
The Relationship Between Product Liability and Product Safety—Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position

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I.	Introduction	305
II.	The Different Nature of Voluntary Standards and Safety Regulation in the U.S. and Europe	309
A.	U.S. Model	309
i.	Mandatory Standards—A Rare Species	309
ii.	Voluntary Standards	310
B.	Europe—Standards Making as Privatized Legislation	310
III.	Process for Developing Standards and Regulations	315
A.	Standards Formation in Europe	315
i.	Structure of CEN	317
ii.	Standards Making Procedure	318
B.	Standards Formation in the U.S.	320
i.	Mandatory Standards—Attempted Innovation	320
ii.	Voluntary Standards	323
iii.	American National Standards Institute	324
IV.	Consumer Representation in the Standards Procedure	327
A.	European Model	327
B.	Consumer Participation in the U.S.	331
V.	General Controls on Unsafe Products	334
A.	The EC's General Product Safety Directive	334
B.	U.S. Product Control	341
i.	Remedial Action for Substantial Product Hazards.....	341
ii.	Imminent Hazards	343
iii.	Reporting	343
VI.	Conclusion	344

I. INTRODUCTION

Products liability is a popular topic for comparative law research between the American and European legal systems. This is understandable. Products liability is a modern phenomenon, and so it is easy and interesting to track how legal systems have, within a relatively short space of time, reacted to this new topic. Solutions have sometimes been developed by the courts out of existing legal principles, and at other times, solutions have been created by legislatures. Because preexisting

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legal principles were similar in most countries,¹ it is interesting to see the extent to which systems were prepared to amend their traditional concepts without having to resort to legislation. As the new regimes claim to adopt strict liability, there is plenty of scope for comparison as to the actual extent to which they deviate from traditional forms of liability.

Comparative doctrinal research is the norm. For instance, I have elsewhere tried to demonstrate that the defectiveness standard in Europe is stricter than that adopted in the U.S.² However, comparing the black letter law is only one aspect, for such a limited analysis would give a misleading impression of the relative state of products liability in the U.S. compared to Europe. In the U.S., products liability is a legal field in its own right. It has its own courses in the law school curriculum, its own textbooks and treatises, and numerous American lawyers make their living from products liability litigation. The number of cases are legion. In comparison, in Europe, products liability is only taught as part of torts or obligations courses or as a topic in consumer law courses. There are a number of European scholarly publications regarding products liability, mainly because of the impact of the European Community³ ("EC") directive⁴ and the need to track implementation in the member states.⁵ However, if anything, this academic interest is out of proportion with the extent to which product liability figures into actual practice. Few European lawyers can make a living out of products liability and only a few more will ever come across a products liability case. There have been only a handful of reported product cases in Europe. Although this can be misleading, because, at least in the United Kingdom, such cases tend to be settled through negotiation before judicial action is necessary. Nevertheless, in Europe, products liability remains a minority area of practice.

It is universally recognized that there are issues relating to the contrasting legal and social cultures in the U.S. and Europe that explain the

1. Certainly, the U.S. and U.K. share a common legal heritage, but Europe also has many similar principles, i.e., tort law based on fault and contract law subject to the limitations of privity. See GERAINT G. HOWELLS, *COMPARATIVE PRODUCT LIABILITY* (1993).

2. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) ("A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings."). See also Geraint G. Howells & Mark Mildred, *Is European Product Liability More Protective than the Restatement (Third) of Torts: Products Liability?*, 65 TENN. L. REV. 985 (1998).

3. The European Community ("EC") member states are as follows: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

4. By 1998, all EC member states had implemented the EC Product Liability Directive of 1985, requiring the adoption of strict products liability legislation. See Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1985 O.J. (L 210) [hereinafter Product Liability Directive].

5. See GERAINT G. HOWELLS, *CONSUMER PRODUCT SAFETY* (1998). See generally CHRISTOPHER HODGES, *PRODUCTS LIABILITY—EUROPEAN LAWS AND PRACTICE* (1993); *EUROPEAN PRODUCT LIABILITY* (Patrick Kelly & Rebecca Attree eds., 1992).

differential impact of products liability. For instance, it is said that Americans are more litigious than Europeans. Certainly the American legal environment is more conducive to litigation—with contingent fee agreements making lawyers accessible to all plaintiffs with significant claims. Additionally, the fact that there is no liability for the other party's costs in an unsuccessful action means there is no deterrent to "trying one's luck" in court. More claims are brought because class action procedures have helped ease the management of large product liability cases. Further, the role of the jury in determining liability and assessing damages has also been viewed as assisting plaintiffs, for cases that might not pass muster before a worldly-wise judge can, perhaps, evoke the sympathy of lay jurors.

The main reason for the greater impact of products liability litigation in the U.S. is the level of damages. American damage awards are considerably higher—this in itself acts as a magnet for litigants. These high awards are due to the lack of a social security system to cushion the impact of accidents, the high costs of medical treatment, the lack of public healthcare services, generous awards of pain and suffering damages, and the availability of punitive damages.

Litigation in the U.S. is widely recognized as a surrogate for the European welfare state.⁶ Thus, products liability litigation fulfills a different function in the U.S. than in Europe; although as the welfare state is being rolled back in Europe more attention is being paid to litigation as a means of satisfying the welfare needs of injured parties.

Products liability has, however, two (often conflicting) functions—compensating injured persons and acting as a gate-keeper and deterrent to ensure producers only market safe products.⁷ The role of punitive damages in the U.S. suggests that the regulatory function of litigation is important. Moreover, the threat of wide scale products liability litigation can be seen as an incentive for producers to improve the quality of their products, often with fiscal incentives from insurers. Although civil liability rules have a regulatory dimension in Europe, my impression is that products liability is more responsive to the compensatory needs of accident victims than to the regulatory aspects. Many Americans consider Europe to have a weak products liability litigation culture, but I gain the impression that there is sometimes a failure to appreciate the depth of the product safety regulatory regimes, which may explain why there is less need for products liability litigation as a means of regula-

6. See generally THOMAS WILHELMSSON, FROM DISSONANCE TO SENSE: WELFARE STATE EXPECTATIONS, PRIVATISATION AND PRIVATE LAW (1999).

7. This has been described as the "two questions—one answer problem" in products liability. See Alan C. Hutchinson and Sue Hodgson, *Who's Zoomin' Who? Comments on Liability for Pharmaceutical Products in Canada*, in *PRODUCT LIABILITY, INSURANCE AND THE PHARMACEUTICAL INDUSTRY* (Geraint G. Howells ed., 1991).

tory control.

The purpose of this article is to explain the European system of product safety regulation to the American reader. I think American readers will be surprised by the sophistication of the rules and the strength of the enforcement culture. The article will contrast the European regime with the U.S. system. What is most striking is the extent to which European standardization has been integrated into the legal regime. This is not an eulogy for the American system. There are still some regulatory aspects in which the U.S. is a world leader, including the accident data collection and recall powers.⁸ When established in the 1970's the U.S. Consumer Product Safety Commission⁹ ("CPSC") was seen as a model for an integrated consumer product safety agency, which Europe has never been able to emulate.¹⁰ There are also many problems with the European system.¹¹ However, my purpose is to emphasize the European commitment to regulation, rather than, litigation as a means of promoting product safety. It will be for the American reader to determine whether it is desirable or even possible for the U.S. to develop similar regulatory controls. My object is simply to give a better insight into the European approach and perhaps add another dimension to be considered when reflecting on the lack of products liability litigation within Europe. Much of this article will be concerned with standards. In contrast to products liability, which is viewed as a lawyer's paradise, standardization is an area of law largely uninhabited by legal practitioners.¹²

There are many dimensions to product safety regulation.¹³ This article will concentrate on just four. First, it will show the different nature of standards in the U.S. and Europe. Whereas in the U.S. these remain very much voluntary standards, established by private actors, in Europe, at least in areas covered by "new approach directives," their use has become quasi-mandatory.

Second, this article will demonstrate how the creation of standards in Europe has become part of the corporatist state structure. This has led to a certain degree of involvement by all interested parties. Contrast this with the U.S. position, where the creation of standards is still largely a private procedure. Mention will be made of the U.S.'s unsuc-

8. See HOWELLS, *supra* note 5, at 203-08, 231-33.

9. The Commission was established by the Consumer Product Safety Act of 1972, 15 U.S.C. §§ 2051-2084 (1994 & Supp. IV 1998).

10. France has a Consumer Safety Commission, but its role is not as extensive as the U.S. Consumer Product Safety Commission. See HOWELLS, *supra* note 5, at 315-19.

11. This topic is discussed briefly in the Conclusion of this article. For more detail see HOWELLS, *supra* note 5.

12. Even in Europe, one is just beginning to see lawyers emerging that view product safety regulation as an important area of practice. See CHRISTOPHER HODGES ET AL., *PRODUCT SAFETY* (1996).

13. See HOWELLS, *supra* note 5.

successful attempts in the 1970's to be innovative in regulation-making. In many ways, the proper comparison is between U.S. regulations and EC standards, for whilst the process of developing EC directives remains a political process, the most crucial decisions are now left to the standardizers. Third, the contrast between the EC and U.S. approaches will then be underlined by looking at the role of consumers in standards development.

Finally, attention will turn from the regulation of specific products to the general controls placed on all products. The EC's General Product Safety Directive¹⁴ provides a far more complete system of protection than the U.S. Consumer Product Safety Commission is able to offer, but in areas like product recall the U.S. system still remains superior.

II. THE DIFFERENT NATURE OF VOLUNTARY STANDARDS AND SAFETY REGULATION IN THE U.S. AND EUROPE

A. U.S. Model

i. Mandatory Standards—A Rare Species

When the CPSC was established under the Consumer Product Safety Act of 1972¹⁵ ("CPSA") it was imagined that one of its major functions would be to establish mandatory product safety standards.¹⁶ This goal has not materialized. The CPSC's objective went unrealized primarily because of a change in regulatory emphasis in favor of deregulation and voluntary self-regulation. During the 1980's, the CPSC became subject to the Reaganite-deregulation tendency and the emphasis switched from mandatory rule-making towards using voluntary standards wherever possible. This preference for voluntary standards is mandated by the CPSA, which in its revised post-1981 form only permits a mandatory standard where compliance with any existing voluntary standard is not likely to result in the elimination or adequate reduction of the risk of injury or it is unlikely that there will be substantial compliance with such standard.¹⁷ Also, the Office of Management and Budget Circular Number A-119¹⁸ and section 12(d) of the National

14. Council Directive 92/59/EEC of 29 June 1992 on General Product Safety, 1992 O.J. (L 228).

15. See *supra* note 9.

16. The Consumer Product Safety Commission ("CPSC") has the power to promulgate consumer product safety standards, which relate either to performance requirements, requirements that consumer products be marked with or accompanied by clear and adequate warnings, or instructions or requirements respecting the form of warnings or instructions. See 15 U.S.C. § 2056(a) (1994). The CPSC can also ban hazardous products. See 15 U.S.C. § 2057 (1994).

17. See 15 U.S.C. § 2058(f)(3)(D) (1994 & Supp. IV 1998).

18. 58 Fed. Reg. 57,643 (1993); 61 Fed. Reg. 68,312 (1996) (proposed revisions to OMB circular A-119).

Technology Transfer and Advancement Act of 1995¹⁹ encourage the involvement of governmental agencies in voluntary standards making procedures wherever possible.

ii. Voluntary Standards

The CPSC now works on eight to fourteen mandatory standards per year and forty to fifty voluntary standards. There are numerous standards writing organizations. The three with which the CPSC works most closely are the American National Standards Institute ("ANSI"), American Society for Testing and Materials ("ASTM"), and the Underwriters Laboratories, Inc. ("UL").

Voluntary standards have no legal effect as such. Although industry is often eager to develop voluntary standards and to comply with them, not only to help defend products liability claims and stave off any remaining threat of mandatory regulation, but also to use compliance as a marketing tool both at home and increasingly in the international marketplace. Also, if a producer inaccurately claims that its product conforms to a product safety standard when it does not, then it will be in breach of the truth and labeling laws administered by the Federal Trade Commission.²⁰

In the U.S., however, there is no bridge between mandatory and voluntary standards. Except in extreme cases, the U.S. system has forgone mandatory regulations and is left to rely upon free standing voluntary standards. In contrast, in Europe, the legislatures have managed to keep a hand on the tiller of product safety regulation by developing directives, which establish a framework that integrates voluntary standards. This integration is an effort to achieve those levels of safety considered politically desirable by means with which industry is comfortable. The integration of the standards into the legal framework has also permitted greater public participation in the formation of standards.

B. Europe—Standards Making as Privatized Legislation

The EC's Council Resolution in 1985 on the *New Approach to Technical Harmonization and Standards*²¹ marked a move away from detailed product-specific rules to broadly categorized directives. These directives lay down essential safety requirements but leave the details to be fleshed out by European standards.²² The linchpin of the system is

19. Pub. L. No. 104-113, 110 Stat. 775, 783 (1996) (codified in scattered sections of 15 U.S.C.).

20. See 15 U.S.C. § 52 (1994).

21. Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards, 1985 O.J. (C 136) [hereinafter *New Approach Resolution*].

22. See *infra* Part III.A (discussing the European standards bodies).

the standardization process.²³ Additionally, there has been the development of a global approach to certification and testing.²⁴ The new and global approaches have three limbs: (i) more flexible legislation, (ii) a prominent role for standardization, and (iii) reliance on conformity assessment procedures (leading to the award of the CE mark which allows access to the European market).²⁵

The “new approach” was intended to be both flexible, leaving a lot of the detailed work to the European standardization bodies, and at the same time attempting total harmonization of all safety aspects in order to reassure member states that they could safely permit free circulation of conforming products. The basic principles of the new approach to technical harmonization are set out in the 1985 Resolution as being:

- Harmonizing legislation should be limited to adopting essential safety requirements to which products should conform, and which if they do so conform, should be their passport to free movement throughout the Community.²⁶
- Standardization organizations should be entrusted with the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements.²⁷
- The technical specification should be voluntary.²⁸
- National authorities are compelled to recognize that products conforming to the harmonized standards are presumed to comply with the essential requirements. Manufacturers should have the choice of not manufacturing in conformity with the standards, but in this

23. This was recognized in 1990 by the publication of the Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, 1991 O.J. (C 20), and a follow up document the Commission Communication on the Standardization in the European Economy, 1992 O.J. (C 96), which preceded the Council Resolution of 18 June 1992 on the Role of European Standardization in the European Economy, 1992 O.J. (C 173). In 1995, there was a Communication From the Commission to the Council and the European Parliament on the Broader Use of Standardization in Community Policy, EUR. PARL. DOC. (COM 95) 412 (1995).

24. A White Paper in 1989 set out the Commission's thinking in this area. See A Global Approach to Certification and Testing: Quality Measures for Industrial Products, 1989 O.J. (C 267). Additionally, the Council Resolution of 21 December 1989 on a Global Approach to Conformity Assessment, 1990 O.J. (C 10), was adopted in 1989, which led to the Council Decision of 22 July 1993 Concerning the Modules for the Various Phases of the Conformity Assessment Procedures and the Rules for the Affixing and Use of the CE Conformity Marking, Which are Intended to be Used in the Technical Harmonization Directives, 1993 O.J. (L 220) [hereinafter Conformity Assessment and CE Marking Decision]. This sought to create a harmonized approach to conformity assessment so that member states could have confidence that all products said to be conforming to European standards actually did so conform. See *id.*

25. Readers may find it useful to know that the European Commission has published the EUROPEAN COMMISSION, GUIDE TO THE IMPLEMENTATION OF COMMUNITY HARMONIZATION DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH (1994). This is intended to serve as a manual and also includes the Commission's interpretation of certain key definitions. See *id.*

26. See New Approach Resolution, *supra* note 21.

27. See *id.*

28. See *id.*

case they are obliged to prove that their products conform to the essential requirements (and third party conformity assessment is usually required).²⁹

The presumption of conformity's purpose is to prevent both the routine testing of products and requirements that documentation be produced once the product has been found to conform to the directive. Conformity is typically signified by the CE mark, which is the effective passport for products to circulate within Europe.

Annex II of the 1985 Resolution contains guidelines listing the main elements that new approach directives should contain—sometimes referred to as the “model directive.”³⁰ These are worth studying both for what they reveal about new approach directives and also because they contain a guide to the structure and content of new approach directives. The model directive covers the following points:³¹

(i) *Scope*

The directives will list the range of products covered and the nature of hazards they are intended to prevent.

(ii) *General Clause*

Products within the scope of the directives may only be placed on the market if they do not threaten the safety of persons, domestic animals, or goods when correctly installed, maintained, and used for the means for which they are designed. However, particularly in the case of worker or consumer protection, this can be strengthened to include foreseeable as well as intended use.

As a general rule, the directives will provide for total harmonization, although the possibility of optional harmonization is allowed. The directives allow the trader the choice of means of attestation of conformity. Thus, member states should not, unless it is expressly provided for in the directives, set up pre-marketing controls. However, the directives do recognize that post-marketing spot checks will be necessary if national authorities are to carry out their obligation to ensure that only safe products are marketed.

(iii) *Essential Safety Requirements*

Whether the general safety objective is satisfied will be assessed by applying the essential safety requirements. These essential requirements are worded precisely enough so that when implemented in national legislation they create legally binding obligations which can be enforced. Additionally, the essential safety requirements should be formulated to allow the certification bodies, without reference to stan-

29. *See id.*

30. *See id.*

31. The following discussion is drawn from the model directive in substantially similar content. *See* New Approach Resolution, *supra* note 21.

dards, to certify immediately that products are in conformity.

(iv) Means of Attestation of Conformity

The means of attestation which the trade may employ are:

- (a) certificates and marks of conformity issued by a third party;
- (b) results of tests carried out by a third party;
- (c) declaration of conformity issued by the manufacturer or his agent based in the Community, possibly coupled with the requirement for a surveillance system; or
- (d) such other means as specified in the directives.

Specific directives establish the appropriate means of attestation and in so doing may limit or restrict the above range of options. Third party certification will be needed where there are no standards or the manufacturer chooses not to observe the standards. Where a manufacturer's own declaration of conformity is relied upon, the national authorities may, when they believe the product does not offer the appropriate level of safety, ask the manufacturer for the data from the safety tests on which they rely. If this report is not forthcoming, then there is sufficient reason to doubt the presumption of conformity. Only through the use of one of the specified means of attestation can the product benefit from the presumption of conformity. However, the trader remains free to use any means it sees fit to establish that its product complies with the general safety obligation and the essential safety requirements.

(v) Free Movement Clause

Member states are obliged to accept goods which conform to the general safety obligation and the essential requirements. Member states cannot as a general rule require prior verification of compliance with the essential requirements, nor should it lead to the sectoral directives systematically requiring third party certification.

Proof of conformity—the product's passport to free movement within the Community—can be assured by one of the means of attestation referred to above; declaring that the product is in conformity with a European harmonized standard, or, as a transitional measure, conforms to national standards. Where no standard is applied, proof of conformity with the essential requirements must be established by attestation by a third party.

(vi) Safeguard Clause

Even if a product is accompanied by a means of attestation, a member state must take all appropriate measures to withdraw or prohibit the placing on the market of the product in question or to restrict its free movement where it finds that the product might compromise the safety of individuals, domestic animals, or property.

The relationship between the essential safety requirements and

standards is central to the new approach. In theory, it provides the means to ensure safety in a manner which is compatible with economic development. The safety objectives are set out by the politicians in the directives, whilst the technocrats from industry take part in the standardization process to ensure that the means to achieve those goals are acceptable to industry. Inevitably, however, the distinction between the standard setting and implementation is not always clearly defined. Indeed, there is an inherent conflict between the mandate that the essential safety requirements be sufficiently precise so as to give rise to binding obligations and the other goals of limiting legislative intervention and delegating responsibility to the standardization bodies.³²

A perusal of the essential safety requirements in the annexes to the new approach directives shows that the rules they contain vary significantly in character. Some rules are very clear and precise. Thus, for instance, the Toy Safety Directive lays down maximum levels of exposure to eight substances.³³ Additionally, the directives may require specific warnings; for example, the Toy Safety Directive requires that a warning accompany all toys not suitable for children under 3 years.³⁴

On the other hand, many of the essential safety requirements found in the directives set down vague objectives, and they refer, for instance, to the need to *minimize* risks or reduce them *as far as possible*. Requirements phrased in this way leave a great deal of room for debate as to how far risks can be minimized or reduced. The clear danger is that the directives can produce the symbolism of safety without providing actual concrete safety.

The establishment of the safety requirements and the standards implementing them may also blur the distinction between safety policy and its technical implementation. As a general rule, the standards do not even prescribe the means by which safety should be assured. They are generally framed in terms of performance rather than means, with the belief being that "only people of the trade can be responsible for choosing the necessary and sufficient technical solutions to obtain the performances defined by the standards so as to meet the essential requirements specified by the directive and intended to guarantee user safety."³⁵

Therefore, product safety in Europe is governed by four layers of controls—the general safety objective in the body of the directive, the

32. See Josef Falke, *Reactions to the New Approach Concerning Technical Harmonization and Standards in the FRG: The Case of the Proposed Directives on Machines*, in *PRODUCT LIABILITY AND PRODUCT SAFETY IN THE EUROPEAN UNION* 92 (Christian Joerges ed., 1989).

33. See Council Directive 88/378/EEC of 3 May 1988 on the Approximation of the Laws of the Member States Concerning the Safety of Toys, 1988 O.J. (L 187) (establishing for users the maximum daily exposure of certain chemicals).

34. See *id.*

35. See CEN, *THE NEW APPROACH* 198 (1994) (comment by Jeanne Milhailov).

essential requirements to be found in its annex, harmonized standards, and the means chosen by manufacturers to achieve those standards. The content of the standards is pivotal as these will be the basis for manufacturers' design and production decisions. The standards will also provide the measure against which products will usually be judged in order to obtain the CE marking and thereby gain access to free movement within the EC.

It is also clear that the European system of product safety regulation is more than just a technical process. Standards do not just provide the technical details to supplement the safety standards laid down in the essential requirements. More precisely, the essential requirements tend to set down the need for various safety concerns to be addressed, whilst the standards give meaning to those exhortations. To put it more bluntly, the directives say that products should be safe, the standards tell us what safe means. However, the important distinction with the position in the U.S. is that whilst the standards remain voluntary in theory, in practice there are substantial incentives attached to complying with the standards. Industry, because of these incentives, is obliged to follow the standards. By doing so, the manufacturers obtain a presumption of conformity and the CE marking, which is a passport to the European market. The value of the standards is that this compliance is achieved without, for the most part, the need for third party verification that products comply with the essential safety requirements set out in the new approach directives.

III. PROCESS FOR DEVELOPING STANDARDS AND REGULATIONS

A. Standards Formation in Europe

Directives are adopted by a political process, generally requiring a qualified majority approval of the relevant Council of Ministers.³⁶ There are consultation procedures with the European Parliament and the Economic and Social Committee.³⁷ This part of the European product safety regime is fairly traditional. However, most of the crucial decisions are delegated to the standards bodies and it is their procedures that are interesting to assess.

There are three European standards organizations: the European Committee for Standardization³⁸ ("CEN"), the European Committee

36. The Council of Ministers is composed of various ministers sent by the member states. Depending on national traditions, the representative may be a member state's minister of trade, minister of economics, or minister of consumer affairs.

37. The Economic and Social Committee is a consultative committee comprised of expert representatives from the member states.

38. For further discussion see CEN, *What is CEN?* (visited Feb. 25, 2000) <<http://www.cenorm.be>>.

for Electrotechnical Standardization³⁹ ("CENELEC"), and the European Telecommunications Standards Institute⁴⁰ ("ETSI"). The EC has entered into an agreement by which these bodies are responsible for the creation of the European standards needed by the EC.⁴¹ This article will concentrate on CEN, which develops the majority of standards for non-electrical consumer products.

Several criticisms have been levied against CEN. These involve suggestions that its procedures are too slow, that it fails to promote the European dimension to standardization, and that it does not fully integrate social partners, such as consumers, into its structures and working methods.⁴² In truth, there were probably unrealistic expectations about the ease with which standards could be created as well as some inefficient procedures. With the push to complete the internal market, strains in the system certainly appeared, but these pressures seem to have diminished and CEN and the EC appear to work more harmoniously at the present time.

Although many of the criticisms made of CEN were valid, it is worthwhile setting them in the context of both the origins of CEN and the changed role it has been called upon to play. When CEN was established in 1961, its role was not so much to harmonize standards, but rather to ensure the more effective implementation of international standards by national standardization bodies in Europe. Between 1961 and 1982, CEN only adopted ninety-six standards. By 1995, 1,700 European standards were in existence with a further 8,300 projected.⁴³ As of June 30, 1996, the number of standards had risen to 2,700.⁴⁴ Not only the new approach directives, but other moves towards European integration (for instance in the public procurement sphere) have placed increased workloads on CEN. Thus in 1992, CEN produced 307 new standards. This number had risen to 408 in 1993⁴⁵ and increased further to a staggering 710 in 1995.⁴⁶ Even with this increase in activity there is a large backlog of projected proposals. The simple truth is, that whilst standards bodies may be more competent to decide technical matters than bureaucrats, they face the same problems of having to resolve conflicting interests. This conflict resolution inevitably involves a lengthy process.

Thus, CEN is trying to perform a task—harmonization—which it

39. For further discussion see CENELEC, *What is CENELEC?* (visited Feb. 25, 2000) <<http://www.cenelec.be>>.

40. For further discussion see ETSI, *About ETSI* (visited Feb. 25, 2000) <<http://www.etsi.org>>.

41. See *supra* note 38.

42. See JACQUES PELKMANS & DR. MICHELLE EGAN, *FIXING EUROPEAN STANDARDS: MOVING BEYOND THE GREEN PAPER* 14-15 (1992).

43. See CEN, *STANDARDS FOR ACCESS TO THE EUROPEAN MARKET* 13 (2d ed. 1995).

44. See CEN, *ANNUAL REPORT 1995/1996* 10 (1996).

45. See CEN, *ANNUAL REPORT 1993/1994* 36 (1994).

46. See CEN, *supra* note 44, at 10.

was not originally established to achieve. Additionally, the size of the harmonization task has grown exponentially in recent years. CEN's basic constitution, as a body representing and comprising national standards bodies, also causes some problems. Industry does not feel it "owns" CEN, and so industry questions why it should fund it.⁴⁷ Equally, national standardization bodies are themselves industry oriented and so other social partners feel excluded. The need to reach consensus between national interests and traditions may both water down proposals and cause them to be delayed. Nevertheless, there are clear indications that the standards making process is being made subject to public accountability.

i. Structure of CEN

General oversight of CEN is carried out by its General Assembly. This comprises representatives of national standardization bodies from the EC and European Free Trade Area ("EFTA") states.⁴⁸ European social and economic organizations can be given associate status within CEN's General Assembly, but this status carries no voting rights. The General Assembly is represented by an Administrative Board which directs and coordinates all the action of CEN bodies. The General Assembly appoints a President and Secretary General.

At a practical level, the Technical Board ultimately controls the standards program and is responsible for all matters concerning the organization, working procedures, and coordination and planning of standards work. In 1991 and 1992, Technical Sector Boards were established to improve coordination of work programs and to increase involvement of CEN's industrial and social partners. They have delegated authority from the Technical Board to define and control the standards program in their sector.⁴⁹ The institutions discussed so far are serviced by CEN's central secretariat. The actual standardization work is carried on by Technical Committees. These are chaired and serviced by national members.

CEN is funded by annual membership contributions from its national member bodies. In 1991, however, the EC Commission contributed seventy percent of CEN's annual budget in the form of mandates to harmonize standards in connection with EC legislation. Of course, there were other costs associated with standardization, namely the time

47. Compare CEN to ETSI where individual companies are members.

48. CEN's National Members include: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. *See supra* note 38.

49. CEN is divided into operational sectors such as "construction," "healthcare," or "machinery." Under these broad categories standards will be developed instead of producing individual standards for particularly identified products.

of experts and their travel expenses which are funded by industry, whilst some of the secretariat support for technical committees is provided by national bodies. Nevertheless, the European standardization bodies were perhaps unhealthily dependent on EC funding. Whilst prepared to continue to commit public funds for the foreseeable future for standardization, the EC was rightly alarmed at this imbalance between public and private funding.⁵⁰ It suggested national contributions be placed on a long term commitment basis but also that new sources of funding be developed. In fact, CEN has decided to reduce its dependency on official sources of funding to twenty-five percent of its total budget.⁵¹

ii. Standards Making Procedure

Standards implementing the essential requirements found in the new approach directives are adopted on the basis of a mandate from the EC Commission (and sometimes also EFTA). The mandate is a contract between the Commission and CEN for CEN to draft standards.⁵² Negotiations between the Commission and CEN on the package of standards should commence from the moment a proposal is made and run in parallel with negotiations on the directive. Problems can arise when CEN is not fully involved in the development of the mandate.

The Commission has introduced the concept of "open" mandates, which allow the standardizers, and hence the economic interests affected, a broad degree of flexibility in structuring the standards program. Such mandates state the areas in which standards are needed, together with an explanation of legislative and related contexts. The mandates, however, leave the standardizers free to decide which standards are actually needed.

Once a draft mandate is agreed upon, it is submitted to the Standing Committee set up under the Technical Standards Directive.⁵³ When approved by that Committee, the Commission puts out a tender to CEN. CEN responds with a detailed quotation specifying the number of standards needed, how the work will be distributed between technical committees, how long the standards will take to prepare, and the cost of administrative support from the CEN central secretariat, including where needed, any research, testing, etc. After financial nego-

50. See Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, 1991 O.J. (C 20).

51. See PARL. EUR. DOC. (SEC 95) 2104, at 1.6 (1995). However, there seems to be some ambiguity as to whether the percentage contributed by the Commission refers simply to the costs of the CEN secretariat or the costs of the CEN and national secretariats servicing CEN committees. This caveat did not seem apparent when as already noted the Commission claimed to meet seventy percent of CEN's annual budget.

52. See CEN, *supra* note 43, at 189 (comment by J. Repussard).

53. Council Directive 83/189/EEC of 28 Mar. 1983 Laying Down a Procedure for the Provision of Information in the Field of Technical Standards and Regulations, 1983 O.J. (L 109).

tiations, a contract is concluded. Requests for standards may also come from CEN national members and European organizations.

When a proposed standard is in the standardization program the Technical Board has three options as to how to proceed:

(i) The proposed standard can be sent to a Technical Committee. This will happen when the matter is a new topic. Once a draft standard ("prEN") has been agreed upon it is exposed to public inquiry for six months. This means it is distributed to CEN members for public comment. The technical committee system, bringing together representatives from 18 countries, has been criticized for being inefficient and the suggestion has been made that it should have smaller "project teams" developing the proposal so as to make the procedure more efficient.

(ii) Where an existing reference document exists (European trade specification, national standard, or International Organization for Standardization ("ISO") standard) there is no need for a technical committee to be established and the questionnaire procedure can be adopted. This replaces the public inquiry procedure, but there is still a six month time limit for replies.

(iii) Under conditions laid down in the "Vienna Agreement," CEN can transfer work for the execution of European Standards to ISO. There are parallel procedures for CEN/ISO public inquiry and formal vote.

After the public inquiry, the National Members have a formal vote on the final draft. This is done using a weighted voting procedure based on article 148 of the Treaty of Rome,⁵⁴ but the procedure is adapted to take account of the larger membership of CEN. However, standardization has a tradition of working by consensus. Because the standards are voluntary, a level of acceptance is required by their potential users. This same philosophy applies to standards adopted under new approach mandates, even if the end result is a *de facto* requirement. This consensus approach is another explanation for the lengthy adoption process.

The procedure is largely the same for standards developed as a result of a mandate from the EC under the new approach as it is for any other standard. Member states may scrutinize new approach standards more closely because of the presumption of conformity to which they give rise. CEN must also send a copy of the standard to the Commission, confirming that it complies with the essential requirements of the directive. CEN also requests that standards be published in the Official Journal and that member states be informed of their existence. CEN ensures quality control by appointing consultants to make sure the members of the technical committees understand the directive and the

54. Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter Treaty of Rome].

implications of the essential requirements and that they stay within their mandate. The consultant can comment during the inquiry period, and prior to the formal vote the consultant must send a report to the Secretary General.

B. Standards Formation in the U.S.

i. Mandatory Standards—Attempted Innovation

The procedures by which the CPSC promulgates a consumer product safety rule⁵⁵ is convoluted and drawn out. It follows the notice and comment procedure which allows interested parties to participate, but there are also numerous obligations on the CPSC to justify its decision to enact a mandatory rule.

It is worth mentioning, however, that when first established, the CPSC had some innovative powers. For instance, there had been a novel and potentially powerful "petitioning process" whereby any interested person, including a consumer or consumer organization, dissatisfied with any action or inaction on the part of the CPSC could petition the CPSC.⁵⁶ The aim of this provision was clearly to prevent the setting in of bureaucratic inertia. During its first three years, the CPSC received 203 petitions. The petitions became a major influence in establishing the CPSC's priorities. This was perhaps unfortunate for an agency with such a limited budget. The new priorities diverted the CPSC from dealing with those products which presented the most serious risks on the CPSC's Consumer Product Hazard Index. The CPSC was soon finding that there was a backlog of petitions which were not being dealt with within the prescribed 120 day period.⁵⁷ The petitioning process is now dealt with under the general rules of the Administrative Procedure Act ("APA").⁵⁸ The 120 day deadline is removed and judicial review of petition denials is based on the arbitrary and capricious standard.⁵⁹

Prior to 1981, the offeror procedure had been the center-piece of the CPSC's rule-making procedure.⁶⁰ Under this procedure, the CPSC would as a first stage, when it determined that a mandatory standard was required, issue a Notice of Proceedings. The notice sought offers to develop a standard from non-CPSC entities. Offerors could be indi-

55. A consumer product safety rule is a consumer safety standard or a rule declaring a consumer product a banned hazardous product. See 15 U.S.C. § 2052(2) (1994).

56. Law of Oct. 27, 1972, § 10, 86 Stat. 1217 (repealed 1981).

57. See *id.*

58. 5 U.S.C. §§ 555(e), 706(2) (1994).

59. See *id.*

60. See Antonin Scalia & Frank Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 UCLA L. REV. 899 (1973).

viduals, consumer groups, state or federal agencies, standards bodies, trade associations, manufacturers, distributors, or retailers. If a self-interested offeror was selected, the CPSC could simultaneously develop its own standard, but this option was never taken. On receiving the offeror's submission, the CPSC had sixty days in which to decide whether to terminate the procedure or to propose a standard. If the latter course was taken, then procedures based on the informal rule-making procedures of the APA applied.

To allow consumer groups the chance to be involved in the offeror process the CPSC was allowed to contribute towards the costs of the offeror. In total, \$666,300 was paid to offerors, the vast majority to consumer organizations. The Consumers Union ("CU") received \$250,924 for the lawn mower rule and the National Consumers League ("NCL") received \$196,811 for the miniature Christmas tree light standard.⁶¹ CU was still only partially reimbursed for the costs it incurred in developing the standard and indicated that it would probably not be an offeror in the future. Failure of the CPSC to agree to cover more than out of pocket expenses had caused it not to accept NCL's tender to be the offeror with respect to architectural glass.⁶² It is difficult to assess how well the consumer groups performed as offerors and it would be wrong to judge the policy on these isolated case studies, especially when the procedures were in their infancy. It is noteworthy, however, that the CU's efforts in relation to lawn mowers have been described, by an academic observer, as "creditable" (and this in the context of a highly complicated standard in relation to which the CPSC made several mistakes) and the NCL seems to have been widely praised.⁶³ This is interesting, for it suggests that consumers, as well as industry, are capable of taking the lead in developing standards. The crucial question is, of course, funding. Whilst it might be unrealistic to expect consumer groups to become the main standards writers, it does suggest that they are capable of more than a mere consultative role.

As well as acting as offerors, consumer groups could also be involved in the development of standards by other offerors, as these were required to provide opportunities for the involvement of interested parties. The CPSC was silent on the power of the CPSC to fund such participation, but in the 1970's it had an active program of funding such ini-

61. See Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 64 (1982).

62. See generally Note, *Inside the Proposed Standard for Architectural Glass: An Outward Look at Consumer Participation in the CPSC's Offeror Process*, 43 GEO. WASH. L. REV. 1173 (1975). The CPSC agreed to pay other costs, such as lost wages, in only one initiative—when the NCL acted as offeror for miniature Christmas tree lights. See *id.*

63. See Carl Tobias, *Early Alternative Dispute Resolution in a Federal Administrative Agency Context: Experimentation with the Offeror Process at the Consumer Product Safety Commission*, 44 WASH. & LEE L. REV. 409, 433, 453-58 (1987).

tiatives. The post-1981 procedure does allow the CPSC to compensate those who help the agency develop compulsory standards,⁶⁴ but apparently budget restraints have prevented it from doing so.⁶⁵

In two articles, Carl Tobias, has considered the role of public funded experts in CPSC procedures, both under the offeror process and otherwise.⁶⁶ His conclusion is that experiences have been mixed, but that citizen involvement has been sufficiently worthwhile to suggest that continued experimentation is desirable. This assessment is certainly correct. Consumers need to be involved in the standardization process. The formal right to be involved in matters of consumer concern identified by the CPSC is to be welcomed, but will be empty rhetoric if consumer organizations do not have the financial resources to take advantage of that privilege.

However, the CPSC model was based on the agency deciding when and what type of consumer input was needed in the process. This approach seems to implicitly be approved of by Tobias, although he criticized the CPSC for sometimes mismatching their needs with participant competence.⁶⁷ Whilst it might be efficient for the CPSC to direct consumer involvement, it should be recognized that consumers should be given the freedom to determine how they conduct and prioritize their involvement in standardization.

The offeror process was widely considered to be a failure.⁶⁸ In large measure this was due to the inexperience of the CPSC and the offerors in handling the procedures.⁶⁹ The process has, however, been held up as a valiant attempt to democratize the rule-making process. In fact, although the CPSC tried to ensure that consumers could take advantage of the public participation requirement, it was business interests who were organized and financially equipped to take advantage of them.⁷⁰ In retrospect, it may have been wiser to have had the offeror procedure as an option for the CPSC to invoke on suitable occasions rather than as a mandatory procedure, no matter how complex the issue at stake.⁷¹ What is needed is a procedure under which the CPSC allows

64. See 15 U.S.C. § 2056(c) (1994).

65. See Tobias, *supra* note 63, at 413.

66. See *id.* See also Carl Tobias, *Great Expectations and Mismatched Compensation: Government Sponsored Public Participation in Proceedings of the Consumer Product Safety Commission*, 64 WASH. U. L.Q. 1101 (1986).

67. See Carl Tobias, *Great Expectations and Mismatched Compensation: Government Sponsored Public Participation in Proceedings of the Consumer Product Safety Commission*, 64 WASH. U. L.Q. 1101, 1161 (1986).

68. See Tobias, *supra* note 63 (providing case studies of the seven occasions on which the offeror process was used).

69. See Schwartz, *supra* note 61, at 62–68. Schwartz suggests projects were badly managed, were too ambitious, worked against a background of inadequate data, and gave rise to extended periods for public participation. See *id.*

70. See *id.* at 75.

71. See *id.* at 68.

the conflicting opinions to be aired and a satisfactory solution for consumer protection produced. At least the offeror process attempted to reach that goal; the present emphasis on voluntary standards is less promising.

In order to promote consumer input, the U.S. might consider establishing an umbrella group of consumer organizations interested in standardization. This could be financed by the CPSC, other governmental agencies, or those standards bodies involved in the development of standards for consumer products. This coalition could then determine which products it should prioritize for attention and whether influence should be exerted on the standards bodies or the CPSC. It might also develop expertise in representing consumers within the standardization process. We shall see that one of the glaring differences between standardization in the U.S. and Europe is the way in which consumers are represented in the process.⁷²

ii. Voluntary Standards

It has been estimated that there are 400 voluntary standards writing bodies in the United States.⁷³ It is therefore a very decentralized model. The American National Standards Institute (“ANSI”) is essentially a “trade association of standards setters”⁷⁴ which approves American National Standards (“ANS”) and represents the United States within the ISO. However, half of the standards bodies are not members of ANSI—non-members rarely submit standards to ANSI for approval—and even some members choose not to submit all their standards for approval. The system has therefore been described as “a hodgepodge of sources of standards rather than a neat pyramid with ANSI at the apex.”⁷⁵ This contrasts markedly with the role of CEN in the context of new approach directives, where the national standards bodies are bound to adopt the European standards, and industry bodies are integrated into the process at the national and European levels.

The largest standards writing body in the U.S. is the American Society for Testing and Materials (“ASTM”) which publishes more than 9,100 standards in its *Annual Book of ASTM Standards*. ASTM accounts for over half of ANSI approved standards and it now submits all of its standards to ANSI. The National Fire Protection Association (“NFPA”) is another important source of standards which are compiled

72. See *infra* Part IV.

73. See ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, CONSUMERS, PRODUCT SAFETY STANDARDS AND INTERNATIONAL TRADE 25 (1991).

74. Robert W. Hamilton, *The Role of Non-governmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329, 1341 (1978) (providing a thorough, but somewhat dated, analysis of U.S. standards procedures).

75. *Id.* at 1343.

in the *National Fire Codes*. The American Society of Mechanical Engineers ("ASME") publishes several hundred codes. Underwriters Laboratories, Inc. ("UL") also produces over 700 of its own standards as well as participating in the work of other standards associations. UL is also the leading third party certifier in the United States and its UL label is a familiar feature on American products.

Voluntary standards were slated by the National Commission on Product Safety in 1970.⁷⁶ The Final Report concluded that "these standards are chronically inadequate, both in scope and permissible levels of risk."⁷⁷ They were also the subject of a damning report by the Federal Trade Commission's Bureau of Consumer Protection, which pointed to a lack of procedural safeguards in the standardization process and claimed standardization and certification procedures delayed or deterred market entry of innovative products, unnecessarily increased costs, deceived consumers about product safety or quality, and unjustifiably limited consumer choice.⁷⁸ However, the initial belief that consumer safety problems could all be resolved by government regulation by the CPSC soon disappeared and there was a realization that for either practical or political reasons voluntary standards would have to continue to play an important role. Although the CPSC would monitor some standards to ensure that they adequately protected consumers, these standards remain truly voluntary, in the sense that manufacturers are not required to use them. This contrasts with the position in Europe where manufacturers in areas covered by new approach directives must apply the standards or otherwise satisfy essential safety requirements. We shall also see that "pure" consumer representation is less well assured in North America than within Europe.

iii. American National Standards Institute

ANSI's most important function is to coordinate standards activity and to develop the system of American National Standards ("ANS"). ANSI does not itself create standards, rather it acts as a federation of interested parties which seeks to find a consensus regarding the proliferation of ANS. ANSI has organizational members,⁷⁹ company members,⁸⁰ and government members.⁸¹ Each member section has its own

76. See NATIONAL COMM'N ON PRODUCT SAFETY, FINAL REPORT (1970).

77. *Id.* at 48.

78. See FEDERAL TRADE COMM'N, STANDARDS AND CERTIFICATION (1983).

79. The American National Standards Institute ("ANSI") has over 300 organizational members including: trade associations such as the Industrial Safety Equipment Association, professional societies such as the American Society of Safety Engineers, and standards bodies such as Underwriters Laboratories, Inc.

80. ANSI has over 600 company members including corporations such as IBM, AT&T, and General Electric.

81. Over thirty governmental agencies or departments are members of ANSI. These entities represent federal and state interests and include: the Department of Defense, NASA, and the Na-

council. Standards activity is coordinated through ANSI's Executive Standards Council. Standards boards look after the day to day management of areas of standards activity. The Board of Standards Review is responsible for deciding whether proposed standards conform to the requirements of ANS formation.

In 1995, there were 11,500 approved ANS. Most ANS are developed by ANSI organizational members, who submit them to ANSI for approval. However, about a quarter of ANS are written by American National Standards Committees. ANSI usually establishes such a committee when no suitable organization is active in an area. These committees are created by ANSI, but are not actually part of ANSI. ANSI usually designates an organizational member to sponsor each committee and to act as its secretariat.

An ANS can only be developed by an Accredited Standards Developer ("ASD").⁸² The procedures of the ASD must ensure that materially affected and interested parties can participate, either as part of the consensus body or in the public review stage. The consensus body must not be dominated by any single interest category. These shall usually be divided into producer, user, and general interest categories, but other more specific categories are possible. Normally, this balance will be achieved by ensuring that no single category constitutes the majority of a committee or in the case of safety standards a third of the committee. ASDs should review any comments or objections, seek to resolve any objections, and must have appeal procedures so that matters can be heard by an impartial body. Standards are adopted on the basis of the consensus which is said to demand "the concurrence of more than a simple majority, but not necessarily unanimity."⁸³

ANSI provides for three forms of accreditation by standards developers.⁸⁴ Each option provides different mechanisms for ensuring due process is adhered to and for arriving at a consensus.⁸⁵

(a) Accredited Organization Method

A number of organizations have been accredited under the organizational method. Typically they are bodies which have developing standards as one of their activities. This form of accreditation leaves the organization with a great deal of flexibility with regard to its procedures and structure so long as they comply with the general criteria for accreditation.⁸⁶

tional Security Agency.

82. See generally ANSI, PROCEDURES FOR THE DEVELOPMENT AND COORDINATION OF AMERICAN NATIONAL STANDARDS ¶ 3 (1997) [hereinafter ANSI PROCEDURES].

83. *Id.* ¶ 1.3.

84. For further discussion see *id.* at app. E.

85. See *id.* ¶ 2.1.

86. For further discussion see *id.*, ¶¶ 2.1 to 2.5.

(b) Standards Committee Method

Accredited Standards Committees comprise representatives of directly and materially affected parties who come together to develop a standard. They typically arise when a standard affects a broad range of interests or where several organizations have similar interests. Although committees may adopt their own procedures, a model procedure is provided by ANSI.⁸⁷

(c) Canvass Method

A third way of establishing consensus is through the canvass method.⁸⁸ This method has traditionally been used by professional societies and small trade associations that have documented current industry practices which they wish to have recognized as a national standard. The standards writing organization canvasses interested organizations. Adoption of a standard requires approval by a majority of the canvass list and at least two-thirds of those voting, excluding abstentions. A major problem with this method of assessing consensus is the low response rate. It is said to be particularly difficult for consumer groups to comment on a standard without having been involved in writing the standard.⁸⁹

Development or modification of an ANS commences with an announcement "in suitable media as appropriate to demonstrate provision of opportunity for participation by all directly and materially affected persons."⁹⁰ Once public notification is complete, actual notice is given to ANSI through the transmission of a Project Initiation Notification System ("PINS") form.⁹¹ The PINS form is then listed in *Standards Action* for public comment.⁹² After the appropriate time for comment,⁹³ the consensus ballot takes place. Of course, where the canvass method is used the public review only takes place during or after the consensus ballot.

The Board of Standards Review ("BSR") considers whether ANSI's procedures have been carried out properly.⁹⁴ Standards are approved by a two-thirds majority of those voting in a letter ballot, provided the number of members returning ballots, excluding abstentions, is at least a majority of the Board. The BSR will also ensure that standards are not contrary to the public interest, do not contain unfair provisions, are not unsuitable for national use, nor conflict with an existing

87. See *id.* at app. A.

88. For further discussion see *id.* at app. B.

89. See Hamilton, *supra* note 74, at 1348-49.

90. ANSI PROCEDURES, *supra* note 82, ¶ 1.2.6.

91. See *id.*

92. See *id.*

93. The time required for comment is dependent on whether the full text of the proposed or revised ANS can be published. See *id.*

94. See *id.*, ¶ 1.3.1.1.

ANS.⁹⁵ There is now a provision, subject to special auditing requirements, for ASDs which have a “consistent record of successful voluntary standards development”⁹⁶ to request authority to designate its standards as ANS without the need for BSR approval.⁹⁷

BSR members are appointed because of their “competence and the ability to render impartial judgment.”⁹⁸ Robert Hamilton concluded that BSR membership took its role seriously and insisted on proof of procedural compliance and the existence of a consensus.⁹⁹ Members of the BSR tend to be drawn from industry, standards bodies, and government. There is no express consumer representation on the BSR, but the BSR is required to refer consumer product standards to the Standards Screening and Review Committee of the Consumer Interest Council, which has the option of reviewing the standard and providing comments to the BSR. However, it shall be seen that the role of consumer representation in the U.S. is under developed.

IV. CONSUMER REPRESENTATION IN THE STANDARDS PROCEDURE¹⁰⁰

A. European Model

There is general agreement in Europe that consumers should be involved in the standards-making process. This has been stated by the European Commission on numerous occasions,¹⁰¹ and is also the position of the European standardization bodies. Such involvement is necessary if standards are to be acceptable to consumers and to legitimize this form of “private legislation.”

Consumer involvement, however, should be more than a few champagne parties for their representatives and pleasant platitudes in annual reports. To operate effectively, consumers need to be represented by technical experts.¹⁰² Technical expertise is needed because

95. *See id.*

96. *Id.*, ¶ 1.3.2.1.

97. *See id.*, ¶ 1.3.2.

98. ANSI, OPERATING PROCEDURES OF THE BOARD OF STANDARDS REVIEW ¶ 2.1 (1995).

99. *See* Hamilton, *supra* note 74, at 1367.

100. For further discussion see Geraint G. Howells, *Consumer Safety and Standardization—Protection Through Representation?*, in *LAW AND DIFFUSE INTERESTS IN THE EUROPEAN LEGAL ORDER: LIBER AMICORUM NORBERT REICH 755* (Hans-W. Micklitz et al. eds., 1997).

101. *See* Council Resolution of 19 May 1981 on a Second Programme of the European Economic Community for a Consumer Protection and Information Policy, 1981 O.J. (C 133), ¶ 19; Council Resolution of 15 December 1986 on the Integration of Consumer Policy in the Other Common Policies, 1987 O.J. (C 3), ¶ 5; Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, *supra* note 23, ¶ 33; Commission Communication on the Standardization in the European Economy, *supra* note 23, ¶¶ 32-37; Making the Most of the Internal Market: Strategic Programme, EUR. PARL. DOC. (COM 93) 632, at 37 (1993) (discussing increasing transparency and making the procedures more accessible to ‘economic operators’ which will presumably also include consumers).

102. As Micklitz graphically puts it: “Without strengthening the technical equipment there will never be a chance of claiming ‘a bit more’ than the industrial side has offered.” Hans-W. Micklitz,

consumer representatives will be participating in working groups and technical committees in which the other members will be technical experts from industry. Finding this sort of personnel to represent the consumer is difficult. Certainly, consumer political activists are of little use in the technical debates surrounding the standardization process. Fortunately, there is a scattering of such consumer-oriented technical people in consumer organizations, research institutes, and test houses across Europe. One problem, however, is that they tend to be concentrated in a few countries, such as the U.K. and Germany.

The move from the national to the European level should, in theory, allow the consumer movement's limited resources to be more focused; permitting consumers in those countries which do not have adequate resources for consumer protection to benefit from the input at the European level. It should also have the advantage of permitting European consumers to speak with a common European voice, whereas industry involvement may be divided along national lines.¹⁰³ However, the Europeanization of the problem also brings with it the problem of coordinating a common consumer position. Legitimate differences in approach can exist between consumer groups, perhaps based upon cultural attitudes to risk or alternative approaches to combating dangers. However, a divided front can, at least if not clearly explained, weaken the impact of the consumer voice. Coordination at the European level, however, involves considerable costs.

Moreover, the move to the European level can represent a step backwards for consumers in those countries that have already developed effective means to permit consumers to influence national standardization procedures. Instead of occupying a place at the national negotiating table, the national consumer voice is represented, at best, as a member of a national delegation which is there to represent the position of the national standards body. Indeed, such representatives are bound to follow the national line even if this is counter to their view of what is in the consumers' best interest.

At the European level, the development of representation through participation in national delegations continues to be an important feature, although there is now some direct consumer representation on CEN committees through the European Association for the Coordination of Consumer Representation in Standardization ("ANEC"). Nevertheless, because these participants need technical knowledge, even the direct European consumer representatives tend to be appointed

Perspectives on a European Directive on the Safety of Technical Consumer Goods, [1986] 1 COMMON MKT. L. REV. 617, 640.

103. Hans-W. Micklitz, *Considerations Shaping Future Consumer Participation*, in EUROPEAN PRODUCT SAFETY 201 (Christian Joerges ed., 1991).

from those countries with developed consumer technical expertise. In practice, this means that Southern European consumers tend to be underrepresented in the standards process, and the French consumer groups tend not to participate because ANEC only has funds to operate in English.

In 1977, CEN published a joint document with CENELEC which stated that there should be “consultation of consumers in the framing of decisions affecting their interests.”¹⁰⁴ The European standards bodies, however, did not foresee themselves as being responsible for accomplishing this objective. The bodies instead believed that encouragement was to be given for the development of consumer representation within national member bodies. In 1982, the Commission reached agreement with CEN and CENELEC for consumer representatives to participate in their work. The consumer observers were nominated by the EC’s Consumer Consultative Council (“EC-CCC”) and organizational support was provided by BEUC (Bureau Européen des Union Consommateurs). Soon, a more independent structure, although still housed within BEUC, was established—the SECO (Secretariat Européen de Co-ordination pour la normalisation). This was to serve as a model for the present structure of consumer representation in European standardization—ANEC.

ANEC was formed in 1995.¹⁰⁵ Its General Assembly comprises one member of a national consumer organization in each EC/EFTA member state, four nominees from the EC, and two from the EFTA and EC-CCC. Giving control of consumer representation to consumer organizations is important as it underlines the independence of the consumer movement. ANEC has carried over SECO’s operational structure. ANEC has six working groups: child safety, electrical appliances, machinery, the environment, gas appliances, and traffic safety. These groups bring together experts to consider particular projects. Their work is overseen in a coordination group, which also deals with any issues falling outside the scope of the six working groups and provides a forum for the discussion of horizontal issues and for exchanging information produced at the national level. Because the working groups tend to be dominated by technical experts from a limited number of countries, the coordination group is important to ensure all countries are involved in the representation of consumers in the standardization process. This has been said to be particularly important for the Southern European countries and Ireland.¹⁰⁶

104. Bruce Farquhar, *Consumer Representation in Standardization*, 3 CONSUMER L.J. 56, 62 (1995) (quoting CEN/CENELEC, CONSUMER INTERESTS AND THE PREPARATION OF STANDARDS (1977)). See also ANEC, CONSUMER PARTICIPATION IN STANDARDIZATION (1996).

105. See ANEC, ANNUAL REPORT 1995 (1995).

106. See *id.* at 18.

In 1995, 750,000 ECU (European Currency Unit) was granted by the EC to support consumer representation in standardization.¹⁰⁷ We will see that this is far more generous than any equivalent funding in the U.S. An important use of these funds is to pay the expenses of consumer representatives attending CEN working groups. Roughly fifty European committees have an ANEC representative, with consumer representation being assured on approximately another 150 committees through national delegations.¹⁰⁸ ANEC is also trying to ensure that greater influence can be exerted at the national level by circulating written comments on drafts to national representatives. The use of written comments has increased, with sixty-three of these written comments being made in 1995 compared to fifteen in 1992.¹⁰⁹ However, successful consumer representation seems to depend upon having technical experts who can engage in debate with, and obtain the respect of, the industry experts on the standardization committees.¹¹⁰

Work in the technical committees and working groups of CEN is important, but by the time that work is undertaken the main features of safety policy have been formed through the directives and mandates. It is also important that consumers do not merely respond to initiatives, but can force the standardization process to evaluate their concerns. Two developments have taken place which have the potential to help address these concerns. CEN has opened up its structures to the extent that groups such as ANEC can become associate members. However, it is still unclear what benefits accrue from associate membership and how much ANEC will be able to influence the overall strategy of CEN. Additionally, at the end of 1995, a framework mandate was agreed upon, which establishes a mechanism whereby consumer representatives can petition the standing committee, under the Technical Standards Directive, for a consumer concern to be addressed through standardization. Implementing mandates could then be issued covering specific products and consumer concerns.¹¹¹

Funding and technical knowledge will be the eventual keys to the success of European consumer participation in the standardization process. In this respect, the launch of ANEC has been disappointing, because it was unsuccessful with respect to all twelve research projects for which it sought Commission funding in 1995.¹¹²

107. See Farquhar, *supra* note 104, at 68.

108. See ANEC, *supra* note 105, at 18.

109. See *id.* at 19. Although of some use, one suspects that written communications are unlikely to significantly influence the development of national policy, unless the national consumer representative is able to comprehend and engage in the debate set out in the written comment. Simply reading a position statement is unlikely to cause industry to take the point seriously.

110. See, e.g., *id.* at 28 (describing the appointment of an ANEC representative as convener of a CEN working group on playground equipment).

111. See *id.* at 9.

112. See *id.* at 43.

Coordinating consumer involvement in standardization with a limited budget is bound to be a difficult task. Inevitably, ANEC is having to draw upon the knowledge of those countries which already have some expertise and national resources. It is doubtful that European consumer representatives will have as much influence in CEN committees as they do in those countries with developed national systems for consumer representation. It is also still to be seen what influence ANEC can have on the political orientation of EC consumer safety policy in the standardization context.

B. Consumer Participation in the U.S.

ANSI's Consumer Interest Council ("CIC") was established, in 1967, as a means of representing the consumer interest within ANSI, but it has no direct influence on the decision-making process.¹¹³ ANSI's Standards Screening and Review Committee does provide for consumer input into the approval of an ANS. Whilst the standards developer need not agree with the objections put forward by the Council, it must respond to them.

However, a former chair of the CIC, has conceded that "consumer participation in U.S. standards policies is minimal at best."¹¹⁴ Moreover, the notion of consumer representation—at least at this political level—appears to be different in nature from that espoused in Europe. For example, Steorts talks about the need for representation on the CIC from consumer organizations, all industry sectors, and ANSI member companies.¹¹⁵ Company participation is encouraged on the basis that they will be involved in decisions which will affect their business.¹¹⁶ This wide based membership is perhaps indicated by the fact that it is a Consumer *Interest* Council, rather than simply a Consumer Council. CIC's membership extends beyond consumer groups to include representatives from business, standards bodies, corporations, and government. Indeed, one ANSI employee is cited as suggesting that representatives of large purchasing organizations provided a considerable amount of pro-consumer expertise.¹¹⁷ However, it appears that ANSI's CIC is hardly a forum for consumers to organize and develop their own independent approach to standardization.

In the U.S., the emphasis seems to be far more on convincing industry that they have something to gain from listening to consumers,

113. See generally ANSI, AMERICAN NATIONAL STANDARDS INSTITUTE CONSTITUTION AND BY-LAWS art. V (1997), available at <http://www.ansi.org/public/library/ansi_proc/bylaws/cic.html> (discussing the role of the CIC).

114. *A Conversation with Nancy Harvey Steorts*, ANSI REPORTER 5-6 (October/November 1996).

115. See *id.*

116. See *id.*

117. See Hamilton, *supra* note 74, at 1385.

than on the right of consumers to be involved in the process in order to protect their interest. This is underlined by a recent ANSI initiative to encourage industry to set up their own Consumer Advisory Boards, comprised of academics, government officials, consumers, etc., to look at the needs of their own consumers. To European ears, this model of consumer representation may appear more appropriate to the development of internal company policy than to the generation of legal or quasi-legal norms. In part, this may be due to the more voluntary nature of standards in the United States, whereas in Europe, standards increasingly fall within regulatory regimes based on new approach directives. This should not be an excuse for down-playing the role of consumers in standards development. Indeed, the CPSC should monitor standards to ensure that it has no need to invoke its rule-making powers. Possibly in the United States, products liability actions act as a greater incentive for producers to ensure that standards adequately address safety issues than do the civil liability rules in Europe.

The CIC's Standards Screening and Review Committee provides for review of standards in their final stages. Effective consumer input requires the ability to influence how standards are developed, not just to comment on the final draft. Of course, some bodies other than consumer organizations will look out for the consumer interest, but this cannot replace the need for direct consumer involvement in the standards writing committees.

Some consumer representation obviously goes on within the standards writing bodies themselves. A general impression is that, taken as a whole, the mechanisms adopted by the U.S. standards bodies tend to be less formal than the European structures for consumer representation, and the role of consumer organizations is less prominent. There are so many standards writing bodies in the U.S. that it would be an enormous task to look at the procedures for consumer representation in all of them. Instead, a brief description will be made of how two of the most important standards bodies, UL and ASTM, involve consumers.¹¹⁸

When commencing a new standards project, UL puts out a public notification inviting interested parties to comment, but the response from consumers seems to be modest. UL has a Consumer Advisory Council which comments on draft standards, but consumer organizations only form a portion of its forty-five members with the others being drawn from retail organizations, academics, government, publishing, etc. Unfortunately, this council considers proposed standards and is not

118. In part, this section relies both on the Hamilton article, *supra* note 74, and more up to-date information gleaned from presentations at the ISO-COPOLCO WORKSHOP, *Consumers in Standards* (London, May 12, 1997) (presentations by John Drengenberg (UL) and Kenneth Pearson (ASTM)).

involved at the early stages when the standards are being formulated. At an early stage in the development of a standard, UL has an Industry Advisory Conference which is closed to everybody except industry representatives. The object is to provide industry the opportunity to raise its concerns without having to go public, but this closed door style of representation must create a danger of excessive influence by industry. Steps are being taken to permit other groups to have an input at an earlier stage. UL has created "Technical Advisory Panels" to provide interested parties an opportunity for early input into the standards development process. Similarly, the CPSC has successfully requested such panels be established for selected consumer products associated with death and injuries. UL also has a consumer sounding board which meets monthly to discuss ideas. This is limited to people who live near UL headquarters and is dominated by elderly people who have the time to devote to these matters. The idea of using consumer sounding boards to discuss issues with consumers developed first in the United States. These have been described as being little more than "rap sessions"¹¹⁹ and, although UL and some other bodies continue to use them, they are less widely used now than they were in the past.

ASTM provides approximately \$50,000 a year to fund consumer representation work on committees; other funding comes from industry sponsorship of specific standards programs with the funding being held in trust by ASTM. This is usually enough to ensure that two consumer representatives sit on selected committees, subject to ASTM approval. In situations where ASTM has felt more information is necessary to assess consumer interest, it has contractually sought information from the National Consumers League. ASTM is more likely to use this type of funding (which is usually in the region of \$15,000-\$30,000 per project) in the future, and the amount ASTM sets aside to support consumer representation will probably increase. ASTM also funds research relevant to consumer standards through the Institute for Standards Research.

The major standards writing organizations permit consumer representatives to participate in their technical committees; generally sitting on committees dealing with consumer products. Consumer representatives on technical committees may be technical experts or informed lay persons. Their involvement, however, has been limited because of a lack of volunteers and technical expertise within the movement. A more fundamental problem is the lack of funds for travel to enable participation. For instance, ASTM's committee dedicated to consumer goods has 578 members several of whom represent consumers, but a good deal of their involvement is through the mail. This is unlikely to

119. See Hamilton, *supra* note 74, at 1384.

be as effective as personal contact.

The consumer movement has some deep seated objections to the standardization process. For instance, even if consumers are involved in a technical committee, most of the substantive work will be undertaken by working groups where consumers may be excluded because the work depends upon having access to laboratory facilities. Certainly in the past, consumers have felt that the consensus principle has not adequately protected the consumer interest. In testimony to the National Commission on Product Safety, the Technical Director of the Consumers Union stated:

The consensus principle means in practice that the industry people have veto power Our proposals [as consumer representatives], our negative votes, are given "due deliberation," but are ultimately vetoed or overridden, as without merit. After a while it seems fruitless to spend time and money to go to such meetings. . . . Volunteerism and token consumer representation have been generally unsuccessful in protecting the consumer interest¹²⁰

Similar resentment about the summary rejection of consumer objections was expressed to a subsequent researcher, who seemed satisfied that the ASTM Committee on Standards did carefully review such objections.¹²¹ Whatever the truth of these criticisms, it is significant that the consumer representatives held negative opinions about the standardization process. This negativity may be the result of an ineffective structure supporting consumer representation—reflected both in the lack of funding for consumer representation in standardization and because of the peripheral role consumers have in the organizations' decision-making procedures. The fact remains that U.S. consumer organizations seem to be less active in the standardization arena than their European counterparts. Of course, the more central role standards play in the European legal framework may explain why consumer groups, in Europe, see participation in standardization as a priority.

V. GENERAL CONTROLS ON UNSAFE PRODUCTS

A. *The EC's General Product Safety Directive*¹²²

The new approach directives are intended to create a raft of harmonized EC directives, which meet the twin objectives of free movement of goods and consumer protection. There was, however, a need to

120. James A. Brodsky & Marsha N. Cohen, "Uncle Sam," *The Product Safety Man: Consumer Product Safety Standards in the Marketplace and in the Courts*, 2 HOFSTRA L. REV. 619, 632 (1974) (quoting 1 NATIONAL COMM'N ON PRODUCT SAFETY HEARINGS 296-98 (1970) (statement of Morris Kaplan)).

121. See Hamilton, *supra* note 74, at 1358.

122. Council Directive 92/59/EEC of 29 June 1992 on General Product Safety, 1992 O.J. (L 228) [hereinafter General Product Safety Directive].

impose a general safety obligation to market safe products—encompassing products not covered by new approach directives and safety aspects not covered in vertical directives. Out of this apparent need came the General Product Safety Directive.¹²³

The General Product Safety Directive's definition of "product" makes it clear that it is only intended to apply to consumer products: "[P]roduct shall mean any product intended for consumers or likely to be used by consumers, supplied whether for consideration or not in the course of a commercial activity and whether new, used or reconditioned."¹²⁴

Thus, the product must be a commercially supplied consumer good. Although the definition of product is restricted to consumer goods, there is surprisingly little help in determining the scope of the word "product" itself. The definition does, however, make it clear that the General Product Safety Directive ("GPSD") covers new, used, and reconditioned products. The only exceptions to this are for "second-hand products supplied as antiques or [for] products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect."¹²⁵

The relationship between the horizontal GPSD and vertical directives is complex.¹²⁶ The GPSD is influenced by the German tradition of preferring specific to general regulation. Thus, the GPSD makes it clear that it shall apply "in so far as there are no specific provisions in rules of Community law governing the safety of the product concerned."¹²⁷ However, whilst the goal of new approach directives may be to cover all safety aspects, this is not achieved in practice, and it is possible to read the GPSD as having some relevance even for products covered by new approach directives.

Article 1 of the GPSD seems to qualify the general exclusion by suggesting that when specific rules of Community law impose safety requirements then the provisions of the GPSD in Articles 2 through 4 shall not, in any event, apply.¹²⁸ This might imply that the other provisions can apply. This is the interpretation of some commentators who see the GPSD as having a role in relation to new approach directives by

123. Although not discussed in this article, the General Product Safety Directive also includes important provisions relating to the exchange of information and novel provisions providing for a Community procedure in emergency situations. *See id.* at art. 8.

124. *Id.* at art. 2(a).

125. *Id.*

126. Horizontal directives cover all products or specific aspects in all products; whereas vertical directives are concerned with particular products or product sectors.

127. General Product Safety Directive, *supra* note 122, at art. 1(2). The preliminary findings of the GPSD note: "Whereas when there are specific rules of Community law, of the total harmonization type, and in particular rules adopted on the basis of the new approach, which lay down obligations regarding product safety, further obligations should not be imposed. . . ." General Product Safety Directive, *supra* note 122 (preliminary findings).

128. *See id.* at art. 1(2).

supplementing them with notification, information exchange, and emergency procedures when these features are absent from the product specific directives.

The question of whether a specific provision ousts the GPSD, even if it offers less protection, is open to debate. The directive concludes the matter by stating: "Where specific rules of Community law contain provisions governing only certain aspects of product safety or categories of risks for the products concerned, those are the provisions which shall apply to the products concerned with regard to the relevant safety aspects or risks."¹²⁹ This seems to imply that where only certain safety aspects are covered by the specific regulations, then the other aspects could be dealt with under the GPSD.

The central concept around which the GPSD is organized is that of the "safe product:"¹³⁰

[S]afe product shall mean any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance,
- the effect on other products, where it is reasonably foreseeable that it will be used with other products,
- the presentation of the product, the labeling, any instructions for its use and disposal and any other indication or information provided by the producer,
- the categories of consumers at serious risk when using the product, in particular children.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "unsafe" or "dangerous."¹³¹

From a consumer perspective there are several positive aspects of this definition. It objectively assesses the actual risks regarding a product and in this respect compares favorably with the defectiveness standard in the Product Liability Directive, which refers to the expectations of consumers.¹³² The GPSD only accepts a product as safe if it either (i)

129. *Id.*

130. Sometimes the directive refers to a "dangerous product," but this is simply a product which does not meet the definition of a "safe product." See *id.* at art. 2(c).

131. *Id.* at art. 2(b).

132. See Product Liability Directive *supra* note 4, at art. 6. The General Product Safety Directive does rely on the concept of consumer expectations. See General Product Safety Directive, *supra* note 122, at art. 4(2). For a comparison of this definition with the defectiveness standard in the Product Liability Directive, see Geraint G. Howells, *Consumer Safety in Europe: In Search of the Proper Standard*, in LEGAL VISIONS OF THE NEW EUROPE (Bernard S. McGoldrick et al. eds., 1993).

does not present any risk, or (ii) presents only the minimum risks compatible with the product's use. Even these minimum risks must be acceptable. Thus, it is not sufficient that a product is the safest design to perform its intended function. The utility of the purpose must be balanced against the minimum inherent risks to judge whether the risk is acceptable. Although there is room for debate about what is considered acceptable, the GPSD indicates that the acceptable level should be compatible with a high level of protection for the safety and health of persons. This is partly a technical/scientific question involving the identification of risk, and partly a social question of determining which risks are acceptable.

The function of a safety standard in a regulatory regime is not to remove all risks from the market, but only those not justified by the benefits derived from the product or because safer alternatives exist. Therefore, the basic definition seems to strike the right balance.¹³³ To some extent this rather stringent definition is undermined by the situations in which the GPSD treats products as being safe.

It is noteworthy that the definition of "safe product" refers to the need to consider the categories of consumers at serious risk when using the product. The definition states that the needs of children should be taken into account,¹³⁴ but this specific inclusion does not prevent the interests of other groups, such as the elderly, blind, deaf, or disabled from being considered.

The definition of "safe product" forms the foundation of the general safety requirement in the GPSD.¹³⁵ The requirement imposes on producers the obligation to place only safe products on the market. The directive lays down a hierarchy of rules and standards against which a product should be judged to determine whether the general safety requirement is satisfied.¹³⁶

The GPSD provides means whereby compliance with the general safety requirement can be established.¹³⁷ The directive states:

Where there are no specific Community provisions governing the safety of the products in question, a product shall be *deemed* safe when it conforms to the specific rules of national law of the Member State in whose territory the product is in circulation . . . laying down the health and safety requirements which the product must satisfy in order to be marketed.¹³⁸

133. See General Product Safety Directive, *supra* note 122, at art. 2(b).

134. See *id.*

135. See *id.* at arts. 3, 4.

136. See *id.* at art. 4.

137. See *id.* at art. 4(1)-(2). These provisions do not bar national authorities from taking appropriate measures to impose restrictions on the placing of the product on the market or to require its withdrawal when there is evidence that despite conformity with the safety requirement the product is dangerous to the health and safety of consumers. See *id.* at art. 4(3).

138. *Id.* at art. 4(1) (emphasis added).

The GPSD continues by stating that conformity to the general safety requirement shall be assessed having regard to a list of standards.¹³⁹ The standards, although not expressly stated to be hierarchical, are listed in such a way that implies the drafters conceived of a hierarchy along the following lines:

- (i) voluntary national standards giving effect to a European standard,
- (ii) Community technical specifications,
- (iii) standards drawn up in the member states in which the product is in circulation,
- (iv) codes of good practice in respect of health and safety in the sector concerned,
- (v) the state of the art,
- (vi) safety which consumers may reasonably expect.¹⁴⁰

The inclusion of the last two criteria presents a real danger. For example, a national enforcement authority could undertake a perfectly proper prosecution against an unsafe product only to be met with defenses that the producers complied with the state of the art or that it offered the safety which consumers might reasonably expect. Determining the merits of such defenses involves complex technical questions; requiring a great deal of expert evidence and resources which enforcement authorities would probably not feel they could devote to the prosecution of such cases.

The general safety requirement places different obligations on producers and distributors. In theory, the principle obligation to assure safety is placed on producers, with distributors having a supportive role.¹⁴¹ The GPSD gives a broad definition of producer.¹⁴² Naturally, this definition includes the manufacturer, but only when it is established in the Community.¹⁴³ Additionally, any entity who presents itself as the manufacturer by affixing to the product its name, trademark, or other distinctive mark is also treated as a producer.¹⁴⁴ This brings into the definition of producer own-branders and franchisees. A person who reconditions a product is also deemed to be its producer.¹⁴⁵ If the manufacturer is not established within the Community, then its representative will be treated as the producer.¹⁴⁶ There may be several representatives in different member states and all would appear to be covered, but national authorities will usually approach the representative in their own

139. *See id.* at art. 4(2).

140. *See id.*

141. *See id.* at art. 3(3).

142. *See id.* at art. 2(d).

143. *See id.*

144. *See id.*

145. *See id.*

146. *See id.*

state. If neither the manufacturer nor its representative are established in the Community, then the importer will be treated as the producer.¹⁴⁷

Any professional in the supply chain is treated as a producer, in so far as their activities may affect the safety properties of a product placed on the market.¹⁴⁸ The definition of distributor is the mirror image of this, namely those professionals in the supply chain whose activity does not affect the safety properties of the product. Thus, the crucial point to be considered is whether a party affects the safety properties of the product. Certainly, this would cover anyone who affected the design or construction of the product.¹⁴⁹ Many parties whom one would colloquially speak of as distributors or retailers, will in fact fall within the definition of producer. Other links in the supply chain are distributors.

The GPSD's general safety requirement obliges producers to place only safe products on the market.¹⁵⁰ This is an obligation of strict liability. Additionally, the safety requirement outlines two types of supporting "information obligations" placed on producers. These involve (i) informing consumers of product risks, and (ii) having systems to keep themselves informed of product risks and to react to them.¹⁵¹ Although these obligations are framed in a mandatory way, they are not all required of every producer—producers need only undertake them if they could be expected to do so within the limits of their activities.

The role of distributors is subsidiary to that of the producer. They are required to act with due care to help ensure compliance with the general safety requirement. Due care suggests that they will only be liable if they have unreasonably failed to assist in satisfying the general safety requirement. Therefore, in contrast to the strict liability of producers, distributors' liability is premised on fault. Due care, however, is usually viewed as an objective standard that would not allow the distributor the defense that it did its incompetent best.

The objective nature of the duty of due care is underpinned by the GPSD, for it states that, in particular, distributors should not supply products which they know, or should have assumed, do not comply with the general safety requirement.¹⁵² Their constructive knowledge is to be assessed having regard both to information in their possession and as professionals. Reference to "as professionals" would seem to include constructive notice of what other professionals were deemed to know.¹⁵³ It would also require that they processed the information they actually

147. *See id.*

148. *See id.*

149. Those who advised the original manufacturer on the design would not be defined as producers as they do not form part of the supply chain.

150. *See* General Product Safety Directive, *supra* note 122, at art. 3(1).

151. *See id.* at art. 3(2).

152. *See id.* at art. 3(3).

153. *See id.*

had, or constructively ought to have had, as a professional, and reached the conclusions that a reasonable professional would have reached. Distributors are placed under a particular duty to participate in monitoring the safety of products placed on the market within the limits of their respective activities. This should involve the dissemination of information on product risks and cooperating in the action taken to avoid those risks.

Although the ultimate objective should be the creation of a climate in which businesses take responsibility for producing safer goods, it would be unrealistic to expect this to be achieved simply by enacting legislation. What is needed are both enforcement authorities to enforce the general safety requirement and sanctions for breaching the requirement which are sufficiently serious that businesses are keen not to attract the attention of the authorities.

The GPSD requires member states to establish or nominate authorities to monitor compliance with the obligation to place only safe products on the market.¹⁵⁴ The national authorities must be given the necessary powers to fulfill their obligations under the directive. The directive lists a series of objectives which these powers should ensure are achieved.¹⁵⁵ The first three of these powers are concerned with ensuring the authorities have the powers to undertake adequate surveillance of products, whilst the remaining five relate to controls which they should be able to impose on the marketing of products. Member states are granted the necessary powers to promote measures aimed at:

- (a) organizing appropriate checks on the safety properties of products, even after their being placed on the market as being safe, on an adequate scale, up to the final stage of use or consumption;
- (b) requiring all necessary information from the parties concerned;
- (c) taking samples of a product or product line and subjecting them to safety checks;
- (d) subjecting product marketing to prior conditions designed to ensure product safety and requiring suitable warnings be affixed regarding the risks which the product may present;
- (e) making arrangements to ensure that persons who might be exposed to a risk from a product are informed in good time and in a suitable manner of the said risk by, inter alia, the publication of special warnings;
- (f) temporarily prohibiting, for the period required to carry out the various checks, anyone from supplying, offering to supply or exhibiting a product or product batch, whenever there are precise and consistent indications that they are dangerous;
- (g) prohibiting the placing on the market of a product or product batch which has proved to be dangerous and establishing the accompanying

154. *See id.* at art. 5.

155. *See id.* at art. 6(1).

measures needed to ensure that the ban is complied with;

(h) organizing the effective and immediate withdrawal of a product or product batch already on the market and, if necessary, its destruction under appropriate conditions.¹⁵⁶

It is a moot point whether the final power includes recall of products which have already reached consumers. For instance, the United Kingdom has expressly failed to introduce such a power.

The national enforcement authorities must exercise the powers in accordance with the degree of risk and in accordance with the free movement of goods provisions under the Treaty.¹⁵⁷

Regarding distributors, measures should only be addressed to them within the limits of their activities.¹⁵⁸ In particular, the distributor responsible for the first stage of distribution on the national market is targeted for enforcement action. However, the responsibilities of distributors are generally less than those of producers, and as noted above, where the manufacturer lies outside the Community, the importer into the Community and not the importer into national markets is deemed to be the producer.

The GPSD makes it clear that the powers of the national enforcement authorities should include the possibility of imposing suitable penalties.¹⁵⁹ According to national traditions, this might take the form of criminal sanctions, administrative fines, etc. Of course, the size of any fine must be adequate and effective.¹⁶⁰

B. U.S. Product Control

The CPSA makes it unlawful to, *inter alia*, manufacture for sale, offer for sale, distribute in commerce, or import any consumer product which is not in conformity with an applicable consumer product safety standard or which has been declared a banned hazardous product.¹⁶¹ Of course, as the CPSC has become less active in the regulatory sphere, there is less scope in which to use these powers. However, in contrast to the position in Europe, the CPSC does have impressive powers to seek remedial action for substantial product hazards and to protect consumers from imminent hazards.

i. Remedial Action for Substantial Product Hazards

The CPSA defines a "substantial product hazard" as existing where

156. *Id.*

157. See Treaty of Rome, *supra* note 54.

158. See *id.* at art. 6(2).

159. See *id.* at art. 5.

160. *Cf.* Case 271/91, *Marshall v Southampton and South-West Hampshire Area Health Authority*, 1993 E.C.R. I-4367, [1993] 3 C.M.L.R. 293 (1993) (imposing damages beyond the U.K.'s statutory limits).

161. See 15 U.S.C. § 2070 (1994).

a substantial risk of injury to the public is created by a product which either fails to comply with a consumer product safety rule or contains a defect.¹⁶² If the CPSC determines that a product presents a substantial product hazard and that notification is required to adequately protect the public, it may order the manufacturer, distributor, or retailer of the product to do one or more of the following:

- (1) To give public notice of the defect or failure to comply.
- (2) To mail notice to each person who is a manufacturer, distributor, or retailer of such product.
- (3) To mail notice to every person to whom the person required to give notice knows such product was delivered or sold.¹⁶³

In addition, if the CPSC considers it to be in the public interest, it can order the manufacturer, distributor, or retailer to choose which of the following actions it wishes to take:

- (1) To bring such product into conformity with the requirements of the applicable consumer product safety rule or to repair the defect in such product.
- (2) To replace such product with a like or equivalent product which complies with the applicable consumer product safety rule or does not contain the defect.
- (3) To refund the purchase price of such product (less a reasonable allowance for use, if such product has been in the possession of a consumer for one year or more (A) at the time of public notice under subsection (c) of this section, or (B) at the time the consumer receives actual notice of the defect or noncompliance, whichever first occurs).¹⁶⁴

Before the CPSC takes any of the above measures in relation to substantial product hazards, it must afford interested persons, including consumers and consumer organizations, the opportunity for a hearing. Significant as a point of comparison, the General Product Safety Directive is generally understood not to grant national authorities the power to order the recall of products which have reached consumers. Certainly under the European regime, the powers of the national authorities are not so extensive or well thought out as those possessed by the CPSC.

These post-market powers have become more significant since the CPSC's pre-market controls have been weakened. Generally, however, the Commission will try to agree to a voluntary corrective plan with the businesses concerned.¹⁶⁵ The Commission divides products posing a substantial product hazard into three categories: class A, B, and C.¹⁶⁶

162. See 15 U.S.C. § 2064(a) (1994).

163. 15 U.S.C. § 2064(c) (1994).

164. 15 U.S.C. § 2064(d) (1994).

165. It is suggested that corrective plans are possible in ninety-five percent of cases. See C.D. Erhardt III, *Manufacturers of Consumer Products, Beware!*, 14 *PRODUCT LIABILITY INT'L* 67 (1992).

166. See *DIRECTORATE FOR COMPLIANCE AND ADMINISTRATIVE LITIGATION OF THE U.S.*

Class A hazards exist when a risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely. Class B hazards exist when a risk of death or grievous injury or illness is not likely to occur, but is possible, or when serious injury or illness is likely, or moderate injury or illness is very likely. Class C hazards exist when a risk of serious injury or illness is not likely, but is possible, or when moderate injury or illness is likely, or possible. The response to substantial product hazards varies according to how the hazard is classified.

ii. Imminent Hazards

The CPSC also has powers to deal with “imminently hazardous consumer products,” which are defined as consumer products that present “imminent and unreasonable risk[s] of death, serious illness, or severe personal injury.”¹⁶⁷ These powers can be exercised even if there is a consumer product safety rule applicable to the product or when other actions under the CPSA are pending.

An action may be filed in a United States district court against (i) the product itself for the purpose of its seizure, and/or (ii) the manufacturer, distributor, or retailer of such product.¹⁶⁸ If the court declares the product to be “imminently hazardous” in an action against the manufacturer, distributor, or retailer the court can

grant such temporary or permanent relief as may be necessary to protect the public from such risks. Such relief may include a mandatory order requiring the notification of such risk to purchasers of such product known to the defendant, public notice, the recall, the repair or the replacement of, or refund for, such product.¹⁶⁹

As soon as possible after the action, the CPSC shall take proceedings to promulgate a consumer safety rule.¹⁷⁰

A significant weakness of this procedure is the lack of official authority to seize the hazardous products before the initiation of judicial action. Presumably, reliance must be had on the civil consequences, including the threat of punitive damages, which could result if damage is caused by the product and the responsible parties have not cooperated with the CPSC.

iii. Reporting

Another positive feature of the U.S. regime is the reporting obligation placed on manufacturers, distributors, and retailers to report potentially unsafe products to the CPSC. Originally, this obligation only

CONSUMER PRODUCT SAFETY COMMISSION, RECALL HANDBOOK (1988).

167. 15 U.S.C. § 2061(a) (1994).

168. *See id.*

169. 15 U.S.C. § 2061(b)(1) (1994).

170. *See* 15 U.S.C. § 2061(c) (1994).

arose when a person obtained information that the product failed to comply with an applicable consumer product safety rule or contained a defect which could create a substantial product hazard. In an attempt to increase the rate of reporting, these grounds were extended by the Consumer Product Safety Improvement Act of 1990.¹⁷¹ The obligation to report is now triggered when a product fails to comply with a voluntary product safety standard relied upon by the CPSC and by situations where the product creates an unreasonable risk of serious injury or death.¹⁷²

Manufacturers were also put under a new duty to report, in a less detailed manner, when their products had, within twenty-four months, been involved in three civil actions alleging death or grievous injury leading to settlement or judgment for the plaintiff.¹⁷³ The civil penalties for failing to notify were also increased. These reporting obligations are undoubtedly valuable both as a source of information for the CPSC and as a means for reemphasizing to manufacturers, and others involved in the supply of goods, that they have responsibilities to ensure consumers are safe. It is disturbing, however, that there are indications that traders fail to comply with this obligation. One would speculate that the threat of punitive damages in a civil trial for failing to report suspicious products would act as an incentive for producers to comply. It seems, however, that the risk of being dragged into products liability litigation is a major disincentive to admit any possibility of defects in one's products.

VI. CONCLUSION

When established in the early 1970's, the CPSC blazed a trail in the field of product safety regulation. However, whilst some aspects of its work remain world class, in other respects it has suffered from underfunding and restrictions being placed on its powers. In particular, the CPSC has almost vacated its role as a developer of mandatory standards in favor of reliance upon voluntary standards. In any event, one might doubt whether an agency the size of the CPSC could adequately protect consumers in a country as large as the U.S. This legislative vacuum has no doubt helped legitimize private law means of protecting consumers through products liability litigation.

This article has outlined the contrast between the U.S.'s "information and litigation" approach to consumer protection and Europe's "regulation and administration" approach.¹⁷⁴ Europe has tried to create a product safety regime based on regulations administered by

171. Pub. L. No. 101-608, 604 Stat. 3110-24 (1990) (codified in scattered sections of 15 U.S.C.).

172. See 15 U.S.C. § 2064(b) (1994).

173. See 15 U.S.C. § 2084 (1994).

174. See generally Geraint G. Howells & Thomas Wilhelmsson, *EC and U.S. Approaches to Consumer Protection—Should the Gap be Bridged?*, in YEARBOOK OF EUROPEAN LAW 207 (1997).

public authorities. As in the U.S., there were pressures to deregulate and move away from old style regulatory interventions, but Europe managed to do this by integrating voluntary standards into the regulatory regime. Europe has also developed a general safety obligation, which ensures that all consumer products are subject to some regulatory controls. My purpose has been to give some insight into the depth of commitment within Europe to this regulatory strategy, with the hope that it provides American readers with a better appreciation of one dimension of the complex reasons that explain why there is less products liability litigation in Europe.

It should, however, not be thought that everything is rosy in the European garden. It is certainly the case that the main impetus for the harmonization in European product safety laws has been the desire to create an internal market, and there is much justification in the criticisms of the European approach. Countries which had high standards may feel harmonization has diluted their regulations. Certainly, there is hesitation about accepting conformity assessments from some member states. Indeed, the fact that the CE marking can often be obtained simply by a manufacturer's self-declaration of conformity must be a matter of some concern. The CE marking acts as a passport for products and encourages more relaxed enforcement. It is not a safety mark, but is often confused by consumers as such. Of course, there is differential enforcement of safety laws in the various member states.

These criticisms do not diminish the fact that the EC has sought a novel way of balancing the desire to create an internal market with the demands of consumer protection. It is also right to applaud the commitment, in the European Commission, to ensure that the consumer interest is represented, even if there remain problems in practice. Nevertheless, these problems should serve to remind us that consumer policy need not be based exclusively on one approach. Therefore, even within Europe, one can argue that product liability remains an important weapon in the consumer's arsenal. It is a question of balance between product safety and product liability, rather than a choice between one or the other.

It is for Americans to decide whether their society would be enhanced by strengthened product safety laws. What should also concern them is the comparative strength of the European standardization movement. CEN already has a close working relationship with ISO, and in some areas there are agreements for the joint development of standards. The decentralized U.S. model makes such cooperation with ISO more difficult. However, in an increasingly global market place, in which even the U.S. cannot afford to remain isolationist, and in which ISO standards are gaining in importance, the U.S. would be well ad-

vised to be alert to the strength of this bond between CEN and ISO. The U.S., therefore, may want to strengthen its standardization movement for competitive reasons. For the sake of consumer protection, this author would respectfully suggest that it might be desirable if the organization of consumer representation within standardization in the U.S. was reviewed.