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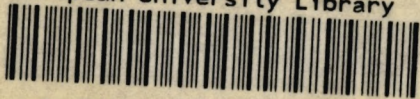
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and the Proposal for a Directive
on General Product Safety**

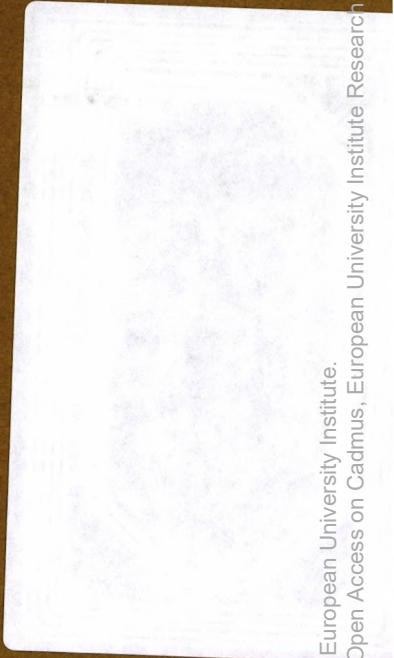
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**Product Safety Law, Internal Market Policy
and the Proposal for a Directive
on General Product Safety**

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Introduction

The Commission proposal for a directive concerning general product safety, discussed by this Workshop, is a noteworthy and typical expression of the specific tasks and problems of European legislative policy. The immediate objective of the proposal is a harmonization of product safety law.

The legitimation and interest of the Community in taking on this area of law is beyond doubt. Various regulations which guarantee product safety constitute barriers to trade which, by virtue of Article 36 EEC, are not in principle surmountable by applying the principle of free movement of goods. The harmonization of product safety law, however, is only a necessary and by no means a sufficient condition to guarantee the freedom of Community internal trade. It is not only product safety law, but even more so, and primarily, "private" standardization which are responsible for barriers to trade in the Common Market. This perception was decisive for the Community when in the context of its intensification of internal market policy it took up Europeanization of standards. At the same time it committed itself and Member States to a basic legislative policy decision that binding product safety law would be confined to laying down essential safety requirements in the form of general clauses, with their specifications being left to private standardization.

The draft General Product Safety Directive now submitted by the Commission should therefore be seen not merely as a response to differences in product safety legislation in Member States, but should be understood in the overall context of Community policy. The reconstruction of this twofold relationship to the product safety law of Member States and to the Community's more recent internal market policy is the object of this paper.

The product safety legislation of Member States cannot be even approximately fully covered; a survey of typical regulatory patterns in product safety law and their inter-penetration with standards must suffice (I below). These inter-dependencies will then be analysed at Community level. For legal systematic reasons and having regard to the recent

development of Community law, the changes in primary Community law brought about by the SEA (Single European Act) and relevant ECJ case law will first be dealt with (II below), then the Europeanization of standards (III below). Discussion of the Commission's proposal will then build on that foundation (IV below).

I. Regulatory Patterns in Safety Law

The law of product safety is a tortuous set of areas that functionally belong together though autonomous from the point of view of legal systematics. There are reasons for this complexity. On the one hand, the State is compelled, in a scarcely reversible development, to take on ever-new responsibilities for the safety interests of citizens - in constitutional law this is expressed in the recognition in principle of the corresponding duty on the State to provide protection¹. On the other hand, this very expansion of responsibilities forces the State to realize its own limitations. The reaction to this is the development or intensification of cooperative networks among national and "private" organizations².

1. Liability law as indirect safety regulation

If the regulatory tasks of relevant areas of law are considered, product safety law certainly also includes manufacturer liability and product liability law. Admittedly, private liability law works only indirectly at the level of product safety, by providing penalties for the infringement of "transactional duties" (para. 23 of the German Civil Code) or the marketing of "defective products" (e.g. Article 6 of the Community

1. See among the more recent literature G. Hermes, Das Grundrecht auf Schutz von Leben und Gesundheit. Schutzpflicht und Schutzanspruch, 1987; E. Klein, 'Grundrechtliche Schutzpflicht des Staates', NJW 1989, 1633 ff.; H.-W. Micklitz, Consumer Rights, typescript Bremen 1989 (Section IV.2).

2. See H. Voelzkov, J. Hilbert, G. Bohlens, 'Wettbewerb durch Kooperation - Kooperation durch Wettbewerb: Zur Funktion und Funktionsweise der Normungsverbände', in: M. Glasgow and H. Willke (eds), Dezentrale Gesellschaftsteuerung: Probleme der Integration polyzentrischer Gesellschaften, 1987, 93 ff, 95 ff.

product liability directive³ 4). Here the courts are in principle autonomous in specifying transactional duties and safety criteria⁵. The standardization of consumer goods, which is de facto primarily responsible for their safety, is not legally binding. This principle has been reconfirmed by the Bundesgerichtshof in its compost-cutter ruling⁶. Despite this autonomy of private liability law, privately set standards do have enormous importance, and often determine the outcome of legal disputes. To be sure, judicial consideration of the results of standardization as a rule considers only the question whether safety standards provided for in these standards are up to the legally required level. But those who do not comply with the level of standards have little prospect of evading liability for negligence⁷; those who assert that a design they prefer that departs from the relevant standards meets the legally required level have to supply positive proof of this⁸.

2. Safety marks and certificates as information policy measures

No-one is obliged to seek certification that his products meet a safety standard⁹. However there are good reasons to do so. Safety marks promote sales; and those who obtain certification can assume that trade supervisory offices will not check their products¹⁰. Therefore those who

3. O.J. L 210/1985, 29.

4. The debate on the control-function of liability law and its shortcomings is not dealt with here; cf. G. Brüggemeier, 'Produkthaftung und Produktsicherheit', ZHR 152 (1988), 511 ff; J. Finsinger and J. Simon, 'An Economic Assessment of the EC Product Liability Directive and Product Liability Law of the Federal Republic of Germany', in: Ch. Joerges (ed), Product liability and product safety in the European Community, EUI Working Paper No.89/404, San Domenico di Fiesole (FI) 1989, 127 ff.

5. See Brüggemeier, Deliktsrecht, 1986, 578 ff; J. Schmidt-Salzer in: Schmidt-Salzer and Hollman, Kommentar EG-Richtlinie Produkthaftung, 1986, Art. 7, at 97; but see also P. Marburger, Die haftungs- und versicherungsrechtliche Bedeutung technischer Regeln, VersR 1983, 597 ff.

6. See BGH, NJW 1987, 2222/2223 f.

7. See MünchKomm-Mertens (2 edn), § 823 at no. 23 b and c and further cases there cited.

8. Brüggemeier, op. cit. (fn. 4), 579.

9. For further details see J. Falke, Praxis der Nachmarkt-kontrolle technischer Gebrauchsgüter in der Bundesrepublik Deutschland, typescript, Bremen 1988, 64 ff.

10. § 6 para. 1 AVV-GSG.

approach recognized test centres must take into account the fact that they must orient themselves primarily to the "generally recognized rules of technology" in the Federal Republic, as well as the "industrial safety and accident prevention regulations" and the DIN safety principles. Conferment of the mark is not contingent on compliance with relevant standards, but complying with them certainly makes testing easier.

3. Marketing bans as preventive measures

The most stringent form of preventive product safety policy is the laying down of binding design standards with compliance supervised by the authorities. For "normal" consumer goods, a comprehensive national control system cannot be seriously considered.

Yet German law in particular and the safety philosophy of the German Standards Organization (DIN) are committed to the idea of preventive protection against hazards¹¹: by para.3 (1) of the Equipment Safety Act (Gerätesicherheitsgesetz GSG), design measures and safety-oriented manufacturing procedures should mean that product users and third parties are protected "against hazards of all kinds to life and health". The conversion of this general product safety obligation into specific safety requirements is brought about through reference to the "generally accepted rules of technology" (allgemein anerkannten Regeln der Technik) and the "provisions on safety at work and the prevention of accidents" (Arbeitsschutz- und Unfallverhütungsvorschriften).

This reference technique need not be explained in detail here. Let us merely emphasize two points, with an eye to the Europeanization of the reference technique in safety legislation:

- The general product safety obligation laid down by the GSG confirms the governmental obligation to provide protection for life and health.

11. See further Ch. Joerges, J. Falke, H.-W. Micklitz, G. Brüggemeiner, Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft, 1988, 144 ff.

- Meeting this responsibility in the form of reference to standards takes place in a context of a highly developed network of cooperation which includes the Federal government (Federal Minister for Labour and Social Affairs), government administrative offices (Federal Institution for Industrial Safety - Bundesanstalt für Arbeitsschutz) and the Länder (their central labour offices - oberste Arbeitsbehörden), semi-governmental offices and statutory bodies (legal accident insurance agencies, independent test¹² centres) and employer organisations and trade unions.

4. Follow-up market controls as governmental protective obligations

One of the advantages of the reference technique is flexibility. The lists of rules of technology that correspond with the legally required safety levels can relatively quickly be supplemented or revised. These adaptive mechanisms apply first of all to sets of standards. They further have effects on test certification¹³. They do not, however, guarantee that products found to be hazardous will be removed from the market, even though their further marketing is banned by § 3 GSG.

This lacuna in protection is rooted not in the scarce resources of the trade supervisory offices, but in the fact that even the severest sanction, namely the ordering of a ban pursuant to § 5 (1) & (2) GSG, merely prevents further marketing of a product. A banning order can only indirectly contribute to recalling already marketed products through its publication or the threat of publication¹⁴.

In view of these striking weaknesses of public law follow-up market control it is hardly surprising that in product liability law the duties of the manufacturer to monitor and recall products are acquiring importance¹⁵. However the potential of using civil-law liability as a means of post-market control has structural limits. Private claims for

12. See in detail Ch. Joerges et al., op. cit. 147 ff.

13. See J. Falke, op. cit. (fn. 9), at 73.

14. De facto, the instrument of the banning order is not even used this way; cf. J. Falke, op. cit., at 93 ff.

15. See the latest BGHZ 99, 167 - Honda; BGH BB 1989, 2429 - horse loose-boxes.

recalls are pointless, since the potential claimants are endangered precisely because they do not recognize their endangerment (and therefore their claim). This paradox of private recall claims could be resolved only by recognizing possibilities of class actions. With the law as it stands, however, such powers of action are recognized only where infringements of recall duties can be termed distortions of competition - and even this recognition is to be found for the moment only in the literature¹⁶.

Follow-up market controls are, we have to conclude, the poor relation of German product safety law. The relevance of this finding for legal policy is, as we know, controversial¹⁷. It is however indisputable that the plausibility of the requirement for more follow-up market controls increases where the national market is open to imported goods whose design and manufacture is not included in the national networks of preventive safety techniques and cannot be checked at the frontiers. We shall return to this point¹⁸.

II. Framework Conditions in Community Law

If, then, private liability law, information policy measures and product safety legislation are partly indirectly and partly directly intermeshed with standardisation, any effort to come to grips with the product safety problem on the Community level would have to deal with the interrelationship between safety law and standardisation. This basically very simple consideration explains first why the Community had to expand its harmonization activities into the field of standardisation. But it also explains why the Council's Resolution of 7 May 1985 on "a new approach on technical harmonisation and standards"¹⁹ not only led to intensification of European standardization activities but has now brought efforts at extension of European product safety law. Legally, of course,

16. See H. Herrmann, 'Die Rückrufhaftung des Produzenten', BB 1985, 1801 ff, 1810 ff and further.

17. See on the German discussion J. Falke, op. cit. (fn. 9), 25ff.

18. Below at III.2 and IV.2.b.

19. O.J. C 136/1985, 1.

this sort of explanation only raises two supplementary questions: does the Community have the powers necessary to implement such a policy, and still more important, is it subject to qualitative restrictions as regards its commitment to the internal market and product safety?

1. The Community's powers and its qualitative restrictions

In its consumer protection and information policy resolutions of 1975²⁰ and 1981²¹, the Council decisively favoured the view that the protection of consumer health and safety belongs among the tasks of the Community described in Article 2 EEC. In the practice of Community policy, these programmatic statements have left no great traces. Only the European accident information system set up in 1981²² but still not finally consolidated²³, and the so-called rapid information system introduced in 1984²⁴ and extended by the Council's resolution of 21 December 1988²⁵ can be counted as visible results of the consumer policy programme²⁶. The Directive concerning Liability for Defective Products²⁷, frequently seen as a legislative act motivated by consumer policy, keeps rigidly in its justification to the terms of Article 100 EEC. The numerous safety provisions of Community law, to be found in all directives on the harmonization of national product regulations, have always been interpreted functionally - as necessary conditions for guaranteeing free intra-Community trade²⁸.

20. O.J. C 92/1975, 1.

21. O.J. C 133/1981, 1.

22. O.J. L 229/1981, 1.

23. See O.J. L 109/1986, 23 as well as the Report concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products, COM (89) 827 final of 20.12.1988 and the communication of the Commission concerning financing O.J. C 300/1989, 14.

24. O.J. L 70/1984, 16.

25. O.J. L 17/1989, 51; cf. the preparatory Report of the Commission of 12.3.1988, O.J. C 146/1988, 8.

26. Perhaps also the rather unique Directive concerning products which, appearing to be other than they are, endanger the health or safety of consumers: O.J. L 192/1987, 49.

27. See above fn. 3.

28. See further Ch. Joerges et al., *op. cit.* (fn. 11), 252 ff. (For food and pharmaceuticals this statement may be modified).

This reticence was quite in line with a traditional conception of Community legislative competence. As J.H.Kaiser was still arguing in 1980, such "borderline areas" as health and consumer protection are "separated by a gulf" from the Community's powers mentioned in the Treaty²⁹. The conclusion was that by adopting a product liability directive the Community would already have exceeded its powers³⁰. This position was also put forward even after the SEA came into force³¹. But for two reasons it has become (even³²) harder to justify them. For on the one hand, Article 130 r EEC now explicitly commits the Community to the goal of protecting human health, and on the other hand Article 100 a (3) EEC enjoins the Commission to ground its proposals for measures to achieve the internal market "on a high level of protection". Admittedly, these two provisions belong to different policy areas. It is only for environmental protection that explicitly comprehensive Community powers have been established. But by Article 130 r (2) (2) EEC, the Community's environmental policy commitment must have effect in all policy areas, and specifically also in projects on internal market policy, taken up pursuant to Article 100 a EEC³³. Accordingly, the allocation of product standards to Article 100 a EEC and its internal market objective cannot remove the Community's substantive commitment to the goal of health protection.

29. 'Grenzen der EG-Zuständigkeit', EuR 1980, 97 ff., 113.

30. See for example B. Börner, 'Die Produkthaftung oder das vergessene Gemeinschaftsrecht', in Festschrift für Hans Kutscher 1981, 43 ff.

31. See especially on the Product Liability Directive, G. Fichna, 'EG-Kommission und Ministerrat als Gesetzgeber?', RIW 1988, 887 ff., 891.

32. On the justification of Community consumer policy powers before entry into force of the SEA, see N. Reich, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, 1987, 42 ff.; B. Langeheine in: E. Grabitz, Kommentar zum EWG-Vertrag, Art. 100 at no. 28 ff. with further references; on the parallel discussion in relation to environmental protection see E. Grabitz, Kommentar zum EWG-Vertrag, Art. 130 r, at 1 ff. sect. II; E. Rehlinger, R. Stewart, 'Environmental Protection Policy' (M. Cappelletti, M. Seccombe, J.H.H. Weiler (eds), Integration through Law, Vol. A.2.2.), 1985, 21 ff.

33. See K. Hailbronner, 'Der "nationale Alleingang" im Gemeinschaftsrecht am Beispiel der Abgasstandards für Pkw', EuGRZ 1989, 101 ff., 105 f.; D.H. Scheuing, 'Umweltschutz auf der Grundlage der Einheitlichen Europäischen Akte', EuR 1989, 152 ff., 176 f.

The formula of a "high" level of protection suggests, by being directed merely to the Commission and not to the Council, freedom of action substantively restricted by the "across the board" clause of Article 130 r (2) (2) EEC and in practice by Article 100 a (4) and (5): The Community must in its internal market policy either itself implement the relatively highest level of protection of life and health - confirming the control test of Article 100 a (4) - or else have it respected by safeguard clause procedures. At the same time there seems no prospect of distinguishing between protection of health against environmental risks (Article 130 r (1) EEC), against risks at work (Article 118 (1) EEC) and in the consumer sphere. Health protection is conceivable only as an end in itself. Its normative dignity cannot depend on the sources of that endangerment. But in practical terms too, in designing standards for products, however, one can hardly differentiate between environmental risks, risks at work and the risks to consumers. It is possible to distinguish only between "process" and "product" regulations³⁴.

All this compels us in my view to see health protection altogether as at least a protective obligation of the Community. It would even seem reasonable to go a step further: the qualitative obligations on Community action show, through their links with possibilities of action remaining with the Member States, that Community law recognises a national duty to protect life and health³⁵. But this protective obligation must then be taken account of by the Community itself. Member States cannot therefore be prevented from responding, in areas covered by harmonization measures pursuant to Article 100a EEC, to newly recognized dangers by new measures³⁶. This one-sided "opting up" can be prevented by the Community only by making its legal harmonization measures revisable from the outset,

34. On the terminology see E. Reh binder and R. Stewart, op. cit. (fn 32), 9 ff.

35. See H.-W. Micklitz, op. cit. (fn. 2), section III.

36. On this reading of Art. 100 a (4), see Ch. Joerges et al., op. cit. (fn. 11), 373 ff with further citations; and from the more recent literature, especially K. Hailbronner, op. cit. (fn. 33), 109 ff.; P.-C. Müller-Graff, 'Die Rechtsangleichung zur Verwirklichung des Binnenmarktes', EuR 1989, 107 ff. 148 ff.; D.H. Scheuing, op. cit. (Fn. 33), 170 ff.

that is, by providing in secondary Community law the possibilities of action that make it possible to react to newly recognized dangers³⁷. This interpretation of the obligations on Community action is entirely compatible with the differing structure of Community powers in environment policy and in internal market policy: the point is not the allocation of new powers but qualitative obligations in carrying out legislative policy tasks unavoidably bound up with the harmonization of the law of Member States³⁸.

2. The mutual recognition of product regulations in the ECJ's case law

The thesis that the Community takes a national responsibility for life and health as a basis and has to take over corresponding protective obligations in assuming regulatory tasks is undoubtedly compatible with the system of Articles 30 and 36 EEC. As regards the interpretation of these latter provisions in recent ECJ case law, however, this requires further justification. It is well known that the Commission, originally in its communication on "the consequences of the Cassis de Dijon judgment of 20 February 1979"³⁹ and then in its "White Paper on completion of the internal market"⁴⁰ put forward the view that products properly manufactured and marketed in one Member State could be sold without restriction in the others, because the "objectives of national legislation are essentially equivalent"⁴¹.

The Court of Justice is more cautious in choice of words and in the practice of its decisions. The equivalence of Member States' provisions on health protection that underlies the move from the principle of "country of destination" to that of "country of origin" is not a "fact",

37. See further below at III.2 and IV.1.

38. Cf. already Ch. Joerges, 'The New Approach to Technical Harmonisation and the Interests of Consumers' (1986), in: R. Bieber, R. Dehousse, J. Pinder, J.H.H. Weiler (eds), 1992: One European Market?, 1988, 175 ff., 179; it is only with entry into force of the SEA that it can be taken that this position has been laid down normatively.

39. O.J. C 256/1980, 2.

40. Luxembourg 1985, para. 61 ff., 77 ff.

41. So formulated at para. 63 of the White Paper (fn. 40).

or even a largely completed development; nor does it simply follow from the fact that all Member States have equally good intentions. Equivalence must rather be established practically in each case, and is, as the relevant cases show, often not establishable. Here the Court exercises caution in reviewing non-harmonized national law⁴². In foodstuffs law Member States may take account of national eating habits and the situation of their population⁴³. The ECJ explicitly allows Member States a prerogative of judgement in the central normative question for health protection and product safety policy of what risks ought to be tolerable or ought to be limited⁴⁴. Admittedly, Community law has an effect on the exercise of this legislative policy competence. Member States must take account of the findings of international scientific research - particularly the work of the Community's scientific foodstuffs Committee⁴⁵. This necessity to take account of research does not confer legal quality on the statements of scientific experts. But it does make it possible to verify the legitimacy of national measures, and further means that these measures must be structured so as to be revisable⁴⁶. This precept of revisability has so far been applied by the ECJ only to prohibitions. It must however also apply to permits, and is in particular also binding on the Community⁴⁷. It means not only that interested parties are to be given the right to have licensing of an additive verified "in an easily accessible procedure that can be completed within

42. See on the following Ch. Joerges et al., *op. cit.* (fn 11), 321 ff. and from the literature to date especially O. Brouwer, 'Free Movement of Foodstuffs and Quality Requirements: Has the Commission got it wrong?', *CML Rev.* 1988, 237 ff.; U. Everling, 'Die Rechtsprechung des EuGH zum freien Warenverkehr im Binnenmarkt', *ZLR* 1989, 304 ff.; A. Falkenstein, *Freier Warenverkehr in der EG: Staatliche Behandelbehinderungen und Wettbewerbsverzerrungen - Erkennen und Abwehren*, 1989, 120 ff.

43. See ECR (1984), 409 - Nisin; (1984), 3263 - Heijn; (1984), 2367 - Melkunie; (1985), 3887 - Motte.

44. ECR (1981), 3277 - Biologische produkten.

45. In the now decisive wording of the "Beer judgment" of 12 March 1987, Case 178/84 at margin no. 44 (ECR 1987, 1262): "...the work of the Community's Scientific Committee for Food, the Codex Alimentarius Committee of the Food and Agricultural Organization of the UN (FAO) and the World Health Organization...".

46. ECR (1986), 1067 - Mirepoix; (1986), 1521 - Muller; "Beer judgement" (fn. 45), margin no. 45.

47. See at end of 1 above.

an appropriate time"⁴⁸. The ECJ additionally calls for "technological", "economic" and "psychological" reasons for use of additives to be taken into account⁴⁹. Once again, this does not mean that such findings must be respected legally or that the mere circumstance that they have been accepted in the country of manufacture must lead to recognition in the country of destination⁵⁰. To be sure the ECJ meets the interest in unhindered implementation of free movement of goods by placing the burden of proof of "justification" of a ban on additives on the banning State⁵¹. This development of the rules on burden of proof has been seen as a "decisive turn" in ECJ case law⁵². It is true that the call for a positive demonstration of damage to health would severely limit a preventive policy of reacting to risks by bans. It need not however be inferred from decisions actually taken that this is the significance of the ECJ's rule on burden of proof. To date the case law can in my view still be understood as requiring the banning State to provide proof of health hazards - and on this interpretation it remains compatible with the prerogative of Member States to assess such hazards⁵³.

In the area of technical safety law the ECJ's case law is sparser and certainly in need of clarification. The most important decision, the one on French wood-working machines⁵⁴, at any rate decisively confirms the discretion of Member States in safety policy. Every Member State has the

48. "Beer Judgement" (Fn. 45), at margin no. 45 f.

49. See ECR (1983), 2445 - Sandoz; (1985), 3887 - Motte; (1986), 1521 - Muller; (1987), 1262 - Beer Case.

50. See G.A. Dausen, Die neuere Rechtsprechung des EuGH im Lebensmittelrecht unter besonderer Berücksichtigung des sog. Bier-Urteils, ZLR 1987, 243 ff., 260 f.

51. See ECR (1983), 2445 - Sandoz as well as the precedents reported by Th. van Rijn, 'A Review of the Case Law of the Court of Justice on Articles 30 to 36 EEC in 1986 and 1987', CML Rev. 1988, 593 ff.

52. See J. Sedemund, 'Statement on the concept of the free movement of goods and the reservation for national action under Art. 36 EEC Treaty', in: J. Schwarze (ed), Discretionary Powers of the Member States in the Field of Economic Policies and their Limits under the EEC Treaty, 1988, 25 ff., 29 ff.

53. A product-related rule on burden of proof, differently worded for pesticides and for food additives, has no future, as van Rijn, op. cit. (fn. 51), emphasizes as against ECR (1986) 1074 - Mirepoix.

54. ECR (1986), 419.

right to ban the import of work equipment that does not demonstrably meet its level of protection - and the proof must be brought by those seeking to make the import⁵⁵. Statistical details on accident figures in the countries of manufacture and of destination are not decisive, since the reason might be that in the country of origin the hazardousness of the machines is compensated by greater skill on the part of users⁵⁶.

In its new "Communication on the free movement of foodstuffs within the Community"⁵⁷, the Commission has clarified its view on the consequences of ECJ case law for the law of Member States. The Commission is concerned above all with delimiting the regulations in need of harmonization in areas where duties of recognition can be derived from primary Community law. These delimitations and the effects of Community law can however also be described positively: the Community law requirements must remain compatible with the legitimate health policy interests of Member States. This compatibility requirement concerns not only Member States, but also the Community itself. In other words, while the compatibility rules developed by the ECJ are directed to Member States, at the same time they circumscribe the content of the overall Community law. They entail that Community law controls should also take account of findings as to health hazards and must not lead to a deterioration of the level of protection attained in Member States.

3. Requirements on cooperation by the administrative authorities of Member States

Public law of product safety is, in practice, mainly administrative law. It is in principle by way of administrative acts that the various competent authorities make legally binding measures. These measures specify the general clause of safety law in a binding manner by refusing permits or requiring the elimination of potential hazards⁵⁸. But the

55. At margin no. 17 ff.

56. At margin no. 21.

57. O.J. C 271/1989, 3.

58. To qualify this, cf. the inclusion of standards in the lists under the GSG.

Community has no genuine administrative powers in the area of product safety policy. In both dimensions of its internal market policy - in guaranteeing the freedom of Community internal trade and in having safety requirements incorporated into Member States' law - it is dependent on the administrations of Member States which means that administrative enforcement follows the national provisions that apply in each case⁵⁹.

a) Secondary Community law

The Community's most important instrument for implementing concerted administrative practice is the adoption of obligations for mutual recognition of administrative decisions. The Community's power to impose such obligations on Member States is derived from Article 100 EEC⁶⁰, and, particularly in product safety law is an unavoidable necessity⁶¹. But it nevertheless means, as M.Seidel⁶² rightly stresses, an "approfondissement" of the process of integration the implications⁶³ of which have not been thought through thoroughly since it restricts the administrative sovereignty of Member States in principle presupposed by the Treaty. At any rate, if the Community postulates reciprocal binding of national administrative authorities, the legal homogeneity of the law to be implemented must be guaranteed, and presumably also the equivalence of the

59. See ECR (1983), 2633 - Deutsche Milchkontor GmbH; W. Rengeling, 'Das Zusammenwirken von Europäischem Gemeinschaftsrecht und nationalem, insbesondere deutschem Recht', DVBl. 1986, 306 ff.; Judgement of ECJ of 21.9.1989, in cases 46/87 and 227/88, EuGRZ 1989, 395 (margin no. 32 ff.) - Höchsth.

60. See Th. Bruha, 'Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft. Deregulierung durch "neue Strategie"?' , ZaÖRV 1986, 1 ff., 20 ff. with further references.

61. See for the law on chemicals E. Rehlinger, 'Harmonisierung des Chemikalienrechts?', in: Gesellschaft für Rechtspolitik (ed), Chemikalienrecht, 1986, 79 ff., 97 ff.; and for the law on pharmaceuticals D. Hart, 'Drug Safety as a Means of Consumer Protection: The Approximation of Laws in the EC Medicinal Products Market and Its Limitations', JCP 12 (1989), 343 ff.

62. 'Grundsätzliche Rechtsprobleme bei der Verwirklichung des Gemeinsamen Marktes', in: S. Magiera (ed), Entwicklungsperspektiven der Europäischen Gemeinschaft, 1985, 169 ff., 180 ff.

63. E.g. in the light of Article 24 GG and the federal structure of the Federal Republic of Germany, public liability of authorities of other Member States, or the guarantee of legal protection in Article 19 (4) GG.

"quality" of the administrative practice assured⁶⁴. At any rate, such guarantees are nothing less than legally indispensable requirements for the adoption of recognition obligations. They are not sufficient conditions for de facto uniform decision-making practice. All experience tends instead to show that "real harmonization" requires at least a continual exchange of information, oriented towards practical coordination of implementation⁶⁵.

b) Primary Community law

The ECJ's case law has not only developed duties of recognition and requirements of cooperation in harmonized legal areas, but derived such obligations from primary Community law too. The principles developed here by the ECJ complement each other.

For the harmonized areas, the starting point in determining the scope of recognition obligations is the content of the secondary Community law. "It is only when Community directives provide for complete harmonization of all measures necessary to protect the health of humans and animals" that recourse to Article 36 EEC does not apply⁶⁶. This degree of perfection is not as a rule attained by Community law. But this does not mean that Member States and their administrations are not subject to any binding by Community law. If, say, national law were, in the interests of health protection, to require certificates on the composition and origin of medicaments and the importer is unable to secure these certificates from the manufacturer, then the national authorities must actively support him, for instance by organizing an exchange of the necessary documents with the authorities of the exporting State⁶⁷. If Community-wide health checks are prescribed, this rules out systematic

64. On the enhanced requirements made on relevant agencies in Member States by directives under the new approach, see III.2.

65. See E. Reh binder, op. cit. (fn. 61), 133 ff.; D. Hart, op. cit., (fn. 61).

66. ECJ judgement of 7.3.1989, Case no. 215/87, NJW 1989, 2185 - Schumacher.

67. ECR (1976), 613, 636 f. - De Pijper.

frontier checks, but not additional police health investigations⁶⁸.

The duties developed in the context of (partially) harmonized areas operate also in non-harmonized areas. Even where health protection and its organisations have been left within the sphere of competence of Member States, these are obliged to refrain from investigation and permit procedures where the exporting State has carried out comparable analyses and the results are available⁶⁹. This rule is supported by a "general principle of mutual trust among authorities in Member States"⁷⁰. Probably the furthest-reaching effects to date have been developed by the ECJ outside health protection: French regulations that textile importers had to verify that textile markings of imports complied with French provisions had to allow proof of this by comparably reliable certifications from the exporting country⁷¹.

Summarizing, we may say that the ECJ is in its case law on duties of recognition and cooperation certainly promoting "a dove-tailing and intermeshing of the administrative activities of Member States"⁷². This case law certainly means that the density of checks by the authorities can be reduced, and it may be that the ECJ is assessing the reliability of national checks rather too optimistically. However, its legal principles for recognition of measures by the authorities in the health protection area remain just as compatible with criteria for recognition of product regulations as with the protective obligations expressed in the new provisions of the EEC Treaty⁷³: the duties of recognition and cooperation

68. ECR (1976), 1871 - Simmenthal; (1979), 3369 - Denkavit; on the charges for border controls see the summary in ECJ judgement of 27.9.1988, Case no. 18/87, NJW 1988, 3081 - Commission/FRG; on the safety controls for new ventures see ECR (1986), 1855 - Schloh; Judgement of 11.6.1987, Case no. 406/85, (1987), 2525 - Gofette and Gilliard; Judgement of 17.6.1987, Case no. 154/85, (1987), 2717 - Commission/ Italy.

69. ECR (1981), 3277, 3290 ff. - Biologische produkten.

70. ECJ judgement of 11.5.1989, Case no. 25/88, ECR 1989, - Ministère Public/ Wurmser & Norlain.

71. ECJ, Case no. 25/88 (fn. 70).

72. M. Seidel, op. cit. (fn. 62), 181.

73. See 1 above.

are to bring about the breakdown of trade barriers, not the breakdown of a nationally achieved "legitimate" level of protection.

III Europeanization of Standardization

Community law thus sees product safety law as not merely a barrier to trade. Instead, it assumes that Member States bear a positive responsibility for health protection and that wherever the Community takes this responsibility upon itself it too assumes such an obligation to protect life and health. ECJ case law on the mutual recognition of product regulations and official measures in the area of health protection checks national law for its compatibility with the obligation under Community law, with an eye to the freedom of Community internal trade. But at the same time this case law subjects achievement of this objective to substantive obligations - namely one of compatibility, which rules out the lowering of safety standards based on health policy, both with recognition of product regulations and with that of official control measures.

In the phase of conceptual preparation of the Community's new standardization policy, the amendment of the EEC Treaty by the SEA provisions was not yet foreseeable, and the principles in the ECJ's case law on the scope of the Cassis de Dijon judgment had not yet been fully developed. The development of the new harmonization policy, starting with the Information Directive of 1983⁷⁴ and then systematically taken up with the "new approach on technical harmonization and standards"⁷⁵ came about because of the crisis of the "traditional" policy of harmonization of laws. These crises resulted both from the over-cumbersome legislative procedures of the Community, bound by the unanimity requirement of Article 100 EEC, and from the fact that traditional

74. O.J. L 109/1983, 8; revised by Reg. 88/182 of 22.3.1988, O.J. L 81/1988, 75.

75. O.J. C 13/1985, 1.

harmonization policy in principle started⁷⁶ from consistent "nationalization" of safety regulation going as far as the details of technical regulations. The primary objective of the move to the regulatory technique of reference to standards was to overcome these two reasons for the stagnation of harmonization policy, which reinforced and conditioned each other⁷⁷. The Cassis doctrine was not understood by the Commission - despite its over-extensive interpretation of the ECJ⁷⁸ - as a substitute for legal harmonization in any way, but instead as an additional legitimation for the new harmonization strategy. The ECJ's case law had established a "kind of presumption" for the equivalence of product safety law in the Community, and the point was now to make the "right to this presumption" operational and "organize the conditions under which the presumption" is to be denied⁷⁹.

This brief comparison between the present state of primary Community law and the starting point for the new approach should have adequately clarified a point that is in any case undeniable: the harmonization policy principles decided in 1985 ought not to be treated as a definitive, completed codification. The new approach is more appropriately to be understood as a legislative policy project in need of clarification, which must respond flexibly to difficulties of implementation and take account of the general advancement of Community law. The nature of these difficulties and the possibilities of overcoming them are more clearly recognizable today than five years ago. Three problem areas need priority treatment here: public-law product safety obligations, the functions of safeguard clause procedures and the certification of the safety conformity of products.

76. With the well known exception of the Low Voltage Directive, O.J. L 77/1973, 29.

77. See the aforementioned Commission Communication concerning a new approach on technical harmonisation and standards, COM (85) 19 final of 19.1.1985, 3.

78. See above II.2.

79. See for example para. 64 of the White Paper (fn. 40) as well as the Commission Communication of 19.1.1985 (fn. 77), 5.

1. Essential safety requirements and general product safety obligation

The Model Directive mentioned above, laying down the structures of the new harmonization policy, contains statements of safety law which are technically utterly vague and remain unclear in their legislative policy consequences. The general technical description of the level of safety to be guaranteed in the new directives corresponds to the formulation of para. 3 (1) GSG. This states that "any products may be placed on the market only if they do not endanger the safety of persons, domestic animals or goods when properly installed and maintained and used for the purposes for which they were intended"⁸⁰. "In certain cases," it continues, however, "in particular with regard to the protection of workers and consumers the conditions set out in this clause may be strengthened (foreseeable use)"⁸¹.

This modification already shows that the clarification of the level of safety in terms of the context of use of products is to be provided in the directives themselves. This corresponds to the much-criticized⁸² description of the regulatory content in safety law of the new directive: "The basic safety requirements" are to be formulated in these directives sufficiently precisely so as "to enable the certification bodies straight away to certify products as being in conformity, having regard to those requirements in the absence of standards"⁸³. The indefiniteness that a safety-law general clause must have is thus not in the least consistently reduced by the reference method, but more by a procedure specific to each area⁸⁴.

80. See Section B II before 1 in the so-called Model Directive on the new approach (fn. 75).

81. Model Directive Section B II 3.

82. See J. Pelkmans, Opheffing van technische handelsbelemmeringen in de EG, 1985, 161.

83. Model Directive, Section B III 1.1.

84. In this connection see also the "criteria for choosing the priority areas in which this new approach could initially be applied", in the Annexes to the Model Directive.

In the practice of Community policy, this indecisiveness has since led to a confusing multiplicity of legal safety regulations:

- The Directive on Simple Pressure Vessels⁸⁵ repeats, in Article 2, the general formulation of the Model Directive, but then contains in Annex 1 surprisingly detailed legally binding safety requirements.
- The Directive concerning the Safety of Toys⁸⁶ requires the normal behaviour of children to be taken into account, and in its Annexes converts the safety-law principles previously developed in European standardization work into law in binding fashion.
- The Directive on construction materials⁸⁷ describes the safety requirements against "normally foreseeable effects" comprehensively, but in general terms; having regard to the tension arising from the scope and the indefiniteness of its requirements, it provides for the production of "technical specifications" and "basic documents", through which the necessary connections between the essential requirements and (in particular) standardization contracts and contracts for "guidelines for European certification...can be created" (Article 3 (3)).
- The Directive relating to Machinery⁸⁸, the comprehensive regulatory functions of which are like those of the German GSG, repeats the Model Directive in its general definition of the required level of safety (Article 2 (1)), but then clarifies this definition in an annex (I 1.1.2 a and c) to the effect that protection is also to be guaranteed for cases even where risks of accident arise from foreseeable abnormal situations.
- The Draft Directive on Mobile Machinery⁸⁹ likewise keeps to the

85. O.J. L 220/1987, 48.

86. O.J. L 187/1988, 1.

87. O.J. L 40/1989, 12 (Art. 3 para. 1 with Annexe I).

88. O.J. L 183/1989, 9.

89. O.J. C 70/1989, 6.

formulations of the Model Directive, but for machines which may "also be intended for use by non-professional users" requires that safety precautions be taken "which could reasonably be expected in a non-professional workplace"⁹⁰.

This list is not complete⁹¹, but the differentiations it nevertheless adequately establishes are not surprising. There are objectively justified reasons why the required level of safety should be specified in the light of the hazard potential and use context of products. But secondary Community law at present lacks an overall legally binding reference that could be used to justify such differentiations. Similarly, the discrepancies between "public-law" and "private-law" Community law that arise without a general product safety obligation can scarcely be justified. The Product Liability Directive indeed obliges Member States to protect their citizens' legitimate safety expectations through the law of liability⁹². Undoubtedly, the private-law obligation to market only safe products and the public safety obligations have different regulatory functions⁹³. But it would be no less than consistent to flank the private-law safety obligation with a comprehensive public-law general clause⁹⁴. In particular, this sort of general safety-law reference framework for checking the content of national provisions against the criteria of primary Community law would be warranted, for two reasons. Firstly, it would lay down criteria by which Member States could

90. Annex I, 1.1.2.

91. The special case of the Draft Directive on Active Implantable Electromedical Equipment (Comm.(88) 717 final) concerns, by its very nature, a preventive licensing system. The Directive relating to electromagnetic compatibility (O.J. L 139/1989, 19) keeps close to the Model Directive. This is also true of the Draft Directive on Appliances Burning Gaseous Fuels (O.J. C 42/1989, 5), which however also contains an extensive list of basic technical design requirements. The Directive on personal protective equipment (O.J. L 393/1989, 18) likewise provides for a general clause along the lines of the Model Directive (Article 2 (1)), but leaves unaffected the power of Member States to make further-reaching requirements to protect users (Article 2 (2)).

92. Cf. Article 6 taken together with the scope of the Product Liability Directive (fn. 3) as defined in more detail in its Article 2.

93. See further under IV.2.

94. See further under IV.1.

orient themselves in areas not specifically regulated and which they would have to take account of in devising and re-shaping their own legal system. At the same time, it would be made clear that control by Community law over national law cannot be intended as a deregulation strategy aimed against justified safety interests.

2. Safeguard clause procedures and follow-up market controls

It is the explicit intention of the regulatory technique of reference to standards to take the load off Community legislative procedure. This unburdening effect ought not however lead to delegation to standards organisations of the legislative responsibility taken over by Community law for harmonizing safety requirements. For this reason, the new approach adopted two measures. Firstly, the development of European standards is prepared by standardization contracts from the Commission, and the outcome of European standardization must - like national standards claimed to conform with the legally binding requirements - be recognized by the Commission in the procedure provided for by the Model Directive⁹⁵. Secondly, and more important, the recognition of standards always establishes a mere presumption of their safety conformity. This limitation on their legal relevance means that the safety assessments made in the standards remain subject to revision. At the same time it means that Member States are, despite recognition of the safety conformity of standards by the Commission, bound only by the legally binding safety objectives and therefore remain entitled to give effect to their interpretations of the meaning of these objectives in measures to protect health and safety. According to the safeguard clause procedures embodied in the Model Directive, confirmed by Article 100 a (5) EEC and incorporated into individual directives since adopted, Member States are however obliged to have the conformity of their measures with Community law verified. Article 100 a (4) EEC opened up further possibilities for Member States to secure their safety policy interests. The dispute over interpretation of this provision⁹⁶ is therefore only of limited

95. (Fn. 80), Section B VIII.

96. See above II.1.

importance. The broad formulation of the safety-law general clauses ought in any case to make it possible for Member States to declare any interest motivated by safety policy in the context of the safeguard clause procedure, so that the practical relevance of the dispute over interpretation of Article 100 a (4) EEC reduces to the question whether entitlement to a national measure is checked in the safeguard clause procedure (and therefore in the first place by the Commission) or in the new procedure introduced by Article 100 a (4) EEC.

The legislative policy function of the safeguard clause procedure is above all to keep safety policy assessments open to new knowledge. This "sunset" function, which takes account of the reference of technical safety law to the Community's and Member States' safety obligations⁹⁷, is expressed above all in the fact that Member States, when justifying their measures, must in particular verify, according to the provision normally contained in Article 7 of the new directives, whether safety objectives have not been met, whether standards are being wrongly applied or are themselves faulty, and if necessary carry out such verification in order to disqualify hitherto recognized standards.

But the safeguard clause procedure is supposed to be able also to affect marketability of products directly, over and above this verification of the safety conformity of standards. According to Section B VII (2) of the Model Directive, the Commission, where it finds a measure taken by one Member State justified, has to "point out to" the "other Member States" that they are (ceteris paribus) likewise obliged to forbid marketing of the item concerned. The Model Directive does not itself contain a legal basis for this Community-wide applicability of a national measure. Where the Commission regards a Member State's measure as justified, it has no means available to compel active intervention by administrative bodies of other Member States.

97. See I above, before 1; on the constitutional justification in German law cf. BVerfG 25, 1, 12f. - Mills Act; BVerfG 50, 290, 335, 377f. - Co-determination; BVerfG 49, 89, 143f. - Kalkar; BVerfG 56, 74, 78f. - Aircraft noise.

The new directives have not filled in this lacuna in the Model Directive. For instance, the Toy Directive⁹⁸ provides that Member States should "take all appropriate measures to withdraw the products from the market, or to prohibit or restrict their placing on the market" (Article 7 (1)), and the Machine Directive⁹⁹ has a corresponding provision (Article 7 (1)). Such provisions of Community law can scarcely be interpreted as an obligation to introduce such new instruments of action within Member States. Even were they so interpreted, they would be much too indefinite to guarantee even only approximately equivalent administrative practice in safety law.

In practice this means that the safeguard clause procedures can carry out both their internal market and safety functions only inadequately. The Community has to expect that the freedom of action at present open to national authorities will lead to new (subsequent) market segmentation, because the competent authorities in Member States will interpret the safety law general clauses differently and implement them with different instruments of action. But the Community is not in a position to apply, Community-wide, measures by one Member State which it regards as objectively justified, thereby meeting the justified safety expectations of the citizens of all Member States.

3. Safety assessment procedures and the protective obligation of the State

The Model Directive bindingly brought in the move to the regulatory technique of reference to standards, with particular regard to the procedure for acquiring safety criteria in Community law. As for the indispensable second element in all product regulation, namely the verification and certification of products' conformity with the standards set, all that the model directive contains is statements on the possible forms of such certification¹⁰⁰. The Council Resolution of 7 May 1985¹⁰¹ accordingly stressed that the new approach would have to be supplemented

98. O.J. L 187/1988, 1.

99. Fn. 89.

100. See especially section B VIII of the Model Directive (fn. 80).

101. Fn. 75.

by "steps in connection with assessment of conformity". The need for such supplementation is indeed indisputable on the new approach. The presumption of safety conformity that establishes the right to access to markets in the Community depends, after all, not only on recognition of European or national standards, but also on demonstration of product conformity with standards¹⁰². If a manufacturer wishes to have recourse to the European deviation clause¹⁰³, he is entirely dependent on attestation of the safety conformity of his product.

a) The Community's legal policy

The directives and draft directives through which the new approach was implemented have therefore also always had to develop solutions to the problems of certification. At the same time, the Commission has embarked on working out an approach to certification that systematically supplements the Model Directive, and brought this to an interim conclusion¹⁰⁴. These efforts at Europeanization of certification rest on two complimentary coordinating mechanisms¹⁰⁵:

(1) Forms of safety assessment: In its Section B VIII devoted to certification, the Model Directive contains a typology of possible safety attestations (conformity certificates and tests by third parties; test results by third parties; conformity declarations by the manufacturer, with and without monitoring systems; "other certification"). The preconditions for using the different forms of certification have not been specified, nor have the nature of the expected tests been clarified any further. Accordingly, in their regulations the new directives on forms of

102. See Section B V and VIII of the Model Directive.

103. Section B V 3 of the Model Directive.

104. See above all the Commission Document "A Policy Statement of the Commission on Technical Specifications, Testing and Certification: The Global Approach, COM III/3510/88 - Certif. 88/10 of 29.11.1988 as well as the proposal for a Council Resolution on Conformity Assessment Procedures of 15.6.1989, O.J. C 31/1989, 3.

105. See on the following the analysis of H. Buerfeind, Die gegenseitige Anerkennung von Produktregelungen und Produktzertifizierungen im Europäischen Recht, Typescript Bremen 1989, 49 ff.

certification and procedure must break conceptually new ground. The solutions have been correspondingly varied.

Thus, in the first relevant Directive, on Simple Pressure Vessels, design testing through construction sample testing and construction sample certification was given unexpected importance¹⁰⁶, whereas simple self-certification by the manufacturer was not provided for at all¹⁰⁷. In the Machine Directive too, testing of construction samples receives an area of application not planned in the Commission's original proposal¹⁰⁸. Also striking is the importance assigned in the new directives to quality guarantee systems. This is true particularly of the Construction Products Directive¹⁰⁹ and also of the Directive on personal protective equipment¹¹⁰.

In its proposal on conformity assessment procedures, the Commission has developed the approaches in the model directive and the new directives further, leading to eight "modules". This clarification of testing and assessment procedures is aimed at increasing their reliability and thus also facilitating mutual recognition of national certification. But the Commission proposal evidently presumes that clarification of test requirements alone will not suffice in order to "guarantee uniform interpretation and application of the modules"¹¹¹. Accordingly, the Commission itself should first of all ensure cooperation by the national testing and licensing bodies and in the longer term the European Organization for Certification and Testing should organize this cooperation.

106. (Fn. 85), Art. 8 Sect. 1 and Art. 10 as well as Art. 13.

107. In this connection cf. now also Annex I (i) of the Proposal on Conformity Assessment Procedures (fn. 104).

108. Cf. Article 8 of the Commission proposal (O.J. C 29/1988, 1) on the one hand, and Article 8 taken together with Annex IV para. 9 ff. of the Directive on Machinery (fn. 88) on the other.

109. (Fn. 87), Art. 13 f. taken together with Annex III.

110. O.J. L 399/1989, 18 (Art. 11).

111. (Fn. 104), Annex I h, at 2.

National experience in the area of certification shows that in order to specify technical standards, exchange of experience among test centres is necessary in order to arrive at equivalent test criteria and prevent a race to those centres that set low design requirements. This is still more true in the case of technical innovations and especially in areas where harmonized standards have not yet been worked out.

In product areas where manufacturers appeal directly to the binding basic safety requirements of directives, Europe-wide exchange of experience among test centres involved could be a preparatory stage in producing harmonized technical standards. Where technical standards have already been produced, important indications might emerge from the exchange of experience among test centres for applying the standards to new technical developments, as might knowledge of hazards. Reaching a pragmatic solution here is desirable also because the new approach, with its fixation on the difficult work of harmonization, has so far tended to neglect the necessary verification of standards. The safeguard clause procedure is oriented more towards exceptional hazard situations, and the procedures for verifying norms focus not on the advance of technical development and on the level of hazard, but on the proper incorporation into law of the general safety requirements.

(2) Requirements on certification centres: The mutual recognition of national certification, which presupposes equivalent testing practice in Member States, is to be further guaranteed through requirements on the organization structure and working methods of national centres. The annexes to the new directives and draft directives contain two differing regulatory patterns here: the list of criteria contained particularly¹¹² in the Toy Directive¹¹³ and the Directive on Construction Materials¹¹⁴ is very vague¹¹⁵; in the other cases, specifically also¹¹⁶ in the Directive

112. See the evidence in H. Buerfeind, op. cit. (fn. 105), 107.

113. Fn. 86.

114. Fn. 87.

115. All that is called for is the "necessary" equipment, the competence and integrity of the staff and their impartiality, the maintenance of professional secrets and the taking out of liability insurance.

116. See further material in H. Buerfeind, op. cit. (fn. 105), 106.

on Machinery, it is considerably more substantial. Nevertheless, here too the Commission evidently takes it that additional measures are essential to guarantee equivalence of the tests required by the directives. The future directives should therefore refer to the CEN/CENELEC standards on testing, certification and accreditation adopted in April 1989¹¹⁷ and the work of national centres should be coordinated within a comprehensive structure of cooperation¹¹⁸.

These ideas are already followed in the Construction Products Directive. This Directive has not only introduced bridgehead institutes to clarify the general safety requirements¹¹⁹, but also assigned to these procedures the task of working out guidelines for certification¹²⁰. Additionally, this directive provides that national centres competent for technical licensing, certification, monitoring and testing should "come together in a body" that cooperates closely¹²¹. The step taken here to build up a cooperative infrastructure corresponds to the insight gained with specification of the certification modules, that the uniformity of testing practice aimed at cannot be achieved solely by making the procedural rules uniform¹²².

The Commission document on the "global approach"¹²³ clarifies the cooperative structures aimed at. This document distinguishes among political, technical and horizontal elements of organization. While for the political element the Commission is to take over an initiative function and the "technical element" is concerned with working out

117. See A. Warner, 'Quo vadis Zertifizierung? Freie und gelenkte Entwicklung der Zertifizierung', *DIN-Mitt.* 68 (1989), 313 ff.

118. See H. Berghaus, 'Europäische Aktivitäten im Bereich der Zertifizierung - Die Intentionen der Brüsseler EG-Kommission', *DIN-Mitt.* 68 (1989), 128 ff.; E. Previdi, 'Quo vadis Zertifizierung? Die Entwicklung in der EG', *DIN-Mitt.* 68 (1989), 203 f.

119. See above III.1 at fn. 87.

120. See Art. 3, sect. 3 together with Art. 12 and Art. 20 sect. 4.

121. Art. 18 together with Annex II, point 2.

122. See further the reference to agreements on mutual recognition in Article 9 (4) of the proposal for a Directive Concerning Telecommunications Terminal Equipment, including the mutual recognition of their conformity, O.J. C 211/1989, 12.

123. Above Fn. 104.

arrangements for specific sectors, for the "horizontal element the foundation of a new organization, the 'European Certification and Testing Board'" is provided for. This board is to include government representatives, representatives of national certification centres and standardization institutions, manufacturers, trade unions and consumers. Performance of these "representative" functions is to be combined with that of the "executive" task of promoting agreements on mutual recognition.

b) Legal questions

With its efforts to build up an infrastructure for certification, the Commission is advancing into territory that has hardly been opened up legally. The question was raised, even against adoption of the regulatory technique of reference to standards of whether confining harmonization policy to general clauses in safety law is compatible with the prohibition on delegation in Community law and the principle of institutional balance between Commission and Council¹²⁴. Against the accusation of infringing the ban on delegation, it may be stated that both European and national standards must go through a recognition procedure, and compliance with them always establishes only a presumption of the safety conformity of standards¹²⁵. Such procedures are provided for, for instance, by the Directive on Simple Pressure Vessels¹²⁶ where recourse is had to the European "deviation clauses". By contrast, for instance, the Directive on Electro-Magnetic Tolerance¹²⁷, and also the Directive on Machinery¹²⁸, do without formal confirmation of decisions of national centres by the Commission. The fact that this abstention from testing at Community level is in line with practical necessities is easy to see. This is particularly true of the whole area of certification, which can reasonably

124. See above 1 as well as R.H. Lauwaars, 'The "Model Directive" on Technical Harmonization', in: R. Bieber et al., *op. cit.* (fn. 38), 151 ff.; Ch. Joerges et al., *op. cit.* (fn. 11), 380 ff.; for discussion of the Low Voltage Directive see *ibid.*, 339 f.

125. See 1 above.

126. (Fn. 85), Art. 17.

127. O.J. L 139/1989, 19, Art. 10.

128. (Fn. 88), Art. 8.

be handled only in de-centralized fashion. At the same time, however, the Commission's efforts to build up a framework system for certification and underpin mutual recognition of national certificates by agreement confirm, as do statements from experienced practitioners¹²⁹, that the safety objectives of European directives as a rule do not provide any adequate guidance to decision for and against the safety conformity of the product and that all presentations of the requirements on national test centres formulated to date fail to eliminate the resulting leeway in decision. But this means that in the area of certification, legal powers on safety, which according to the new directives are incumbent on the Community, are transferred back to national level. The fact that all that is involved is the establishment of presumptions of the safety conformity of products, which can be challenged in the safeguard clause procedure¹³⁰, changes nothing. The fact that the presumptions of safety can be refuted certainly does maintain the official responsibility for protecting health and safety interests¹³¹. But the ban on delegation in Community law also means that the Commission has itself to implement, through precise measures, decision-making powers entrusted to it by secondary Community law¹³². To remove these reservations, directives that do not provide for any verification of national certification decisions by the Commission would have to distinguish between the regulation of forms of certification and the recognition of certification decisions. The Europeanization of certification ought then to be seen as an inter-governmental task. But then the question arises how the Community is to uphold its duties to protect life and health in the face of inadequacies of certification practice.

129. Evidence of J. Falke, *op. cit.* (fn. 9), in fn. 42.

130. See 2 above.

131. See for the German Law R. Breuer, 'Direkte und indirekte Rezeption technischer Regeln durch die Rechtsordnung', *AÖR* 101 (1976), 46 ff., 66.

132. ECR (1975), 1279/1307 - *Rey Soda* and the considerations of AG Mayras, *ibid.*, 1319 f.

IV. The Tasks of a Directive on General Product Safety

In the three problem areas mentioned, the general product safety obligation, the Europeanization of follow-up market controls and conformity assessment, in which the linkage between standardization and product safety law has not yet been established, internal market policy objectives overlap with interests of product safety policy. It is in line with the logic of the new harmonization policy for the Commission here to have first worked out its internal market policy concept and on several occasions announced the consequences for product safety law¹³³, but to have waited until now to provide clear outlines of its ideas, through the Proposal for a Directive on General Product Safety¹³⁴.

This Proposal for a Directive is as ambitious as it is complicated. This analysis will not deal with all the details of the project. Instead, it will consider the question of how the Commission itself sees the relationship between internal market and product safety policy, and seeks to compensate for the deficits found in the new harmonization policy.

1. The integration of product safety policy into internal market policy

The "explanatory note" to the Commission's proposal for a directive¹³⁵ and the recitals contain, disregarding surprising statements on the political manifestation of the Community¹³⁶, two lines of argument, both rooted in Article 100 a EEC. The first justificatory approach sounds familiar. The Commission refers to the diversity in "horizontal"

133. See the Commission "Communication on a new impetus for consumer protection policy", COM (85) 314 final of 23.7.1985 and the Council Resolution thereon of 25.6.1986, O.J. C 167/1986, 1; "Communication from the Commission on safety of consumers in relation to consumer products", COM (87) 209 final of 8.5.1985 and the Council Resolution thereon of 25.6.1987 on the Safety of Consumers, O.J. C 176/1987, 3; see further the Council Resolution of 4.11.1988 on the participation of consumers in standardisation, O.J. C 293/1988, 1 as well as that of 9.11.1989 on the priorities of consumer policy, O.J. C 294/1989, 1.

134. O.J. C 193/1989, 1.

135. COM (89) 162 final of 7.6.1989, 2 f.

136. See COM (89) 162, 2, and the 15th recital in the Draft Directive.

legislation of Member States on product safety¹³⁷, to the autonomy of national administrative authorities in verifying Community-law presumptions of safety¹³⁸, and to the powers of action of Member States pursuant to Article 100 a (5)¹³⁹. All these references refer to legal and administrative provisions that directly affect the functioning of the Common Market and therefore belong among the "classical" canons for justifying approximation of laws.

But this framework has already been broken by Article 100 a. The Community's policy of approximation of laws is made subject to qualitative requirements by the combined operation of Articles 100 a (4) and (5), 130 r and 130 t. It must base itself on a high level of protection (Article 100 a (3)); it can achieve complete removal of barriers to trade, at least de facto, if it itself applies the relatively highest level of protection, and it must, if an obligation to protect life and health in Community law is taken as a basis, at least respect measures by Member States against newly recognized hazards¹⁴⁰.

The Commission's proposal draws the conclusion that the policy of removing obstacles to trade caused by product safety law should be treated as Europeanization of product safety law, which takes the protection of life and health as a positive obligation on the Community. This is expressed partly in the extensive validity claims of the general product safety obligation, which fills in the protective lacunae in secondary Community law¹⁴¹. It further emerges from the instruments of action to be introduced by Member States and coordinated at Community level¹⁴².

137. See the 2nd recital in the draft, and more thoroughly the Commission Communication of 8 May 1987 (En. 133), 5 ff.

138. 5th and 13th recitals.

139. See COM (89) 162, 3.

140. See above at the end of II.1.

141. See especially 6th recital, and part 2 below.

142. See especially 10th recital and parts 2 and 3 below.

2. The tasks of a Community-law general clause

The legislative description of general product safety obligations must answer two related questions. Firstly, it must name the criteria to be used for the legal assessment of product hazards, and secondly, it must delimit the spheres of responsibility of product manufacturers and product users¹⁴³. These two tasks are taken up in the Commission's draft with the objectively appropriate differentiation, though the drafting is obscure. The legal safety reference point of the draft appears in Article 2 in the term "unacceptable risk" to safety and health. But this term must be read in the context of the more detailed requirements on the form of products given in Article 2 b. It follows from Article 4 (1) that product users are also to be protected by suitable indications against "significant risk which is acceptable as such". In essence, then, the safety requirement in the draft is no more restrictive than, for instance, the "unreasonable risk" formula of the American CPSA 1972¹⁴⁴. The differentiation between "significant" and "unacceptable" risk refers only to the need to adjust the measures required by safety law to the hazard potential of products - and this proportionality requirement is in any case thoroughly taken account of in the draft¹⁴⁵. Put more specifically, the distinction between unacceptable risks, to be dealt with by design standards, and acceptable but significant hazards which merely require warning instructions is too crude and is superfluous. A noteworthy point is the explicit rejection of purely economic justifications of the legally binding level of safety (Article 3). This is in line with the normative approach of the draft - and with experience gained in the US with proposals for a consistent orientation of safety-law assessments to cost-benefit analyses¹⁴⁶.

143. See detailed in Ch. Joerges et al., *op. cit.* (fn. 11), 42 ff.

144. P.L. 92-573, 86 Stat. 1207, for example Sec. 2 and 8.

145. Cf. 2nd recital and part 3 below.

146. On this see in more detail Ch. Joerges et al., *op. cit.* (fn. 11), 47 ff., 220 ff., and the rejection of economic criteria for risk decisions by the US Congress: M. Schulenberg, The Law of Product Recall: A Comparative Analysis Between the Laws of the United States and the Federal Republic of Germany, LL.M. Thesis (University of Madison-Wisconsin, Law School), 1988, 265 f.

The draft operates similarly in distinguishing between the spheres of responsibility of manufacturers and product users. The general provision of Article 2 (c) requires manufacturers to focus on "intended" use of a product under "normal circumstances" but also on "any other reasonably foreseeable" use. It is further evident from the provisions of Article 9 on accident information systems that all product hazards that arise out of foreseeable ("not manifest or unforeseeable") misuse¹⁴⁷ can justify measures by the authorities, and that warning instructions can be assessed as an adequate risk measure only when they prove actually effective (Article 7 (1) (d)).

For the regulatory functions of safety-law general clauses, their formulation is less important than the normative and institutional context in which they are to operate. The Commission's draft is very careful in specifying this context. The normative value of the general product safety obligation is more closely defined by four principles:

- The product safety obligation is binding in Community law as a whole. It does not in principle replace existing more detailed regulations; it should however fill regulatory lacunae and set a standard which may not be lowered by more specific ("inadequate") regulations¹⁴⁸. This comprehensive validity claim also means that product safety obligations binding according to the law of Member States are to be replaced by the Community-law standards. The standard mentioned in para. 3 (1) GSG, "generally recognized rules of technology" would accordingly be replaced by the more stringent "state of science and technology".
- The product safety obligation confirms the autonomy of the legal assessment of safety risks. Here the draft is in line with the principles applying to the relationship between the legally binding safety objectives of the new directives and their specification

147. On the terminology and its relationship with standardization principles applying in the Federal Republic see Ch. Joerges et al., op. cit., (fn. 11), 43 ff., 155 ff.

148. See the 3rd recital of COM (89) 162, 2, 5.

through norms that are recognized and apply in product liability law too¹⁴⁹. But the draft goes a step beyond these principles by explicitly allowing national authorities also to take measures where a product meets specific legal provisions but there is a basis for believing that an unacceptable risk is likely to be present (Article 7 (2)). Similarly (and more certainly), intervention by the authorities can be considered where the safety conformity of products emerges only "having regard to the state of scientific and technical knowledge" or "good business practices" (Article 5 (2)). This principle is the clearest indication that the proposal sees the product safety obligation as the expression of a duty in Community law to protect life and health¹⁵⁰.

The protective function of the general product safety obligation is hazard-related, not damage-related. This difference is rightly stressed in the Commission's explanations¹⁵¹. Since the decision on a measure by the authorities depends on recognizable hazards, such action cannot alone prejudice the decision in liability law where there is a defect within the meaning of Article 6 of the product liability directive (cf. Article 16). Whether these differences in fact compel differing definitions of the product quality required in liability law and safety law, however, seems doubtful. Action by the authorities justified at the time of assessing a hazard does not prejudice the final assessment of the safety conformity of a product. The criteria mentioned in the proposal for this assessment, including the gradation between unacceptable risk and significant remaining risks (which in principle require only warning instructions) ought scarcely to differ from the viewpoints which are, pursuant to Article 6 of the Product Liability Directive, to

149. See Art. 7 d of the Product Liability Directive (fn. 3).

150. See above at the end of 1.

151. COM (89) 162, 5.

decide the legitimacy of safety expectations¹⁵².

- The three specifications of the normative content of the product safety obligation mentioned so far, relate to legislative and administrative action. These "vertical" functions of the product safety duty supplement Article 6 with a "horizontal" dimension. This means that the product safety obligation entails not only tasks and powers for the authorities, but also organizational requirements and duties of response on "suppliers"¹⁵³. The material content of these duties is explained in Annex 1 of the draft. It corresponds to the organizational consequences developed in German law from the product monitoring duty¹⁵⁴. Again, the product safety obligation in public law is more stringently oriented towards avoidance of hazards than a private-law product monitoring duty can be¹⁵⁵.

3. Preventive harmonization of product safety legislation

The practical incorporation into law of the normative content of the public-law product safety obligation is dependent on suitable institutional and procedural measures. Here the Community must, both in

152. See Ch. Joerges et al., *op. cit.*, (fn. 11) 450 f. However, the Product Liability Directive excludes liability for development hazards (Article 7 (e)), whereas the Safety Directive's approach based on the emergence of hazards does make it possible to proceed against development hazards. But in product liability law too, the exclusion of liability for development hazards does not mean that products can continue to count as safe within the meaning of Article 6 once this hazardousness has become known. In German manufacturer liability law this aspect of transactional duties is in any case recognized: the product monitoring duties relate specifically to hazards not yet recognizable at the time of marketing.

153. On the concept see Article 2(d); the safety duties of importers, traders and other persons engaged in commerce correspond to the transactional duties on non-manufacturers in product liability or manufacturer liability law.

154. See C.E. Hauschka, 'Die vorbeugenden Organisations- und Produktbeobachtungspflichten des Herstellers in rechtlicher und unternehmerischer Sicht', *AG* 1988, 29 ff., 38 ff. as well as J. Falke, *op. cit.* (fn. 9), 15 ff. with further references.

155. See I.4 above. However, the proposal has omitted to introduce an obligation on suppliers to notify information on product hazards that would correspond with this function (and follow the example of section 15 (b) CPSA).

the interests of its internal market policy objectives and having regard to the "qualitative" commitment of its law-approximation policies take the relatively most developed examples in the product safety law of Member States as a guide. It cannot, however, meet the resulting requirements by, for instance, borrowing from the legislation of the Member State with the highest level all round, but must take the extent of the machinery of product safety policy in the various Member States into account and bring it into a coherent synthesis. In fact the Draft obliges Member States to extend their range of safety policy machinery to cover the whole spectrum of possibilities of government action. This step will undoubtedly bring about objections not only from a legal policy viewpoint but also from a purely legal one. To date, directives have required Member States in particular to comply with freedom to act; henceforth Member States are to be induced to take positive protective measures. But the duty to respect freedoms is hard to distinguish qualitatively from the duty to protect health and safety interests. If Community law may restrict the powers of Member States and their administrations in the interest of bringing about the internal market, then it must in principle also be possible to formulate the "quality" of the rules that flesh out the internal market in positive terms.

a) Information systems

A product safety policy that wishes to justify its approach needs data on accident figures and information on accident situations from which priorities can be derived and strategies to avoid risks developed. This task is one for accident information systems. The pioneer here was the American National Electronic Injury Surveillance System (NEISS), built up after adoption of the Consumer Product Safety Act, 1972. It was internationally the first attempt at a data survey that would supply not only information on the numbers and consequences of accidents but also on the products involved¹⁵⁶. The American experience has been utilized by Britain to set up its Home Accidents Surveillance System (HASS) and by the

156. See on this system Ch. Joerges et al., op. cit. (fn. 11), 211 ff.

Netherlands in their Privé Ongevallen Registratie Systeem (PORS)¹⁵⁷.

The Community's attempts to extend these initiatives into a European project have met with considerable resistance. The Council Decision of 13 July 1981¹⁵⁸ confined itself - against further-reaching proposals from the Commission¹⁵⁹ - to the carrying out of a "model experiment" which left it up to Member States to determine the form of their participation and was de facto taken seriously by only three States¹⁶⁰. The Council's follow-up Decision of 22 April 1986 on the "European Home and Leisure Accident Surveillance System" (EHLASS)¹⁶¹ was adopted as a "demonstration project". Over a period of five years, data were collected Community wide. The declared object of this project is to evaluate the data "with an eye to accident prevention"¹⁶². But this very evaluation is to be reserved to the final report on the demonstration project - and at present not even the financial requirements for continued data collection seem to be guaranteed¹⁶³.

The Commission's Draft and its explanatory statement exclude the controversies over the accident information systems and treat the issue of determining hazard pragmatically. Article 7 (d) merely prescribes minimum requirements for the setting up of national agencies, leaving Member States broad room for manoeuvre. But the Draft's reticence also has its programmatic components. The Commission is plainly aiming less at more or less perfect data collection than at a "responsive" bureaucratic structure that can take up approaches by consumer organizations, professional associations and workers (Article 7 (e)) and also engage in public debate on product hazards or respond to approaches by "public interest" groups or

157. On the British HASS see *ibid.*, 119 f.; on the Dutch PORS see J.H.A. Bruggers and W.H.J. Rogmans, Registratie van ongevallen in de privésfeer, 1982.

158. O.J. L 229/1981, 1.

159. O.J. C 252/1978, 2.

160. See Ch. Joerges et al., *op. cit.* (fn. 11), 289 f.

161. O.J. L 109/1986, 23.

162. The 6th recital of the Council Decision.

163. See the reference by J. Falke, 'Normungspolitik der Europäischen Gemeinschaften und Schutz von Verbraucherun und Arbeitnehmern', Jb.z.Staats- und Verwaltungswissenschaft 3 (1989), 217 ff., 231 f.

organizations¹⁶⁴. Following experience with the accident information systems of the USA, Britain and the Netherlands¹⁶⁵, it would clearly be wrong to do entirely without systematic surveying of hazards. But the leeway the proposal allows Member States here (Article 9 (1)) is unproblematic insofar as the draft guarantees mutual information by Member States, at any rate on serious risks of more than local importance (Article 9 (2))¹⁶⁶.

b) Powers of action

"Although safeguard clauses in vertical Community legislation, in particular in texts following the "new approach", mention withdrawal from the market as a means of action to be taken by Member States' authorities against unsafe products...they do not give any details in that respect"¹⁶⁷ - this explanation of the provisions on so-called follow-up market control contained in Article 7 (1) of the Commission's Draft hits at a weakness not only of existing harmonization policy¹⁶⁸ but also of product safety legislation in Member States¹⁶⁹.

Article 7 (1) (c) responds to these shortcomings of follow-up market controls in Member States with a provision that is scarcely any more precise than the power provided for Member States in Article 7 of the new directives to withdraw hazardous products "from the market or forbid or restrict their marketing"¹⁷⁰. Article 7 (1) (c) of the Draft goes beyond these models only to the extent that it obliges Member States actually to equip their authorities with the "necessary powers". It is only through

164. In this connection see the liability rules in Article 17 (2).

165. See the references in fn. 156 f.

166. This provision is, moreover, intended to put the present accident information system (fn. 24 f. above) on "a more general level and on a firmer legal basis" (COM (89) 162, 10).

167. COM (89) 162, 10 f.

168. See above III.2.

169. See I.4 above, and in detail the country reports in H.-W. Micklitz (ed), Post Market Control of Technical Consumer Goods (Commission-sponsored study, 1988), forthcoming.

170. See above III.2.

Annexe 2 of the Draft that it becomes clear what powers are meant. It provides in particular for:

- checks by the authorities on marketed products, and on suppliers' monitoring systems (Point 1)
- rights of information and investigation (Points 2 (a) and (b))
- requests to manufacturers to warn users or the public of hazards (Point 2 (e))
- public warnings (Point 2 (d))
- seizure of products and other marketing restrictions (Points 2 (g), (h) and (i) (cc))
- recall actions by manufacturers, either carried out voluntarily following an invitation, or ordered (Points 2 (i) (aa) and (bb)).

This list is of purely "indicative" significance. However, it follows from Article 12 (3) that Member States can, where necessary, be obliged by the Commission¹⁷¹ to carry out the investigations and checks mentioned in Points 2 (a)-(c) of the "indicative list". It further follows from Article 11 (c) that the Commission can itself provisionally order the warnings, marketing restrictions and recalls specified in more detail in Points 2 (d)-(i) of the indicative list, in cases of grave and immediate risk. Moreover, by Article 8 (2), all measures of Member States, thus including those against mere "unacceptable risks", can be verified at Community level where the risks are not of purely local importance. Accordingly, the indicative list in Annexe 2 takes on quite binding effect. Member States retain the freedom, in shaping their follow-up market controls, to base themselves on their existing administrative structures and regulatory traditions. But they must provide the whole list of instruments mentioned in Annexe 2.

171. See further on this in 4.a immediately below.

4. Europeanization of decision-making practice

For the years 1966-1987, American statistics report, for the automobile sector alone, recall actions on 100 million cars, 7 million spare parts and 24.6 million tyres, with over 9 million recalls of vehicles in 1987. The Consumer Product Safety Commission, a fairly marginal agency by American standards, reports over 3000 actions for the period from 1973 to 1982, affecting 291 million products, and for the subsequent period some hundred actions annually, each affecting some 5 million products¹⁷². The idea that decisions on such a scale ought in future to lie with the Commission is obviously unrealistic, and hard to reconcile with the administrative competences that Member States in principle have. The Commission Draft at any rate brings in measures to avoid extensive involvement by the Commission in follow-up market controls, and to distribute the decision-making burden arising over the Commission's departments¹⁷³.

a) Emergencies

Measures of effect for the whole Community are envisaged by the Draft only for emergencies. An emergency is defined by Article 9 (1) and Articles 10 (1), 11 (1), as "grave and immediate risk". Such risks are by Article 9 (2) to be notified to the Commission if they have "not only local effects"; likewise, the Commission is to be notified of a Member State's intention to take measures against grave and immediate risks of more than regional significance (Article 8 (1)); the Commission may also itself respond to such indications and call for information (Article 9 (4)).

The "Commission's knowledge of the existence of a grave and immediate risk" is the "trigger mechanism" for the Community-law procedures described in Articles 11-14:

172. See Ch. Joerges, Nachmarktkontrollen im amerikanischen Recht, typescript Bremen, Section 1.3.3 and 2.3.4 with further references.

173. See COM (89) 162, 3 f.

- The consultation and investigation procedure pursuant to Article 12 is provided for cases not yet ripe for decision. Here the Commission's powers are "in particular" confined to requesting Member States to carry out investigations and checks (Article 12 (3), taken together with Annexe 2 (2) (a), (b), and (c)).
- By contrast, the procedure of Article 14 provides for measures of direct effect in urgent cases. Such measures may be proposed and decided by the Commission (Article 14 (1)). They are to be implemented by Member States within ten days, but apply initially for only six months (Article 14 (3) and (2)).
- In the procedure of Article 14, additionally, national measures against grave and immediate product risks with more than local effects are checked (Article 8 (2), taken together with Article 10 (2)).

b) Measures against "unacceptable" and "significant" risks

The Commission expects that "extreme situations" requiring treatment at Community level will be relatively rare, and as a rule be satisfactorily solved with the exchange of relevant information¹⁷⁴. As appears from Article 8, however, the Commission must be informed of all planned national measures against "unacceptable" risks of more than regional importance. It can intervene in these national procedures with regulatory proposals of its own. Article 8 (2) provides further, however, that all notifiable measures be verified at Community level. According to these provisions, therefore, uniformity of practice in follow-up market controls should be guaranteed in all cases in which a Member State acts against unsafe products. Only those safety defects needing only warnings pursuant to Article 4 are excluded from verification at Community level.

5. Cooperation between Member States and the Commission.

174. COM (89) 162, 4.

In the context of preparation of Commission decisions pursuant to Articles 11-14, but also in preparation of national measures pursuant to Article 7 and the information exchange linked with the national information systems¹⁷⁵, the Draft seeks to create a dense network of cooperative relationships, which however not only guarantees the requisite information to provide knowledge of product hazards but also aims at Europeanization of risk assessment, instruments of action on safety and measures. Here the Draft takes a decisive step beyond the existing rapid information system. The importance, but also the difficulty, of this step is made clear by the Commission's explanations, which speak of a "great need" for a product safety "forum" to deal immediately with differences of opinion between Member States and the Commission and make uniform measures possible¹⁷⁶.

The institutional consequences are drawn by Articles 13 and 14. The "Committee on product safety in emergencies" provided therein is to be set up as an administrative committee within the meaning of the Council decision of 13 July 1987¹⁷⁷.

The status of the Committee on product safety emergencies as an administrative Committee is in striking contrast with the Standing Committee set up by the Standards Information Directive¹⁷⁸, which by the Council Resolution of 7 May 1985 is to deal with all proposals for directives under the new approach¹⁷⁹, and also with Commission proposals for a European infrastructure for certification¹⁸⁰.

The Committee for questions of standards has been set up as an Advisory Committee, although the issuing of contracts for standards and administration of the list of standards can affect safety policy interests of Member States for longer than the decisions to be taken in accordance

175. See above II.1 (fn. 24 f.).

176. See COM (89) 162, 3.

177. OJ L 197/1987, 33 (Procedure II, type a).

178. O.J. L 109/1983, 8; amended by Directive of 22.3.1988, O.J. L 181/1988, 75.

179. See section B IX of the Model Directive (fn. 80).

180. See above III.3.

with the Draft Product Safety Directive in emergency situations or in checking national measures. For certification, the Commission is aiming at a private organizational structure (even though "with the prerequisite of appropriate political supervision"¹⁸¹), though at any rate with certification of products not conforming with standards, assessing their safety can hardly be easier than the risk assessments involved in follow-up market control. The real reason is that measures that help to open up the market are to be facilitated, and those restricting free movement of goods are instead to be subject to controls by the Commission and other Member States.

In favour of the option for an advisory committee in standardization is the consideration that this committee can, firstly, have recourse to the continuing work of the standards organizations¹⁸² and secondly that its decisions always have only a presumptive effect. On the other hand, with the control procedures of the General Product Safety Directive, a European "safety philosophy" has still to be developed. But these viewpoints have limited relevance. On the one hand, there will be routine decisions in the area of follow-up market control too¹⁸³. On the other hand, the decisions needed in safeguard clause procedures concerning the justification of objections to standards and certificates or questioning the recognition of a national test centre also concern safety policy interests of Member States. This is also true of disputes as to the justifiability of measures by Member States.

More stringent structuring of committees in the area of standardization and product safety law should start with the Community's and Member States' obligation to protect life and health. It follows from this protective obligation that decisions on the legally required level of safety may not be delegated to private organizations and that

181. See the Commission Document on the "global concept" for certification of 29.11.1988 (fn. 104), 25.

182. So that the choice of administrative committee procedure under the construction products directive is entirely consistent (fn. 87).

183. In this connection see COM (89) 162, 4: the mere exchange of information often already tends to produce uniform practice.

institutional prerequisites for adapting safety standards in force and for intervening against newly recognized hazards have to be created. Considering the Community's substantive commitments and the powers allowed Member States by Article 100 (a) (4) and (5) EEC, it is only consistent to treat the questions of principle on product safety policy and assessment of newly recognized hazards as a joint task of Community and Member States. These considerations militate in favour of choosing the procedure of the administrative committee in all cases where Member States call for measures against newly recognized hazards or assert the inadequacy of standards accepted by the Community. For the decisions envisaged in the general product safety directive, however, this applies probably only where the Commission or Member States recognize "unacceptable risks" despite a product's compliance with Community or national provisions, and call for or take measures to remove them (cf. Article 7 (2), taken together with Article 5 (1)). It might be best to confine the choice of the procedure of the administrative committee to such situations. It would then be consistent, however, to give the Standing Committee on standardization the same status, to the extent that it has to deal with the extension of standards under Community law¹⁸⁴.

V. Final remark

At present one can do no more than speculate as to the further destiny of the Commission's proposal. But the relevance of the approaches adopted by the proposal is not thereby affected. It is part of the "logic" of achieving the internal market for the Community to become ever more deeply involved in the areas of responsibility assigned to Member States by Article 36 EEC, and it is an unavoidable consequence of this "approfondissement" of the integration process that Community solutions to regulatory tasks will also have to be found - and the proposal for a Directive on General Product Safety well documents this new quality of European integration.

184. See the considerations in Joerges et al., *op. cit.*, (fn. 11), 385 f., 442 ff., 457 ff.

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