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PRODUCT LIABILITY LAWS IN THE
EUROPEAN COMMUNITY IN 1992

GREGORY G. SCOTT†

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I. INTRODUCTION

The European Community is rapidly developing comprehensive strict liability rules for uniform application within the EC. This development advantages U.S. manufacturers that export to the EC because they no longer need to comply with the various products liability laws within each EC member state. A disadvantage, however, is that while the new EC liability laws resemble U.S. law, they also depart from U.S. law in many respects.

This Article explains EC products liability law by first presenting the principles underlying U.S. products liability law and then using them to illustrate EC products liability law. The Article begins in Part II by comparing U.S. and EC strict liability laws generally and then, in Parts III and IV, compares the more specific design and manufacturing defect and failure to warn theories. Part V introduces and discusses the EC’s proposed strict services liability laws. Part VI discusses the liability of product endorsers and how, if strict services liability laws are adopted, manufacturers may have third-party claims against them.
II. COMPARISON BETWEEN UNITED STATES AND EUROPEAN COMMUNITY STRICT LIABILITY LAWS

A. Restatement Section 402A and the Strict Liability Directive Compared

1. General Principles of Strict Liability

In the United States, the principle of strict liability, which developed in the 1960s, is codified in section 402A of the Re- statement (Second) of Torts. Most states have expressly adopted this principle. The general rule of section 402A is that one who sells a product in a defective condition, thus making it unreasonably dangerous to the user or consumer or his property is liable to the user or consumer for injuries or property damage that are caused by the product, and the seller must be in the business of selling the product that causes injury. The product must reach the user in substantially the same condition in which it is sold. The seller is liable under this principle even where it has exercised all possible care. Whether a product is "unreasonably dangerous" depends upon whether the product has adequate warnings or instructions, and whether it is reasonably designed.

In the European Community, a similar principle of strict lia-
bility is found in Council Directive 85/374 of July 25, 1985 on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products, otherwise known as the Strict Liability Directive. Article 1 of this directive provides, "The producer shall be liable for damage caused by a defect in his product." This general statement of liability is similar to that found in section 402A. Both rules provide that sellers are liable for injuries caused by defects in products, irrespective of "fault" or other concepts of negligence. How closely these principles parallel each other in the United States and European Community depends upon how similarly the key terms under the respective statements are defined.

2. Key Terms Affecting Liability

Three basic terms must be defined to understand the application of the principle of strict liability in U.S. law. These are "seller," "product," and "defective condition unreasonably dangerous." Under the EC directives, the relevant terms are "producer," "product," and "defect." as to the product's characteristics." See also Prosser and Keeton, supra note 2, § 99, at 698.


10. Id.

11. See Restatement, supra note 1, § 402A cmt. f (applying § 402A to "any person engaged in the business of selling products for use or consumption").

12. Id. § 402A cmt. d (the term product includes "any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer").

13. Id. § 402A cmt. i (an unreasonably dangerous article "must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics").

14. Strict Liability Directive, supra note 9, art. 3. The directive defines "producer" as "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." Id.

15. Id. art. 2. The directive defines product as "all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable." Id.

16. Id. art. 6. A product is defective when it "does not provide the safety which a person is entitled to expect, taking all circumstances into account, including . . . the presentation of the product; the use to which it could reasonably be expected that the product would be put; [and] the time when the product was put into circulation." Id.
a. Seller Versus Producer

It is clear under section 402A that strict liability applies only to persons engaged in the business of selling products for use or consumption—manufacturers, wholesalers, retailers, and distributors.\(^\text{17}\) It encompasses all entities in the production process from the supplier of raw materials, to the builder of component parts to the manufacturer of the finished product,\(^\text{18}\) and extends still further to the wholesalers, retailers, and distributors of the product.\(^\text{19}\) It does not, however, apply to the occasional or casual seller.\(^\text{20}\)

The Strict Liability Directive uses the term “producer” instead of seller and defines it in article 3 as follows: “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, trademark or other distinguishing feature on the product presents himself as its producer.\(^\text{21}\)

This definition is quite similar to the definition of “seller” in the United States in that it encompasses all persons in the chain of manufacture, from the raw material supplier to the retailer.\(^\text{22}\) Though no reference is made to the casual seller, article 7 of the directive provides a defense to a producer if a product was not manufactured by the producer for sale or for any form of distribution with an economic purpose.\(^\text{23}\) This indicates that a producer, like a seller, must be in the business of manufacturing the product in order to be found liable.

However, the directive’s definition of “producer,” like the U.S. definition, includes more than just manufacturers, retail-


\(^{18}\) See supra note 1, § 402A cmt. f. The rule set out in § 402A “applies to any manufacturer of . . . a product, [or] to any wholesale or retail dealer or distributor. . . . It is not necessary that the seller be engaged solely in the business of selling such products.” Id.

\(^{19}\) Id. § 402A cmt. f. “[T]he rule does not . . . apply to the occasional seller of food or other such products who is not engaged in that activity as part of his business.” Id.

\(^{20}\) Strict Liability Directive, supra note 9, art. 3(1).

\(^{21}\) See supra notes 11 and 17-20 and accompanying text.

\(^{22}\) Strict Liability Directive, supra note 9, art. 7(c).
ers, and distributors. Sections 2 and 3 of article 3 of the Directive establish potential liability for persons who import products into the European Community for sale, hire, or lease. 24 A supplier of a product may also be treated as a producer unless it informs the injured person of the identity of the producer or of the person who supplied the product. 25 The scope of this definition is therefore roughly equivalent to that of “seller” in the United States.

b. Product Definition

“Product” under U.S. strict liability laws includes any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer. 26 It does not include services. The definition has evolved to include food intended for human consumption, 27 automobiles, 28 airplanes, 29 power presses, 30 insecticides, 31 and products intended for intimate bodily use, such as cosmetics. 32 Electricity is a product in most states, but supplying electricity is a service. 33

“Products” defined in article 2 of the directive are “all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable.” 34 Primary agricultural products may be included if a given member state so chooses. 35

The definition of a “movable,” however, is not clear under

24. Strict Liability Directive, supra note 9, art. 3(2), 3(3).
25. Id.
26. Restatement, supra note 1, § 402A cmt. d.
27. See, e.g., Mazetti v. Armour & Co., 135 P. 633 (Wash. 1913) (discussing liability of a food manufacturer for a product which included “a foul, filthy, nauseating and poisonous substance”).
32. See, e.g., Rogers v. Toni Home Permanent Co., 147 N.E.2d 612 (Ohio 1958) (finding liability for a defective “home permanent” for hair, which caused injury).
33. See, e.g., Houston Lighting & Power Co. v. Reynolds, 765 S.W.2d 784 (Tex. 1988) (holding that electricity is a product); Scharner v. Pennsylvania Power & Light Co., 501 A.2d 1128 (Pa. 1985) (holding that electricity becomes a product only upon passing through customer’s meter).
34. Strict Liability Directive, supra note 9, art. 2.
35. Id. Each member state may “by way of derogation from Article 2, provide in
the directive. If it is read to mean goods, as defined in the Uniform Commercial Code (UCC), the term could be read more narrowly than "product" under section 402A. Section 2-105(1) of the UCC defines "goods" as "all things . . . which are movable at the time of identification to the contract for sale."36 Many items considered "products" for strict liability purposes are not necessarily "goods" under the UCC.37 This interpretation is more narrow than the U.S. definition of product. If, on the other hand, the definition is not so restricted, and is taken literally to mean anything movable, the term may be as broad as the definition under section 402A. However, even fixtures—items actually attached to real property that are not "movable"—can be "products" under U.S. strict liability laws.38

c. "Defect" Versus "Defective Condition Unreasonably Dangerous"

The phrase "defective condition unreasonably dangerous" is the most important in strict liability law. It is defined in various ways in various states.39 The section 402A definition provides that the product must be more dangerous than would be contemplated by the ordinary consumer purchasing it with the knowledge common to the community. There are generally three different types of defects: design,40 manufacturing,41

its legislation that within the meaning of Article 1 of this directive 'product' also means primary agricultural products and game." Id.


37. Section 402A includes "any product [sold] in a defective condition . . . if (a) the seller is engaged in the business of selling such a product, and (b) [the product] is expected to and does reach the user or consumer without substantial change in the condition in which it is sold." Restatement, supra note 1, § 402A(1).


39. See, e.g., Lindsay v. McDonnell-Douglas Aircraft Corp., 460 F.2d 631 (8th Cir. 1972); Lester v. Magic Chef, Inc., 641 P.2d 353 (Kan. 1982); Restatement, supra note 1, § 402A cmt. g.

40. See, e.g., Leichtamer v. American Motors Corp., 424 N.E.2d 568 (Ohio 1981) (holding that strict liability principles apply to the design of a jeep rollbar, which did not withstand back-to-front flip over); General Motors Corp. v. Simmons, 545 S.W.2d 502 (Tex. Ct. App.) (finding manufacturer liable for the loss of an eye resulting from defective automobile window glass which shattered into small particles), rev'd on other grounds, 558 S.W.2d 855 (Tex. 1977).
and inadequate warnings and instructions. Generally, a plaintiff must prove that the product is both defective and unreasonably dangerous.

Many courts have found the Restatement's test to be unworkable. It is commonly referred to as the "consumer expectation test" because it focuses on the expectations of the ordinary consumer who purchases the product. The test is generally easy to state but difficult to apply. How does it apply, for example, to obvious defects known to the consumer? How is the "ordinary consumer" defined? Because of such problems, courts have developed other definitions.

The leading alternative definition is called the risk utility test. In essence, the test calls for weighing the utility of the product against the risks inherent in its use. Factors considered include the usefulness and desirability of the product.

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42. RESTATEMENT, supra note 1, § 402A cmts. h, j; see also Ross Labs. v. Thies, 725 P.2d 1076 (Alaska 1986). Notwithstanding the "strict liability" label, failure to warn cases are better characterized as decisions based on negligence principles. Many courts, for example, have held that there is no duty to warn of dangers which are generally known or recognized. See, e.g., Maguire v. Pabst Brewing Co., 387 N.W.2d 565 (Iowa 1986) (no duty to warn of danger associated with excessive consumption of alcohol).
43. RESTATEMENT, supra note 1, § 402A cmt. i. "[T]he rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer." Id.
44. Barker v. Lull Eng'g Co., 573 P.2d 443, 446 (Cal. 1978) (expressly rejecting the Restatement approach, which would have required that the plaintiff show the product was unreasonably dangerous).
45. RESTATEMENT, supra note 1, § 402A cmt. j. "Where . . . the product [or its] . . . ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it . . . ." Id.
46. For example, some courts have replaced the "ordinary consumer" with a "foreseeable user" for the purpose of extending the law's protection to non-purchasers. Bellotte v. Zayre Corp., 352 A.2d 723, 725 (N.H. 1976) (holding that a child who lacks the ability to appreciate a dangerous product is still protected under strict liability laws). See also Prosser and Keeton, supra note 2, § 99, at 698 & n.24 (stating that what would be contemplated by purchaser or consumer may not be contemplated by a foreseeable user).
48. Prosser and Keeton, supra note 2, § 99, at 699. "Under this test, a product can be said to be defective in the kind of way that makes it 'unreasonably dangerous' if a reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product." Id.
49. Id. The test looks to design and marketing, availability of alternative products, and alternative designs.
the likelihood and seriousness of injury, the availability of an alternative product, the ability of the manufacturer to eliminate the unsafe characteristic of the product, the user's ability to avoid the danger, the user's awareness of the danger, and the manufacturer's ability to spread losses through pricing and insurance. This test is most commonly used in design defect cases where the ordinary consumer would not form an expectation with regard to a relevant safety feature.

The concept of "defect" is defined in article 6 of the directive as follows:

1. 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.
2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.

While this definition seems to be more closely aligned to the consumer expectation test than to the risk-utility test, it contains elements of both tests. On the one hand, the basic standard is "the safety which a person is entitled to expect," which is quite similar to the component of the consumer ex-

50. See, e.g., Knitz v. Minster Mach. Co., 432 N.E.2d 814, 818 (Ohio 1982) (holding that the likelihood of injury is a relevant factor in determining whether a defect exists).
51. See, e.g., Dawson v. Chrysler Corp., 630 F.2d 950, 957 (3d Cir. 1980) (alternative design available to make police car more crashworthy); Reeves v. Cincinnati, Inc., 439 N.W.2d 326, 329 (Mich. Ct. App. 1989) (allegation that alternative design incorporating safety guard was available for power press is admissible to demonstrate defectiveness).
52. See, e.g., Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 414-15 (Colo. 1986) (where plaintiff alleged that the oral contraceptive drug was defectively designed, the court gave jury instructions on unavoidable danger); see also John W. Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825, 837-38 (1973).
53. Wade, supra note 52, at 837-38.
54. Id.
55. Id.
57. Strict Liability Directive, supra note 9, art. 6.
pection test in section 402A, which provides that the product "must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer." 59

However, under the directive, the definition of a defective condition also includes factors such as the use of the product and the presentation of the product. 60 These factors more closely resemble the risk-utility balancing test because they require the court to consider the utility of the product and whether the risks were communicated to the buyer. However characterized, plaintiffs generally will find it easier to prove a defect under this definition than under section 402A of the Restatement because it is not necessary to prove that the product is both defective and unreasonably dangerous.

"Presentation of the product" undoubtedly includes warnings and instructions, as in section 402A of the Restatement. This means that, like section 402A, the Strict Liability Directive may impose liability where the warnings and instructions on a product are found to be inadequate. 61 This phrase may also create liability for how the product is displayed or advertised. This would be similar to U.S. law dealing with misrepresentations and the dilution of warnings or instructions. 62

Though section 2 of article 6 of the directive makes clear that a product is to be judged at the time it was manufactured, and not judged on the basis of subsequently developed products, 63 a producer may not be able to rely on the state of the art defense under the directive. Article 15, section 1(b), allows European Community member states to decide individually

59. See Restatement, supra note 1, § 402A cmt. i. To illustrate, comment i suggests: "Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fuel oil, is unreasonably dangerous." Id.

60. See Strict Liability Directive, supra note 9, art. 6.

61. See Strict Liability Directive, supra note 9, art. 7. A defense for a component manufacturer is 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." Id.

62. See, e.g., Little v. Liquid Air Corp., 952 F.2d 841 (5th Cir. 1992); Mozeke v. International Paper Co., 933 F.2d 1293 (5th Cir. 1991).

63. See Strict Liability Directive, supra note 9, art. 6(2). A "product shall not be considered defective for the sole reason that a better product is subsequently put into circulation." See also id. art. 7(e). "The state of scientific and technical knowledge at the time when [the producer] put the product into circulation was not such as to enable the existence of the defect to be discovered . . . ." Id.
whether state of the art will be a defense under the directive.64 In the United States, the state of the art at the time the product was manufactured is a factor to be considered by the jury in deciding whether the product is defective.65

3. Defenses to a Strict Liability Claim

There are a number of defenses to a strict liability claim in the United States. For example, a manufacturer may show that the plaintiff has failed to prove the basic elements of a strict liability claim required by section 402A,66 or that the product has been substantially altered since it left the manufacturer’s possession.67 A manufacturer also may show that the product is not defective by showing compliance with the state of the art68 or with government standards.69 This evidence will be considered by the jury, but will not be conclusive in proving a defect. A manufacturer may also rely on a statute of limitations70 or a statute of repose71 to avoid old claims. Of course, 64. Strict Liability Directive, supra note 9, art. 15. Article 15(b) provides in relevant part,

By way of derogation from Article 7(e), [each Member State may] maintain or, subject to the procedure set out in paragraph 2 of this article, provide in this legislation that the producer shall be liable even 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 a defect to be discovered.

Id.

65. See, e.g., O’Brien v. Muskin Corp., 463 A.2d 298, 305-06 (N.J. 1983) (holding that, notwithstanding the absence of a safer alternative design at the time the product, a swimming pool, was marketed, the jury was entitled to consider whether the risk of injury so outweighed the swimming pool’s utility that liability should be imposed).

66. See supra Part II.A.3. for a discussion of defenses to a § 402A claim.

67. Restatement, supra note 1, § 402A(1)(b). The seller of product is subject to liability where the product is sold in a defective condition unreasonably dangerous, and “it is expected to and does reach the user or consumer without substantial changes in the condition in which it was sold.” Id.

68. See, e.g., Clarksville-Montgomery County Sch. Syst. v. United States Gypsum Co., 925 F.2d 993 (6th Cir. 1991) (holding that state of the art evidence is admissible and represents “the amount or extent of scientific and technological knowledge available to the manufacturer or seller [of the product] at the time the product was placed on the market”). Id. at 1005.

69. See, e.g., Shipp v. General Motors Corp., 750 F.2d 418 (5th Cir. 1985) (compliance with government standard is persuasive, but not necessarily conclusive, evidence against a finding of defective design).

70. See, e.g., Digioia v. H. Koch & Sons, 944 F.2d 809 (11th Cir. 1991); Kullman v. Owens-Corning Fiberglass Corp., 943 F.2d 613 (6th Cir. 1991).

71. See, e.g., Anderson v. M.W. Kellogg Co., 766 P.2d 637 (Colo. 1988) (holding that liability was barred by 10-year statute of repose governing claims for personal
the manufacturer may also argue that a plaintiff's own conduct or misuse of the product caused the accident, or that there were other causes of the accident in addition to, or to the exclusion of, its product. The Strict Liability Directive contains a number of similar defenses scattered throughout articles 7, 8, 10, 11, and 17. For example, under article 7(b), a producer will not be liable if it can prove that the defect did not exist at the time the product was put into circulation. If the defect resulted from an alteration, this proof is similar to a substantial alteration defense. However, it is not clear how this defense relates to a producer's potential post-sale obligations under the Proposed Product Safety Directive discussed below.

The producer also will escape liability if it can prove that it did not put the product into circulation, or that the product was not manufactured in the course of business or for an economic purpose. This is similar to a defense under section 402A that the seller is only an occasional seller and is not in the business of selling the product. The producer also is not liable if it can prove that the defect in the product is due to compliance with mandatory regulations issued by public authorities. Professor Taschner and others have indicated that this provision will be strictly construed and very narrowly applied. The only possible coun-

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73. See, e.g., Watson v. Lucerne Mach. and Equip. Inc., 347 So. 2d 459 ( Fla. Dist. Ct. App. 1977) (finding no liability for manufacturer where death was caused by reckless disregard of supervisor's warnings to stay away from a citrus processor which presented obvious dangers during operation).
74. Strict Liability Directive, supra note 9, art. 7(b).
75. RESTATEMENT, supra note 1, § 402A(1)(b).
77. Strict Liability Directive, supra note 9, art. 7(a).
78. Id. art. 7(c).
79. RESTATEMENT, supra note 1, § 402A(1)(a) cmt. f. Seller "applies to any person engaged in the business of selling products for use or consumption ... [but] does not . . . apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business." Id.
80. Strict Liability Directive, supra note 9, art. 7(d).
terpart in U.S. law is the military contractor defense under which manufacturers are not liable where their products are found to be defective as a result of complying with specifications provided by the military. In the United States, compliance with voluntary standards like those promulgated by the American National Standards Institute, the Occupational Safety and Health Administration, and other groups and agencies is not an absolute defense, but only a factor to be considered by the jury in deciding whether the product is defective.

Unlike U.S. law, where compliance with state of the art is merely a factor for the jury to consider in deciding whether a product is defective, member states that allow the state of the art defense consider compliance to be an absolute defense under the European Community’s Strict Liability Directive. In fact, all of the defenses listed under article 7 are absolute defenses. The first sentence of article 7 provides that “the producer shall not be liable . . . if he proves,” and then lists six separate circumstances in which the producer will not be held liable for damage or injury caused by a defective product.

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371 Practising Law Institute 81 (1989) (noting that article 7 of the Strict Liability Directive has been worded to give courts a duty of careful review); see also Hans C. Taschner, La Future Responsabilité du Fait des Produits Défectueux dans la Communauté Européenne, Revue du Marché Commun 257 (1986).


83. Strict Liability Directive, supra note 9, art. 7 (defenses available to producers).

84. Id. Article 7 provides:
   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 afterward; 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.

Id.
Under article 8 of the Strict Liability Directive, the liability of a producer may be reduced or disallowed when damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.\textsuperscript{85} This is similar to U.S. notions of assumption of the risk\textsuperscript{86} and comparative fault.\textsuperscript{87} However, the Strict Liability Directive does not specify how the reduction of liability is to be applied or calculated. It is unclear whether a plaintiff who is fifty-one percent responsible for his injuries will be allowed to receive forty-nine percent of the verdict, or be totally barred from a recovery.

Article 10 of the Strict Liability Directive provides a statute of limitations.\textsuperscript{88} However, the limitations period depends in part on existing laws on limitations periods within member states. Strict liability statutes of limitations in the United States vary from two to eight years,\textsuperscript{89} and generally begin to run when the plaintiff becomes aware of the injury.\textsuperscript{90} A strict liability action must be initiated within three years from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect, and the identity of

\textsuperscript{85}. Strict Liability Directive, supra note 9, art. 8(2). "The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible." Id.

\textsuperscript{86}. See, e.g., Vargas v. Pitman Mfg. Co., 510 F. Supp. 116 (E.D. Pa.) (holding that where plaintiff voluntarily exposes herself to a known or obvious danger, plaintiff is deemed to have assumed the risk of harm and cannot recover), aff'd, 673 F.2d 1304 (3d Cir. 1981).

\textsuperscript{87}. See, e.g., Austin v. Raybestos-Manhattan, Inc., 471 A.2d 280 (Me. 1984) (holding that all tort actions are subject to a comparative negligence statute); Duncan v. Cessna Aircraft Co., 665 S.W.2d 414 (Tex. 1984) (holding that contributory negligence focuses on the reasonableness of actor's conduct). But see Simpson v. General Motors Corp., 483 N.E.2d 1 (Ill. 1985) (consumer's failure to discover or guard against product defect should not be used as a damage-reducing factor).

\textsuperscript{88}. Strict Liability Directive, supra note 9, art. 10.

\textsuperscript{89}. See Sidney-Vinstein v. A.H. Robins Co., 697 F.2d 880 (9th Cir. 1983) (ruling that one-year statute of limitations had run against plaintiff suing manufacturer of Dalkon Shield); Franzen v. Deere & Co., 334 N.W.2d 730 (Iowa 1983) (two-year statute of limitations applies in strict liability actions); Dortch v. A.H. Robins Co., 650 P.2d 1046 (Or. 1982) (eight-year statute of limitations applies to strict liability actions).

\textsuperscript{90}. See, e.g., Britt v. Arvanitis, 590 F.2d 57 (3d Cir. 1978) (action for selective wire surgical suture accrued when plaintiff discovered defect); Wojcik v. Almase, 451 N.E.2d 336 (Ind. 1983) (cause of action accrued when catheter broke in body, not when it was discovered); Snell v. Columbia Gun Exchange, Inc., 278 S.E.2d 333 (S.C. 1981) (cause of action accrued at time defective pistol discharged).
the producer. 91 The statute of limitations under the Strict Liability Directive is much more generous, because the limitations period does not begin to run until the defect and identity of the producer are also revealed to the plaintiff. 92

Some states in the United States have statutes of repose, but many do not. 93 Under article 11 of the directive, no suits may be brought later than ten years from the date on which the producer put the product into circulation. 94

Lastly, under article 17 of the directive, a manufacturer may be able to defend against a strict liability claim by proving that the product that caused the damage was put into circulation before the Strict Liability Directive was implemented in the member state of venue. 95 This defense certainly will disappear over time, but should be quite viable during the early years of the applicability of the directive.

III. PRODUCT SAFETY AND DESIGN

A. Proposed Product Safety Directive

The European Community considers product safety a basic requirement to the creation of the one-market system. The European Community's commitment to product safety is reflected in the Proposed Directive Concerning General Product Safety. 96 The proposed directive establishes an overall requirement that no products should present "any risk" or "only those [risks] reduced to such a level ... considered as acceptable and consistent with a high standard of protection for the

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91. See supra note 90.
92. Strict Liability Directive, supra note 9, art. 10(1). But see id. art. 10(2) ("The Laws of Member States regulating suspension or interruption of the limitation period shall not be affected by this directive.").
93. Strict Liability Directive, supra note 9, art. 11. A statute of repose is distinguishable from a statute of limitations in that a statute of repose cuts off all rights to legal action after a specified time. Kline v. J.I. Case Co., 520 F. Supp. 564, 567 (D.C. Ill. 1981). This time is usually measured from the delivery of a product or the completion of work, regardless of time of accrual of a cause of action or notice of invasion of legal rights. See, e.g., Universal Eng'g Corp. v. Perez, 451 So. 2d 463, 465 (Fla. 1984).
94. Strict Liability Directive, supra note 9, art. 11.
95. Id. art. 17. "This directive shall not apply to products put into circulation before the date on which the provisions referred to in Article 19 enter into force." Id.
safety and health of persons." It proceeds, in a rather radical way, to require permanent monitoring of marketed products to ensure that no unacceptable risks occur in the use of those products. It also places a duty on the individual countries to ensure that surveillance occurs. The legislation covers both consumer and non-consumer products. These provisions go far beyond anything that has been required in the United States.

The need for more precise warning labels is clearly delineated in the Proposed Product Safety Directive. Article 3 requires that warnings "provide the potential user or consumer with the relevant information to enable him to assess the risks presented by a product when such risks are acceptable as such but are not immediately obvious and are not insignificant . . . ."

This proposed directive is clearly supplementary and does not restrict the applicability of the Strict Liability and Machinery Directives. Its impact will be substantial. It inevitably will result in increasingly severe safety standards being placed on products. Its labeling and monitoring requirements go far beyond anything currently required by American products liability law. Depending on the extent to which risk assessment or cost benefit analysis is made a part of European Community strict liability law, the implications of this directive for product manufacturers, and the impact on their potential liability, will be significant.

B. The Machinery Directive


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97. Id. art. 2(b) ("safe product").
98. Id. art. 3.
99. Id. art. 5.
100. Id. art. 2(a).
102. Proposed Product Safety Directive, supra note 96, art. 3(2).
103. See id. pmbl., art. 13.
Product Safety Directive will be implemented. Also, when read in conjunction with the Strict Liability Directive, the Machinery Directive has potentially great ramifications for U.S. companies selling machinery in the EC.

The Machinery Directive creates uniform design and safety requirements for machinery. It has the dual purpose of promoting safety and eliminating barriers to trade arising from the member states' differing safety standards. The directive requires manufacturers, or their authorized representatives, to certify, in accordance with specified procedures, that their products comply with European Community standards. The precise certification procedures to be followed depend upon the type of product involved. Certain types of machines are subject to more restrictive certification procedures. Manufacturers selling products in Europe after 1992 must be familiar with the certification process.

1. Harmonization and Mutual Recognition

To understand how the Machinery Directive is intended to operate, one must first understand the concepts of "harmonization" and "mutual recognition" and how they relate to the single market system. The free circulation of products, including machinery, within Europe requires that the technical standards used to design and construct those products be uniform or "harmonized." Otherwise, the differing technical standards of the member states will continue to be a barrier to the free flow of goods. The European Community has concluded that this "harmonization" of technical norms is necessary to protect health, safety, and the environment.

Historically, the adoption of binding regulations at the European Community level required the unanimous agreement of all member states. Initially, little progress was made toward the unification of the European Community because unanimity was nearly impossible to achieve. Now, the principle of
"mutual recognition" permits the European Community to proceed by way of directives, such as the Machinery Directive, which require all member states to pass consistent implementing legislation. The process of unifying the laws of the European Community may be compared to a system in the United States which would require acts of Congress to be approved by all fifty states. The Machinery Directive is an example of the new "mutual recognition" approach to harmonization, which means that implementing legislation can contain some local provisions that do not change a directive's basic provisions.

2. The Directive's Purpose

The clear purpose of the Machinery Directive is to establish a high level of machine safety for consumers and workers. It is therefore consistent with the strong consumer protection purpose of the Strict Liability Directive. The Machinery Directive is, in part, a recognition that the member states "are responsible for insuring the health and safety on their territory of their people . . . and in particular, of workers notably in relation to the risks arising out of the use of machinery." The focus on protecting workers is illustrated by the special treatment given certain types of industrial products. Seven annexes expand upon and implement the thirteen articles of the directive.

The directive seeks to improve machine safety in the member states and proclaims that the "social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installations and maintenance." In addition, in keeping with the fundamental goal of creating one market and removing obstacles to the movement of products within the European Community, the Machinery Directive

111. Id. at 48; see also Machinery Directive, supra note 104, ch. IV, art. 13.
112. See BREALEY & QUIGLEY, supra note 109, at 49; see also Machinery Directive, supra note 104, pmbl., at 9-10.
116. Id. ch. II, art. 8(2), annex IV (imposing stricter certification requirements on specified woodworking and molding machines).
117. Id. annex I-VII.
118. Id. pmbl., at 9-10.
establishes a certification procedure by which products are deemed safe and are therefore entitled to be freely distributed within the EC.  

In keeping with the goal of raising the current level of machinery safety, the directive requires manufacturers to take measures "to eliminate any risk of accident throughout the foreseeable lifetime of the machinery."  

Manufacturers are also required to inform users of machinery "of the residual risk due to any shortcomings of the protection measures adopted," as well as to design the machinery "to prevent abnormal use if such use would engender a risk." While these safety objectives likely will result in increased consumer protection, U.S. manufacturers must realize that accomplishment of these objectives may require a heightened awareness of safety issues.

3. The Directive's Scope: What Constitutes "Machinery"

The Machinery Directive applies to broad categories of machinery. Article 1, section 2, states: "For the purposes of this Directive, 'machinery' means an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material." Section 2 continues, "the term 'machinery' also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole." Machinery also means "interchangeable equipment."

This is obviously a very broad definition. In determining whether a particular product falls within the definition, the breadth of the definition, considered with the consumer safety purpose of the directive, likely requires an inclusive interpretation, especially in the absence of other directives specifically covering the product. However, certain products are specifi-

119. Id. ch. II, art. 8.
120. Id. annex I, § 1.1.2(a).
121. Id. annex I, § 1.1.2(b).
122. Id.
123. Id. ch. I, art. 1(2).
124. Id.
125. Id.
ally excluded from the scope of the definition. These include lifting equipment designed or constructed for raising or moving persons, machinery for medical use used in direct contact with patients, special equipment for use in fairgrounds or amusement parks, steam boilers, tanks and pressure vessels, machinery specially designed or put into service for nuclear purposes, radioactive sources forming part of a machine, firearms, and storage tanks and pipeline for petrol, diesel fuel, inflammable liquids, and dangerous substances.126

The Machinery Directive does not cover products specifically covered by other directives.127 At present, there are specific directives proposed or adopted relating to a number of products that probably fall within the scope of the Machinery Directive, including tower cranes,128 household appliances,129 hydraulic diggers,130 lawn mowers,131 toys,132 telecommunications equipment,133 motor vehicles,134 and agriculture and for-

126. Id. ch. I, art. 1(3).
127. Id. ch. I, art. 1(4).
4. Standards and Certification

Article 4 of the Machinery Directive is the key provision for the elimination of technical barriers and the implementation of the mutual recognition and harmonization principles discussed above. Article 4 prohibits member states from restricting or impeding in any way the entry into their respective territories of machinery that complies with the provisions of the Machinery Directive. Article 5 embellishes this principle by requiring member states to regard all machinery that bears a mark and is accompanied by a declaration of conformity as conforming to the essential health and safety requirements of the directive.

a. Creation of Standards

Machinery manufacturers should pay special attention to article 5 of the Machinery Directive, which controls the standards by which machinery sold in the European Community will be judged. At present, there are two levels of standards. The first are national standards and are provided by the various member states. The second level is the “harmonized” or European standards. Since the goal of the directive is harmonization, these are likely to replace the national standards.

The Machinery Directive assumes the existence of harmonized standards. In reality, harmonized standards have been relatively slow in coming and are probably not as well developed as the Machinery Directive anticipated. As a result,
American manufacturers should be careful to monitor new developments in the standards. Harmonized standards are being formulated by two committees: the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). These developments will determine the standards American machinery products must meet in Europe and will identify the authorities with which American manufacturers can work to achieve compliance.

b. Certification Procedures

Article 8 sets forth the certification procedures that apply to article 5 standards and implements the harmonization principle. The certification procedure to be followed depends upon the type of product. It varies from manufacturer's determination of compliance to detailed testing by a properly certified laboratory. There are two main product areas: annex IV machinery and non-annex IV machinery.

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143. Id. These committees are recognized by the Commission as competent to adopt the harmonized standards. In fact, the definition of harmonized standard is a technical specification adopted by either the CEN or the CENELEC. See id.


145. Id. ch. I, art. 5(1).

146. See id. ch. II, art. 8(2)(a)-(c).

147. Non-annex IV machinery is any machinery not listed in annex IV. See Machinery Directive, supra note 104, ch. II, art. 8. Annex IV machinery is:

1. Circular saws (single- or multi-blade) for working with wood and meat.
   1.1 Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.
   1.2 Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.
   1.3 Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.
   1.4 Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.


3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.

4. Band-saws with a mobile bed or carriage and manual loading and/or unloading for working with wood and meat.

5. Combined machines of the types referred to in 1 to 4 and 7 for woodworking.

6. Hand-fed tenoning machines with several tool holders for woodworking.


8. Portable chain saws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with
For machinery not included in annex IV, the certification process is fairly straightforward, relying heavily on the integrity of the manufacturer. 148 Unlike products included in annex IV, which are apparently deemed by the directive to be in special need of safety regulation, 149 compliance for non-annex IV products is governed by the decisions of the manufacturer, subject to policing by the certifying bodies. 150

The manufacturer of a non-annex IV product is required to “draw up the file provided for in Annex V.” 151 Annex V requires the manufacturer to compile a technical file consisting of an overall drawing of the machinery, detailed drawings, a list of the essential requirements of the Machinery Directive, and any relevant test reports. 152 This information must be kept available for examination by the “competent national authorities” for at least ten years 153 and must be drawn up in one of the official languages of the European Community. 154

Once the annex V file is assembled, the manufacturer prepares the European Community declaration of conformity and attaches the European Community mark. 155 The European Community declaration of conformity must contain the name of the manufacturer, a description of the machinery, and an identification of the applicable standards. 156 The declaration likely will become part of the literature distributed with the machinery and will also be placed in the annex V technical manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10. Injection or compression plastics-moulding machines with manual loading or unloading.
11. Injection or compression rubber-moulding machines with manual loading or unloading.

Id. annex IV.

148. See id. pmbl., at 10. “Manufacturers should retain the responsibility for certifying the conformity of their machinery to the relevant essential requirements ... whereas it is left to the sole discretion of the manufacturer, where he feels the need, to have his products examined by a third party ...” Id. pmbl., at 10.

149. Id. “For certain types of machinery having a higher risk factor, a stricter certification procedure is desirable . . . .” Id.

150. See id. annex V.
151. Id. ch. II, art. 8(2)(a).
152. See id. annex II(3)(a).
153. Id. annex IV(4)(b).
154. Id. annex V(4)(c).
155. Id. annex V(2); see also annex III (replicating the “EC” symbol).
156. Id. annex V (establishing criteria for required conformity declaration).
The European Community mark consists of the European Community symbol, "CE," followed by the last two digits of the year in which the mark was affixed. The mark must be attached to the machinery "distinctly and visibly"; marks which may be confused with the European Community symbol may not be put on the machinery.

No additional testing or procedures are required for non-annex IV products. In essence, the manufacturer determines whether the machinery complies with applicable standards, prepares the annex V technical file and the declaration of conformity, and attaches the European Community mark. The penalty for fraudulently certifying compliance is not specifically set out in the Machinery Directive, but article 7, section 3 allows member states to "take appropriate action" against the manufacturer. The precise penalty likely will be left to the member states to determine, but may be criminal in nature.

c. Annex IV Machinery

The directive targets the machinery listed in annex IV as being in special need of safety certification procedures. This list of products includes saws, presses, and rubber and plastic molding machines. These machines are generally used in the industrial workplace. The industrial worker is thus the chief benefactor of the safety features of the Machinery Directive. Heightened regulation will not surprise U.S. manufacturers of annex IV machinery because many of these machines already are subject to special regulation in the United States.

Because of the special concern these products engender, it is quite likely that specific harmonized standards will soon be in place for these products, resulting in considerably less guess-

157. Id. Failure to produce the documentation when requested by national authorities may result in a presumption of non-conformity with directive requirements. 
158. Id. annex III; see also id. ch. III, art. 10.
159. Id. ch. III, art. 10.
160. Id. ch. I, art. 7(3).
161. See id. ch. II, art. 8; see also annex IV.
162. Id. annex IV.
work for their manufacturers. However, determining which certification procedures apply depends upon a number of variables, including, perhaps, the sophistication of the manufacturer.

d. The Players

To understand the certification procedures, one must first be aware of the principal players: the manufacturer, the "notified body," and the "certifying authority." The notified body is the laboratory responsible for determining whether machinery complies with applicable standards. Certifying authorities review the testing data of the notified bodies and make decisions regarding certification compliance. The directive does not expressly provide for these authorities and one must read between the lines to ascertain their existence. The European Community is now taking measures to adopt criteria for appointing certifying bodies. The likely outcome is that each member state will have one certifying body analyzing the data of the notified bodies. In some smaller member states, the notified body may also be the certifying body, resulting in one-step manufacturer compliance.

Article 9 requires that each member state notify the Commission of the European Community and other member states of its body or bodies approved for carrying out the article 8 certification procedures. The commission is required to publish the list of approved bodies in the Official Journal of the European Communities and to ensure that the list is current. In the implementation of the certification procedure, manufacturers will likely choose an approved body based on the speed with which the body can deliver a decision.

e. The Procedures

The particular certification procedure to be followed depends upon a number of factors and utilizes an increasingly greater level of scrutiny, depending upon compliance with ex-

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165. Id. annex VII (providing for the establishment by member states of notifying bodies).
166. See id. ch. II, art. 8.
167. See generally Whitehead & Scott, supra note 163.
169. Id.
isting standards, the sophistication of the manufacturer, and the manufacturer’s need for certainty.170

Where machinery listed in annex IV fails to comply or partially complies with the harmonized standards or if no standards exist, the manufacturer must submit an example of the machinery for the full-scale examination set out in annex VI.171 This examination is conducted by a notified body, and compliance must be certified.172 This testing and procedure is most rigorous under the Machinery Directive and reflects the directive’s concern about annex IV products that do not fully comply with existing harmonized standards, or for which no standards exist.

Where annex IV machinery meets a harmonized standard pursuant to article 5(2), one procedure allows a manufacturer to create an annex VI file—the same file required for a full-scale examination—and forward it to a notified body which will acknowledge receipt and keep it.173 At this level, the manufacturer is allowed to comply in much the same manner as the manufacturer of non-annex IV products is allowed to do, so long as a more detailed technical file is kept.174 The manufacturer must inform the notified body of any modifications to the product, including minor modifications.175 The manufacturer also must create the technical file in the language of the member state where the notified body is established or in some other language acceptable to the notified body.176

Under a second, more stringent procedure, the manufacturer creates the same technical file as it would under the first procedure, but the notified body must first verify that the product complies with the harmonized standards and then create a certificate of adequacy for the technical file.177 While the directive is not clear as to what will be required for the notified body to “verify that the standards ... have been correctly ap-

170. Id. ch. I, arts. 5, 6; ch. II, art. 9.
171. Id. ch. II, art. 8(2)(b).
172. Id. annex VI, §§ 3-4.
173. Id. ch. II, art. 8(2)(c).
174. Compare id. annex V(3) (describing the technical construction file required for machinery not referred to in annex IV) with id. annex VI(2) (describing the technical file required for machinery referred to in annex IV). Remember, non-annex IV manufacturers need only maintain an annex V file.
175. Id. annex VI, § 5.
176. Id. annex VI, § 7.
177. Id. ch. II, art. 8(2)(c).
plied, it will undoubtedly require some degree of testing. The directive is therefore more likely to result in the reversal of a manufacturer's decision that its product complies with the directive. The same requirements apply with regard to notification of changes. In addition, a notified body that refuses to issue an examination certificate must inform other notified bodies of its decision. This is done so that a manufacturer cannot go to a different notified body to achieve compliance.

The third procedure requires a manufacturer to submit the machinery for a full-scale, annex VI examination. This may be done by a manufacturer to verify its own decision that the machinery is in compliance or may be required of the manufacturer if a policing body believes the product to be non-conforming.

Regardless of which certification procedure is required, manufacturers must realize that once the European Community mark is in place and the certification procedures are completed, the manufacturer is responsible for complying with all other applicable directives. The mark must indicate that the machinery also fulfills the requirements of those directives. Some machinery will likely be governed by other directives. For example, machinery powered by electricity may also be governed by the Electromagnetic Compatibility Directive. Manufacturers must be aware of, and in compliance with, all applicable directives before marketing the machinery.

IV. WARNINGS AND INSTRUCTIONS IN THE UNITED STATES AND EUROPEAN COMMUNITY

A. The Duty To Warn and Instruct

1. United States

In the United States, a manufacturer has a duty to warn of dangers that are known or reasonably foreseeable at the time

178. Id. annex VI, § 3.
179. Id. annex VI, § 5.
180. Id. annex VI, § 6.
181. Id. ch. II, art. 8(2)(c).
182. Id. pmbl., at 10 ("manufacturers should retain the responsibility for certifying the conformity of their machinery").
of marketing the product.\textsuperscript{185} A manufacturer also must warn against reasonably foreseeable misuses and unintended uses that could cause injury or damage.\textsuperscript{186} This requires a manufacturer to consider the product in the context in which it will be used, consider the persons who will use it, and determine how the product might foreseeably be used or misused in a manner not intended by the manufacturer.\textsuperscript{187} A manufacturer must also instruct the user how to operate the product safely.\textsuperscript{188} Exceptions to this duty to warn include open or obvious dangers,\textsuperscript{189} commonly known dangers,\textsuperscript{190} unforeseeable dangers and uses,\textsuperscript{191} and knowledgeable users.\textsuperscript{192}

2. The Strict Liability Directive

The Strict Liability Directive does not expressly create a duty to warn or instruct. Instead, a duty is implied in the definition of a defective product.\textsuperscript{193} As noted earlier, article 6, section 1, provides that 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.”\textsuperscript{194} Although warnings and instructions are not specifically addressed under article 6, the “presentation of the product” may be interpreted to include warnings and instructions. Warnings and instructions also may be required if the reasonably expected uses of the product

\textsuperscript{185} A manufacturer’s duty to warn about a product’s inherent risk is derived from negligence law, Boyl v. California Chem. Co., 221 F. Supp. 669 (D. Or. 1963) (applying Oregon law), but a failure to warn against risks created by a product’s defects may also render the product unreasonably dangerous for purposes of imposing strict liability, Hahn v. Sterling Drug, Inc., 805 F.2d 1480 (11th Cir. 1986) (applying Georgia law).
\textsuperscript{187} Hughes v. Magic Chef, Inc., 288 N.W.2d 542 (Iowa 1980).
\textsuperscript{188} See, e.g., Frey v. Montgomery Ward & Co., Inc., 258 N.W.2d 782 (Minn. 1977).
\textsuperscript{189} See, e.g., Balder v. Haley, 399 N.W.2d 77 (Minn. 1987).
\textsuperscript{190} See, e.g., Grady v. American Optical Corp., 702 S.W.2d 911 (Mo. 1986).
\textsuperscript{191} See, e.g., Stabnick v. Williams Patrol Serv., 390 N.W.2d 657 (Mich. Ct. App. 1986) (holding that defendant had no duty to warn of strong gusty wind, which blew debris from some unknown place and blinded employee leaving building for which defendant provided security services).
\textsuperscript{192} See, e.g., Campos v. Firestone Tire & Rubber Co., 469 A.2d 943 (N.J. 1983).
\textsuperscript{193} Strict Liability Directive, supra note 9, art. 6(1).
\textsuperscript{194} Id.
involve hazards that do "not provide the safety which a person is entitled to expect." Therefore, a product may be found to be defective under the Strict Liability Directive if it lacks adequate warnings and instructions. 195

3. The Machinery Directive

The Machinery Directive, in contrast to the Strict Liability Directive, expressly creates a duty to warn and instruct. 196 The Machinery Directive requires a manufacturer to "inform users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required and specify any need to provide personal protection equipment." 197 The directive also requires warnings "where risks remain despite all the measures adopted or in the case of potential risks that are not evident (for example, electrical cabinets, radioactive sources, bleeding of a hydraulic circuit, hazard in an unseen area, etc.)." 198 It is not clear whether these warnings should be placed directly on the machine or in an instruction book. In the United States, manufacturers generally place the warnings in appropriate locations on the product and in an instruction manual. 199

The Machinery Directive also expressly creates a duty to provide instructions. 200 All machinery must be accompanied by instructions. These instructions must include certain specific information, including information required to establish that the machinery complies with safety certification standards; instructions for safely servicing, using, assembling, and maintaining the machinery; and the foreseeable uses of the machinery. 201 With the exception of the safety certification information, these requirements are similar to U.S. requirements for instruction manuals.

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197. Id. annex I, § 1.1.2(b).

198. Id. annex I, § 1.7.2.


200. See id. annex I, § 1.7.

201. Id. annex I, § 1.7.4.
4. The Proposed Product Safety Directive

The Proposed Product Safety Directive also requires warnings and instructions. The term "safe product" is defined, in part, as meaning:

[A]ny product which, during its foreseeable time of use, does not present any risk or only those reduced to such a level, taking account of the product's use, considered as acceptable and consistent with a high standard of protection for safety and health of persons . . . given its composition, . . . wrapping, presentation and labelling, conditions of assembly, maintenance or disposal, [or] instructions for handling.\(^{202}\)

Inadequate labeling and instructions therefore render a product "dangerous."\(^{203}\)

Article 3, subsection 2, of the Proposed Product Safety Directive expressly requires that suppliers "provide the potential user or consumer with the relevant information to enable him to assess the risks presented by a product when such risks are acceptable as such but are not insignificant."\(^{204}\)

Presumably, this "relevant information" is to be communicated by way of instructions and warnings. The same warnings must inform the potential user or consumer of precautions that can be taken against the risks throughout the foreseeable time of use of the product.\(^{205}\) Article 3 also makes clear that providing a warning does not "constitute a means of escaping the general safety requirement nor a defense when the product proves to be dangerous."\(^{206}\) This appears to be an acknowledgement of the safety hierarchy; namely dangers should be designed out, guarded against if they cannot be designed out, and then warned against as a last resort.

The Machinery, Strict Liability, and Proposed Product Safety Directives create a duty to provide appropriate warnings and instructions. This duty is very similar to the legal standard in the United States. Precisely what constitutes an inadequate warning or an adequate instruction under the directives is less


\(^{203}\) Id. art. 2(c) ("any product which does not meet the definition of 'safe product' according to" part (b) of this article).

\(^{204}\) Id. art. 3(2).

\(^{205}\) Id.

\(^{206}\) Id.

B. Adequacy of Warnings and Instructions

1. United States

In the United States, the courts have provided some guidelines for manufacturers to utilize in analyzing the adequacy of warnings. For example, it has been held that an adequate warning is one that reasonably could be expected to catch the attention of a reasonably prudent person in the circumstances of its use, and one where the content is understandable and conveys a fair indication of the nature and extent of the danger to that person.207 Other courts have defined the message of an adequate warning as one which clearly communicates the nature of the risk so that the user will understand it, the seriousness of the risk involved, and information that will allow the user to avoid the risk.208 Manufacturers also must consider the conspicuousness of the warning, the use of symbols or pictorials to convey appropriate messages, the location of the warning label, and the clarity of the warning language.209 Although the courts have not made any definitive rulings on the use of pictorials, an American National Standards Institute standard encourages the use of pictorials that are readily understood, effectively communicate the message, and provide the viewer with an immediate opportunity to recognize an existing hazard.210

Instructions affirmatively guide the user in the proper and safe use of the product. The warnings on the product and in the instruction book should be interrelated. The adequacy of the instructions is generally judged in the same manner as warnings. In writing the instructions, the manufacturer must consider such things as the ultimate reader's education and experience, mechanical aptitude, manual dexterity, and intelligence. Also, the instructions should be written to reach the lowest common denominator. It is better for the book to be too simple than too complex.

210. See generally Ross & Scott, supra note 195.
2. The Strict Liability Directive

The Strict Liability Directive does not expressly describe or discuss the content of warnings and instructions. Presumably, an adequate warning or instruction under this directive would be one that provides "the safety which a person is entitled to expect, taking all circumstances into account."211 The content of the warning or instruction under this directive is of primary importance to the manufacturer because the Strict Liability Directive allows a manufacturer to reduce or avoid liability when the damages are caused in part by the fault of the injured person.212 This means that a manufacturer could raise as a defense a person's failure to read or comply with an adequate warning or instruction. The three factors used to determine adequacy under U.S. law are noticeably absent from the Strict Liability Directive.

3. The Machinery Directive

The adequacy requirements of the Machinery Directive generally follow the U.S. requirements quite closely. For example, the information needed to control the machinery must be unambiguous and easily understood.213 Warnings must not be excessive to the point of "overloading" the operator.214 Instructions for machinery that may be used by "non-professional" operators must "take into account the level of general education and acumen that can reasonably be expected from such operators."215

In addition to these general requirements, the Machinery Directive contains a number of specific requirements for the content of warnings and instructions that may go beyond U.S. requirements. For example, if machinery is intended for use in a potentially explosive atmosphere, a manufacturer must indicate that fact on the machinery.216 The instructions must contain the manufacturer's statement of both the normal use of the machinery and uses that reasonably could be expected. The instructions must specifically point "to ways—which expe-

211. Strict Liability Directive, supra note 9, art. 6.
212. Id. art. 7(b).
214. Id. annex I, § 1.7.0.
215. Id. annex I, § 1.7.4(h).
216. Id. annex I, § 1.7.3.
rience has shown might occur—in which the machinery should not be used.\textsuperscript{217} This is similar to the U.S. concept of warning about foreseeable misuses, but it seems to go further and require some type of post-sale updating.

If the machine runs the risk of breakup during operation, the manufacturer must indicate in the instructions the type and frequency of inspection and maintenance required for safety reasons.\textsuperscript{218} The manufacturer must also indicate the parts subject to wear and tear and the criteria for replacement.\textsuperscript{219} The instructions also must contain drawings and diagrams that are necessary for putting the machinery into service, maintaining and inspecting it, and operating it safely.\textsuperscript{220} These are identical to the U.S. requirements. The instructions also must inform the operator of the installation and assembly requirements necessary to reduce noise or vibration.\textsuperscript{221} Lastly, the directive requires that the manufacturer’s sales literature not contradict the instructions with regard to safety.\textsuperscript{222}

Many of these requirements generally go beyond what would be required under U.S. law. Of course, these requirements will be supplemented by those found in any directive applying to a specific product.

4. The Proposed Product Safety Directive

The Proposed Product Safety Directive does not contain specific requirements for the content of warning labels or instructions. However, article 3 requires that suppliers provide the user or consumer with sufficient information to enable him to assess risks associated with the product that may be acceptable but neither immediately obvious nor insignificant.\textsuperscript{223} The supplier must also inform the user or consumer how to take precautions against these risks throughout the foreseeable life of the product.\textsuperscript{224}

\textsuperscript{217} Id. annex I, § 1.1.2(c).
\textsuperscript{218} Id. annex I, § 1.1.2.
\textsuperscript{219} Id.
\textsuperscript{220} Id. annex I, § 1.7.4.(a).
\textsuperscript{221} Id. annex I, § 1.7.4.(e).
\textsuperscript{222} Id. annex I, § 1.7.4.(d).
\textsuperscript{223} Proposed Product Safety Directive, supra note 96, art. 3(2).
\textsuperscript{224} Id.
V. LIABILITY FOR SERVICE PROVIDERS IN THE EUROPEAN COMMUNITY

The European Community is considering implementing a directive creating strict liability for the suppliers of services.\textsuperscript{225} The scope of the Proposed Service Directive is very broad, encompassing architects to mechanics, day care providers to doctors, playground supervisors to hotel operators, and plumbers to electricians.\textsuperscript{226} The ramifications of this proposed directive cannot be overstated. It is very important for all service providers to monitor its progress and prepare for its implementation.

A. Theory of Liability

A preliminary draft of the Proposed Service Directive begins with the somewhat innocuous statement that "the supplier of a service shall be liable for damage caused by a safety defect in his service."\textsuperscript{227} The focus of liability is not the reasonableness of the service provider's conduct but the notion of "safety defects" and the expectations of the public.\textsuperscript{228} The commentary to the preliminary draft directive made clear that "the aim is to introduce objective liability on the part of the supplier of defective services, regardless of any concept of fault."\textsuperscript{229}

Thus, it is clear that the Proposed Service Directive would replace negligence with strict liability. Presently, article 1 reads:

\begin{quote}
The supplier of a service shall be liable for damage to the health and physical integrity of persons or the physical integrity of movable or immovable property, including the persons or property which were the object of the service, caused by a fault committed by him in the performance of the service.\textsuperscript{230}
\end{quote}

In addition, paragraph 3 of article 1 clearly states that the concept of "fault" referenced in paragraph 1 is indeed negli-

\begin{footnotes}
\footnote{226. Id. pmbl.}
\footnote{228. Id. art. 5.}
\footnote{229. Id. pmbl.}
\footnote{230. Proposed Service Directive, supra note 225, art. 1(1).}
\end{footnotes}
gence-based. Paragraph 3 provides, "In assessing the fault, account shall be taken of the behavior of the supplier of the service, who, in normal and reasonably foreseeable conditions, shall ensure the safety which may reasonably be expected." Thus, at present, the focus of the analysis is on the conduct of the supplier of the service, not merely on damage and causation.

B. Scope of the Proposed Directive

1. Who Is a Service Provider?

The phrase "supplier of services" is defined in article 3 as "any natural or legal person governed by private or public law who, in the course of his professional activities or by way of a public service, provides a service referred to in Article 2." This is an extremely broad definition with few exceptions. Both commercial traders and public entities are included within the scope of the definition. The policy behind the definition is to ensure that the person who derives the commercial or public gain from a service is held responsible for their superior technical knowledge. However, the directive does not apply to public services intended to maintain public safety, or to package travel or waste services. Franchisors and franchisees are both deemed to be suppliers of services and are deemed to be jointly and severally liable. However, a franchisor and franchisee may avoid liability in certain situations. It is not clear whether notified or certifying bodies provided for under the Machinery or other Directives fall within the scope of this Proposed Service Directive. As presently drafted, the directive seems to include these entities, as well as standards-creating entities.

231. Id. art. 1(3).
232. Id. art. 3(1).
233. Id.
234. Id.
235. Id. art. 3(2), 3(3).
236. Id. art. 9.
237. Id. art. 2. The Proposed Service Directive does not apply "to damage covered by liability arrangements governed by international agreements ratified by the Member States or by the Community." Id.
2. What Is a Service?

Article 2 defines "service" as:

[A]ny transaction carried out on a commercial basis or by way of a public service and in an independent manner, whether or not in return for payment, which does not have as its direct and exclusive object the manufacture of movable property or the transfer of rights in rem or intellectual property rights. 238

The Proposed Service Directive does not apply to damage covered by liability arrangements governed by international agreements ratified by the member states or by the European Community.239 Unlike the preliminary draft directive, the Proposed Service Directive does not specifically refer to health care services, presumably meaning they are included within the scope of the directive.

The term "service" apparently is intended to include the physical protection of persons and their property, not their economic protection. Only services that injure the health and physical integrity of persons and their property are included within the scope of the directive. This is made clear in article 4, where the term "damage" is defined as

(a) death or any other direct damage to the health or physical integrity of persons;

(b) any direct damage to the physical integrity of movable or immovable property, including animals, provided that this property:

(i) is of a type normally intended for private use and consumption, and

(ii) was intended for or used by the injured person, principally for his private use or consumption;

(c) any financial material damage resulting directly from the damage referred to at (a) and (b).240

This seems to mean that professionals such as accountants, stockbrokers, and attorneys are not covered by the directive. Protection from financial damage is only provided where there is also damage to a person or property.241

The preliminary draft directive specifically allowed for re-
covery of pain and suffering damages. The Proposed Directive does not include pain and suffering within the definition of "damage" and makes no reference to the issue throughout the directive.

3. What Is a Defective Service?

Even though it purported to implement strict liability, the preliminary draft directive included "reasonableness" concepts. For example, article 5 defined the phrase "safety defect" as a service that "does not provide the degree of safety which may reasonably be expected as regards health and physical integrity of persons and the physical integrity of movable and immovable property including that forming the object of the service." A comment to this article made clear that the standard to be applied was that of the "reasonable expectation of the public."

The Proposed Service Directive replaces the concept of a "safety defect" with the notion of a "fault committed . . . in the performance of [a] service." The word "fault" is not specifically defined. It appears to be a negligence concept, focusing on the conduct of the supplier of the service. The return to negligence concepts is certainly good news for service providers. However, the supplier of the service has the burden of proving the absence of fault.

C. Elements of a Cause of Action

There are two elements set out in the Proposed Service Directive that an injured person must prove: (1) damage; and (2) a causal relationship between the performance of the service and the damage. Unlike the preliminary draft directive, where safety defects were "presumed" to exist, the proposed

243. Id. art. 4.
244. Id. art. 5.
245. Id. art. 5, cmt.
247. See id. art. 1(3). "In assessing the fault, account shall be taken of the behavior of the supplier of the service, who, in normal and reasonably foreseeable conditions, shall ensure the safety which may reasonably be expected." Id.
248. Id. art. 1(2).
249. Id. art. 5. "The injured person shall be required to provide proof of the damage and the causal relationship between the performance of the service and the damage." Id.
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Once the injured persons proves these two elements, the burden of proof then shifts to the service supplier to prove the absence of fault. The injured person apparently does not have to show fault or prove that the conduct of the supplier was somehow unreasonable. The supplier of the service has the exclusive burden of proving the reasonableness of his conduct.

D. Defenses Available to the Service Provider

Under the preliminary draft directive, a number of defenses were available to service providers. For example, the service provider was not liable if it proved that the safety defect was due to a force majeure. The service supplier also was not liable if the safety defect was due to compliance with binding European Community law, national legislation, or mandatory rules laid down by public authorities. These defenses are not available under the Proposed Service Directive. The only defense apparently available is for the supplier of a service to prove that he was not at "fault."

A notion of comparative fault is found in article VI, paragraph 2, which provides "The liability of the supplier of the service may be reduced, or even waived, where the damage is caused jointly by a fault on his part and by the fault of the injured person, or a person for whom the injured person is responsible." The specifics of this provision are obviously lacking. Under what circumstances will liability be "waived"? What does it mean to "waive" liability? For what types of persons will injured persons be deemed "responsible"?

The supplier of the service may not use as a defense the fact that the injured party's damage was caused jointly by his fault and the fault of a third party. Also, the supplier may not contractually limit or exclude his liability to the injured person.

250. See Preliminary Draft Service Directive, supra note 227, art. 6(2).
252. Preliminary Draft Service Directive, supra note 227, art. 7(1).
253. Id.
255. Id. art. 6(2).
256. Id. art. 6(1).
257. Id. art. 7.
E. Statutes of Limitation

An injured person must bring proceedings for recovery within three years of the date on which the injured person became or should reasonably have become aware of the damage,\(^{258}\) or within five years from the date the service is provided.\(^{259}\) However, where the service relates to the design or construction of immovable property, the five-year period is increased to twenty years\(^{260}\) and the three-year period is increased to ten years.\(^{261}\)

V. Potential Liability of Product Endorsers Under the Proposed Directive Implementing Liability for Service Providers

The term "service supplier" under the Proposed Service Directive may include agencies that certify quality control systems, certify and endorse products, or create standards for products.

A. Liability of Product Endorsers in the United States

In the past, U.S. courts have imposed liability upon product endorsers when a certified product causes injury. For example, when a product endorser certifies a product and places it on its list of certified goods, plaintiffs injured by that product may claim that the product endorser is liable under a negligence theory.\(^{262}\) Some plaintiffs have attempted to hold product endorsers strictly liable for injuries, but courts have rejected claims that were not based on negligence.\(^{263}\)

Courts have stressed that endorsers and certifiers voluntarily assume a duty toward consumers when they enter into the business of endorsing products.\(^{264}\) Several theories of negligence have been used to impose liability. One theory is based on misrepresentation of the amount of testing that was actually

\(^{258}\) Id. art. 10(1).
\(^{259}\) Id. art. 9.
\(^{260}\) Id.
\(^{261}\) Id. art. 10(1).
\(^{263}\) See, e.g., Toman v. Underwriters Labs., Inc., 532 F. Supp. 1017 (D. Minn. 1982).
\(^{264}\) See Hanberry, 81 Cal. Rptr. at 519.
done.\textsuperscript{265} For example, in \textit{Hempstead v. General Fire Extinguisher Corp.}, the court allowed a claim that a product endorser had negligently misrepresented the amount of testing that had been done on the design of a defective fire extinguisher.\textsuperscript{266} The plaintiff argued that the seal of the certifier indicated careful testing of the product, even when no testing occurred at all.\textsuperscript{267}

Plaintiffs also have argued that certifiers and endorsers should be held liable for negligent testing of products. One plaintiff claimed that a product endorser failed to discover a defect in a pair of shoes she purchased in reliance on the product endorser’s seal.\textsuperscript{268} She argued that the product endorser would have discovered this defect with diligent testing. The court agreed, reasoning that once a product endorser has assumed a duty to test a product, it should be held liable for failing to discover defects that would have been apparent with reasonable testing.\textsuperscript{269}

Finally, plaintiffs have argued that endorsers should be held liable for failure to warn of the dangers of certain products.\textsuperscript{270} If a product endorser certifies a space heater, for instance, courts have indicated that it might be held responsible for failing to warn purchasers that the space heater is suitable only for use in well ventilated areas.\textsuperscript{271} This theory of recovery places the greatest burden upon certifiers as they could be held liable for a duty that is traditionally attributed only to manufacturers.

Endorsers have limited their liability through the use of disclaimers.\textsuperscript{272} A disclaimer used by one product endorser states:

The Subscriber agrees to hold the Laboratories harmless and to defend and indemnify the Laboratories against any loss, expense, liability, or damage, including reasonable attorney’s fees, arising out of any misuse by the Subscriber of the Listing Mark of the Laboratories or arising out of any violation by the Subscriber of the terms and conditions of

\begin{itemize}
\item \textsuperscript{265} See, \textit{e.g.}, \textit{Hempstead v. General Fire Extinguisher Corp.}, 269 F. Supp. 109 (D. Del. 1967).
\item \textsuperscript{266} \textit{Id.}
\item \textsuperscript{267} \textit{Id.} at 111.
\item \textsuperscript{268} See, \textit{e.g.}, \textit{Hanberry}, 81 Cal. Rptr. at 519.
\item \textsuperscript{269} \textit{Id.}
\item \textsuperscript{270} \textit{Vaughn v. J.C. Penney}, 822 F.2d 605 (6th Cir. 1987).
\item \textsuperscript{271} \textit{Id.}
\item \textsuperscript{272} \textit{Toman v. Underwriters Labs., Inc.}, 532 F. Supp. 1017 (D. Minn. 1982).
\end{itemize}
this Agreement.\textsuperscript{273}

This disclaimer is intended to protect the product endorser from claims arising from the negligence of the manufacturer and may account for a decrease in U.S. cases in this area.

U.S. courts have thus held product endorsers liable in products liability cases when the endorser voluntarily undertakes to test and endorse the product and this undertaking is performed negligently. Once the product endorser undertakes this duty toward the eventual consumer, the product endorser must exercise reasonable care in testing and disseminating information about the product. Courts have found liability under negligence theories only, expressly rejecting strict liability.

\section*{B. Implications for the European Community}

If the European Community implements the proposed directive, U.S. case law may provide assistance to product endorsers, accrediting and certifying agencies, and standard-setting organizations attempting to analyze their potential liability. However, because the burden of proving the absence of fault will be on the supplier of the service, these standard-setting organizations may have to deal with increased liability.

\subsection*{I. Accrediting and Certifying Agencies}

Accrediting and certifying agencies may be liable to injured persons or manufacturers under the directive. The analysis is quite simple. Article 1 establishes that the “supplier of a service shall be liable for damage . . . caused by a fault committed by him in the performance of the service.”\textsuperscript{274} If an accrediting and certifying agency is defined as a “supplier of a service,” and its activities are considered to be a “service,” the directive seemingly applies, and liability will result from a “fault” in the service.

Accrediting and certifying agencies clearly are included within the definition of “supplier of a service,” which is defined as “any natural or legal person governed by private or public law who, in the course of his professional activities or by way of a public service, provides a service referred to in article

\begin{itemize}
\item \textsuperscript{273} \textit{Id.} at 1019.
\item \textsuperscript{274} Proposed Service Directive, \textit{supra} note 225, art. 1(1).
\end{itemize}
II. The term "service" is defined in Article 2 as:

Any transaction carried out on a commercial basis or by way of a public service and in an independent manner, whether or not in return for payment, which does not have as its direct and exclusive object the manufacturer of movable property or the transfer of rights in rem or intellectual property rights.

The service of accrediting or certifying ISO 9000 programs falls within this definition. Therefore, accrediting and certifying agencies could be liable under the directive if the ISO 9000 program is improperly accredited and certified and thus contains a "fault." But, the word "fault" is not specifically defined. Apparently the directive intends it to be a negligence concept, focusing on the conduct of the supplier of the service.

Under the directive, unlike under the law in the United States, the supplier of a service has the burden of proving the absence of fault. Under article 5, the injured person is required to prove damage and a casual relationship between the performance of the service and the damage. Under article 1, paragraph 2, the supplier of the service then has the burden of proving the absence of fault, meaning that the supplier's conduct was "reasonable" or ensured the safety "which may reasonably be expected."

The liability of accrediting and certifying agencies could arise in the following context. A person is injured as a result of a claimed defect in a product. The injured person alleges that the defect occurred as a result of improper design of the product, possibly expressly implicating the implementation of the ISO 9000 program. The liability of the accrediting agency may arise in one of two ways. First, the injured party may decide to sue the accrediting agency directly under the directive. This is especially likely to happen if the manufacturer is bankrupt, out of business, outside of the jurisdiction, or otherwise unable to satisfy a judgment. Second, if the manufacturer is still in busi-

275. Id. art. 3(1).
276. Id. art. 2.
277. ISO 9000 is a quality assurance standard published by the International Standards Organization. It provides quality assurance standards for design, manufacturing, testing, and management.
278. See Proposed Service Directive, supra note 225, art. 1(3) ("account shall be taken of the behavior of the supplier of the service").
ness, the injured person will likely sue the manufacturer. The manufacturer will then determine whether to sue the accrediting and certifying agency for the defects in the ISO 9000 program. Manufacturers may therefore decide to bring the equivalent of third-party lawsuits against accrediting and certifying agencies.

The possibility that a manufacturer would sue an accrediting and certifying agency raises interesting issues about contractual terms and indemnity agreements. Generally speaking, indemnity agreements are widely used in the United States by product endorsers. The agreements basically provide that the manufacturer for whom certification services are performed agrees to indemnify and hold harmless the certifying laboratory in the event of litigation.

Such an arrangement may or may not be possible under the proposed directive. Article 7 of the directive provides that “the supplier of a service may not, in relation to the injured person, limit or exclude his liability under this Directive.” This raises the issue of what constitutes an injured person. Does this mean the person must be actually physically injured by the service? Could it also include a manufacturer who is “injured” by a lawsuit brought against it as a result of alleged problems in the ISO 9000 program? If manufacturers can be considered injured persons, accrediting and certifying agencies may not be able to limit their liability with respect to them. Even if manufacturers are not considered injured persons, accrediting and certifying agencies clearly cannot limit their liability to the person actually injured. This could become particularly important where a manufacturer is insolvent or otherwise unable to satisfy a judgment. Even if an accrediting or certifying agency has an indemnity agreement with such a manufacturer, it may prove to be of no value to the injured person.

2. Consultants

The same liability issues apply not only to accrediting and certifying agencies but also to the ISO 9000 consultants who

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280. Id.
work with companies in setting up ISO 9000 programs. The consultant's advice is certainly a service under the directive, and it seemingly applies with equal, if not greater, force to consultants.

3. **Product Endorsers and Standards-Creating Organizations**

This same analysis may also hold true for product endorsers and standards-creating organizations. Creating standards for the design and performance of a product and endorsing products certainly seem to constitute services, and the organizations creating the standards and endorsing the product certainly seem to be suppliers of services. Injured persons who claim that standards were inadequate may try to sue the standard-setting organizations directly, or manufacturers who are sued in cases involving allegations of deficient standards may attempt to sue the standards-creating organization under this directive. The same is true for product endorsers.

VI. **Conclusion**

The new EC products liability scheme borrows heavily from U.S. law. While there are several technical ambiguities in EC law, they do not expose manufacturers to unpredictable liability. The salient aspects of the EC scheme are its often rigorous certification requirements and the potential liability for service providers. While the latter may have little direct impact because of its apparent consistency with negligence principles, the former may absolutely insulate manufacturers from liability. In addition, combining certification requirements and strict service liability theories may allow manufacturers to reduce their liability exposure through successful third-party suits against product endorsers.