesses and their foreign competitors.²⁰ Although European businesses were not affected on a global level, the Directive was found to have a significant impact on European manufacturers operating in the U.S.²¹ Small and mid-size European manufacturers reported that they refrained from exporting products to the U.S. because U.S. law created a “climate of unpredictability” for producers given high punitive damage awards and the possibility of class actions.²²

The critical portion of the Commission’s second report was its discussion of reform. The first issue considered for reform was the burden of proof standard.²³ Under Article 4, the injured party was required to prove damage, defect, and a causal relationship between defect and damage.²⁴ However, the Commission found that it was often difficult to prove defect because of the product’s complexity or the cost of obtaining an expert witness.²⁵ Multiple reforms ranging from inferring a causal relationship if an individual proves damages to requiring the manufacturer to pay the cost of an expert witness were presented as solutions.²⁶ There were differing responses to the recommendations, with one group rejecting the idea of manufacturer liability based on presumptions and another advocating for the burden of proof to be placed on the manufacturer.²⁷ After considering various options, the Commission recommended against amending Article 4 because there were no known problems relating to the current standard and national courts had developed various ways to deal with burden of proof issues.²⁸

The second issue addressed by the Commission dealt with Article 16 of the Directive. Article 16(1) states that “[a]ny member state may

19. *Id.* at 8.

20. *Id.* at 9.

21. *Id.*

22. *Id.*

23. *Id.* at 13.

24. Product Liability Directive, *supra* note 3, art. 4, at 31.

25. Second Report, *supra* note 17, at 13.

26. *Id.* at 13-14.

27. *Id.* at 14.

28. *See id.* at 14-16.

provide that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million ECU."²⁹ At the time of the Commission's second report, only Germany, Spain, and Portugal had adopted financial ceilings.³⁰ The Commission concluded that Article 16 should be left as an option for member states because there was no information indicating that the 70 million ECU threshold left consumers injured by defective products without compensation.³¹ The Commission ended its second report by determining that it would be unwise to amend the Directive given its limited experience with the Directive in practice.³² The Commission also advocated against amending the Directive because it wanted to maintain the balance struck by the Directive between consumers and manufacturers.³³

The Commission reexamined implementation of the Directive on September 14, 2006, when it published its third report.³⁴ Between 2001 and 2006, the Council and the Commission prepared two studies to outline the practical effects of the Directive in EU member states.³⁵ The two reports adopted by the Commission were the Lovells Report, published in 2003, and the Fondazione Rosselli Report, published in 2004.³⁶ The Lovells study focused on different product liability systems in EU member states and considered "the extent to which there was a need to further harmonize product liability laws in the EU, or to make

29. Product Liability Directive, *supra* note 3, art. 16, at 32.

30. Second Report, *supra* note 17, at 20.

31. *Id.*

32. *Id.* at 28.

33. *Id.*

34. See *Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee: Third Report on the Application of Council Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products 85/374/EEC of 25 July 1985, Amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999*, COM (2006) 496 final (Sept. 14, 2006) [hereinafter Third Report].

35. *Id.* at 5.

36. *Id.* at 6.

any amendments to the Directive.”³⁷ The Lovells report found that the Directive was being implemented in the majority of member states and that the Directive provided a fairly uniform system of law on consumer protection and manufacturer liability.³⁸

The Fondazione Rosselli Report was carried out in order to assess Article 7(e) of the Directive, also known as the Development Risk Clause.³⁹ The clause states, “[t]he producer shall not be held liable as a result of this Directive if he proves ... that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.”⁴⁰ Since the Directive was enacted, there has been much debate over whether this clause should be removed so as to allow consumers greater access to redress.⁴¹ However, manufacturers point out that removing Article 7(e) would “stifle innovation” and result in an increased number of product liability claims.⁴² The report concluded that Article 7(e) should be maintained as a defense because it struck the proper balance between manufacturer innovation and consumer access to redress.⁴³

The third report on implementation of the Directive concluded that member states were generally satisfied with the balance struck between consumer and manufacturer interests and that manufacturers had not seen an increase in the number of EU product liability suits.⁴⁴ However, the report did find areas of confusion for national courts and began monitoring these areas to determine whether future amendments would be needed.⁴⁵ First, the Commission reexamined the burden of proof standard to determine whether it unfairly disadvantaged consumers.⁴⁶ Notably, the Commission found no evidence that the standard was

37. *Product Liability in the European Union: Lovells Report for the European Commission*, at i, MARKT 2001/11/D (Feb. 2003).

38. *See generally id.* at 47-58.

39. Third Report, *supra* note 34, at 6.

40. Product Liability Directive, *supra* note 3, art. 7(e), at 31.

41. Third Report, *supra* note 34, at 6-7.

42. *Id.* at 7.

43. *Id.*

44. *Id.* at 9.

45. *Id.* at 8-11.

46. *Id.* at 9.

impracticable and left this area to national courts to adjudicate.⁴⁷ The other area that the Commission concluded needed further study was the Article 6 concept of defect.⁴⁸ Article 6 states,

A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation.⁴⁹

The Commission found that problems with the Directive's definition led to confusion in national courts as to whether a product's design should be taken into account and whether the court may engage in a risk-utility analysis.⁵⁰ For example, some member states, such as France, require only that a consumer show the product failed and caused harm, while in other states, such as the United Kingdom, courts require that the consumer identify the specific defect.⁵¹ Given the confusion among courts, there is reason to believe that the EU may amend this definition in the near future to achieve greater harmonization among member states.

The most recent report published by the Commission on implementation of the Directive was released on September 8, 2011 and found that the Directive has been widely accepted in almost all EU members states.⁵² The report noted that between 2006 and 2011 there was an increase in product liability claims based on the Directive and that the Court of Justice of the European Union (the "Court") had found

47. *Id.*

48. *Id.* at 10.

49. Product Liability Directive, *supra* note 3, art. 6, at 31.

50. Third Report, *supra* note 34, at 10.

51. *Id.*

52. *See Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Fourth Report on the Application of Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products Amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999*, COM (2011) 547 final (Sept. 8, 2011) [hereinafter Fourth Report].

ways to mitigate the differences in member state interpretations.⁵³ The Commission also reiterated that the point of the Directive was to bring about a general framework of liability that provided adequate protection for consumers without stifling innovation and increasing costs for manufacturers.⁵⁴ As such, the Commission decided not to amend the Directive because amendments could upset the balance struck by the Directive between manufacturers and consumers.⁵⁵ Another report on implementation of the Directive is not scheduled to be undertaken until 2016 in accordance with Article 21 of the Directive.⁵⁶

II. A COMPARISON OF THE EU PRODUCT LIABILITY DIRECTIVE AND U.S. PRODUCT LIABILITY LAW UNDER THE RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY

This portion of the paper will examine the difference between product liability law in the EU under the Directive and product liability law in the U.S. under the Restatement (Third) of Torts: Product Liability (the “Restatement (Third)”). While both systems have multiple similarities, including strict liability, there are some notable differences that manufacturers who wish to sell products under either regime should be aware of. Overall, it appears that the EU offers a more comprehensive product liability framework under both the Directive and the GPSD, which will be discussed later in this paper. However, there are areas in which the U.S. regime offers a better compromise between the interests of consumers and manufacturers.

The first notable difference between EU and U.S. law is that in the United States there is no federal product liability statute.⁵⁷ As a result, product liability law varies according to jurisdiction and theory of liability. However, there has been some harmonization of U.S. law, first

53. *Id.* at 4-5.

54. *See generally id.* at 9-11.

55. *Id.* at 11.

56. Product Liability Directive, *supra* note 3, art. 21, at 33.

57. Harvey L. Kaplan & Jon A. Strongman, *Developments in US Product Liability Law and The Issues Relevant to Foreign Manufacturers*, PRACTICAL LAW (Mar. 1, 2012), <http://us.practicallaw.com/6-501-9379#null>.

under the Restatement (Second) of Torts and then under the Restatement (Third).⁵⁸ Although no state is required to adopt the Restatement (Third), a majority of states have adopted many of its provisions.⁵⁹ In comparison, the EU Directive is addressed to all members states and provides, “[m]ember states shall bring into force, not later than three years from the date of notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive.”⁶⁰ However, Article 13 also allows member states to have a system of liability under which both national laws and the Directive operate.⁶¹ Overall, both regimes have sought to harmonize product liability laws. In the future, the U.S. should consider creating a federal framework applicable to all states so as to subject consumers and manufacturers to the same laws in all jurisdictions.

In the U.S., Section 402A of the Restatement (Second) of Torts established strict liability for sellers of defective products.⁶² However, implementation of Section 402A became problematic for a number of reasons, including its definition of unreasonably dangerous and its inability to deal with design defect claims.⁶³ Sections 1 and 2 of the Restatement (Third) maintain the strict liability framework for manufacturing defects but allow individuals to bring both design defect and warnings claims under a negligence-based framework.⁶⁴ Section 1 states “[o]ne engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”⁶⁵ Following the U.S. lead, the EU adopted a version of the Section 402A theory of strict liability in the 1985 Directive. Article 1 of the Directive maintains that

58. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. INTRO. (1998).

59. *Id.*

60. Product Liability Directive, *supra* note 3, art. 19, at 33.

61. *Id.* art.13, at 32.

62. RESTATEMENT (SECOND) OF TORTS § 402 (a)(1) (1965).

63. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 cmt. a, reporter’s note cmt. a (1998).

64. *Id.* § 1, cmt. a.

65. *Id.* § 1.

“[t]he producer shall be liable for damage caused by a defect in his product.”⁶⁶

Although both the EU and U.S. initially developed product liability regimes based on strict liability, the evolution of the law in the U.S. and EU later diverged. Among the differences is how the EU and U.S. treat economic operators who supply defective products.⁶⁷ In the EU, “producer” is broadly defined and includes anyone from the manufacturer of a finished product to individuals who import and distribute products.⁶⁸ Article 3(1) and (2) of the Directive state,

(1) ‘Producer’ means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

(2) Without prejudice to the liability of the producer, any person who imports into the community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.⁶⁹

Further, if the product’s producer cannot be identified, the supplier may be treated as the producer unless he informs the consumers of the identity of the producer.⁷⁰

Similar to the EU Directive, §1 of the Restatement (Third) indicates that nonmanufacturing sellers and distributors, which include wholesalers and retailers, can be held liable for defective products.⁷¹ However, these individuals are often shielded from strict liability under state law.⁷² The theory underlying this policy is that allowing individuals

66. Product Liability Directive, *supra* note 3, art. 1, at 30.

67. *Id.* art. 3, at 30-31; RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1, cmt. e (1998).

68. Product Liability Directive, *supra* note 3, art. 3, at 30-31.

69. *Id.*

70. *Id.*

71. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 (1998).

72. *Id.* § 1 cmt. e.

to sue nonmanufacturing distributors would increase costs and produce more litigation.⁷³ As a result, the EU regime likely provides greater redress for consumers injured by defective products because consumers may initiate an action against a supplier in cases where the manufacturer cannot be identified. In the U.S., state law often prohibits these suits, thereby precluding redress for consumers against nonmanufacturing distributors of defective products.⁷⁴

Another important difference between EU and U.S. product liability law is how the concept of defect is interpreted. In the EU, Article 6(1) of the Directive states,

A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation.⁷⁵

Article 6(2) provides that “[a] product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.”⁷⁶ These provisions evidence that fact that the Directive is based on a consumer expectations test rather than a risk/utility balancing test. Risk utility focuses on whether a reasonable alternative design would have reduced the harm brought about by a defective product and whether that design would have introduced risk into other components of the product.⁷⁷ A consumer expectations test focuses on whether the product was unreasonably dangerous to consumers and whether the product failed to meet a consumer’s reasonable expectations.⁷⁸

National courts have largely been left to interpret Article 6 and the concept of defect under the Directive’s consumer expectations test themselves. In *A v. National Blood Authority*, the plaintiffs sought

73. *Id.*

74. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1 cmt. e, reporter’s note cmt. e (1998).

75. Product Liability Directive, *supra* note 3, art. 6(1), at 31.

76. *Id.* art. 6(2), at 31.

77. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. d (1998).

78. *Id.* § 2 cmt. g.

damages under Article 6 after contracting Hepatitis C from blood transfusions.⁷⁹ The defendants argued that they were not liable because a screening test that would have detected such risks was not available at the time.⁸⁰ The High Court of England and Wales inquired into whether the public knew and accepted the risk that a virus could be transmitted through blood transfusions.⁸¹ The court held that the transfusions were defective under Article 6 because the public could expect blood transfusions to be free of infection as the risks were not made known to the public at large and no warnings were issued.⁸²

In 2013, the German Federal Supreme Court issued a decision under the German Product Liability Act, which transposed the Directive. The plaintiff claimed that an under sink boiler was defective under Article 6 when it exploded after being incorrectly fitted.⁸³ Applying the consumer expectations test, the court found that the boiler was not defective because “the consumer could not reasonably expect a product to be safely designed for inappropriate use.”⁸⁴ The court reasoned that incorrect use included inaccurately fitting the boiler.⁸⁵ This case is an example of the practical effect of the consumer expectations test under Article 6 as it was transposed in national legislation.

Notably absent from the Directive are the specific definitions of manufacturing defect, design defect, or warnings defect. Unlike the EU Directive, §2 of the Restatement (Third) lays out three categories of product defects. Section 2 states,

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

79. *A v. National Blood Authority* (No.1), [2001] 3 All E.R. 289 (Eng.).

80. *Id.*

81. *Id.*

82. *Id.*

83. Shook, Hardy & Bacon, *Product Liability Developments in 2013: What Do They Mean for Your Business?*, THE IN-HOUSE LAWYER (Feb. 4, 2014), <http://www.inhouselawyer.co.uk/index.php/product-liability/10405-product-liability-developments-in-2013-what-they-mean-for-your-business>.

84. *Id.*

85. *Id.*

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe[.]⁸⁶

In terms of a manufacturing defect, the U.S. invokes the consumer expectations test because manufacturing defects disappoint consumer expectations by being flawed, damaged, or inadequately assembled.⁸⁷ The test is whether the product departed from its intended design.

For example, in *Johnson v. Black & Decker Inc.*, the court considered whether a router contained a manufacturing defect after the plaintiff sustained injuries when the router failed to turn off.⁸⁸ The plaintiff alleged that the router's switch contained a manufacturing defect that caused the off switch to fail, subsequently causing the plaintiff's injury.⁸⁹ The court reasoned that in order to prove that the router contained a manufacturing defect, the claim "must be supported by evidence that the allegedly defective product did not conform to the manufacturer's own product standards."⁹⁰ The court held that the router did not contain a

86. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998).

87. *Id.* § 2 cmt. c.

88. *Johnson v. Black & Decker Inc.*, 408 F. Supp. 2d 353, 355 (E.D. Mich. 2005).

89. *Id.* at 357.

90. *Id.*

manufacturing defect because there was no evidence that the router deviated from the manufacturer's design.⁹¹

Although similar in regards to manufacturing defects, EU and U.S. product liability laws depart substantially in terms of design defects. Unlike the consumer expectations test used in the EU, the overwhelming majority of states have adopted the risk utility approach advanced by the Restatement (Third) to adjudicate design defect cases.⁹² Whether a product has met consumer expectations is a factor to be considered but does not constitute an independent test for design defect.⁹³ For example, in *Dawson v. Chrysler Corp.*, the plaintiff alleged that his patrol car was defectively designed because it was not made with a continuous steel frame after the vehicle wrapped around a pole, crushing the lower half of the plaintiff's body.⁹⁴ In determining whether the car was defectively designed, the New Jersey Supreme Court identified several factors relevant to a risk utility analysis including: (1) the utility of the product, (2) the safety aspects of the product, (3) availability of a reasonable alternative design, and (4) whether the reasonable alternative design would introduce new dangers into the product.⁹⁵ The court held that under the risk utility approach, the plaintiff presented sufficient evidence that a reasonable alternative design existed and that the defective design was the proximate cause of the plaintiff's injuries.⁹⁶ Although the majority of states have adopted the risk utility test for design defect cases, there are states that use a mix of consumer expectations and risk utility or strictly apply a consumer expectations test.⁹⁷ For example, in *Barker v. Lull Engineering Co*, the plaintiff was injured when the high

91. *Id.*

92. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. g (1998).

93. *Id.*

94. *Dawson v. Chrysler Corp.*, 630 F.2d 950, 954 (3d Cir. 1980).

95. *Id.* at 957.

96. *Id.* at 958-60.

97. Aaron D. Twerski & James A Henderson Jr., *Manufacturer' Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 BROOK. L REV. 1061, 1069 (2009).

lift loader he was operating tipped.⁹⁸ Plaintiff claimed that his injuries were caused by the loader's defective design.⁹⁹ The court held that,

[A] product may be found defective in design, so as to subject a manufacturer to strict liability for resulting injuries, under either of two alternative tests. First, a product may be found defective in design if the plaintiff establishes that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. Second, a product may alternatively be found defective in design if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design.¹⁰⁰

This case presents an example of a court using both consumer expectations and risk utility in a design defect case. In practice, the use of a consumer expectations test is outdated. As Professors Henderson and Twerski state, "there is little doubt that risk-utility balancing has carried the day The test for design defect set forth in the *Products Liability Restatement* merges sound legal theory and actual litigation practice."¹⁰¹

After a comparison between liability regimes, it appears that § 2 of the Restatement (Third) provides a more comprehensive definition of defect and eliminates much of the confusion prevalent under the Directive. The use of a risk utility balancing test rather than a pure consumer expectations test is more effective since consumers are generally unable to judge how an alternative design will affect the product's overall safety or how a complex product should function. Furthermore, consumer expectations are subjective and courts often end up engaging in some form of risk utility balancing so that they may consider reasonable alternative designs.

98. *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 447 (Cal. 1978).

99. *Id.* at 445-46.

100. *Id.* at 455-56.

101. Twerski & Henderson, *supra* note 97, at 1106, 1108.

There are also similarities and differences in the way courts have interpreted burden of proof standards under the Directive and the Restatement (Third). In the EU, Article 4 places the burden on the injured individual to prove “the damage, the defect and the causal relationship between defect and damage.”¹⁰² However, it is often practically difficult to prove that a causal link exists because of a product’s technical complexity or the cost of expert testimony. As a result, member states have dealt with burden of proof issues in different ways.¹⁰³ For example, in Belgium, courts will allow a judge to infer a causal relationship between damage and defect.¹⁰⁴ In contrast, judges in Denmark establish burden of proof on a case-by-case basis and will ask the manufacturer to provide evidence to rebut the presumption of a defect.¹⁰⁵ Therefore, although it appears that the Directive established a standard, in practice, courts often deviate to afford more protection to consumers and to compensate for the difficulty in proving defect.

Similar to the Directive, the Restatement (Third) places the burden on the plaintiff to prove manufacturing and design defects.¹⁰⁶ For manufacturing defects, the burden is on the plaintiff to prove that the product was defective when it left the manufacturer or commercial distributor.¹⁰⁷ For design defects, the plaintiff is required to show that a reasonable alternative design was possible at the time of sale and that the alternative design would have made the product safer overall.¹⁰⁸ However, there are circumstances in which the plaintiff is not required to meet the standard, such as when evidence demonstrates that the defect existed at the time of sale and contributed to the plaintiff’s harm or when the product fails to perform its intended function and common experience leads to an inference that the product was defective.¹⁰⁹

102. Product Liability Directive, *supra* note 3, art. 4, at 31.

103. Second Report, *supra* note 17, at 14.

104. *Id.*

105. *Id.*

106. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. c, d (1998).

107. *Id.* § 2 cmt. c.

108. *Id.* § 2 cmt. d, f.

109. *Id.* § 2 cmt. b.

Another notable similarity between the Directive and the Restatement (Third) is that both contain provisions relating to manufacturer defenses. Defense provisions are justified under the reasoning that manufacturers should be able to exonerate themselves from liability under the existence of certain circumstances.¹¹⁰ In the EU, Article 7 of the Directive governs the circumstances under which a manufacturer can avoid liability.¹¹¹ Article 7 states,

The producer shall not be liable as a result of this Directive if he proves:

- (a) that he did not put the product into circulation; or
- (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or
- (c) that the product was neither manufactured by him for sale or any form of distribution for economic purposes nor manufactured or distributed by him in the course of his business; or
- (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
- (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or
- (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.¹¹²

110. See Product Liability Directive, *supra* note 3, at 30.

111. *Id.* art. 7, at 31.

112. *Id.* art. 7, at 31.

Working in conjunction with Article 7(e), Article 15(1)(b) provides an exception that member states may enact to hold the manufacturer liable even when the state of scientific and technical knowledge would not enable a manufacturer to discover the existence of the defect.¹¹³ The listed defenses, in conjunction with Article 15(1)(b), reflect the emphasis the EU places on consumer protection.

The German Case 5 U 3158/10, decided by the Munich Higher Regional Court, provides an example of a manufacturer asserting multiple defenses.¹¹⁴ The plaintiff was holding a glass bottle when the bottle exploded and sent a shard of glass into the plaintiff's eye.¹¹⁵ The manufacturer argued that the bottle, which contained undetectable micro-fractures, was not defective under Article 7(b) or 7(e).¹¹⁶ The manufacturer first argued that he was not liable under Article 7(b) because the defect in the bottle occurred after it was put into circulation.¹¹⁷ The court rejected this argument because the manufacturer was unable to present any evidence that the bottle had been damaged after leaving the manufacturer's control.¹¹⁸ The manufacturer then argued that he was not liable under Article 7(e) because the state of scientific and technical knowledge at the time the bottle was manufactured could not detect the micro-fractures.¹¹⁹ The court also rejected this argument because "the risks of an exploding glass bottle were known and preventable by applying a protective coating."¹²⁰ The court ultimately found that the bottle was defective and that the manufacturer was liable.¹²¹

113. *Id.* art. 15(1)(b), at 32.

114. Shook, Hardy & Bacon, *Product Liability Developments in 2011: What do they mean for your business?*, THE IN-HOUSE LAWYER (Feb. 3, 2012), <http://www.inhouselawyer.co.uk/index.php/product-liability/9757-product-liability-developments-in-2011-what-do-they-mean-for-your-business>.

115. *See id.*

116. *See id.*

117. *See id.*

118. *Id.*

119. *See id.*

120. *Id.*

121. *Id.*

In the U.S., defenses are governed by the Restatement (Third) and state and federal law. The most potent defense for manufacturers in product liability cases is preemption. Federal preemption is rooted in the Supremacy Clause of the U.S. Constitution, which states, “[t]his Constitution, and the laws of the United States . . . shall be the supreme law of the land.”¹²² Courts recognize two types of federal preemption, express preemption and implied preemption. Express preemption occurs when a federal law or agency regulation explicitly states that the law supersedes contrary state law.¹²³ Implied preemption falls into three categories: (1) field preemption, (2) direct conflict preemption, and (3) obstacle preemption.¹²⁴ Field preemption occurs when a federal regulation is “so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it.”¹²⁵ Conflict preemption occurs when it is impossible for a manufacturer to comply with both federal and state law.¹²⁶ Lastly, obstacle preemption occurs when “state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law.”¹²⁷ In deciding whether a state law is preempted, courts look at Congress’ reason for regulating, the regulatory history, the federal agency’s stance on the law, and state law.

Federal preemption defenses appear to be the most common in motor vehicle, drug, and medical device litigation. The landmark Supreme Court decision on motor vehicle preemption is *Geier v. Am. Honda Motor Co.*, in which the plaintiff brought a design defect claim, contending that Honda was negligent for failing to place driver side airbags in its vehicles.¹²⁸ The manufacturer claimed that the design defect and negligence claims were preempted by Federal Motor Vehicle Safety Standard (“FMVSS”) 208, which required manufacturers to equip only

122. U.S. CONST. art. VI, cl. 2.

123. *Lake v. Memphis Landmen, LLC*, 405 S.W.3d 47, 56 (Tenn. 2013).

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 865 (2000).

some of their vehicles with passive restraints.¹²⁹ The Court held that the state tort claim was preempted by federal law because it conflicted with FMVSS 208 and the National Traffic and Motor Vehicle Safety Act, which “deliberately provided the manufacturer with a range of choices among different passive restraint devices.”¹³⁰ The Court has also considered whether preemption applies to medical devices. In *Riegel v. Medtronic*, the Court held that state law claims for defective medical devices are expressly preempted under the Medical Device Amendments if state law requires the manufacturer to deviate from any provisions of the Act or relates to the safety or effectiveness of the device.¹³¹ However, the Court took a different approach to pharmaceutical litigation in *Wyeth v. Levine*, when it held that there is no express preemption for drug claims.¹³² Although there is no express preemption, pharmaceutical claims may be impliedly preempted under federal law.¹³³

U.S. manufacturers may also defend against a product liability claim under the Restatement (Third).¹³⁴ As the Restatement (Third) illustrates, a manufacturer will not be held liable if the plaintiff cannot establish that a defect existed when the product left the hands of the manufacturer.¹³⁵ Product misuse, modification, or alteration may also provide defenses against defective product claims. For example, if the misuse, alteration, or modification was unreasonable or unusual, a manufacturer has no duty to design or warn against risk.¹³⁶ Additionally, product misuse, alteration, or modification might also be used as a defense to reduce the plaintiff’s recovery for comparative fault.¹³⁷

U.S. manufacturers also seek to defend against design defect claims on the ground that their product’s design is state of the art. “The term ‘state of the art’ has been variously defined to mean that the product design conforms to industry custom, that it reflects the safest and most

129. *Id.* at 864-65.

130. *Id.* at 874-75.

131. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

132. *See Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

133. *Mut. Pharm. Co. Inc., v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

134. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. c, p, d (1998).

135. *Id.* § 2 cmt. c.

136. *Id.* § 2 cmt. p.

137. *Id.*

advanced technology developed and in commercial use, or that it reflects technology at the cutting edge of scientific knowledge.”¹³⁸ The manufacturer may also introduce evidence that an alternative design was not practicable at the time of manufacture.¹³⁹ However, conformance with state of the art design is not an absolute defense.¹⁴⁰ In order to prevail on a design defect claim, the plaintiff must prove that the reasonable alternative design was or could have been available at the time of sale.¹⁴¹ Therefore, whether a product conformed to state of the art technology is relevant in determining whether an alternative design was feasible but is not dispositive.¹⁴²

The Restatement (Third) also contains a provision relating to inadequate warnings or instructions. Currently, a similar provision does not exist in the EU Directive. Section 2(c) of the Restatement (Third) provides that a product,

[I]s defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.¹⁴³

In order to prevail on a claim under §2(c), the plaintiff must prove that adequate instructions or warnings were not provided with the product.¹⁴⁴ In making a determination of whether a warning is defective, courts consider “content and comprehensibility, intensity of expression, and the characteristics of expected user groups.”¹⁴⁵ Manufacturers must also warn about non-obvious and not generally known risks so that consumers can make an informed decision whether or not to continue using the

138. *Id.* § 2 cmt. d.

139. *Id.*

140. *Id.* reporter’s note §IV B.

141. *Id.* § 2 cmt. d.

142. *Id.*

143. *Id.* § 2(c).

144. *Id.* § 2 cmt. i.

145. *Id.*

product.¹⁴⁶ However, manufacturers are generally not subjected to liability for failing to warn consumers of an obvious and generally known risk.¹⁴⁷

For example, in *Moran v. Faberge*, the plaintiff claimed that the manufacturer's failure to place a warning on a cologne bottle regarding the product's flammability was negligent.¹⁴⁸ The plaintiff suffered serious burns after the cologne, which was poured on a lit candle, ignited.¹⁴⁹ Testimony revealed that Faberge was aware of the hazard and foresaw that the cologne was likely to ignite when placed near an open flame.¹⁵⁰ The court held that it was not necessary to prove that Faberge foresaw that the cologne would be poured onto a candle.

[R]ather, it was only necessary that the evidence be sufficient to support the conclusion that Faberge, knowing or deemed to know that its Tigress cologne was a potentially dangerous flammable product, could reasonably foresee that in the environment of its use . . . this cologne might come close enough to a flame to cause an explosion of sufficient intensity to burn property or injure bystanders¹⁵¹

This case provides an example of how courts interpret §2(c) of the Restatement (Third) in practice.

By comparing the product liability regimes of the EU and U.S., one can see how consumers and economic operators are impacted by the practical effects of the Directive and the Restatement (Third). Overall, it appears that the Directive offers a more comprehensive scheme in regards to consumers' access to redress for injuries from defective products. On the other hand, the use of risk-utility balancing in the U.S. affords manufacturers an opportunity to adequately defend against design defect claims and sets out an improved framework for adjudicating design defect cases.

146. *Id.*

147. *Id.* § 2 cmt. j.

148. *Moran v. Faberge, Inc.*, 332 A.2d 11, 14 (Md. 1975).

149. *Id.* at 13.

150. *Id.* at 14.

151. *Id.* at 20.

III. THE GENERAL PRODUCT SAFETY DIRECTIVE

Notably absent from the Directive is any mention of product warnings or recalls. While the Directive established strict liability for defective products, the GPSD was enacted to ensure general product safety and created a rapid alert system to facilitate the exchange of information between countries in case of defective products.¹⁵² As the Commission noted, the GPSD and the Directive have “a complementary function: the first instrument ensures that only safe products are put on the market (prevention); the second instrument establishes the rules under which personal injury and damage to property caused by a defective product are compensated (compensation).”¹⁵³ Before examining the current GPSD, it is important to review its predecessor to understand how general product safety laws have changed overtime in the EU.

A. The 1992 General Product Safety Directive (92/59/EEC)

The first General Product Safety Directive (“1992 Directive”) introduced European member states to a general product safety obligation. The purpose of the 1992 Directive was to “ensure a consistent, high level of safety in respect of consumer products throughout the EU.”¹⁵⁴ The directive was adopted on June 29, 1992 and was to be implemented in all member states by June 29, 1994.¹⁵⁵ The 1992 Directive sought to implement a broadly based, horizontal legislative framework that would harmonize member state legislation and

152. Emergo Group, *supra* note 1.

153. Second Report, *supra* note 17, at 21.

154. John Meltzer & Rod Freeman, Hogan Lovells Int’l LLP, *The EU General Product Safety Regime*, in THE INT’L COMP. LEGAL GUIDE TO PROD. LIAB. 2011 at 5, 5 (2011).

155. *Commission Report to the European Parliament and the Council on the Experience Acquired in the Application of Directive 92/59/EEC on General Product Safety* at 4, COM (2000) 140 final (Mar. 29, 2000) [hereinafter *Commission Report on 1992 Directive*].

impose obligations on manufacturers to market safe products.¹⁵⁶ Prior to implementation of the 1992 Directive, member states differed in their approaches to the marketing of safe products. For example, France, the United Kingdom, Norway, Sweden, and the Netherlands all had legislation placing a general obligation on manufacturers to put safe products on the market.¹⁵⁷ Some countries, such as Belgium and Germany, had to expand previously adopted legislation to comply with the 1992 Directive.¹⁵⁸ Others, such as Ireland, Greece, Italy, and Spain had no legislation and chose to adopt the 1992 Directive.¹⁵⁹

In order to harmonize general product safety across the EU, the 1992 Directive focused on ensuring that only safe products were placed on the market. To do this, the 1992 Directive implemented Article 3(1), which states “[p]roducers shall be obliged to place only safe products on the market.”¹⁶⁰ The 1992 Directive also established the Rapid Exchange of Information System (“RAPEX”) for products that pose “a serious and immediate risk.”¹⁶¹ RAPEX provides that when a member state has detected a serious and immediate risk to consumers, the member state should inform the Commission of the identity of the product and the danger, provide reasons why the product is dangerous along with any tests or relevant analyses, and state what measures should be taken to mitigate the harm.¹⁶² The Commission will then inform the relevant authorities in all member states of the danger posed by the product.¹⁶³ Overall, the 1992 Directive introduced into the EU general product safety alongside a sophisticated product alert system.

Although the 1992 Directive’s effort to harmonize general product safety worked well in theory, in practice, the directive failed to achieve many of the goals it set out to accomplish. One of the biggest issues was

156. See Council Directive 92/59/EEC, of The Council of European Communities of 29 June 1992 on General Product Safety, 1992 O.J. (L 228) 24 [hereinafter 1992 Directive].

157. *Commission Report on 1992 Directive*, *supra* note 155, at 7.

158. *Id.*

159. *Id.*

160. 1992 Directive, *supra* note 156, art. 3(1), at 26.

161. *Commission Report on 1992 Directive*, *supra* note 155, at 6.

162. 1992 Directive, *supra* note 156, Annex, at 31-32.

163. *Id.*

that there was not a clear understanding among authorities or economic operators regarding which products were subject to community legislation and which products were governed by the 1992 Directive.¹⁶⁴ As a result, multiple product sectors were excluded from regulation, and authorities had a difficult time enforcing compliance.¹⁶⁵ Problems with the 1992 Directive also arose in regard to the monitoring and withdrawal of defective products. Although the Commission's report found that obligations for monitoring and withdrawal existed in all member states except France, the report concluded that these procedures were not followed in practice.¹⁶⁶ The Commission noted that,

[t]he absence of penalties for non-compliance with this obligation, ignorance of its existence and the lack of guidelines as to what has to be notified and the manner and time at which the notification has to be made may explain the failure to comply with an obligation which would however be very useful for the administration.¹⁶⁷

As a result, the relevant authorities and the Commission were unable to carry out withdrawals or inform other member states and consumers of product dangers.¹⁶⁸

The notification and rapid exchange of information system also contributed to the diminished effect of the 1992 Directive. Generally, member states reported that the Commission was slow to react to notification and failed to keep member states informed, resulting in states failing to learn of product defects until months or years after the initial report.¹⁶⁹ Furthermore, the Commission was concerned that national authorities were having a difficult time keeping up with the amount of notifications, that failure to precisely define "serious and immediate risk" was significantly contributing to the lack of harmonization, and that there was a lack of clarity in the notifications the Commission did send out.¹⁷⁰

164. Commission Report on 1992 Directive, *supra* note 155, at 9.

165. *Id.*

166. *Id.* at 11.

167. *Id.* at 19.

168. *Id.* at 18.

169. *Id.* at 14.

170. *Id.* at 15.

As a result, improvements to RAPEX were at the center of discussions for amending the 1992 Directive.

B. The Current General Product Safety Directive (2001)

The 1992 Directive was replaced with the current version on December 3, 2001.¹⁷¹ The GPSD entered into force on January 15, 2002 and all member states adopted the directive by January 15, 2004.¹⁷² The GPSD significantly amended the 1992 Directive to impose more stringent obligations on economic operators and market surveillance authorities to correct many of the issues surrounding the RAPEX notification system. As attorneys John Meltzer and Rod Freeman note, “[t]he Directive marked a fundamental point of change in the approach to the regulation of the safety of consumer products . . . It brought with it an end to the ‘silent’ recall of consumer products in the EU, imposing onerous new obligations on suppliers of consumer products to EU markets.”¹⁷³ Through amendments, the Council sought to increase compliance, clarify the scope of the GPSD, expand the power of market surveillance authorities, and create more effective procedures for monitoring and reporting.¹⁷⁴ Overall, the GPSD instituted a more effective product safety regime in the EU.

The first significant change brought about by the GPSD relates to the scope of products covered under the directive. Under the 1992 Directive, Article 2 included in its definition of product only “products intended for consumers or likely to be used by consumers.”¹⁷⁵ Under Article 2(a) of the revised GPSD, the definition of product was expanded to include

[A]ny product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and

171. Council Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, 2001 O.J. (L 11) 4 [hereinafter 2001 General Product Safety Directive].

172. *Id.* art. 21, 14.

173. Hogan Lovells, *supra* note 154, at 5.

174. *Id.*

175. 1992 Directive, *supra* note 156, art. 2, at 26.

is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used, or reconditioned.¹⁷⁶

The effect of the amendment has been to broaden the scope of the GPSD and bring more products under its regime, ensuring that all products are governed by legislation that imposes a general safety obligation on economic operators. Notably, food and pharmaceuticals fall beyond the GPSD's scope since these industries are governed by a separate product safety regime.¹⁷⁷

Article 2(b) of both the 1992 Directive and the current GPSD define the meaning of safe product.¹⁷⁸ The 2001 amendments left this provision relatively unchanged, with the exception being that the GPSD defines "serious risk." Article 2 states,

Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons¹⁷⁹

To determine whether a product is safe, economic operators take into account the product's characteristics, the product's effect on other products, the product's presentation, the product's labeling, warnings, or instructions, and the risk to consumers using the product, particularly children and the elderly.¹⁸⁰ As mentioned above, the most significant change to this section of the GPSD was the inclusion of the definition of serious risk. Article 2(d) defines serious risk as "any serious risk, including those the effects of which are not immediate, requiring rapid

176. 2001 General Product Safety Directive, *supra* note 171, art. 2(a), at 8.

177. Hogan Lovells, *supra* note 154, at 5.

178. 1992 Directive, *supra* note 156, art. 2(b), at 26; 2001 General Product Safety Directive, *supra* note 171, art. 2(b), at 8.

179. 2001 General Product Safety Directive, *supra* note 171, art. 2(b), at 8.

180. *Id.*

intervention by public authorities.”¹⁸¹ Although this provision sought to eliminate confusion over the differing interpretations of risk in member states, it is unlikely that the definition has met its goal. This vague definition provides little clarity regarding what constitutes a serious risk under the GPSD and leaves manufacturers and distributors free to interpret this provision a number of different ways.

Article 5 of the GPSD, previously Article 3 of the 1992 Directive, has also undergone substantial revision. Article 5 focuses on the obligations of economic operators, other than simply placing safe products on the market, and introduces new and demanding obligations. Article 5 reiterates that producers have an obligation to warn consumers about inherent products risks which are not “immediately obvious” and makes clear that the presence of warnings does not exempt a producer from liability.¹⁸² Copying language from Article 3 of the 1992 Directive, Article 5(1) states,

Within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

- (a) be informed of the risks which these products might pose;
- (b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.¹⁸³

Notably, the GPSD clarifies that producers have an obligation to “adequately and effectively” warn consumers about dangerous products or recall products directly from consumers.¹⁸⁴ Under the 1992 Directive, producers only had an obligation to withdraw the product from the market and notify the Commission.¹⁸⁵ This amendment appears to have

181. *Id.* art 2(d), at 8.

182. *Id.* art. 5(1), at 9.

183. *Id.*

184. *Id.*

185. 1992 Directive, *supra* note 156, art. 3, at 26-27.

made the GPSD much more effective since consumers are being warned earlier about defective products.

In addition to requiring that producers notify consumers directly, Article 5 also requires that producers take specific measures to ensure that dangerous products do not find their way onto EU markets. Article 5(1) paragraph 4(a) requires that producers trace marketed products so that they can effectively monitor product safety. Appropriate tracing measures include “an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs”¹⁸⁶ The GPSD also requires that producers carry out sample testing, investigate and keep records of consumer complaints, and keep distributors informed of these activities.¹⁸⁷ These measures seek to ensure that products placed on the market are continuously monitored for possible issues and alleviates much of the confusion over economic operators duties under the 1992 Directive.

Distributors also have an obligation under Article 3(3) of the 1992 Directive and Article 5(2) of the GPSD to ensure that products placed on the market comply with the general products safety requirements. Article 5(2) makes clear that distributors are required to act with “due care” to ensure compliance with the directive.¹⁸⁸ Under this obligation, distributors cannot supply products which they know or should know do not comply with the safety requirements.¹⁸⁹ Distributors must also “participate in monitoring the safety of products placed on the market, especially by passing on information regarding product risks, keeping and providing the documentation necessary for tracing the origin of products, and cooperating in any action taken by producers and competent authorities to avoid risks.”¹⁹⁰ This provision ensures that distributors function as an additional safeguard for consumers and as an alert system for producers.

186. 2001 General Product Safety Directive, *supra* note 171, art. 5(1) para. 4(a), at 9.

187. *Id.* art. 5(1) para. 4(b), at 9.

188. *Id.* art. 5(2), at 10.

189. *Id.*

190. *Id.*

The GPSD also made significant amendments to the obligations and powers of member states. Article 8 relates to the enforcement measures authorities are entitled to take to ensure compliance with general safety requirements. In regards to products placed on the market, Article 8(1)(a) authorizes authorities to organize safety checks, collect information regarding products marketed in the state, and take and conduct tests on product samples.¹⁹¹ Most importantly, unlike the 1992 Directive, the GPSD includes provisions relating to warning labels. Article 8(1)(b) provides that authorities may:

- (i) require that it [the product] be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present; (ii) to make its [products] marketing subject to prior conditions so as to make it safe.¹⁹²

The 1992 Directive provided only that “suitable warnings be affixed” to the product.¹⁹³ Additionally, Article 8(1)(c) allows authorities to order economic operators to include special warnings for any product that could pose a risk to a particular subset of consumers.¹⁹⁴ Lastly, authorities may order that defective products be temporarily or permanently banned from the market as a safety precaution.¹⁹⁵

The most significant amendment to Article 8 dealt with the power of market surveillance authorities when dangerous products have already been placed on the market. Under Article 8(1)(f), authorities may “(i) order and organize its [dangerous product] actual and immediate withdrawal, and alert consumers to the risks it presents; (ii) order or coordinate or, if appropriate, to organize together with producers and distributors its recall from consumers and its destruction in suitable conditions.”¹⁹⁶ Under the 1992 Directive, national authorities had the power to organize the withdrawal and destruction of the product but were

191. *Id.* art. 8(1)(a), at 10.

192. *Id.* art. 8(1)(b), at 10.

193. 1992 Directive, *supra* note 156, art. 6(1)(d), at 27-28.

194. 2001 General Product Safety Directive, *supra* note 171, art. 8(1)(c), at 10.

195. *Id.* art. 8(1)(d), at 10; *Id.* art. 8(1)(e), at 10.

196. *Id.* art. 8(1)(f), at 10.

not specifically granted the power to alert consumers.¹⁹⁷ The GPSD explicitly gives national authorities the power to recall dangerous products and alert consumers of the risks.¹⁹⁸ As a result, consumers receive greater protection against dangerous products since producers can no longer quietly initiate recalls.

One of the most prominent issues that plagued the 1992 Directive was the fact that authorities within each member state did not have the resources to carry out their monitoring and enforcement obligations. As a result, Article 9 of the GPSD mandates that member states provide adequate resources to ensure effective market surveillance. Article 9(1) states,

Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include in particular:

(a) establishment, periodical updating and implementation of sectoral surveillance programs by categories of products or risks and the monitoring of surveillance activities, finding and results;

(b) follow-up and updating of scientific and technical knowledge concerning safety of products;

(c) periodical review and assessment of the functioning of the control activities and their effectiveness and, if necessary, revision of the surveillance approach and organization put in place.¹⁹⁹

Member states are also required to ensure that there are adequate channels through which consumers can submit product complaints.²⁰⁰ It is now unacceptable for member states to allow authorities to be understaffed or underfunded, which solves many of the problems that made national authorities ineffective under the 1992 Directive. In conjunction with requiring that national authorities have the appropriate

197. 1992 Directive, *supra* note 156, art. 6(1)(h), at 28.

198. 2001 General Product Safety Directive, *supra* note 171, art. 8(2), at 11.

199. *Id.* art. 9(1), at 11.

200. *Id.* art. 9(2), at 11.

resources to carry out their obligations, Article 9(1)(a) -(c) provides a framework for how national authorities can carry out those obligations.

The main RAPEX procedures established under the 1992 Directive were not substantially changed under the GPSD. However, the GPSD added provisions regarding notifications to other countries, non-member states, and the public. Article 12(4) states, “[a]ccess to RAPEX shall be open to applicant countries, third countries or international organizations”²⁰¹ As a result, the Commission and the U.S. Consumer Product Safety Commission “routinely share information with each other about dangerous products and product recalls that come to their attention.”²⁰² The GPSD now also makes product safety information available to the public. Article 16(1) provides,

[i]nformation available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public . . . [T]he public shall have access to information on product identification, the nature of the risk and the measures taken.²⁰³

The addition of these provisions provide a greater level of protection to consumers not just in the EU but throughout the world, and allows countries to work together to ensure that only safe products are placed on any market.

Notably absent from any provision in the GPSD are penalties for breach of the general product safety requirement. Currently, penalties for breach of the GPSD are implemented by member states and vary considerably.²⁰⁴ For example, economic operators in the United Kingdom who breach the GPSD may be subject to fines up to 20,000 pounds or 12 months in prison.²⁰⁵ In the Czech Republic, breaches can be penalized by a fine of up to CZK 50 million, 8 years in prison, or sanctions on the activity of the producer.²⁰⁶ In Sweden, economic operators can be subject

201. *Id.* art. 12(4), at 12.

202. Hogan Lovells, *supra* note 154, at 7.

203. 2001 General Product Safety Directive, *supra* note 171, art. 16, at 13.

204. Hogan Lovells, *supra* note 154, at 7.

205. *Id.*

206. *Global Product Liability Guide: Czech Republic*, DLA PIPER

to a fine ranging from SEK 5,000 to SEK 5 million and an export prohibition.²⁰⁷ Given that penalties vary so widely across member states, the GPSD will likely be reformed to harmonize penalties and dissuade economic operators from breaching their obligations.

On January 1, 2009, the Commission issued a report to the European Parliament and Council on the implementation of the GPSD.²⁰⁸ Overall, the Commission found that the GPSD has been effective in ensuring that only safe products are placed on the market. However, the Commission noted that there was concern over member states transposition of the directive.²⁰⁹ The report also raised the possibility of including more regional and international organizations into RAPEX.²¹⁰ Most importantly, the Commission found that unlike under the 1992 Directive, economic operators have taken the GPSD seriously and have even implemented measures within their businesses to contain risks posed by dangerous products.²¹¹ However, the Commission did find that amendments could be made to the traceability provisions to make it mandatory for economic operators to put their contact information directly on the product or its packaging.²¹²

IV. RECENT DEVELOPMENTS IN EU PRODUCT LIABILITY LAW

Although the GPSD was an integral step towards assuring increased consumer safety in the EU, reports from the Commission noted multiple areas under which the GPSD could be improved. As discussed above, the

<http://www.dlapiperproductliability.com/countries/czech-republic.html> (last visited Feb. 22, 2014).

207. *Global Product Liability Guide: Sweden*, DLA PIPER

<http://www.dlapiperproductliability.com/countries/sweden.html> (last visited Feb. 22, 2014).

208. *Report from the Commission to the European Parliament and to the Council on Implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety*, at 4, COM (2008) 905 final (Jan. 14, 2009) [hereinafter Commission Report on 2001 Directive].

209. *Id.* at 13.

210. *Id.*

211. *Id.*

212. *Id.* at 14.

Commission was most concerned over the traceability of products, penalties for non-compliance, and differing interpretations regarding the scope of the GPSD. In light of these concerns, on February 13, 2013, the Commission introduced a reformed Product Safety and Market Surveillance Package to the European Parliament, the Council, and the European Economic and Social Committee.²¹³ Projected to come into force in 2015, the Package will significantly alter economic operators and market surveillance authority's obligations.²¹⁴ Some of the more notable measures include country of origin labeling, penalties for non-compliance, repeat offender labeling, and new market surveillance and reporting obligations.²¹⁵ The Package includes two new regulations which will be the focus of this section: the General Product Safety Regulation ("GPSR"), which covers all consumer products not regulated by sector specific regulation, and the Market Surveillance of Products Regulation ("MSPR"), which covers market surveillance and enforcement.²¹⁶ The proposed Package also includes a Multi-Annual Action Plan for Market Surveillance that is beyond the scope of this Article.

A. The GPSR

The first regulation of the proposed Package is the GPSR. Following the Commission's report on implementation of the GPSD, the Commission held public consultations with national authorities, economic operators, experts, and consumer organizations concerning revision of the directive.²¹⁷ Following these consultations, the Commission introduced the GPSR, which "imposes clear and detailed

213. Communication on More Product Safety, *supra* note 2, at 1-9.

214. Rod Freeman, *Newsflash: Long live the Evolution! European Commission unveils proposals to reform product safety regime*, HOGAN LOVELLS (Feb. 14, 2013) <http://ehoganlovells.com/cv/f5f4ec85c4046f77b4544a801eee3592dc4d76c9>.

215. *Id.*

216. *Id.*

217. *Product Safety and Market Surveillance Package: Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC*, at 3, COM (2013) 78 final (Feb. 13, 2013) [hereinafter General Product Safety Regulation].

rules which do not give room for divergent transposition by Member States.²¹⁸ The first change made in the proposed GPSR concerns the scope of the regulation. While the proposed regulation is similar to Article 2 under the GPSD, the GPSR lays out specific products to which the regulation will not apply including medicinal products, antiques, food, materials intended to come into contact with food, living plants and animals, feed, animal by-products and derived products, plant protection products, and equipment on which consumers ride or travel.²¹⁹ The goal is to reduce economic operator's confusion regarding which piece of legislation applies to their products.

One of the most important additions to the proposed GPSR is the country of origin labeling requirement promulgated in Article 7. The requirement is part of a larger focus on ensuring traceability of products so that market surveillance authorities can be more effective in responding to defective product alerts. Article 7(1) states, “[m]anufacturers and importers shall ensure that products bear an indication of the country of origin of the product or, where the size or nature of the product does not allow it, that indication is to be provided on the packaging or in a document accompanying the product.”²²⁰ If this article is implemented, the likely effect will be a reduction in the number of instances where products reported to RAPEX do not contain the manufacturer's information. Another benefit of this requirement is that it will be easier for market surveillance authorities and consumers to identify the manufacturer in cases where there is no contact information or the product is imported from a country outside the EU.

In addition to country of origin labeling requirements, manufacturers also have enhanced obligations under the proposed GPSR in regards to product labeling. Article 8(6) will require manufacturers to place a batch or serial number on the product that is “easily visible and legible for consumers.”²²¹ The GPSR will also make it easier for consumers and market surveillance authorities to locate the product manufacturer by requiring that contact information be included with the product. Article

218. *Id.* at 7.

219. *Id.* art. 2(3), at 12.

220. *Id.* art. 7(1), at 15.

221. *Id.* art. 8(6), at 16.

8(7) and Article 10(3) require that both the manufacturer and importer of a product provide their registered name or trademark, the address at which they can be contacted, and a single point of contact for their products.²²² These requirements will also lead to greater consumer protection and more effective market surveillance authorities since the manufacturer of the product will be easily identifiable.

The final significant provision introduced in the GPSR relates to penalties for non-compliance. Article 18 instructs member states to implement penalties for economic operators who do not comply with the regulations.²²³ Specifically, “[t]he penalties provided for must be effective, proportionate and dissuasive.”²²⁴ Article 18(2) also provides that, “[t]he penalties . . . shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringement.”²²⁵ The possibility of large fines and criminal sanctions is likely to deter companies from paying multiple fines while continuously placing dangerous products on the market. The fact that the penalty would be proportionate to the size of the economic operator also adds an additional deterrence effect for large scale economic operators. The proposed GPSR has the potential to further enhance general product safety in the EU and makes the necessary changes to the legislative framework to resolve the problems currently affecting the GPSD.

B. The MSPR

The second proposed regulation in the Package is the MSPR. This regulation merges the market surveillance provisions of the GPSD, Regulation 765/2008, which sets out accreditation requirements for market surveillance authorities, and various other pieces of sector-

222. *Id.* art. 8(7), art. 10(3), at 16-17.

223. *Id.* art. 18, at 21.

224. *Id.*

225. *Id.*

specific legislation into one framework.²²⁶ The goal of the MSPR is to establish a coherent framework for market surveillance in one piece legislation.²²⁷ Similar to the GPSD, the MSPR will require that each member state establish a market surveillance authority and provide adequate resources so that authorities can carry out their obligations.²²⁸ Authorities will be obligated to perform regular inspections on product characteristics, carry out documentary and laboratory checks, alert consumers of product risks, allow consumers to submit product complaints, and verify that corrective action is being taken by economic operators.²²⁹ Most importantly, authorities will now be allowed to enter the premises of manufacturers, importers, and distributors facilities to test products.²³⁰ Along with allowing authorities access to products, economic operators are required to provide the authorities with any documentation that is needed to carry out their obligations, including information that allows authorities to trace the product.²³¹ These measures will help strengthen the market surveillance framework and provide authorities with more effective tools to ensure compliance.

Market surveillance authorities will also have expansive power under the MSPR to remedy situations involving defective products. First, market surveillance authorities will be obligated to carry out a product risk assessment, taking into account any relevant tests that have already been conducted.²³² If authorities find that the product presents a risk to consumers, they can specify the remedial actions that economic operators must to take within a specified period of time or carry out the remedy

226. *Product Safety and Market Surveillance Package: Proposal for a Regulation of the European Parliament and of the Council on Market Surveillance of Products*, at 0, COM (2013) 75 final (Feb. 13, 2013) [hereinafter *Market Surveillance of Products Regulation*].

227. Comm. on the Internal Mkt. and Consumer Prot., Report on the Revision of the General Product Safety Directive and Market Surveillance, 5, A7-0033/2011 (Feb. 24, 2011).

228. *Market Surveillance of Products Regulation*, *supra* note 226, art. 5, at 17.

229. *Id.* art. 6, at 17.

230. *Id.* art. 4, at 16-17.

231. *Id.* art. 8, at 19.

232. *Id.* art. 9, at 20-21.

themselves.²³³ Corrective action may include attaching warnings to the product, alerting consumers to the danger, temporarily preventing the marketing of the product, withdrawing or recalling the product, prohibiting the product from being placed on the market, or destroying the product.²³⁴ However, in cases of non-compliance regarding products that do not present a serious risk, authorities must allow an economic operator ten days to explain why action has not been taken.²³⁵ In the case of a product that poses a serious risk, authorities may take corrective action without first informing the economic operator.²³⁶ Additionally, if authorities have to take corrective action, the economic operator will bear the cost.²³⁷ These provisions will clarify much of the confusion prevalent under the GPSD and streamline the market surveillance process to make it more effective and easier to implement.

The final improvement that will be brought about by the adoption of the MSPR relates to the exchange of information between member states, the Commission, and other countries. Although the MSPR will retain RAPEX, the notification system will be greatly improved so as to allow authorities to receive more detailed information about product defects. The MSPR proposes that each member state select a single contact point who will notify the Commission directly of actions taken by economic operators, market surveillance authorities, or external border controls.²³⁸ The RAPEX contact will have a duty to provide details regarding the nature and level of risk, any non-compliance with the regulation, the product's identity, the product's origin and supply chain, and any corrective actions taken.²³⁹ The Commission will then communicate the information to other EU member states and any countries that have signed an agreement to participate in the RAPEX

233. *Id.*

234. *Id.*

235. *Id.* art. 10, at 21-23.

236. Market Surveillance of Products Regulation, *supra* note 226, art. 10(4), at 22.

237. *Id.* art. 10(2), at 22.

238. *Id.* art. 19, art. 20, at 29-30.

239. *Id.* art. 20(2), at 29.

system.²⁴⁰ Overall, the MSPR will simplify the process for economic operators and facilitate greater cooperation between authorities.

C. EU Parliament Endorsement and Conclusions about the Proposed Package

The European Parliament Committee on the Internal Market and Consumer Protection voted to endorse the proposed Package on October 17, 2013.²⁴¹ Notably, the Committee on the Internal Market and Consumer Protection approved of the controversial country of origin labeling requirements and proposed that the Package include a voluntary requirement for an “EU safety tested” label.²⁴² The endorsement also signaled support for provisions relating to penalties for non-compliance and suggested that the Commission create a “black-list” of economic operators who continuously breach the safety requirements.²⁴³ In general, the Package will strengthen market surveillance, reduce confusion, and provide consumers with an even greater level of protection against defective products.

CONCLUSION

After analyzing product liability laws in the EU and U.S., it becomes apparent that both regimes have taken significant steps to revise and implement laws that provide a fair balance between the interest of consumers and manufacturers. Although both product regimes were founded on the concept of strict liability, overtime evolution of the laws created distinct differences that both positively and negatively impact each regime. On the whole, it appears that the combination of the EU Product Liability Directive and GPSD provide greater harmonization for product liability law across all member states than the Restatement

240. *Id.* art. 20, at 29-30.

241. Rod Freeman, *European Parliament Committee Endorses Proposed Consumer Product Safety Reforms*, INT’L CONSUMER PROD. HEALTH & SAFETY ORG., <http://www.icphso.org/newsletters/2013/enews112213.html> (last visited Feb. 26, 2014).

242. *Id.*

243. *Id.*

(Third) does in the U.S. However, the EU regime is not without its faults. Although the regime may function better in terms of consumer protection, the U.S. regime under a risk utility analysis provides a more comprehensive and effective system for manufacturers than the EU's consumer expectations test. This is one area that the EU should consider reforming when it looks to adopt the proposed Product Safety and Market Surveillance Package in 2015. The Package, composed of the GPSR and MSPR, will overhaul economic operator's obligations and market surveillance provisions. Such reform will have a significant impact for consumers and economic operators in the EU.

The original version of this Article has been shortened for publication. To obtain a copy of the full Article, please contact Lauren Sterrett at sterret4@msu.edu.

