The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act[+]

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Introduction

Following several declarations by the European Council since 1982, achievement of a single European internal market has become the focus of the Commission's efforts towards integration.[1] The general economic and social policy consequences of achievement of an integrated internal market can hardly be overestimated, and the issues of the relationship between internal market and product safety policies, on which this study concentrates, cover only a small range of the questions that will have to be thought through in order to "complete the internal market". But even this range is wide enough. The far-reaching integration policy hopes bound up with internal market policy presuppose the overcoming of technical barriers to trade arising particularly from differences in product safety law in Member States: the European Internal Market cannot be achieved without Europeanization of product safety law.

The description of law approximation policy under the general programme to remove technical barriers to trade of 1969[2] has repeatedly confirmed the notion that internal market policy must always include coverage of product safety policy implications of legal harmonization measures. Let us recall only the spread of escape clauses in relevant Community directives,[3] the collapse of initiatives in the area of construction products[4] the lack of success in efforts to supplement harmonized product standards in the automotive

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[1] Cf. esp. the Commission's White Paper to the European Council on "Completion of the Internal Market", COM (85) 310 final of 14 June 1985.

[2] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[3] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.5. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[4] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

sector with an integrated safety policy programme[5] and the general resistance to a "horizontal" European product safety policy.[6] The problems with internal market policy can clearly not be explained exclusively by the fact that Member States seek to assert their own economic interests in negotiations on legal approximation measures; they point at the same time to the fact that the issue of product safety is felt as a politically sensitive area where political actors resist delegating powers of action and decision to the Community.

The documents in which the Commission explained its interpretation of the stagnation of legal harmonization policy and the need for a new approach to harmonization did not address the connections between internal market policy and product safety policy particularly clearly. Instead, the Commission points primarily to the general difficulties of the European legislative process: the hurdles of the unanimity principle, the multiplicity of technical provisions in need of harmonization and the quantity of national standardization material, the need for flexible adaptation of harmonized provisions to technical developments.[7] This diagnosis is in line with the therapy recommended by the White Paper on completion of the Internal Market:[8] the Community should in future base itself as far as possible on mutual recognition of the equivalence of national provisions or standards, confining itself in legal approximation policy to harmonizing binding safety and health requirements, to be specified by the European standardization organizations, supplemented by mutual recognition of national standards. The following description starts from the Commission's diagnosis and view of the problems. It therefore initially ignores the connections between internal market policy and product safety policy, to concentrate on analysing the pre-conditions stated by the Commission and the new harmonization policy elements so far discernible. But this procedure should in no way be regarded as uncritical acceptance of the White Paper's premises and expectations. The principle of equivalence and mutual recognition of national provisions referred to by the Commission will instead be considered in the light of an analysis of relevant ECJ case law and Articles 30 and 36 EEC regarding its scope; it will emerge that this case law already largely respects safety policy interests of Member States (Section 1 below). But the Commission's second premise, namely that the regulatory model of the Low-Voltage Directive of 19 February 1973,[9] the first to apply the technique of harmonization of safety objectives and reference to standards at Community level, can be generalized, will likewise be shown to be highly problematic, since the regulatory technique of the Low-Voltage Directive was bound-up with specific conditions in the electrical sector, and the safety policy and legal problems arising out of the Directive are by no means entirely solved (2 below). We shall then return to describing the new approach to technical harmonization and standards (3 below). A further point to be clarified will be how the Single European Act, in particular Art. 100 a (4), will affect the

[5] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.4.3 end. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[6] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 3. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[7] For more details see *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.7, and references. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[8] Op. cit. (fn. 1), 14 et seq.

[9] OJ L 77 of 26 March 1973, 29.

applicability of the new approach (4 below). Finally, the new harmonization policy will be considered in terms of its compatibility with the EEC Treaty (5 below).

1. Mutual tension between marketability of goods and product safety in the light of Articles 30 and 36 EEC

The relationship between marketability of goods and product safety requirements is fundamentally regulated in Articles 30 and 36 EEC. In recent years extensive ECJ case law has developed here, meeting with an extremely strong response in the literature.[10] As *Table 1* shows, of 140 judgments delivered by the ECJ by 31 March 1987 on free movement of goods, only a little over a quarter (42) were based on an action for breach of treaty brought by the Commission; such actions occurred in any significant quantity only with the case law following-up the Cassis judgment.

[10] From the already enormous literature, mention should be made especially of *Gormley, L.W.*, Prohibiting Registrations on Trade within the EEC. The Theory and Application of Articles 30-36 of the EEC Treaty, Amsterdam/New York/Oxford 1985 and *Oliver, L.*, Free Movement of Goods in the EEC under Articles 30 to 36 of the Rome Treaty, London 1982. See also the commentaries on Art. 30-37 EEC by *Colliard, C.-A./Herzog, P.E.*, Kommentar zu den Art. 30-37, in: Smit, H./Herzog, P.E., The Law of the European Economic Community. A Commentary on the EEC Treaty, New York/San Francisco*; Matthies, H.*, Kommentar zu den Art. 30 bis 37 EWGV, in: Grabitz, E. (Ed.), Kommentar zum EWG-Vertrag, München 1986 and *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983. A review of individual groups of cases is given also by *Dauses, M.A.*, Dogmatik des Freien Warenverkehrs in der Europäischen Gemeinschaft, RiW 1984, 197 et seq., 201-206; *Masclet, J.-C.*, La libre circulation des merchandises dans les Communautés européennes. Perspectives législatives et réalités jurisprudentielles, RTDM 22 (1986), 243 et seq, 253-267; *Mattera, A.*, Les nouvelles formes du protectionisme économique et les articles 30 et suivants du Traité C.E.E., RMC 1983, 252 et seq.; *idem*, Protectionism Inside the European Community. Decisions of the European Court, J. of World Trade Law 18 (1984), 283 et seq.; *Moench, Ch.*, Der Schutz des freien Warenverkehrs im Gemeinsamen Markt. Zur Auslegung der Artt. 30, 34, 36 EWGV in der Rechtsprechung des EuGH, NJW 1982, 2689 et seq. and *Rabe, H.-J.*, Garantien und Sicherungen des freien Warenverkehrs im Lichte der neuesten Rechtsprechung des EuGH - Cassis de Dijon und die Folgerechtsprechung, in: Schwarze, J. (Ed.), Das Wirtschaftsrecht des Gemeinsamen Marktes in der aktuellen Rechtsentwicklung, Baden-Baden 1983, 41 et seq. On the connection between the case law on Art. 30 et seq. EEC and consumer protection see *Reich N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 11-26; *Bourgoignie, T./Trubek, D.*, Consumer law, common markets and federalism in Europe and the United States, 1987, 159-172; *Stuyck, J.*, Free Movement of Goods and Consumer Protection, in: Woodroffe, G. (ed.), Consumer Law in the EEC, London 1984, 77 et seq.; *Grabitz, E./Borchardt, K.-D./Klippstein, Th.*, Verbraucherschutz als Rechtsproblem des Gemeinsamen Marktes, Integration 6 (1983), 55 et seq.

Table 1: ECJ judgments on free movement of goods over particular periods, by type of proceedings[I]

Period of time	***Preliminary ruling (Art. 177)***	***Breach of Treaty (Art. 169)***	***Total***	***Judgments per year***
From 1968[II] until Dassonville judgment[III]	8	1	9	1.8
From Dassonville judgment until Cassis judgment[IV]	25	3	28	6.2
From Cassis judgment until March 1987[V]	65	38	103	12.7
Total	98	42	140	7.8

In the period after the Dassonville judgment the number of judgments handed down annually triples, and after the Cassis Judgment doubles again. Quantitatively, the most important group of cases relates to health protection, industrial property rights, regulations for the prescribing, designation and presentation of products and price regulation measures. The decisions relate mainly to the foodstuffs sector, with alcoholic drinks continually presenting the ECJ with an opportunity of developing its case law on free movement of goods. Outside the foodstuffs sector, there is a strikingly high proportion of judgments concerning medicaments, and a small one for technical products. The following survey shows the product groups covered by judgments on free movement of goods handed down by the ECJ up to 31 March 1987:

Alcoholic drinks *20*
Other foodstuffs.....*41*
Medicaments *17*
Technical products.....*8*
Publications.....*7*
Fuels, used oil *7*
Foodstuffs.....*5*
Pesticides *4*
Animals.....*4*
Tobacco.....*3*

[I] Calculated from the European Court reports and communications regarding the ECJ's work.
[II] Case 7/68, Judgment of 10 December 1968, ECR [1968] 634 et seq.
[III] Case 8/74, Judgment of 11 July 1974, ECR [1974] 834 et seq./Dassonville.
[IV] Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 et seq./Cassis de Dijon.
[V] Case 178/84, Judgment of 12 March 1987, published in NJW 1987, 1133 et seq./Beer Purity Ordinance.

We shall now review the development of the case law on free movement of goods to the extent that it is of importance for the development of the new approach to technical harmonization and standards and to the need for a horizontal Community product safety policy. The case law on Art. 30 EEC and the conclusions for law approximation policy will be discussed first (1.1.), then the case law on Art. 36 EEC and Member States' possibilities of action (1.2.).

1.1. Development of the case law on Art. 30 EEC and conclusions for legal approximation policy

Art. 30 EEC prohibits quantitative restrictions on imports and measures having equivalent effect between Member Stats; Art. 34 does the same for exports; Art. 36 allows Member States, under specific severely restricted conditions, to make exceptions to these prohibitions.

1.1.1. The concept of measures having equivalent effect and the Cassis de Dijon Judgment

It was first with the "Dassonville" judgment[11] that the ECJ undertook a comprehensive definition of the central concept of measures having equivalent effect. This basic rule has been repeated by the Court in large numbers of later judgments, and continues to be the basis for the case law; the Commission too observes it in bringing actions for breach of treaty against Member States. It says:

> *Any trade regulations of Member States likely to obstruct Community internal trade directly or indirectly, actually or potentially, is to be regarded as a measure having equivalent effect to a quantitative restriction.*[12]

With this, the ECJ has in the interest of free movement of goods gone far beyond the statement made by the Commission in Directive 70/50/EEC.[13] There it had distinguished between measures applicable without distinction to domestic and imported goods (Art. 3) and those applicable other than without distinction (Art. 2). The latter group of discriminatory measures, of such a nature as to restrict imports, should without exception come under the prohibition of Art. 30 EEC. Measures applicable without distinction would by contrast conflict with Art. 30 EEC only where "the restrictive effects on the movement of goods exceed the limits of the typical effects of such commercial regulations" (Art. 3 (1)). This is said to be the case notably where "the restrictive effect on free movement of

[11] Case 8/74 judgment of 11 July 1974, ECR [1974] 837/Dassonville. On this see the note by *Willinghausen*, EuR 1975, 322 et seq.
[12] Case 8/74 judgment of 11 July 1974, ECR [1974] 837 (852)/Dassonville.
[13] OJ L 13, 19 January 1970, 29. For details on the concept of measures having equivalent effect and a comparison of the Dassonville judgment with Directive 70/50/EEC see *Veelken, W.*, Maßnahmen gleicher Wirkung wie mengenmäßige Beschränkungen, EuR 1977, 311 et seq.; *Ehlermann, C.-D.*, Das Verbot der Maßnahmen gleicher Wirkung in der Rechtsprechung des Gerichtshofes, in: FS Hans Peter Ipsen, Tübingen 1977, 579 et seq.; *Timmermans, Ch.W.A.*, Der freie Warenverkehr, in: EG-Kommission (Ed.), Dreißig Jahre Gemeinschaftsrecht, Luxemburg 1981, 259 et seq., 285-290; *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 30, para. 5-31.

goods is disproportionate to the object aimed at" or "where the same objective can be attained by another means hindering trade as little as possible" (Art. 3 (2)). The broad interpretation of the concept of measures having equivalent effect is also expressed in the fact that mere likelihood of a trade- restrictive effect is sufficient, so that the effect of restricting trade need not have actually occurred or have reached a particular intensity. Any sovereign measure likely even only indirectly to negatively affect flows of goods between States is according to this in principle a prohibited measure having equivalent effect. The "broad, catch-all criterion" for measures having equivalent effect opens up for the Community "wide-ranging possibilities for control of national measures".[14]

On general interpretive principles, Art. 36 EEC, which allows Member States to evade the prohibition in principle on quantitative restrictions and measures having equivalent effect for the sake of particular objects of legal protection, is to be interpreted narrowly, and the list of objects of legal protection contained in it to be treated as exhaustive.[15] With this as a starting point the ECJ faced a dilemma, if it did not want to subject the general power of Member States to regulate production and marketing or to control economic policy completely to the verdict of Art. 30 EEC. Either it could give an expansive interpretation to the object of legal protection in Art. 36 EEC or it could restrict the concept of measures having equivalent effect, at any rate for the area of measures applicable without distinction, by contrast with the Dassonville formulation.[16] With the well-known judgment in the "Cassis de Dijon" case of 20 February 1979,[17] the Court of Justice took the latter path, thereby laying the foundation stone for a new approach to legal approximation policy in the area of free movement of goods and for systematic monitoring by the Commission of Member States' compliance with the Treaty in this area.

In this case, the ECJ dealt for the first time with a measure applicable without distinction. It explicitly stressed that in the absence of Community regulation of manufacture and

[14] In the elastic formulation of *Steindorff, E.*, Gemeinsamer Markt als Binnenmarkt, ZHR 50 (1986), 687 et seq., 697.

[15] Continuing case law: cf. case 7/61 judgment of 19 December 1961, ECR [1961] 695 (720)/Commission v. Italy; case 13/68, judgment of 19 December 1968, ECR [1968] 679 (694)/Salgoil; case 113/80, judgment of 17 June 1981, ECR [1981] 1625 (1637)/Commission v. Ireland.

[16] *Ehlermann, C.-D.*, Das Verbot der Maßnahmen gleicher Wirkung in der Rechtsprechung des Gerichtshofes, in: FS Hans Peter Ipsen, Tübingen 1977, 579 et seq., 589.

[17] Case 120/78, judgment of 20 February 1979, ECR [1979], 649/Cassis de Dijon. Cf. on this judgment also *Barents, R.*, New Developments in Measures Having Equivalent Effect, CMLR 18 (1981), 271 et seq., 291-299; *Capelli, F.*, Les Malentendus Provoqués par l'Arrêt sur le Cassis de Dijon, RMC 1981, 421 et seq.; *Masclet, J.-C.*, Les articles 30, 36 et 100 du Traité C.E.E. à la lumiere de l'arrêt "Cassis de Dijon", RTDE 1980, 611 et seq.; *Mattera, A.*, L'arrêt "Cassis de Dijon": une nouvelle approche pour la réalisation et le bon fonctionnement du marché intérieur, RMC 1980, 505 et seq.; *Micklitz, H.-W.*, Technische Normen, Produzentenhaftung und EWG-Vertrag, NJW 1983, 483 et seq., 485-487; *Millarg, E.*, Anmerkung zum Urteil in der Rs. 120/78, EuR 1979, 420 et seq.; *Oliver, P.*, Measure of Equivalent Effect: A Reappraisal, CMLR 19 (1982), 217 et seq., 227-237; *Rabe, H.-J.*, Garantien und Sicherungen des freien Warenverkehrs im Lichte der neuesten Rechtsprechung des EuGH - Cassis de Dijon und die Folgerechtsprechung, in: Schwarze, J. (Ed.), Das Wirtschaftsrecht des Gemeinsamen Marktes in der aktuellen Rechtsentwicklung, Baden-Baden 1983, 41 et seq.; *Seidel, M.*, Die sogenannte Cassis de Dijon-Rechtsprechung des Europäischen Gerichtshofs und der Schutz von Herkunftsangaben in der Europäischen Gemeinschaft, GRUR International 1984, 80 et seq.; *Verloren van Themaat, P.*, La libre circulation des merchandises après l'arrêt Cassis de Dijon. Cahiers du Droit Européene 1982, 123 et seq.; *Wägenbaur, R.*, Woher kommt, wohin führt Cassis? Eine Fallstudie, in: Lüke, G./Ress, R./Will, M.R. (Eds.), Rechtsvergleichung, Europarecht, Staatsintegration, Gedächtnisschrift für L.-J. Constantinesco, Köln/Berlin/Bonn/München 1983, 899 et seq.; *idem*, R., Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 30, para. 32-41.

marketing, it was a matter for Member States to enact the relevant regulations for their territory, and continued:

> *Barriers to Community internal trade arising from the differences in national regulations on the marketing of its products must be accepted as long as these provisions are necessary in order to meet binding requirements, notably the requirements of effective tax control, public health protection, the integrity of trade and consumer protection.*[18]

This makes it clear that restrictions on Community internal trade arising from regulations applicable equally to domestic and foreign products do not automatically fall under the prohibition of Art. 30 EEC, but may be justified, though always requiring justification, where there is no relevant Community regulation. The binding requirements do not constitute additional grounds of justification besides the objects of legal protection listed exhaustively in Art. 36 EEC; instead, their presence makes a regulation or proceeding no longer describable as a measure having equivalent effect.[19]

The list of binding requirements is not exhaustive: others that enter in are environment protection and measures to improve working and living conditions.[20] This must, though, involve a non-economic objectives in the general interest, which takes precedence over the requirements of free movement of goods. The Court of Justice does not rely here on the external justification for a measure, but seeks to disclose the "true reasons", to prevent, say, protectionist industrial policy objectives of Member States being pursued under the cloak of consumer protection.[21]

Member States' measures must be necessary, and also proportionate in nature and implementation; they must be the means that restrict free movement of goods as little as possible.[22] Accordingly, for instance, marketing bans are not in general justified in order to protect consumers against confusion and deception; as a rule, indications on the packaging will suffice.[23] In testing the binding requirements the principle of the second sentence of

[18] Case 120/78, judgment of 20 February 1979, ECR [1979] 649 (662)/Cassis de Dijon.

[19] Unambiguosly clarified in case 113/80, judgment of 17 June 1981, ECR [1981], 1625 (1638)/Commission v. Ireland; case 220/81, judgment of 22 June 1982, ECR [1982] 2349 (2360)/Robertson.

[20] Cf. answer to written question No. 749/81, OJ C 309, 30 November 1981, 7.

[21] Cf. *Reich, N*., Rechtliche Grundlagen zur Schaffung eines Konsumentenschutzrechts innerhalb der Europäischen Gemeinschaften, in: Europäisches Rechtsdenken in Geschichte und Gegenwart, FS für Helmut Coing zum 70. Geburtstag, vol. 2, München 1982, 441 et seq., 455; *idem*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 25. Two particularly instructive examples are case 120/78, judgment of 20 February 1979, ECR [1979], 649 (662)/Cassis de Dijon, and case 178/84, judgment of 12 March 1987, published in NJW 1987, 1133 et seq. – Beer purity law. This last judgment provides a clear statement that the law of a Member State must not be used to "fix existing consumer habits in order to maintain an advantage acquired by the domestic industry involved in satisfying them" (op. cit., para. 32). On this judgment see *Dauses, M.A.*, Die neuere Rechtsprechung des EuGH im Lebensmittelrecht unter besonderer Berücksichtigung des sogenannten Bier Urteils, ZLR 1987, 243 et seq., 256-263; *Funck-Brentano, L.*, Freier Warenverkehr und nationale Handelshemmnisse bei Lebensmitteln. Vom Cassis aus Dijon bis zum Bier - oder die Schwierigkeit, einen europäischen Raum ohne Grenzen zu schaffen, RIW 1987, 379 et seq.; *Moench, Ch.*, Reinheitsgebot für Bier. Zum Urteil des EuGH vom 12. 3.1987, NJW 1987, 1133, NJW 1987, 1109 et seq.; *Rabe, H.-J.*, Freier Warenverkehr für Lebensmittel nach dem Bier Urteil des EuGH, EuR 1987, 253 et seq.; *Zipfel, W.*, Zu den Gründen und rechtlichen Folgen des Bier-Urteils des EuGH, NJW 1987, 2113 et seq.

[22] Cf. *Steindorff, E*., Probleme des Art. 30 EWG-Vertrag, ZHR 148 (1984), 338 et seq., 346; *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 36, para. 68-72; case 104/75, judgment of 20 May 1976, ECR [1976] 613 (635 et seq.)/de Peijper; case 35/76, judgment of 15 December 1976, ECR [1976] 1871 (1885 et seq.)/Simmenthal.

[23] Case 120/78, judgment of 20 February 1979, ECR [1979]649 (664)/Cassis de Dijon; case 788/79, judgment of 26 June 1980, ECR [1980] 2071 (2078)/Gilli & Andres; case 27/80, judgment of 16 December 1980, ECR [1980] 3839

Art. 36 EEC should be applied, with the result that no primacy can be assigned to national regulatory powers where these are used as a means of arbitrary discrimination or a disguised restriction on trade between Member States. Altogether, the ECJ has developed a carefully graded scheme for balancing between the Community objective of free movement of goods and particular interests of Member States in protection, not a rigid scheme of rules and exceptions.[24]

1.1.2. The consequences of the Cassis Case Law for law approximation

In view of an increasing number of restrictions on free movement of goods and against the background of the evident bottlenecks resulting from the classical harmonization concept, the Commission took the Cassis case law as a basis for explaining the scope of the Cassis judgment to Member States, the European Parliament and the Council in a communication, and for drawing some conclusions and guidelines for verifying treaty compliance and reorienting law approximation policy.[25] It summarizes the case law as follows, underlining the principle of mutual recognition:

> *The principles deduced by the Court imply that a Member State may not in principle prohibit the sale in its territory of a product lawfully produced and marketed in another Member State even if the product is produced according to technical or quality requirements which differ from those imposed on its domestic products. Where a product `suitably and satisfactory' fulfills the legitimate objectives of a Member State's own rules (public safety, protection of the consumer or the environment, etc.), the importing country cannot justify prohibiting its sale in its territory by claiming that the way it fulfills the objectives is different from that imposed on domestic products.*[26]

It draws the conclusion that many barriers to trade can be removed merely by strictly applying the prohibition of Art. 30 EEC, where they are not justified by Art. 36 EEC or as mandatory requirements within the meaning of the ECJ case law. It announces that it intends to tackle commercial rules covering the composition, designation, presentation and packaging of products or requiring compliance with certain technical standards. For preventive control of potentially trade restricting measures by Member States, it announces its proposal for an information procedure in the area of standards and technical provisions.[27] Above all, however, efforts at approximating laws are to be concentrated in

(3854)/Fietje; case 130/80, judgment of 19 February 1981, ECR [1981] 527 (536)/Kelderman; case 261/81, judgment of 10 November 1982, ECR [1982] 3961 (3973)/Rau - De Smedt; case 178/84, judgment of 12 March 1987, para. 35 and 36, published in NJW 1987, 1133 et seq. - Beer purity law.

[24] Cf. *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 25; *idem*, N., Rechtliche Grundlagen zur Schaffung eines Konsumentenschutzrechts innerhalb der Europäischen Gemeinschaften, in: Europäisches Rechtsdenken in Geschichte und Gegenwart, FS für Helmut Coing zum 70. Geburtstag, Bd. 2, München 1982, 441 et seq., 454.

[25] Commission communication on the implications of the ECJ judgment of 20 February 1979 in case 120/78 (*Cassis de Dijon*), OJ C 256, 3 October 1980, 2 et seq. See *Barents, R.*, New Developments in Measures Having Equivalent Effect, CMLR 18 (1981), 271 et seq., 296-299; *Gormley, L.W.*, Cassis de Dijon and the Communication from the Commission, ELR 6 (1981), 454 et seq.; *Mattera, A.*, L'arrêt "Cassis de Dijon": une nouvelle approche pour la réalisation et le bon fonctionnement du marché intérieur, RMC 1980, 505 et seq.; *Oliver, P.*, Measure of Equivalent Effect: A Reappraisal, CMLR 19 (1982), 217 et seq., 234 et seq.; *Welch, D.*, From Euro Beer to Newcastle Brown. A Review of European Community Action to Dismantle Divergent Food Laws, JCMSt 22 (1983), 47 et seq., 63-68; *Micklitz, H.-W.*, Technische Normen, Produzentenhaftung und EWG-Vertrag, NJW 1983, 483 et seq., 486 et seq.

[26] OJ C 256, 3 October 1980, 2 et seq.

[27] The corresponding proposal was submitted to the Council on 25 August 1980, OJ C 253, 1 October 1980, 2 et seq.

areas "where barriers to trade to be removed arise from national provisions which are admissible under the criteria set by the Court".[28]

The case law on Art. 30 and 36 EEC means a demarcation between the principle of the country of destination, according to which all goods or services must meet the standards of the respective country of destination, and the contrary principle of the country of origin, whereby import of all goods legally marketed in the country of origin is unrestricted. With this demarcation, it simultaneously determines the extent to which measures on approximation of laws are necessary in order to eliminate barriers to trade.[29]

The Cassis judgment (and the Commission communication) were on the one hand welcomed as in principle allowing marketing of the most diverse local specialities everywhere in the Community, thereby increasing consumer choice,[30] but on the other hand criticized as facing the national legislator with the dilemma of either discriminating against domestic industry or giving up higher quality standards in favour of adaptation to the lowest common denominator.[31] The latter standpoint was represented particularly strongly by the government of the Federal Republic of Germany in the Cassis case:

> *Ultimately, the regulation binding in all Member States would be that of the country setting the lowest requirements; since this legal conclusion would be based on the directly applicable provision of Art. 30, these legal changes will have to have been effected already, at latest by 1 January 1970. Because of the automatic effect of Art. 30, in future further amendments to national legal provisions could occur continually as soon as only one Member State adopted a new regulation with lower requirements. In the extreme case, then, one Member State could, without any cooperation or information of other Member States, determine legislation for the whole Community. The outcome would be that the minimum requirements would, without the harmonization provided for in Art. 100 EEC, requiring consensus by Member States, be reduced to the lowest level to be found in the regulations of any one of the Member States.*[32]

To date, the fear of leveling down to the lowest common denominator has not occurred.[33] This is partly because Member States can defend themselves against undermining of standards by appealing to mandatory requirements, where a legitimately pursued general

[28] OJ C 256, 3 October 1980, 3. For the new approach in Community foodstuffs law the Commission draws the conclusion that in future it should only contain provisions based on considerations of the protection of essential general interests, namely the protection of public health, consumer needs for information and protection in areas other than health, fair competition, need for government supervision. See the Commission communication to Council and European Parliament on "Completing the Internal Market: Community Foodstuffs Law", COM (85) 603 final of 8 November 1985, points 8 and 9. Cf. the critical opinions from the ESC, OJ C 328, 22 December 1986, 23, and the European Parliament, OJ C 99, 13 April 1987, 45, and *Sedemund, J.*, Cassis de Dijon und das neue Harmonisierungskonzept der Kommission, in: Schwarze J., (Ed.), Der Gemeinsame Markt, Bestand und Zukunft in wirtschaftlicher Perspektive, Baden-Baden 1987, 37 et seq., 51-53.

[29] Cf. *Steindorff, E.*, Gemeinsamer Markt als Binnenmarkt, ZHR 50 (1986), 687 et seq., 689-699.

[30] Cf. *Mattera, A.*, L'arrêt "Cassis de Dijon": une nouvelle approche pour la réalisation et le bon fonctionnement du marché intérieur, RMC 1980, 505 et seq., 511 et seq.

[31] See the opinion of the Consumer Advisory Committee on the consequences of the ECJ's Cassis de Dijon Judgment, CCC/29/81 Rev. ENV 159/81, 16 October 1981; *Seidel, M.*, Die sogenannte Cassis de Dijon-Rechtsprechung des Europäischen Gerichtshofs und der Schutz von Herkunftsangaben in der Europäischen Gemeinschaft, GRUR International 1984, 80 et seq., 87; *Micklitz, H.-W.*, Technische Normen, Produzentenhaftung und EWG-Vertrag, NJW 1983, 483 et seq., 483.

[32] Case 120/78, judgment of 20 February 1979, ECR [1979], 649 (656)/Cassis de Dijon.

[33] See *Stuyck, J.*, Free Movement of Goods and Consumer Protection, in: Woodroffe, G. (ed.), Consumer Law in the EEC, London 1984, 77 et seq., 95 et seq.

object of protection of a non-economic nature is endangered.[34] Above all, however, it goes much farther to meet Member States interests in protection, especially as regards the very frequently mentioned protection of health,[35] than the Commission with its rigid scheme of rule and exception and its stress on "very strict criteria" and on the possibility of departures "only under very restrictive conditions" tries to make out. In its endeavour to bring in a change to its policy on eliminating technical barriers to trade, the Commission has enthusiastically had recourse to the Cassis case law, but has one-sidedly generalized the interpretive principles, which the ECJ, particularly in its subsequent case law, has differentiated still more finely.[36]

It is plain that laws are still to be approximated only in areas where Member States can base themselves on objects of protection under Art. 36 EEC or on mandatory requirements.[37] However, a few restrictions should be mentioned: the Commission's rigid scheme of rules and exceptions between free movement of goods and Member States' interests in protection is not quite right; the circumstances in which a Member State can appeal to mandatory requirements depend on the balancing out of many considerations, which can be done only from case to case. The principle of mutual recognition operates bilaterally between the States involved in the trade concerned but not uniformly at Community level.[38] Elimination of barriers to trade through Art. 30 EEC presupposes unless. Member States voluntarily refrain from asserting particular domestic standards for imported products, an initiative by manufacturers, importers or the Commission, and can come about only reactively and case by case; law approximation can act prophylactically and much more comprehensively.[39] Furthermore, pronouncements of the Court of Justice can act only by way of quashing, in the sense that rules may be abolished without substitute, but not replaced by new requirements under the Community Treaty.[40] Finally, overstressing negative harmonization

[34] See *Matthies, H.*, Kommentar zu den Art. 30 bis 37 EWGV, in: Grabitz, E. (Ed.), Kommentar zum EWG-Vertrag, München 1986, Art. 30, para. 24; *Welch, D.*, From Euro Beer to Newcastle Brown. A Review of European Community Action to Dismantle Divergent Food Laws, JCMSt 22 (1983), 47 et seq., 66.

[35] This will become clear from the analysis of individual cases in 1.2., below.

[36] *Micklitz, H.-W.*, Technische Normen, Produzentenhaftung und EWG-Vertrag, NJW 1983, 483 et seq., 487; and with particular clarity *Barents, R.*, New Developments in Measures Having Equivalent Effect, CMLR 18 (1981), 271 et seq., 298. On the tendency in the Commission communication to overshoot, see also *Bourgoignie, T./Trubek, D.*, Consumer law, common markets and federalism in Europe and the United States, 1987, 159-172, 171 et seq.; *Welch, D.*, From Euro Beer to Newcastle Brown. A Review of European Community Action to Dismantle Divergent Food Laws, JCMSt 22 (1983), 47 et seq., 64; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 25; *Steindorff, E.*, Probleme des Art. 30 EWG-Vertrag, ZHR 148 (1984), 338 et seq, 347.

[37] On the new approach to approximation of laws see New Roads for Harmonization of Legislation?, CMLR 17 (1980), 463 et seq.; *Masclet, J.-C.*, Les articles 30, 36 et 100 du Traité C.E.E. à la lumiere de l'arrêt "Cassis de Dijon", RTDE 1980, 611 et seq., 622-630; *Mattera, A.*, L'arrêt "Cassis de Dijon": une nouvelle approche pour la réalisation et le bon fonctionnement du marché intérieur, RMC 1980, 505 et seq., 510 et seq.; *Sedemund, J.*, Cassis de Dijon und das neue Harmonisierungskonzept der Kommission, in: Schwarze J., (Ed.), Der Gemeinsame Markt, Bestand und Zukunft in wirtschaftlicher Perspektive, Baden-Baden 1987, 37 et seq.; *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 30, para. 41.

[38] See *Rabe, H.-J.*, Garantien und Sicherungen des freien Warenverkehrs im Lichte der neuesten Rechtsprechung des EuGH - Cassis de Dijon und die Folgerechtsprechung, in: Schwarze, J. (Ed.), Das Wirtschaftsrecht des Gemeinsamen Marktes in der aktuellen Rechtsentwicklung, Baden-Baden 1983, 41 et seq., 63.

[39] *Wägenbaur, R.*, Woher kommt, wohin führt Cassis? Eine Fallstudie, in: Lüke, G./Ress, R./Will, M.R. (Eds.), Rechtsvergleichung, Europarecht, Staatsintegration, Gedächtnisschrift für L.-J. Constantinesco, Köln/Berlin/Bonn/München 1983, 899 et seq., 906 et seq.

[40] *Seidel, M.*, Die sogenannte Cassis de Dijon-Rechtsprechung des Europäischen Gerichtshofs und der Schutz von Herkunftsangaben in der Europäischen Gemeinschaft, GRUR International 1984, 80 et seq., 81.

through Art. 30 EEC would mean transferring to the Court evaluative tasks that normally fall within the province of the legislator.[41]

There is agreement that application of Art. 30 EEC cannot be made dependent on prior approximation of laws. This was unmistakably stated by the Court of Justice in case 193/80,[42] when it also stressed the different objectives of Articles 30 and 100 EEC: [43]

> *The fundamental principle of a unified market and its corollary, the free movement of goods, may not under any circumstances be made subject to the condition that there should first be an approximation of national laws for if that condition had to be fulfilled the principle would be reduced to a mere cipher. Moreover, it is apparent that the purposes of Articles 30 and 100 are different. The purpose of Article 30 is, save for certain specific exceptions, to abolish in the immediate future all quantitative restrictions on the imports of goods and all measures having an equivalent effect, whereas the general purpose of Article 100 is, by approximating the laws, regulations and administrative provisions of the Member States, to enable obstacles of whatever kind arising from disparities between them to be reduced. The elimination of quantitative restrictions and measures having an equivalent effect, which is ... carried into effect by Article 30, may not therefore be made dependent on measures which, although capable of promoting the free movement of goods, cannot be considered to be a necessary condition for the application of that fundamental principle.*

Art. 30 EEC offers citizens of the Common Market the possibility through the preliminary-ruling procedure of securing the application of Community law in the national sphere, especially since they do not have to bear political aspects in mind to the same extent as the Commission.[44]

Technical standards drawn up by private institutions and therefore not legally binding do not count as measures having equivalent effect within the meaning of Art. 30 EEC. There is a different case where compliance with them is mandatorily prescribed *de jure* or *de facto* by government action.[45] To date the Court of Justice has found there to be a measure of equivalent effect in only one case where the measure was neither a sovereign one nor binding on its addresses. It arrived at this conclusion, against the Advocate-general's opinion, in the case of the "Buy Irish" publicity campaign by the Irish Goods Council, an association of leading representatives of the business world set up as a company limited by guarantee without investment of capital to promote the sale of Irish products. It attributed the campaign as a whole to the Government, which had established the programme, made

[41] See the preliminary remark on the new approach to technical harmonization and standards, COM (85), 19 final, 31 January 1985, 5.

[42] Case 193/80, judgment of 9 December 1981, ECR [1981] 3019 (3033)/Commission v. Italy.

[43] *Roth, W.-H.*, Freier Warenverkehr und staatliche Regelungsgewalt in einem Gemeinsamen Markt. Europäische Probleme und amerikanische Erfahrungen, München 1977, 24-30; *Dauses, M.A.*, Dogmatik des Freien Warenverkehrs in der Europäischen Gemeinschaft, RiW 1984, 197 et seq., 206; *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, preliminary observation on Arts. 30 - 37, para. 68-73; *Matthies, H.*, Kommentar zu den Art. 30 bis 37 EWGV, in: Grabitz, E. (Ed.), Kommentar zum EWG-Vertrag, München 1986, para. 25.

[44] Cf. in Table 1 above the numerical relation between actions for breach of treaty brought by the Commission and preliminary ruling procedures, which often go back ultimately to actions brought by citizens of the Common Market.

[45] See answer to Written Question No. 835/82, OJ C 93, 7 April 1983, 1 et seq. - Buy Irish; and *Mattera, A.*, Protectionism Inside the European Community. Decisions of the European Court, J. of World Trade Law 18 (1984), 283 et seq., 286 et seq.

the major staffing decisions and borne the overwhelming share of the financing.[46] Comparable circumstances are not present in the case of technical standardization by private standardization bodies.[47]

1.2. Development of the case law on Art. 36 EEC

On the conditions set out in Art. 36, Member States may break the prohibition in principle on quantitative restrictions and measures having equivalent effect and maintain or introduce regulations or practices restricting free movement of goods, in order to protect the objects of legal protection listed. These measures may not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States (Art. 36 EEC, second sentence).
With its underlying pro-integration approach, the Court has given this exceptional provision a narrow interpretation in several respects. Among the principles that can be taken as established are: Art. 36 covers only situations of a non-economic nature and cannot be understood as an escape clause against the economic effects of the opening up of markets[48]; the list of objects of protection in Art. 36 EEC is exhaustive and cannot be extended by conclusions from analogy, Art. 36 EEC is not intended to reserve particular fields for the exclusive competence of Member States.[49]

1.2.1. Art. 36 EEC and Member States' room for manoeuvre

Only where Community directives provide for *complete* harmonization of *all* measures necessary to guaranteeing protection of the objects of legal protection mentioned in Art. 36 EEC and there are Community procedures to secure compliance, are Member States no longer able to appeal to Art. 36 EEC and take individual measures. Instead, they must press for amplification or amendment of the Community regulation, or take advantage of escape clause procedures contained in the Community regulation.[50] Here verification is required as to whether a Community provision constitutes a definitive regulation or was introduced only as a minimum measure, not ruling out additional national provisions.[51] Moreover, the content of the individual Community regulations and harmonization programmes must be looked at to see whether all relevant objects of protection under Art. 36 EEC are already

[46] Case 249/81 Judgment of 24 November 1982, ECR [1982] 4005 (4021-4023). See the note by *Rabe*, EuR 1983, 341-343.
[47] For details on the relationship between technical standards and Art. 30 EEC cf. *Lecrenier, S.*, Les Articles 30 et suivants CEE et les Procédures de Contrôle prévues par la Directive 83/189/CEE, RMC 1985, 6 et seq., 12-23. Cf. also *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 33-55.
[48] Case 7/61, Judgment of 19 December 1961, ECR [1961] 695/ Commission v. Italy.
[49] Continuing case law: case 35/76, Judgment 15 December 1976, ECR [1976] 1871 (1886)/Simmenthal; case 5/77, Judgment 5 October 1977, ECR [1977] 1555 (1576)/Tedeschi; case 153/78, Judgment 12 July 1979, ECR [1979] 2555 (2564)/Commission v. Germany.
[50] Case 5/77, Judgment of 5 October 1977, ECR [1977] 1555 (1576)/Tedeschi; case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 (3388)/Denkavit; case 227/82, Judgment of 30 November 1983, ECR [3883 (3904)/ van Bennekom; case 28/84, Judgment of 3 October 1985, ECR [1985] 3097 (3123)/Mischfuttermittel; case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 (3903 et seq.) Léon Motte. See also *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 36, para. 12-17.
[51] As in case 4/75, Judgment of 8 July 1975, ECR [1975] 843 (859)/Rewe-Zentralfinanz.

covered.[52] In other words, Community regulations have a blocking effect on Member States only to the extent that they actually meet the individual interests in protection under Art. 36 EEC. Should, for instance, a Community regulation take account of the mechanical hazards of a product but not the toxic ones, to that extent Member States' competence will remain. This applies, too, where hitherto unrecognized hazards become manifest in an area that has been definitively regulated by the Community. Here the widespread escape clause procedures should ensure that the stage of harmonization reached is not endangered by the need for additional action to guarantee protection of the objects of Art. 36 EEC; the desire of a Member State for additional safety measures will either prove unfounded following testing by the Commission or in breach-of-treaty proceedings before the ECJ, or else be incorporated in the Community regulation with effect for all Member States, where it proves justified and the necessary majority for an adaptation is secured.

1.2.2. Proportionality controls by the ECJ

The Court of Justice subjects measures justified in principle under Art. 36 EEC to strict proportionality control, refusing approval for a measure where the same objective could be secured by measures that restrict internal Community trade less. The Court of Justice has concluded from this that, for instance, Member States "may not needlessly require technical or chemical analyses or laboratory tests where the same analyses and tests have already been carried out in another member country and these findings are available to their authorities or can be made available on request".[53] Admissibility in one Member State does not automatically justify admissibility in another unless a directive explicitly lays down mutual recognition of permits and certification. However, an importing Member State must for purposes of permits take similar tests and analyses already done in another Member State into account. Administrations of Member States must provide each other with administrative assistance in making test results available.[54] The Court of Justice has frequently stressed that it is in the interest of free movement of goods to carry out sanitary controls in the country of manufacture, and that is appropriate for the sanitary authorities of the Member States concerned to cooperate in order to avoid duplication of checks.[55] This leaves untouched the power to carry out random checks. The Court has also concluded from the proportionality principle that the aim of reducing the burden on the administration or reducing public expenditure does not justify any stronger intervention, and that administrations are bound to make reasonable efforts to secure the necessary indications by active administrative efforts.[56]

[52] Very instructive on this is case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 (3389 et seq.)/Denkavit, which also contains an indication that the Council should in harmonization use the method of gradual advance covering individual points.
[53] Case 272/80 Judgment of 17 December 1981, ECR [1981] 327 (3291)/Biologische Producten. Cf. answer to the Written Question No. 1928/84, OJ C 233, 12 September 1985, 5.
[54] For details cf. *Gormley, L.W.*, Prohibiting Registrations on Trade within the EEC. The Theory and Application of Articles 30-36 of the EEC Treaty, Amsterdam/New York/Oxford 1985, 154-174.
[55] Cf. case 73/84, Judgment of 27 March 1985, ECR [1985] 1013 (1025)/Mischfuttermittel.
[56] Case 104/75, Judgment of 20 May 1976, ECR [1976] 613 (634 et seq.)/ de Peijper.

1.2.3. Member States' leeway in evaluating questions of health protection and safety design

In recent years voluminous case law has developed on the question of health protection within the meaning of Art. 36 EEC.[57] It amounts to allowing Member States to engage in preventive health policies of their own where a Community regulation is absent, with the objective of keeping foodstuffs as free as possible from hazardous substances. National regulations may take account here of climatic conditions, the population's eating habits and their state of health, and therefore be different from one country to another. Continuing uncertainties over scientific findings may also be taken into account.
On the basis of Art. 36 EEC, the Dutch prohibition on nisin as a conservation additive for processed cheese intended for the Dutch market was found to be justified:

> *If these studies have not yet reached unambiguous conclusions regarding the maximum quantity of nisin that a person can consume without serious danger to health, this is mainly because of the fact that evaluation of the risk bound up with consumption of this additive depends on a number of variable factors, in particular on eating habits in the country concerned and on whether in determining the maximum quantity of nisin to be set for every product not only the level to be set for a particular product, for instance processed cheese, is to be taken into account, but also those to be set for all other products to be rendered imperishable.*[58]

If uncertainties still exist at a given stage of research, where complete harmonization is absent it is a matter for Member States, taking into account both the eating habits of their population and the needs of free movement of goods, to determine the extent to which they wish to guarantee protection of the health and life of people.[59] Accordingly, the Dutch ban on adding vitamins whose health-endangering effect was not proven yet could not be ruled out given excessive consumption in the whole diet in its unforeseeable, unverifiable composition, was declared to be compatible with Community law, as long as marketing were permitted where the addition of vitamins corresponded to a genuine need, in particular having regard to technology or nutrition.[60]

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[57] Cf. *Kommers D./Waelbroeck, M*., Legal Integration and the Free Movement of Goods: the American and European Experience, in: Cappelletti, M./Seccombe, M./Weiler, (eds.), Integration though Law, Europe and the American Federal Experience, vol. 1, book 3, Berlin/New York 1986, 165 et seq., 203-206; *Gormley, L.W*., Prohibiting Registrations on Trade within the EEC. The Theory and Application of Articles 30-36 of the EEC Treaty, Amsterdam/New York/Oxford 1985, 139-181; *Dauses, M.A*., Die neuere Rechtsprechung des EuGH im Lebensmittelrecht unter besonderer Berücksichtigung des sogenannten Bier Urteils, ZLR 1987, 243 et seq., 252-256.

[58] Case 53/80, judgment of 5 February 1981, ECR [1981] 409 (422)/Eyssen (Nisin).

[59] Case 272/80, Judgment of 17 December 1981, ECR [1981] 3277 (3290)/Biologische Producten; case 174/82, Judgment of 14 July 1983, ECR [1983] 2445 (2463)/Sandoz; case 227/82, Judgment of 30 November 1983, ECR [1983] 3883 (3905)/van Bennekom; case 97/83, Judgment of 6 June 1984, ECR [1984] 2367 (2386)/Melkunie; case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 (3904)/Léon Motte; case 54/85, Judgment of 13 March 1986, published in NJW 1987, 565 et seq., para. 15/Maleinsäurehydrazid; case 304/84, Judgment of 6 may 1986, published in RIW 1986, 1002 et seq., para. 21/Muller. In general on the alleviation of the requirement of proof in favour of a State acting against previously and recognized hazardous situations, see *Skordas, A*., Umweltschutz und freier Warenverkehr im EWG-Vertrag und GATT, Steinbach 1986, 122-127.

[60] Case 174/82, Judgment of 14 July 1983, ECR [1983] 24445 (2460-2464)/Sandoz. In an observation on this judgment, *Meier*, RIW 1983, 866, suggests the presumptive rule that in all cases where national provisions on marketability allow exceptions for goods intended for export, there is a presumption that the consumer protection provisions involved are not necessary.

A particularly illuminating judgment regarding the far-reaching powers that the Court allows Member States in the area of preventive health protection is the one in case 97/83.[61] This says that Member States are free to set threshold values for microbiological substances in milk to protect particularly sensitive consumers that may be well below the endangerment levels for normal consumers discussed by scientists but not established with certainty. Account may also be taken here of national usage regarding storage of milk products between purchase and consumption.

Member States may also prohibit pesticide residues in foodstuffs entirely, leading to the result of blocking trade in treated food and vegetables. In this connection they may adopt regulations which may be different according to the country, climatic conditions and the population's eating habits and state of health, and set different rates for the same pesticides in different foodstuffs.[62] While this judgment found a policy for preventing pesticide residues in foodstuffs to be compatible with Community law, another judgment found a policy to limit additives in food preparation to be permissible. Imported foodstuffs can accordingly be subjected to national licensing procedures which test not only whether the colouring agent used may be dangerous to human health, but also whether there is a technological, economic or psychological need for colouring the foodstuffs concerned. In assessing hazards, Member States must here take account of the findings of international scientific research, especially the work of the Community's Scientific Committee on Foodstuffs, but may in evaluating them take specific eating habits in the importing Member State into account.[63]

In judgments on food additives and pesticide residues, the Court of Justice deduced from the proportionality principle of Art. 36 EEC, second sentence, the requirement that marketing bans be restricted to the extent actually necessary for the protection of health. A marketing ban will have to be lifted where according to the state of international scientific research a substance presents no danger to health and meets a genuine need, notably one of a technological nature. Moreover, economic actors should be allowed the possibility of applying, in an easily accessible procedure which must be completable within an appropriate time, to have use of particular additives made admissible through a legal act of general effect.[64] On the basis of these criteria, the German beer purity law proved incompatible with Community law, on the grounds that it was disproportionate to rule out all additives admissible in other Member States in general fashion on grounds of preventive health protection, instead of adducing proof of health risk for each substance.[65] The submission of the German government, the defendant, that beer was a foodstuff consumed in considerable quantities by the German people and that on general preventive health protection grounds it was advisable in principle to restrict the quantity of additives

[61] Case 97/83, Judgment of 6 June 1984, ECR [1984] 2367 (2386)/Melkunie.

[62] Case 94/83, Judgment of 10 September 1984, ECR [1984] 3263 (3280)/Heijn. Cf. answer to Written Question No. 1581/84, OJ C 176, 15 July 1985, 4 et seq. Cf. also case 54/85, Judgment of 13 March 1986, published in NJW 1987, 565 et seq., para. 15/Maleinsäurehydrazid.

[63] Case 247/84, judgment of 10 December 1985, ECR [1985] 3887 (3904)/Léon Motte. Cf. also case 304/84, judgment of 6 May 1986, published in RIW 1986, 1002 et seq., para. 24/Muller; case 178/84, judgment of 12 March 1987, para. 44, published in NJW 1987, 1133 et seq./Beer Purity Law.

[64] Cf. case 174/82, judgment of 14 July 1983, ECR [1983] 2445 (2463 et seq.)/Sandoz; case 247/84, judgment of 10 December 1985, ECR [1985] 3887 (3905 et seq.)/Léon Motte; case 304/84 judgment of 6 May 1986, published in RIW 1986, 1002 et seq., para. 23-26/Muller.

[65] Case 178/84, judgment of 12 March 1987, para. 47-53, published in NJW 1987, 1133 et seq./Beer Purity Law.

consumed as far as possible[66] was rejected as insufficient. It was necessary to justify the exclusion of particular substances on grounds of specific hazards.

A judgment of direct relevance for technical safety law is the one in case 188/84 on the licensing of woodworking machines in France.[67] The French conception of industrial safety starts from the idea that users of machinery must be protected against their own mistakes, so that machines must be designed in such a way that they can be used, mounted and maintained without risk to the persons doing so (design safety).[68] In Germany, by contrast, the principle is that the worker must through thorough vocational training and further education be made capable of acting properly where a problem arises in operating a machine. The Commission put forward the view that Member States ought not to block the import of machines based on other conceptions of industrial safety but demonstrably having the same level of safety and not causing more accidents than appliances in accord with the national regulation.[69] The Court of Justice accepted this principle but arrived at a different conclusion:

> *Moreover it may not prevent the marketing of products originating in another Member State which in respect of level of protection of safety and human life are in line with what is aimed at in the national regulation. Accordingly, it would be contrary to the principle of proportionality for a national regulation to require that imported products should comply with every jot and tittle of the provisions and technical requirements applying to products manufactured in the Member State concerned, though they provide the same level of safety to users. By contrast, Community law in its present state does not oblige Member States to permit hazardous machines on their territory where these do not demonstrably guarantee the same level of protection to users on that territory.*[70]

The Court of Justice found in favour of France, since the Commission, which was bringing the action, had not shown that the conception of industrial safety underlying the German safety provisions guaranteed the same safety for users of the machines as the French conception. It would even be irrelevant if it were statistically shown that machines manufactured according to the industrial safety conceptions of other Member States cause no more accidents than machines in accord with the French regulation, since mere consideration of statistics left out other factors such as the differing level of training of users.[71]

Failing a Community regulation, accordingly, Member States are free to pursue their own safety conceptions and reject appliances and machines that cannot be shown to offer the same degree of safety, taking differing habits of use into account. The establishment of essential safety requirements according to the new approach is aimed at getting Member States to agree to a unitary safety conception or to several safety conceptions recognized as equivalent, so as to exclude in the harmonized area the sealing-off of markets by appeals to differing safety conceptions.

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[66] Op. cit., para. 48. Cf. also the corresponding submission by the Federal Republic of Germany in case 53/80, judgment of 5 February 1981, ECR [1981] 409 (414-416)/Eyssen (Nisin).

[67] Case 188/84 judgment of 28 January 1986, ECR [1986] 419/Woodworking machines. On this judgment see also *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 1.10.1. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf and Sedemund/Montag, 1987, 548.

[68] Decree 80-543 of 15 July 1980 on the labour code, Art. R. 233-85 (1).

[69] Case 188/84 judgment of 28 January 1986 ECR [1986] 419 para. 10/Woodworking machines.

[70] Op. cit., para. 16 et seq.

[71] Op. cit., para. 17-22.

2. From special case to model - the harmonization method of the Low-Voltage Directive

Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits – the low-voltage Directive[72] – with its new harmonization technique of sliding reference to harmonized standards, became the model for the new approach to technical harmonization and standards,[73] after it had for years been regarded by many officials in governments and the Commission as an original sin that ought not to be repeated[74]. With annual output worth some 80,000 million ECU in 1981, Community internal trade in electrical appliances amounted to some 35,000 million ECU; an estimated 70% of turnover in the electrical sector comes under the low-voltage Directive.[75]

2.1. Peculiarities of the electrical sector

There are good reasons why for years it was specifically only in the electrical sector that the general-clause method of reference to the European state of safety technology was applied.[76] These reasons also indicate that experience with the low-voltage Directive can be transferred only to a limited extent to other areas of industry.[77] Electrical standardization has for decades in all industrial countries occupied a especial place. The rapid pace of development in the electrical area would have been inconceivable without a highly developed regulatory apparatus for technical safety, containing comprehensive provisions for the hazards arising from electricity, which is not directly perceptible by the senses. By comparison with other manufacturing sectors, safety standards have in electrical engineering by far the greatest importance within the whole set of relevant standards. Electrical standards are more highly systematized and intermeshed than in other areas. This is because despite almost limitless variety of products there are comparable modes of

[72] OJ L 77, 26 March 1973, 29. Cf. *Winckler, R./Cassassolles, J./Verdiani, D.*, Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin 1974; *Orth, K.-L.*, Die Niederspannungsrichtlinie der EG. DIN-Mitt. 63 (1984), 376 et seq.; *Tronnier, H.-K.*, Standardization and Harmonization Efforts in Europe. The role of CENELEC and the Experience with the Low Voltage Directive, in: Pelkmans, J./Vanhenkelen, M. (eds.), Coming to Grips with the Internal Market, Maastricht, 1986, 35 et seq.

[73] Cf. *Garvey, T.*, The Enforcement of Product Safety Laws and Standards in the Community, in: Proceedings of the European Conference on Inter-Administrative Cooperation, Montpellier, 28-30 May 1984, 39 et seq., 46; *Braun, F.*, Nationale Rechtsvorschriften für Anlagen, Geräte und Stoffe in der Gemeinschaft, in: Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte im deutschen und im europäischen Recht, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 176 et seq., 182; *Bruha, Th.*, Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft, Deregulierung durch "Neue Strategie"?, ZaöRV 1986, 1 et seq., 9. See also the Commission communication on the application of the low-voltage Directive, OJ C 59, 9 March 1982, 2 et seq. (3), which announces the transference of this model to other branches of industry.

[74] Cf. *Winckler, R.*, Rechtsvorschriften für Anlagen, Geräte und Stoffe - Bestandsaufnahme und kritische Würdigung. Materialien und Geräte unter besonderer Berücksichtigung des Gerätesicherheitsgesetzes, der 2. DurchführungsVO zum EnWG und der Niederspannungsrichtlinie, in: Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 26 et seq., 34; *Schloesser, P.*, Europäische Gemeinschaft und Europäische Normung, in: Europäische Normung in CEN und CENELEC, DIN-Normungskunde, Heft 8, Berlin/Köln 1976, 21 et seq., 27.

[75] Cf. the communication on the application of the low-voltage Directive (op. cit., fn. 73), 2.

[76] On this see *Leber, R./Oehms, K.-H./Winckler, R./Orth, K.-L.*, Normung aufdem Gebiet der Elektrotechnik, Elektronische Zeitschrift 104 (1983), 825 et seq.

[77] Also skeptical is *Mertens, A.*, Neues Richtlinienkonzept, EG auf neuem Kurs, s.i.s. 1985, 613 et seq., 616 et seq.

operation and sources of hazards, but also because electrical products are almost without exception dependent on particular supply and transmission systems. This means that very often appliances and installations from the most diverse manufacturers are connected with each other. Accordingly, comprehensive, and in view of the very high international trade in this sector preferably international, or at least internationally compatible, provisions are essential for the numerous intersection points and in order to guarantee interchangeability of parts. This has meant that with electrical standards, by comparison with other industrial sectors, there is wide-spread technical consensus both nationally and internationally, a very high density of regulation and a particularly high degree of application and bindingness of standards.[78]

The particularly rapid technical development here calls for correspondingly quick and independent possibilities of action and a flexible organizational structure in standardization work. On the basis of the good experience with private standardization organizations, there are in most countries no special national provisions in the electrical area. Table 2 gives a picture of the set of electrical and other standards in 1986 worldwide, in Europe and in Western Germany, bringing out the particularly strong position of electrical standardization and its autonomy in standardization as a whole.

Table 2: Numbers of electrical and other technical standards at national, regional and international level in 1986(1)

Level of standardization	***Electrical***	***All other sectors***
Worldwide	IEC: 2,325	ISO: 6,401
Europe	CENELEC: 501	CEN: 159
Federal Republic of Germany	DKE in DIN: 6,792	DIN: 13,145

Source: DIN-Geschäftsbericht 1986/87, 24-33.

2.2. A conspectus of the Low-Voltage Directive

The low-voltage Directive applies to all electrical equipment for use with a voltage rating of between 50 and 1,000 volts for alternating current and between 75 and 1,500 volts for direct current (Art. 1). It covers in particular household electrical appliances, portable tools, lighting equipment, wires, cables and transmission lines and installation equipment. The Directive does not apply to particular groups of appliance in which there is great public interest, covered by specific directives (electrical equipment for use in an explosive

[78] Accordingly, in view of manifest overlap of interests, the statement (*Leber, R./Oehms, K.-H./Winckler, R./Orth, K.-L.*, Normung aufdem Gebiet der Elektrotechnik, Elektronische Zeitschrift 104 (1983), 825 et seq.,827) that electrical standards are as a rule neutral as regards interests, since organized expert knowledge can be found not only in the manufacturing industry but also among energy supply undertakings, telecommunications agencies and installers, is by contrast not very convincing.

atmosphere,[79] electrical equipment for radiology and medical purposes, electrical parts for goods and passenger lifts, electricity meters) nor to electric fence controllers nor radio electrical interference (see the list of exceptions in Annex II to the Directive). It is particularly important that even domestic plugs and socket outlets are also explicitly excluded.[80]

Art. 2 lays down the basic requirements for marketable electrical products. Electrical equipment may be marketed only if "having been constructed in accordance with good engineering practice in safety matters in force in the Community, it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made". The reference to the state of the art – good engineering practice - means that what applies is technical development at a given point in time, not widespread recognition and a proof in practice of particular rules – which would mean that the rule would always lag behind steadily advancing technical development, as with the reference to "generally recognized rules of art" in the German Appliances Safety Act.[81] The affirmative statement that in the event of a differing level of safety technology in individual Member States all ought to apply the highest level[82] does not fully bring out the graded harmonization machinery of the Directive, which had to be developed because the desired success in harmonization at an enhanced safety level could not be secured simply by having requirements on products follow directly from such a formulaic prescription.

Firstly, the principal elements of the safety objectives are listed in Annex I. This list of eleven safety objectives, kept extremely general in its terms, is a compromise between the countries that wished to content themselves with the general reference to good engineering practice in safety matters (the general clause method in pure form), and those that called for the safety objectives to be specified more exactly.[83] The safety objectives contain, among others, the following statements:

- Instructions on proper, risk-free use must appear on the electrical equipment.
- Manufacturers' or brand-names or trademarks should appear on the electrical equipment.
- The electrical equipment should be made in such a way as to ensure that it can be safety and properly assembled and connected.
- For protection against hazards that might arise from the electrical equipment, technical measures are to be prescribed, of such a nature that if the equipment is used in applications for which it was made and is adequately maintained, then protection against direct and indirect electrical contact is guaranteed, no dangerous temperatures, arcs or radiation are produced, there is adequate protection against non-electrical dangers and that the insulation is suitable for foreseeable conditions.

[79] OJ L 43, 20 February 1979, 20. This Directive works with the technique of rigid reference to standards.

[80] Cf. *Winckler, R./Cassassolles, J./Verdiani, D*., Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin 1974, 29.

[81] A detailed comparison of the GSG and First Ordinance under the Act on technical work materials, whereby the low-voltage Directive was transported into German law, can be found in *Zimmermann, N.*, Das Gerätesicherheitsgesetz, in: Brendl, E., Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Bd. III, Gruppe 11, S. 123 et seq., 146-161.

[82] Op. cit., 149. *Schmatz, H./Nöthlichs*, M. Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnnik, Berlin, Kennz. 1610, 9.

[83] Cf. Winckler *Winckler, R./Cassassolles, J./Verdiani, D*., Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin 1974, 28.

- echnical measures are to be laid down to ensure that the electrical equipment meets expected mechanical requirements, is resistant to non-mechanical influences and stands up to foreseeable conditions of overload.

It is presumed that electrical products meet these safety objectives where the equipment:

- complies with harmonized standards (Art. 5), i.e. those produced by CENELEC,
- where harmonized standards within the meaning of Art. 5 have not yet been drawn up and published, complies with the safety provisions of the International Commission on the Rules for the Approval of Electrical Equipment (CEE) or of the International Electrotechnical Commission (IEC) (Art. 6),
- where no harmonized standards within the meaning of Art. 5 or international standards pursuant to Art. 6 exist, has been manufactured in accordance with the safety provisions of the Member State of manufacture, if it ensures equivalent safety to that required in the country of destination (Art. 7).

In order not to block technical innovations, which are in general followed only after a certain lapse of time by technical standards,[84] products not complying with the technical standards mentioned but meeting the general safety objectives are also admitted to free movement (Art. 8 (1)). Conformity with the safety objectives may be shown by an expert report (Art. 8 (2)). The free movement of electrical products meeting the safety objectives on the terms just set out may not be impeded on safety grounds (Art. 3).

The presumed conformity of products with technical standards within the meaning of Articles 5, 6 and 7 is attested by a conformity mark issued by an accepted national body,[85] or by a "certificate of conformity", or in the absence thereof, in particular in the case of industrial equipment, the manufacturer's "declaration of conformity" (Art. 10). Measures to restrict marketing or free movement may be taken by Member States only through the safeguard clause procedure (Art. 9).

2.3. Individual questions on the Low-Voltage Directive and its application

For years there was considerable uncertainty as to the interpretation of the low-voltage Directive. This resulted not least from the regulatory technique, which was unusual for many Member States, and was not cleared up until the ECJ ruling of 2 December 1980 in preliminary ruling procedure 815/79-Cremonini v. Vrankovich.[86] On the basis of this ruling, the Commission once again summarized the legal framework of the Directive and its application in a clarificatory communication to all concerned.[87] Further important clarifications emerged from the meeting of the working group on elimination of technical obstacles to trade in the electrical sector held on 20 December 1983, on application of the low-voltage Directive.[88] The following observations on individual provisions of the low-voltage Directive are based essentially on the Commission communication and the findings of that working session.

[84] Communication on the application of the low-voltage Directive (op. cit., fn. 73), point 3.3.
[85] The list of centres is published in OJ C 184, 23 July 1979, 1.
[86] Case 815/79, judgment of 2 December 1980, ECR [1980] 3583/ Cremonini v. Vrankovich. Cf. Hartley, 1982. Also illuminating is case 123/76, judgment of 14 July 1977, ECR [1977] 1449/Commission v. Italy.
[87] Communication on the application of the low-voltage Directive, (op. cit., fn. 73).
[88] COM/III/1412/83 - Rev. 3.

2.3.1. Harmonized standards

The pillars of the low-voltage Directive are the harmonized standards within the meaning of Art. 5. They definitively replace other categories of technical standard mentioned in the Directive. They are to be laid down by the standards organizations joined together in CENELEC by mutual agreement, and should be brought up to the latest state of technological advance and of development of the rules of art of safety technology (Art. 5 (5), second sentence). To date CENELEC has in connection with the low-voltage Directive produced well over 100 harmonized standards. Harmonized standards may be arrived at by

- drawing up a European standard, published by all national committees of CENELEC unchanged as a national standard, or by
- use of a harmonization document to be incorporated verbatim, without change, in their national standards by all national committees of CENELEC.[89]

The Commission publishes the harmonized standards in the Official Journal; this publication is for purposes of information and thus has a purely declarative function.[90] The list published in September 1984 summarized harmonized standards agreed up to that date[91]. The 94 harmonization documents[92] covered extend to the following areas:

Household appliances 43,
Electricity lines.....15,
Work appliances and tools 13,
Lamps.....7,
General safety provisions.....6,
Measuring devices.....5,
Miscellaneous.....5.

The results of CENELEC's work may be adopted by majority vote, effective for outvoted committees too, though in principle unanimity is aimed at and almost always obtained.[93] This procedure of unanimous voting by the national committees accords with Art. 5 of the Directive, which says that harmonized standards are to be drawn up by "common

[89] After the judgment in the Cremonini v. Vrankovich case, CENELEC took the decision henceforth to publish only European Standards in the area of the low-voltage Directive, instead of the hitherto usual harmonization documents; see CENELEC memorandum No. 10 on publication of CENELEC work results in the area of the low-voltage Directive as European Standards.

[90] Otherwise it would be even more disastrous that publication has so far been effected only with very considerable delay. This is complained of by *Winckler, R.*, Rechtsvorschriften für Anlagen, Geräte und Stoffe - Bestandsaufnahme und kritische Würdigung. Materialien und Geräte unter besonderer Berücksichtigung des Gerätesicherheitsgesetzes, der 2. DurchführungsVO zum EnWG und der Niederspannungsrichtlinie, in: Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 26 et seq., 36.

[91] OJ C 235, 5 September 1984, 2 et seq. The previous three lists are published in OJ C 184, 23 July 1979, 5 et seq., OJ C 107, 30 April 1980, 2 et seq., OJ C 199, 5 August 1980, 2 et seq.

[92] This does not take the numerous amendments to harmonized standards into account.

[93] As with Art. 148 EEC, the votes for each country are weighted. The blocking minority is three members, or 16 weighted Noes. In other respects, the procedure is so arranged that on the one hand agreement among the Community partners cannot be prevented by non-Member States, and on the other as a rule as far as possible a comprehensive regional result, even going beyond the Community, is secured; for details see the CENELEC rules of procedure, last amended in September 1985.

agreement".[94] This is justified on the basis that the Community legislator has left the method of reaching mutual agreement within the discretion of the standardization bodies. Moreover, compliance with harmonized standards could not be mandatorily prescribed, but is merely a presumption that the safety objectives, the only decisive things, have been complied with. Finally, adoption and updating of the harmonized standards constitute a continuous process which in its effects is very similar to the procedure for adjusting directives to technical progress, which also operates by qualified majority. It should be added that specifically the comparison between CEN and CENELEC shows how much the adoption of harmonized standards and their adaptation to technical progress required on safety grounds is hampered if majority decisions do not also bind outvoted committees. Where there are serious reservations as to safety, the Member State, not the standardization committee, has the safeguard clause procedure of Art. 9 open to it.

In the case of many harmonization documents various types of national divergence were provided for, namely

- mandatory departures of type "A" on the basis of differing legally prescribed requirements as to the extent of safety;
- mandatory departures of type "A" on the basis of the conditions of the electricity supply system;
- departures of type "B" on the basis of particular technical circumstances, elimination of which is a matter for the standardization bodies.[95]

Following the ruling in the Cremonini v. Vrankovich case, it was clarified[96] that type B departures are not admissible, since no discrepant national standards apply alongside the harmonized standards. Nor could type A divergences continue to claim any validity alongside a harmonized standard, since compliance with discrepant national safety provisions operates as a presumption of compliance with the general safety objectives only where no harmonized standards pursuant to Art. 5 or no safety requirements published pursuant to Art. 6 exist. They can be adduced only in connection with the safeguard clause procedure of Art. 9.

In this explosive conflict of interests, the Commission seeks as far as possible to ensure that the safeguard procedure of Art. 9 is not opted for, but solutions found in informal ways by removing national discrepancies or incorporating them in the standard concerned.[97] Indeed, it explicitly notifies Member States of the possibility of affecting the production of harmonized standards through the various standardization bodies.[98] K. Fitting has the following to say about a remarkable practice by the German authorities of securing for themselves a right of participation in European standards:[99]

[94] On this see the communication on application of the low-voltage Directive (op. cit., fn. 73), point 4.2.1; COM/ III/1412/83 - Rev. 3, point 2.3.2; Advocate General *J.-P. Warnke* in his closing speech in case 123/76, ECR [1977] 1449 (1466-1468).

[95] Cf. CENELEC memorandum No. 5, "Document of principle for national departures from harmonization documents, with particular reference to the low-voltage Directive" and COM III/1412/83 - Rev. 3, point 2.3.3. In 1983, according to expert estimates, about one third of harmonized standards were affected by departures of type A because of differing statutorily prescribed requirements regarding the extent of safety.

[96] Cf. communication on application of the low-voltage Directive (op. cit., fn. 73), point 6.2.1; COM III/1412/83 - Rev. 3, point 2.3.3.; CENELEC memorandum No. 10 (op. cit., fn. 89), points 3.3 to 3.5.

[97] Cf. COM III/1412/83 - Rev. 3, point 2.3.3 end.

[98] Op. cit., point 2.3.1.

[99] *Fitting, K.*, Europäische Normen und Harmonisierungsvorhaben der Europäischen Gemeinschaften (EG), in: Europäische Normung in CEN und CENELEC, DIN-Normungskunde, Heft 8, Berlin/Köln 1976, 83 et seq., 87.

> *Following adoption of a harmonization document by CENELEC ... the DKE sends the competent German government department ... initial copies of the drafts for incorporation into national standards. The German government department, on the basis of the safeguard clause contained in the low-voltage Directive, tests the substantive content of the standard to see whether there are serious technical safety objections to its adoption. If there are no grounds for applying the safeguard clause, a communication is sent to the DKE to the effect that publication in the relevant VDE publications can proceed. Following this publication the standard is finally also published in the Federal Gazette ... with the consequence that a harmonized standard can now come about if the procedure in other Member States has likewise come to a positive outcome .... Where the Federal Government has severe technical safety objections, it informs the DKE of these. There is no publication in the Federal Gazette, so that there can be no harmonized standard. Since the Federal Government is now applying the safeguard clause, it notifies the Commission of this fact, pursuant to Art. 9 of the low-voltage Directive.*

The safeguard clause, really intended as a remedy against the marketing of electrical equipment that complies with standards but is unsafe, is here being used so that the German authorities can check compliance of the intended harmonized norms with the general safety objectives. The new approach provides for a procedure of its own, though a Community one, in order to test harmonized standards adopted by the European standardization bodies, or else the national standards that for the moment continue to apply, for compliance with the essential safety requirements.[100]

National requirements arising from differences in climate, electricity network, voltages, types of plug and socket etc., which cannot be changed for a fairly long time, are incorporated into the text of the European standard as "especial national conditions".[101]

Publication of safety requirements of international standardization bodies pursuant to Art. 6 of the Directive has remained of no importance in practice. Consistently, this possibility of reference is no longer taken up in the new approach. If even the standards organizations cannot manage to agree on harmonized standards pursuant to Art. 5, it is very probable that the objections raised are so weighty that Member States will oppose planned publication in the consultation procedure provided for by Art. 6 (3).[102] Not should, however, above all be taken of the CENELEC mode of procedure: it takes up work of its own only where no international standards are likely to be available in a reasonable time, but otherwise bases itself on IEC standards and confines joint amendments to these to a minimum.[103]

2.3.2. Equivalence of safety level

Art. 7 has raised severe problems of interpretation. It says that where harmonized standards do not exist and no international safety provisions have been published, electrical equipment is admitted to free movement where it meets the safety requirements of the manufacturing country and offers the same safety as required in the country of destination. Following the Cremonini v. Vrankovich ruling, it may be taken as clarified that Art. 7 is transitional in nature, applying only to the period where harmonized standards have not yet

[100] Cf. 3.3 below.

[101] CENELEC memorandum No. 10 (op. cit., fn. 89), point 3.3.

[102] *Winckler, R./Cassassolles, J./Verdiani, D.*, Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin 1974, 16.

[103] Cf. *Winckler, R.*, Europäische Normung in CENELEC, DIN-Mitt. 62 (1983), 79 et seq.; *Leber, R.*, Harmonisierung elektrotechnischer Normen, in: Europäische Normung im CEN und CENELEC, DIN-Normungskunde, Heft 8, Berlin/Köln 1976, 55 et seq., 65.

been established for the whole area of application of the low-voltage Directive.[104] It is conceivable that in this transitional period national standards will in one Member State or another continue to apply which lag behind the requirements of Art. 2 taken together with Annex I, that is, the general safety objectives. In this case, it should be ensured that the safety level prescribed in the importing Member State is not reduced. The importing country cannot however require the same safety also to be achieved by the same means, nor can it call for any higher degree of safety than required by Art. 2 and Annex I.[105]
Art. 7 also makes it clear that Member States may not link the marketing of electrical equipment that meets the prescribed safety objectives to the condition of complying with particular provisions regarding quality or performance.[106]

2.3.3. Safeguard clause procedure

A Member State which for safety reasons prohibits the marketing of electrical equipment or restricts its free movement, need only, but must always, employ the safeguard clause procedure of Art. 9, if conformity with the general safety objectives is to be presumed because a conformity mark, certificate of conformity from an authorized office, declaration of conformity from the manufacturer or expert report pursuant to Art. 8 (2) is available. It has to inform the Commission and all Member States on measures taken, since all are – at least possibly – "involved", and has to indicate the ground for its decision. If a measures has been taken because of a shortcoming in a technical standard, the Commission sees itself as obliged to act in order to maintain a uniform safety standard in the Community even where other Member States have no objections to the national measures,[107] though the Directive does not provide for any action in this case. In its details, the safeguard clause procedure is rather unclearly and awkwardly constructed as regards the conditions, course and consequences. Its main function is in preventing Member States unilaterally interfering with movement of electrical equipment meeting the general safety objectives, and in setting up a mechanism for mutual consultation and opinion. The Commission takes the role of a moderator here; it may secure opinions and pass them on, and may having done so formulate recommendations or opinions.

2.3.4. The CENELEC certification agreement

The application of a conformity mark to electrical equipment or the issue of a certificate of conformity by the authorized centers in Member States must, as the Cremonini v. Vrankovich judgment explicitly clarifies, be recognized by all Member States as a rebuttable presumption of compliance with the technical standards pursuant to Articles 5, 6 or 7 and thus also with the safety objectives laid down in the Directive. This conformity mark or certificate thus gives entitlement to marketing and to free movement, subject to the safeguard clause procedure, in the whole Community. Conformity marks are not only proof of conformity, but in countries where they have been issued by the competent centres in

[104] According to industry figures, harmonized standards already existed for over 90% of turnover in equipment covered by the low-voltage Directive;cf. COM III/1412/83 - Rev. 3, point 2.4.1.
[105] On the foregoing cf. the closing speech by Advocate-General *J.-P. Warner* in case 815/79, ECR [1980] 3583 (3624 et seq.); cf. also *Hartley, T.C.*, Consumer Safety and the Harmonization of Technical Standards: the Low Voltage Directive, ELR (1982), 55 et seq., 59.
[106] Communication on application of the low-voltage Directive (op. cit., fn. 73), point 6.3.
[107] COM III/1412/83 - Rev. 3, point 2.5.2.2.

that country additionally mean an indisputable commercial advantage. Accordingly, it is in the interest of manufacturers to secure the national mark of every Member State in which they wish to market their products. The CENELEC certification agreement of 11 September 1973 in the version of 29 March 1983[108] (CCA) facilitates the acquisition of such marks without needless repetition of tests. A manufacturer who has already secured a conformity mark on the basis of the prescribed tests may by submitting the tests result on a form secure the mark of another office too, in a rapid, informal procedure.[109] There are agreements between the test centres on initial inspection of the place of manufacture and on monitoring of the manufacturing process and of marketing. Where a manufacturer so desires, he can on the basis of one test acquire national conformity marks for all Member States more or less automatically. The Commission energetically supports this agreement, which it regards as an advance on the system of mutual recognition of conformity marks and certification in the low-voltage Directive and as making introduction of a Community mark practically superfluous.[110] What is ultimately decisive is the initial test which does not necessarily have to be done in the manufacturer's country.

The HAR agreement describes a procedure for issuing and using a jointly agreed marking for cables and insulated wires meeting the harmonized standards.[111] National test centres mark the cables and wires not only with the national test mark but also with the CENELEC test mark HAR. Accordingly, in the area of cables and wires there does exist a European test mark which all certification centres have to treat as if it were their own mark. A further special procedure exists for construction components in electronics, regulated by the CENELEC Committee for Electronic Components (CECC).[112]

Internationally, other with a restriction mainly to Europe, the certification of electrical products is organized by the International Commission for Conformity Certification of Electrical Products (CEE), recently integrated into the IEC.[113] Since 1963 its predecessor organization,[114] which until 1981 also issued standards itself in the electrical sphere, had made available a certification procedure, the CB procedure.[115] In it, tests by one member

[108] Which replaces similar agreements of 2 May 1968, 1 April 1971 and 11 September 1973.

[109] For details see *Warner, A.*, Nationale und internationale Prüfstellen- und Zertifizierungsaktivitäten auf dem Gebiet der Elektrotechnik, DIN-Mitt. 62 (1983), 85 et seq., 87 et seq.; *idem*, Das elektrotechnische Prüfwesen im Rahmen der deutsch-französischen Zusammenarbeit, in: AFAST, Zusammenarbeit zwischen deutschen und französischen Prüf- und Normungsinstituten, Kolloquium am 4. und 5. Juni 1984 in Straßburg, Bulletin Nr. 10, Bonn 1984, 33 et seq., 36 et seq., -For instance, the VDE test centre has in recent years given some 140 tests annually in the form of CENELEC communications of test results to German manufacturers that had presented them to the various foreign CENELEC test centres to secure their test marks.

[110] COM III/1412.83 – Rev. 3, points 2.6.2 and 2.6.3.

[111] Details in *Warner, A.*, Nationale und internationale Prüfstellen- und Zertifizierungsaktivitäten auf dem Gebiet der Elektrotechnik, DIN-Mitt. 62 (1983), 85 et seq., 87 et seq.; *idem*, Das elektrotechnische Prüfwesen im Rahmen der deutsch-französischen Zusammenarbeit, in: AFAST, Zusammenarbeit zwischen deutschen und französischen Prüf- und Normungsinstituten, Kolloquium am 4. und 5. Juni 1984 in Straßburg, Bulletin Nr. 10, Bonn 1984, 33 et seq., 37 et seq., 50 et seq.

[112] For more details see *Bier, M.*, Das CECC-Gütebestätigung-System für Bauelemente der Elektronik, in: CECC-Gütebestätigungssystem für Bauelemente Elektronik. Referate und Podiumsdiskussion des ZVEI-Bauelemente-Symposium '83, Berlin/Offenbach 1983, 11 et seq.

[113] Details in *Warner, A.*, Nationale und internationale Prüfstellen- und Zertifizierungsaktivitäten auf dem Gebiet der Elektrotechnik, DIN-Mitt. 62 (1983), 85 et seq., 88 et seq.; *idem*, Das elektrotechnische Prüfwesen im Rahmen der deutsch-französischen Zusammenarbeit, in: AFAST, Zusammenarbeit zwischen deutschen und französischen Prüf- und Normungsinstituten, Kolloquium am 4. und 5. Juni 1984 in Straßburg, Bulletin Nr. 10, Bonn 1984, 33 et seq., 38 46 et seq.

[114] CEE – International Commission for rules on approval of electrical products.

[115] CB – Certification Body – In the period from 1963 to 1984 some 6,500 CB certificates were issued.

organization were recognized by the others. The CB certificate as such does not give entitlement to application of a test mark, but merely facilitates the securing of other national test marks among the CEE member countries.
Public supervision, government influence or even any sort of consumer involvement are scarcely conceivable in the CENELEC certification system. There is only very restrictively any competitive situation among individual test centres, or mutual verification. It is clear that in the case of certification marketing interests outweigh verification of compliance with standards. An international certification system ought, besides the necessary cross-cooperation among certification centres, to require that certification be centralized in the individual Member States, precise requirements be placed on the staffing and equipment of centres, clear test criteria worked out and ample consensus reached among centres involved as to the target safety standard. The requirements would have to be strict. Once conformity marks have been conferred, marketing restrictions can be arrived at only through a time-consuming, rather cumbersome safeguard clause procedure.
For certification questions arising in implementing the new approach, reports ought to be useful on the extent to which use is made of certification by manufacturers even outside the industrial use of products, and what precautionary measures ought to or can be taken against misuse.[116]

2.4. Inadmissible delegation of public tasks to private standardization bodies?

Finally, it should be considered whether the form of sliding reference to technical standards chosen in the low-voltage Directive does not constitute inadmissible delegation of public tasks to private standardization bodies. The ECJ has not dealt explicitly with this question, but has not expressed any doubt as to the admissibility of the reference technique employed in the low-voltage Directive.[117] The possible criticism has been brought out very succinctly by E. Röhling,[118] in specific reference to the low-voltage Directive, and can be summarized as follows:
Sliding reference to technical standards in their current version is alleged to constitute inadmissible delegation of sovereign powers to non-sovereign organizations, since the tasks transferred go far beyond mere implementing powers, Community agencies are allowed practically no influence on the production of the technical standards and the balance between Community institutions is encroached upon. Reference to standards can allegedly not be justified even on the ground that it is a very technical matter, regulation of which would present Community institutions with insoluble tasks. Given that only vague, undisputed general safety objectives are laid down, standard-setting bodies are alleged to decide by themselves as to the extent of hazards the public is to be exposed to. Community institutions, moreover, are not so much allowing themselves in the case of application of reference standards to be guided by consideration of the hazardousness of the individual products, but more by the extent to which international standards exist for the given areas, or at least international standardization bodies are viable. The standard-setting bodies are

[116] Cf. COM III/1412/83 – Rev. 3, point 2.6.4.
[117] Case 123/76, judgment of 14 July 1977, ECR [1977] 1449/Commission v. Italy; case 815/79, judgment of 2 December 1980, ECR [1980] 3583/Cremonini v. Vrankovich.
[118] *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 122-127. Reservations are also expressed by *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 78 et seq.

made up largely of representatives of interested business circles, not subject to any effective public control, and on the whole do not offer the guarantee of setting technical specifications oriented solely towards the requirements of the common good (consumer and environment protection, safety). Finally, there is an objection on grounds of democratic legitimation, namely that the anyway weak control over Council members by national parliaments is still further undermined.

These massive objections will not be gone into any further here in connection of the low-voltage Directive. They arise in connection with the new approach, in part with modified parameters, and will be discussed in detail there.[119] The low-voltage Directive and the new approach have carefully been designed in such a way that the following legal fallback position is open:[120] products need meet only the essential safety requirements laid down by the Council. Harmonized standards, and to a restricted extent national standards too, justify only a presumption of compliance with the general safety objectives, which could in principle also be met in other ways. Member States could satisfactorily meet their responsibility for consumer safety through the safeguard clause procedure as well as through the laying down of the fundamental safety requirements.

3. The new approach to technical harmonization and standards

The development of a strategy aimed at guaranteeing the conditions for marketability of goods on European markets is among the essential legal requirements for the renewed efforts to bring about the internal market. The new approach to harmonization policy is justified above all by the principle of "equivalence" of safety policy objectives in Member States, supported by the Cassis de Dijon Judgment of 1978, which should made possible mutual recognition of national provisions[121] and permit the generalizability of the reference technique first practised in the 1973 low-voltage Directive.[122] But the political impulses and preliminary conceptual work go much further back.[123] Both the European Parliament[124] and the Economic and Social Committee[125] had already recommended the reference method in their resolutions or opinions on the general programme to eliminate technical barriers to trade of 1969, as an alternative to the "traditional" method of approximation of laws.[126] In

[119] Cf. 5 below.

[120] See COM III/1412/83 – Rev. 3, point 2.3.1 and *Winckler, R./Cassassolles, J./Verdiani, D.*, Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin 1974, 31 on the low-voltage Directive. On the new approach cf. the four basic principles in the Council resolution of 7 May 1985, OJ C 136, 4 June 1985, 1 (2 et seq.). The legal conception was early worked out in basic outline by *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 143-160.

[121] Cf. in the Commission's White Paper on Completion of the Internal Market (fn. 1) in particular points 63 and 77, and for qualifications to this principle section 1 above, esp. 1.2.3.

[122] The White Paper (fn. 1), point 63, is able to point in this connection to the Council resolution on conclusions regarding standardization of 16 July 1984 (OJ C 136, 4 June 1985, 2); see also the Commission communication "Technical Harmonization and Standards: a new approach", COM (85) 19 final of 31 January 1985, 6.

[123] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.3 (c). Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[124] OJ C 108, 19 October 1968, 39 et seq.

[125] OJ C 132, 6 December 1968, 1, 4 et seq.

[126] The ESC's opinion (op. cit.) reads like a downright anticipation of the new approach: "Thus, it would be conceivable for the Community directives first to list the safety objectives to be secured, and then to indicate that these would be taken as achieved as long as a particular standard, initially harmonized at the level of the Member States, is

the early 70s, these hints were taken up in the German literature, and the outlines of the new approach worked out:[127] Directives should lay down "basic requirements", and conformity with technical standards should justify a presumption of compliance with these requirements.[128] In accordance with this presumption, Member States ought to take "all necessary measures to ensure that administrative authorities recognize as conforming with the basic requirements such goods as meet standards laid down by the Commission following consultation of the Standardization Committee".[129] Manufacturers are furthermore to be left the possibility of declaring and where necessary proving the basic conformity of products not complying with standards.[130]

But these proposals were by no means uncontroversial. The regulatory technique of reference to standards, it was objected, notably by Röhling,[131] substantively meant delegation of legislative powers, inadmissible according to the EEC Treaty;[132] if the Community wished to take advantage of the expert knowledge of standardization organizations, it ought first to guarantee the Commission's influence on the standardization procedure in any such cooperation, and then adopt the procedure of Art. 155, fourth indent, for the legal "ratification" of the results of standardization.[133]

This already brings out the major legislative policy problems to be overcome in working out the new approach. The following survey will however give legal assessment second place to the solutions or proposed solutions developed by the Commission,[134] in order firstly to consider their practicability.

3.1. The Information Directive of 20 March 1983

The first legislative act in which the Community systematically embarked on the transition to a new harmonization policy was the Directive of 20 March 1983 "laying down a procedure for the provision of information in the field of technical standards and regulations".[135] This Directive went beyond the existing restriction of harmonization policy to the legal and administrative provisions mentioned in Art. 100 (1) EEC to cover also their

complied with. This would give a chance to bring proof that the safety objectives have been met even without compliance with the standard concerned".

[127] Cf. esp. *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 104 et seq., 143 et seq.; more recently, also *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 82-91 and earlier *Seidel, M.*, Die Problematik der Angleichung der Sicherheitsvorschriften für Betriebsmittel in der EWG, NJW 1969, 957 et seq., 960 et seq. and *idem*, Die Beseitigung der technischen Handelshemmnisse, in: Angleichung des Rechts der Wirtschaft in Europa, Kölne Schriften zum Europarecht, Bd. 11, Köln/Berlin/Bonn/München 1971, 733 et seq., 745 et seq.

[128] Cf. *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 82 et seq.

[129] *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 151.

[130] *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 115 et seq.; *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 88.

[131] *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 114 et seq.

[132] See 2.4 above, as well as 5.1 below.

[133] *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 132 et seq.; on this more at 5.2 below.

[134] On this cf. 5 below.

[135] OJ L 109, 26 April 1983, 8.

non-governmental appendage, namely national technical standards.[136] The directive was also innovative because of the measures by which it sought to oppose the emergence of technical barriers to trade. Art. 8 obliges Member States (and Art. 4 national standardization bodies) to "immediately communicate to the Commission any draft technical regulation" (and national standards programmes and draft standards).[137] This information is to enable the Commission to seek European solutions for the area concerned and initiate negotiations on such solutions. The legal instrument the information Directive gives it for this purpose is a time-limited anticipation of the primacy doctrine,[138] which replaces the "Gentlemen's Agreement" of 28 May 1969.[139] The Commission or a Member State can cause adoption of technical regulations to be delayed for six months (Art. 9 (1)) and the Commission even by 12 months, if it announces an intended directive (Art. 9 (2)). Art. 7 (1) obliges Member States to ensure that standards are suspended for a period of six months if production of a European standard is intended. It is noteworthy that the information Directive "institutionally" restricts the primacy claim of European law by taking Member States' interests into account and giving standards institutions too a possibility of collaboration.[140] These opportunities of influence are guaranteed by the Standing Committee of Member States' representatives set up by Art. 5, which shall be consulted on all important matters and may deal with any questions it finds important (cf. Art. 6 (5) and (6)). National and European standardization organizations may be represented on the Committee themselves directly through experts or through advisers; in other respects they are recognized by Art. 6 (1) as permanent interlocutors. Member States' safety policy interests are taken into account by Art. 9 (3), which grants Member States the right "for urgent reasons relating to the protection of public health and safety" to introduce effective national provisions immediately.

The objectives of Europeanization of technical regulations and standards and the institutional innovations in the information Directive already adumbrate important components of the new approach. The information Directive itself admittedly means in the first place that the Commission has taken a very considerable burden of work upon itself. Following entry into force of the Directive on 1 January 1985, the Commission had by May 1986 already received 80 relevant communications, brought about the postponement of procedures in 32 cases and announced the adoption of directives in 10 cases.[141]

Evidently, however, the "information ethics" documented in these figures is still not enough. At any rate, the Commission pointed out in a communication of 1 October 1096

[136] Cf. *Macmillan, J.*, Qu'est-ce que la Normalisation?, RMC 1985, 93 et seq.; *Lecrenier, S.*, Les Articles 30 et suivants CEE et les Procédures de Contrôle prévues par la Directive 83/189/CEE, RMC 1985, 6 et seq.

[137] The information from national standards organizations is collected by the European standards organizations CEN/CENELEC and passed on to the Commission; see *Anselman, N.*, Die Rolle der europäischen Normung bei der Schaffung des europäischen Binnenmarktes, RIW 1986, 936 et seq., 937.

[138] Cf. *Rehbinder, E./Stewart, R.*, Environmental Protection Policy, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), Integration Through Law. Europe and the American Experience, vol. 2, Berlin/New York 1985, 331.

[139] OJ C 76, 17 June 1969, 9.

[140] On the general context, see *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 1.2.2. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[141] "First report from the Commission to the Council and the European Parliament on the implementation of the Commission's White Paper on completion of the internal market", COM (86) 300 final of 26 May 1986, 14; also the answer to written question No. 1376/86 OJ C 143, 1 June 1987, 12 et seq. In its second report on the implementation of the White Paper the Commission reported on 294 drafts notified, on 124 of which it had formally asked for a change, COM (87) 203 final of 19 May 1987, 13.

that failure by Member States to comply with their information and postponement obligations was an infringement of Community law from which citizens of the States concerned could derive a right to non-application of provisions enacted in contradiction with the provisions of the information Directive.[142] The Commission can base its legal position on ECJ case law on the direct effect of secondary Community law. However, the expectation that the postponement periods provided for in the information Directive could allow European solutions for the technical regulations and standards covered by the Directive to be found and applied would be unrealistic. The most important effect of the information directive is no doubt instead that it made it possible for an information system to be set up at Community level and has involved the Member States and their standardization organizations in the process of Europeanization of technical regulations and standards.[143]

This assessment is confirmed by the proposals submitted by the Commission on 20 February 1987. By these, the scope of the information Directive is to be considerably expanded, extending in future to farm products, foodstuffs and fodder, medicaments and cosmetics;[144] at the same time, it is intended that the Standing Committee set up by Art. 5 of the information Directive should be involved in working on standardization contracts (Art. 1 (2)). The postponement periods in Art. 9 of the Directive are not extended. However, in future, communication of a proposal for a directive to the Council (and not only announcement of a corresponding "intention") would bring on the postponement obligation (Art. 1 (3)(b)). The Commission's explanatory document of 13 February 1987[145] stresses that the postponement periods resulting from the announcement to Member States of an intention and the communication of proposals for directives to the Council are not to be added together.

3.2. Harmonization of safety objectives and their implementation in standards

The overstraining of the Community's law-making capacities by procedures under Art. 100 (1) EEC has led to the trying out of three[146] strategies to unburden it. All are to be continued under the new approach too. In accordance with the extensive interpretation of Art. 30 EEC[147] advocated by the Commission following the Cassis de Dijon decision,[148] in areas where reliance can be placed on mutual recognition of national regulations and

[142] Commission communication on non-compliance with particular provisions of Directive 83/189 EEC, OJ C 245, 1 October 1986, 4; see also the answers by Lord *Cockfield* to question No. 39/86 in the European Parliament, OJ C 270, 27 October 1986, 23 and EP question No. 1376/86, OJ C 143, 1 June 1987, 13, and *Anselmann, N*., Die Rolle der europäischen Normung bei der Schaffung des europäischen Binnenmarktes, RIW 1986, 936 et seq., 937, on the adoption of national standards.

[143] Cf. also *Pelkmans, J*., Opheffing van technische Handelsbelemmeringen. Pilot-Studie in Apdracht van het Verbond van Nederlandse Ondernemmingen, Den Haag 1985, 69 et seq.

[144] Cf. Art. 1 (1) of the proposal for a Council directive amending Directive 83/189 EEC on an information procedure in the area of technical regulations and standards, OJ C 71, 19 March 1987, 12; on agricultural products see the supplementary proposal in OJ C 71, 19 March 1987, 13.

[145] COM (87) 52 final, point 9.

[146] A fourth road is so-called optional harmonization (*Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.3 (b) Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf), which is however not mentioned in the White Paper and is critically commented on in the explanatory memorandum on the new approach (op. cit., fn. 122, 4).

[147] Cf. 1.1.2 above, text on fn. 26.

[148] Case 120/78, Judgment of 20 February 1979, ECR [1979] 649.

standards, approximation of laws is where possible to be avoided; existing regulations and standards are to be checked for proportionality.[149] The scope of this strategy is, admittedly, limited.[150] Another way of unburdening the procedure of directives is through delegation of power to enact implementing directives to the Commission pursuant to Art. 155, fourth indent.[151] The White Paper mentions the success of this method,[152] which however cannot necessary be reconciled with efforts at increasing involvement of standardization organizations in harmonization policy.[153] The third method of unburdening, the reference technique first practised in the low-voltage directive of 19 February 1973,[154] is unambiguosly and emphatically favoured in the new approach.

This means, in the White Paper's terms, that harmonization of legal regulations should in future be confined to "binding health and safety requirements", to "basic preconditions for a product's marketability", while production of relevant technical specifications should be left to European standardization organizations.[155] The unburdening effect of this inclusion of standardization organizations in harmonization policy depends in the first place on the demarcation between the "basic safety requirements" and the "technical specifications". The low-voltage Directive, explicitly emphasized in the explanatory memorandum on the new approach as a model for the new regulatory technique,[156] does describe the mandatory safety objectives comprehensively, but only by vague general clauses.[157] Descriptions of this nature, as the literature on the low-voltage Directive brings out, allow only preliminary assessments; they become "practically applicable...only by actually adducing the standards".[158] It is just this consequence of the reference technique that the new approach evidently does not wish to accept. According to the preparatory document of 31 January 1985, the essential safety requirements must be worded precisely enough "in order to create, on transposition into national law, legally binding obligations which can be imposed".[159] The model directive approved by the Council contains the following addition: "They should be so formulated as to enable the certification bodies immediately to certify products as being in conformity, having regard to those requirements in the absence of standards".[160]

This addition has led to considerable hesitation and controversies. Pelkmans, for instance, warns[161] that it endangers the whole planning of the new approach and ought therefore to be

[149] See point 65 in the White Paper (fn. 1).
[150] See 1.2.3 above and point 64 in the White Paper (fn. 1).
[151] Cf. the proposal for a directive on construction products, OJ C 308, 23 December 1978, 3 and *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf, and the ESC's opinion on problems of barriers to trade and the harmonization of relevant legal provisions, OJ C 72, 24 March 1980, 8.
[152] Op. cit. (fn. 1), point 70.
[153] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.
[154] OJ L 77, 26 March 1973, 29.
[155] Op. cit. (fn. 1), points 65, 68.
[156] Op. cit. (fn. 122), 5.
[157] Cf. 2.2 above.
[158] *Schmatz, H./Nöthlichs, M*. Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnnik, Berlin, Kennz. 1610, 11, 13, cf. 17 et seq.
[159] Op. cit. (fn. 122), 11.
[160] Council resolution of 7 May 1985, OJ C 136, 4 June 1985, 2.
[161] *Pelkmanns, J.,* Opheffing van technische Handelsbelemmeringen. Pilot-Studie in Apdracht van het Verbond

understood merely as a call for involvement of national certification centres in cases where neither European or national standards guarantee the safety of a product.[162] The European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy called in its report on technical harmonization and standards in the Community[163] for the deletion of this addition, and an April 1986 question by one MEP[164] suggested that it be treated as non-mandatory. The answer to this question, communicated by Lord Cockfield on behalf of the Commission,[165] makes the legal position clear and yet seems to dodge the issue:

> *As far as the requirements on the precision of safety objectives are concerned, the addition is "only a comment intended to define the relationship between the essential safety requirements (point B III) and the means of proof of conformity and effects (point BV3). An essential aspect of the harmonization arrangements proposed by the Commission in its communication of 31 January 1985 is that the manufacturer would be able to choose between certification by a third party on the basis of the essential requirements, on the one hand, and the declaration of conformity with standards, on the other hand. It is therefore a choice that makes it possible to retain the optional nature of standards, which is the basic feature of the 'new approach'.*
>
> *The Commission in no way takes the view that this principle will necessarily lead the Council to adopt directives laying down very detailed essential safety requirements, since the testing bodies appointed by the Member States to check the conformity of manufactured products with the essential requirements normally have expertise based on lengthy experience which holds out the assurance that the obligations deriving from a directive that has clearly formulated the standard of safety to be attained by the products in question will be correctly interpreted and applied.*
>
> *It will also be possible for suitable informal procedures to be established in each case, so as to allow satisfactory cooperation between the appointed certification and testing bodies, thus ensuring that the provisions of the directives in question are correctly and uniformly applied ... The Commission considers, at all events, that such a question should be examined in connection with each specific case, rather than form the subject of a general discussion on the interpretation of the Council resolution of 7 May 1985".*

In the meantime the first directives or draft directives based on the model directive are available, providing clearer indications of the function of the laying down of safety objectives. The Directive for simple pressure vessels,[166] with its descriptions of the essential safety requirements, is not comparable with the general clauses of the low-voltage Directive. The characteristics of the materials to be used are laid down in detail in

van Nederlandse Ondernemmingen, Den Haag 1985, 115, says that this is "de dood in de pot" (see also *Pelkmanns, J.*, The New Approach to Technical Harmonization and Standardization, JCMSt 25 (1987), 249 et seq, 265 et seq.). See further *Hartlieb, B./Krieg, K.G.*, Europäische Normung ja - aber wie?, DIN-Mitt. 66 (1977), 125 et seq., 1987, 127 as well as the interesting opinion in *Dey, W.*, EG-Richtlinie über die Sicherheit von Maschinen, DIN-Mitt. 66 (1987), 233 et seq., 234 on the planned directive on safety of machines: that it is appropriate "to continue ... efforts at a general, comprehensive standard on the safety of machines and not wait for the appearance of a directive". In any case, a few months later the Commission presented its proposal for a Council directive harmonizing the legal provisions of Member States for machines, OJ C 29, 3 February 1988,1.

[162] Cf. 3.3 below.

[163] PE Doc. A 2-54/86, 16 June 1986, point 7.

[164] OJ C 19, 26 January 1987, 5.

[165] Op. cit., 5.

[166] OJ L 220, 8 August 1987,48; the Directive of 27 June 1976 harmonizing Member States' provisions via common provisions for pressure vessels and on procedures for testing them, OJ L 262, 27 September 1976, 153 and the three individual directives subsequently adopted remain unaffected.

Annex I;[167] further binding provisions deal with design and loading capacity, manufacturing procedures and requirements for commissioning the vessels. Regarding the volume of these provisions, the explanatory statement to the draft directive says that "differences of principle regarding aspects of safety" ought to be decided by the competent bodies of the Community, since otherwise they would "inevitably reappear at the level of European standardization bodies".[168]

The second draft directive submitted on the basis of the new approach concerns the safety of toys.[169] Art. 2 (1) lays down a general safety obligation whereby manufacturers must bear in mind the foreseeable use of toys and the "normal behaviour of children". This general safety obligation is specified in Annex II, initially in "general principles", according to which children are to be protected not only against risks due to the construction and composition of the toy, but also, where design measures are not possible, against those inherent in its use.[170] The lengthy Annex II lays down requirements on physical and mechanical properties, flammability, chemical properties, explosion, electrical properties, hygiene and radioactivity. Annex IV additionally contains differentiated requirements as to warnings concentrating partly on the age of children, partly on the nature of the toys and partly on risks involved. All categories of risks and warnings were contained in the Commission's proposal for a directive of 3 July 1980,[171] from which they were taken over into the proposal for a framework Directive of 23 June 1983.[172] The 1980 draft dealt in Annexes V and VI with Community standards for physical and technical properties and for the flammability of toys, but in 1983 corresponding standards were incorporated into separate directives.[173] A simplified procedure for amending these mandatory standards had been provided for both in 1980 (Art. 17) and in 1983 (Art. 13). The regulatory technique of the draft as now submitted thus builds on preliminary work already done. This continuity emerges particularly clearly from the fact that the binding standards in the 1980 and 1983 drafts merely took over provisions from the European standardization organizations, seeking to make them mandatory even though not yet formally adopted at the time by the national standards organizations. These draft standards have since been developed into mandatory European standards. Article 5 of the new proposal can therefore now refer to the very regulations that previous drafts sought to make legally binding.[174]

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[167] In the explanatory statement to the "proposal for a Council directive harmonizing the legal provisions of Member States for simple pressure vessels", COM (86) 112 final of 14 March 1986, 9, the possibility of rapidly amending these provisions is pointed out; the possibilities of Art. 155, fourth indent, EEC were, however, not fully utilized.

[168] Op. cit., 6; by contrast, the EP Committee for Economic and Monetary Affairs and Industrial Policy, op. cit. (fn. 163), 11, finds that the proposal for a directive bears the traces of the "old ... now outdated method"; the EP resolution of 19 June 1987 goes in the same direction; OJ C 190, 20 July 1987, 173.

[169] Proposal for a Council directive harmonizing the legal provisions of Member States on the safety of toys, OJ C 282, 8 November 1986, 4. On this the amended proposal of 2 October 1987 is now available, COM (87) 467 final.

[170] The quality of the German version of the draft directive is such that the meaning of the text can be often be deduced only by considering the other languages.

[171] OJ C 228, 8 September 1980, Annex III, and IV.

[172] OJ C 203, 29 July 1983, 1, Annex II and III; cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 3.2. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[173] OJ C 203, 29 July 1983, 12 (mechanical and physical properties); OJ C 203, 29 July 1983, 1 (flammability).

[174] On the role of national standards and of conformity certificates for toys not conforming to standards see point 3.3 below.

The Commission's most recent project to date,[175] the proposal for a directive on construction products,[176] is likewise a resumption of a long-discussed project.[177] The development is very easy to follow, because the original draft provided for wide-ranging "implementing powers" for the Commission pursuant to Art. 155, fourth indent, and (partly) because of that provoked considerable resistance from business circles involved. On the other hand the circumstances that had at the time induced the Commission to take advantage of these regulatory powers have not changed: there are still hardly any European or international standards for construction products, and the multiplicity of existing national standards on them relates to differing national statutory provisions on buildings.[178] In these circumstances, the Commission's proposal cannot apply the new approach the way the model directive assumes. The safety requirements in the construction products Directive contain "essential requirements to which construction works, i.e. buildings and civil engineering works, have to conform, and which may influence the specific characteristics for products" relating to such points as stability, safety in case of fires, hygiene, health , the environment, safety in use, durability, protection against noise and energy saving.[179] The Commission explicitly stresses that it would not in general be possible on the basis of these requirements "to establish directly a presumption of conformity with the essential requirements by means of a type-examination carried out by an approved body".[180] Since the regulatory lacunae between the "essential requirements" and actual construction products will not in the foreseeable future be closed by European standards either, the Commission proposal provides for "European technical approval". Approval bodies authorized by Member States should, "on the basis of common approval guidelines for the product" in coordination with approval bodies in other States issue "European technical approval" on the legal basis of this directive (Annex II, (3) (1) and (6)).

The multiplicity of regulatory proposals through which the Commission has sought to apply the new approach confirm the doubts of earlier commentators on the realizability in practice of the model directive,[181] but also corresponds to the pragmatically sybilline statements by

[175] April 1987; intensive preparation was done in particular on the Directive on the safety of machines, the potential scope of which seems to be so comprehensively set out that it could be seen as a supplement to the low-voltage Directive and at the same time as an appendix to the GSG (see references in *Dey, W.*, EG-Richtlinie über die Sicherheit von Maschinen, DIN-Mitt. 66 (1987), 233 et seq.). How the relationship here between legally binding safety objectives and legally non-binding standardization principles is to be arranged is not yet clear; it can be expected, though, that the working out of "basic safety objectives" will also have to be shifted more to the standardization organizations, the more comprehensive the scope of a machine directive is supposed to be - this is decidedly the view of *Dey, W.*, Status Europäischer Normen oder: Dürfen maßgebliche Sicherheitsanforderungen genormt werden?, DIN-Mitt. 66 (1987) 392-393, 392 et seq. The proposal since submitted for a directive on machines, OJ C 29, 3 February 1988, contains an extensive catalogue of basic safety requirements.

[176] Proposal for a Council directive harmonizing the legal and administrative provisions of Member States on construction products, OJ C 93, 6 April 1987, 1.

[177] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf; this stagnation is supposed to be overcome by reshaping it in accordance with the new approach.

[178] See the references in Commission document COM (86) 756 final of 8 January 1987, point 11, which explains the new draft.

[179] According to the list in Annex I.

[180] Op. cit. (fn. 178), point 10.

[181] See *Joerges, Ch.*, Die neue Konzeption zur technischen Harmonisierung und die Interessen der Verbraucher: Überlegungen zu den Notwendigkeiten und Schwierigkeiten einer Europäisierung der Produktsicherheitspolitik, EUI-Colloqium, DOC. IUE 159/86 (COL 72), Section III 1 b.

its leading supporters.[182] These were to the effect that when delimiting basic requirements, in need of harmonization, from the specifications of those requirements, not needing it, the ideas of the model directive could obviously not be taken over without review; instead, this delimitation would in each case have to be oriented according to the state of national and international standardization, the range and objects of provisions in force, the nature of the risks concerned and the likely product users.

It should be noted that these internal differentiations inevitably affect a further area already mentioned in the preparatory document to the new approach[183] and now specifically stressed in the proposal for a directive on construction products:[184] the abandonment of detailed design specifications in favour of "performance" standards. The distinction between "performance" and design is evidently intended not merely to paraphrase the difference between "safety objectives" and their "specifications", but at the same time to refer to a more general competition-policy dimension of the debates on the regulatory technique of product safety law. The preferability of performance standards is because as repeatedly asserted in the US, such provisions leave room for technical innovation and make it harder to turn the standard-setting process into a way of warding off competition.[185] The theoretically clear distinction between performance and design standards has come in the practice of standard setting repeatedly to lead to wellnigh unsolvable demarcation problems. It may, moreover, prove questionable from a safety policy viewpoint where and in so far as alternative design solutions are not conceivable.[186] Accordingly, the draft toy Directive, to the extent that it deals with chemical properties of toys, contains threshold values for particular substances and references to relevant prohibitions in Community law.[187] The explanatory statement on the proposal for a directive on simple pressure vessels points out, in connection with restrictions relating to materials, a further problem with performance standards:[188] the more the leeway open to the manufacturer is cut down, the more urgent and at the same time more difficult becomes the development of suitable certification procedures and mutual recognition of conformity certifications.

3.3. Proof of conformity, mutual recognition, certification[189]

The internal market and competition policy interests pursued through the retreat from approximation of laws to harmonization of basic requirements are met by the new approach through its opening up to manufacturers a range of ways of showing the safety conformity of their products patterned on the low-voltage Directive.[190] Section B VIII and V of the model directive of 7 May 1985[191] offers them the following alternatives:

- They can design their products according to European standards, or where such standards do not (yet) exist, national standards (section B V (1) (a) and (b)).

[182] See fn. 165 above.
[183] Op. cit. (fn. 122), 5.
[184] Op. cit. (fn. 176), Art. 5 (2).
[185] See Klayman, 1982, 104 et seq.
[186] Op. cit., 105 et seq.
[187] Op. cit. (fn. 169), Annex II (3).
[188] Op. cit. (fn. 167), 9.
[189] A general survey is given by *Volkmann, D.*, Aktivitäten in der EG auf dem Gebiet der Zertifizierung und Qualitssicherung, DIN-Mitt. 66 (1987), 419 et seq.
[190] See 2.2 above, text in fn. 84.
[191] Fn. 160.

- They are however also free to use designs not foreseen in the standards that still meet the mandatory safety objectives (section B V (3)).

Conformity is attested by

- certificates, marks of conformity or reports of results of tests by a "third party" (section B VIII (1) (a) and (b)),
- a declaration of conformity issued by the manufacturer, in which case there may be a requirement for a surveillance system (section B VIII (1) (c)).

Self-certification by manufacturers was also accepted in principle by the low-voltage Directive, though for products not conforming to standards the submission of an expert report was required.[192] The model directive correspondingly draws a distinction: "when the product is not in conformity with a standard", its safety conformity must be "declared by the means of an attestation delivered by an independent body" (section B V (3) (2)).

3.3.1. Recognition of national standards

Reference to national standards is explicitly termed a "transitional measure" in the model directive (Section B V (1) (b)). Nevertheless, this recognition of national standards is of fundamental importance. It corresponds to the assumption, contained in the Commission's White Paper[193] and repeated in the explanatory material on the new approach,[194] that the objects of national safety provisions mostly coincide and that one may therefore take the equivalence of differing mandatory provisions and voluntary standards as a basis. Where this confidence derives from, why the statements in the general programme on elimination of technical barriers to trade of 28 May 1969 that harmonization measures are indispensable[195] have since been superseded, is not entirely clear. The technical safety development in the electrical sector, which the regulatory technique of the low-voltage Directive could take as a basis,[196] has, after all, not happened in other sectors. This is amply confirmed by the difficulties in delimiting the "essential safety objectives" from mere "manufacturing specifications" in the Commission's new proposals for directives;[197] and the proposal on construction products, above all, shows that a basic pattern of "equivalent" safety objectives that merely have to be specified by standards is by no means achievable without further ado, still less presumable.

In its provisions on mutual recognition of national standards, then, the model directive is more cautious than the thesis of the equivalence of national safety provisions would imply. The model directive thus provides for a special procedure that must be gone through before national standards are recognized. National standards which in the view of Member States meet the safety objectives of Directives are to be communicated to the Commission, which forwards them to the other Member States and consults the Standing Committee before

[192] Art. 8 (2); cf. point 2.2 above, text in fn. 84. Similar provisions are found in "traditional" directives in so far as they contain deviation clauses; c.f. EG Art. 7 (2) and Art. 23 of the Directive of 17 September 1984 on lifting and conveying equipment, OJ L 300, 19 November 1984, and the pressure vessels Directive of 17 June 1976 (fn. 166); see also Art. 5 of the proposals for directives on toys of 1980 (fn. 171) and 1983 (fn. 172).

[193] Op. cit. (fn. 1), point 65.

[194] Op. cit. (fn. 160), 2 and in the relevant Commission communication (fn. 122), 6.

[195] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.2. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf, text in fn. 38.

[196] 2.1 above.

[197] 3.2 above.

allowing official publication.[198] Even though the description of the Committee's remit states that consultation is aimed more at providing "a framework ... for discussion of any reservations on the part of the Commission or a Member State" than at "carrying out a systematic check on the whole content of the standards", the model directive does basically take account of the perception that there can be an obligation on Member States to mutually recognize national standards only within a context of harmonization of the legal provisions underlying these standards.[199] There is certainly a reduction from the requirements of the first paragraph of Art. 100 EEC if the Commission is to have a right of ultimate decision on inclusion of national standards in the "standards catalogue" of Community law. But this power is compensated for by Member States' right of objection in administering the standards catalogue (and also by the fact that conformity to standards can always justify only a presumption of compliance with the safety objectives).[200]

3.3.2. Mutual recognition of conformity certificates and certification procedures

Uniformity of the safety level through European standards and the equivalence of national standards is a necessary but not yet a sufficient condition for the practicability of the new approach. Safety presumptions bound up with compliance with standards must be attested, and these attestations must be mutually recognized. This principle of the model directive can be accepted by Member States only where the equivalence of those attestations is guaranteed. This is especially true in connection with the model directive's reference in its deviation clause (Section B V (3) (2)) to the certification of safety conformity of products not conforming to standards by "independent bodies". In the case of such attestation, each Member State has to rely on the seriousness of foreign centres' safety testing.

The model directive largely ignores the thorny question of how equivalence of national safety certificates can be guaranteed. It merely lists a number of different means of attestation[201] (certificates and marks of conformity issued by a third party, results of tests by a third party, manufacturer's declarations of conformity and surveillance systems), but does not specify the requirements that these certification bodies have to meet.[202] It is only with the directives and proposals for directives submitted on the basis of the new approach that we come upon more precise regulatory proposals, meant as examples, on the certification issue.

The Directive on simple pressure vessels, following numerous predecessors,[203] distinguishes between design testing to verify the safety conformity of the manufacturer's designs (EC type-examination) and monitoring of the production process relating to actual compliance with the accepted designs (EC verification).[204] The Commission favours the setting up of quality guarantee systems under official control in factories themselves,

[198] Sections V 2, VI 2 of the Model Directive (fn. 160).

[199] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 1.1., text in fn. 11. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[200] C.f. sections VI(2), VII and VIII (3) of the Model Directive (fn. 160), and on the safeguard procedure, more details in 3.4 below.

[201] The Community approaches are based on the ISO/IEC guidelines issued in recent years; cf. Volkmann, 1987, 420.

[202] Op. cit. (fn. 160), section VIII.

[203] In particular following the pressure vessels Directive of 1976 (fn. 166); cf. also, among the directives adopted as a package in 1984, the Directive on lifting and conveying equipment (fn. 192).

[204] Op. cit. (fn. 166), Arts. 10-15.

through which manufacturers would assume primary responsibility for monitoring their production processes.[205] Arrangements of this type are provided for in the draft toy Directive. Here too a distinction is drawn between type examination (Articles 8 (2), 10) and surveillance of the manufacturing process, for which again the manufacturer himself is to be primarily responsible (Art. 8 (1)).

Both design checks (type examination) and surveillance of quality control systems are incumbent on national bodies. Accordingly, the new directives must seek to guarantee the equivalence of the administrative practice of these bodies. For this, they lay down requirements for the independence, technical competence and requisite equipment of those bodies.[206] The administrative sovereignty of Member States, however, remains unaffected, since they alone decide whether the bodies they have designated meet the Community requirements.[207]

The urgency and also the complexity of the certification and recognition issue emerges most clearly from the new proposal for a directive on construction products,[208] since in this sector the disparities between national provisions on building and engineering works are considerable and the absence of international and European standards is unlikely to change much in the foreseeable future. Even the recognition of national standards and of technical approval, pursuant to Art. 12 and Art. 7-10 of the proposal respectively, in reality call for Europeanization of those standards and approval decisions and can therefore be attainable only gradually as part of a continuous cooperation process.[209] This applies equally to conformity certificates, provided for in Art. 3 and 13. Significantly, Art. 13 and the related Annex IV (2) assume that the certification procedures will have to differ according to type of products and risks, and that the appropriate attestations will in each case have to be laid down in the standards and technical approvals (Art. 13 (4), (5)). Standardization and certification thus emerge as interdependent and indispensable elements in the new approach.

This summary of a perusal of the new directives or proposals for directives is in line with the outcome of Community endeavours hitherto to clarify the relationship between safety objectives and design specifications. Regulatory conceptions based on the new approach contain clear guidelines for future Community policy, but have at the same time to yield to needs for differentiation.[210] Ultimately it will be only the practical application of the new directives that will show how far Member States are really prepared to trust the test practice

[205] Cf., in the explanatory statement cited in fn. 167 above, point I (9) and Art. 12 of the Directive.

[206] Directive for simple pressure vessels (fn. 166), Annex III (and with the same wording, Annex III of the 1976 directive, fn. 166); proposal for a directive on toys (fn. 169) Annex III; cf. also ISO guideline 24-1978 (D) on the recognition of testing and monitoring marks by certification centres, printed in DIN-Mitt. 59 (1980), 613 et seq. and for more details on the situation regarding electrical appliances, 2.3.4 above.

[207] See Art. 9 (3) in both directives or proposals for directives (fn. 166 and 169).

[208] Fn. 176 above.

[209] Cf. 3.2 above, text in fn. 175 et seq. and the bilateral "special procedure" provided for in Art. 16 of the Directive.

[210] A separate regulatory technique was chosen in the Directive of 1 December 1986 on airborne noise emitted by household appliances (OJ L 344, 6 December 1986, 24). This Directive does not as the title would suggest deal directly with limiting noise emission. Instead, it seeks to guarantee the freedom of internal Community trade in cases where one Member State obliges manufacturers of household equipment to indicate its noise emissions (Art. 5). For these case the Directive prescribes a measuring procedure permitting tolerances of "at most 2dB" and also referring, to specify the procedure, to European standards and to national standards and regulations (Art. 6 and 8). The Community-law requirements on the test procedure and the provisions on verification of emission figures by a random sampling method (Art. 5 and 6) are intended to make checks by national centres on manufacturer self-certification superfluous.

of foreign centres, and whether they will be able to come to terms with the system of manufacturer self-certification favoured by the Community, which can only indirectly be controlled by national or independent bodies. The primary competence of Member States' administrations in interpreting safety objectives, implementing control measures and applying certification programmes can at any rate be exploited openly or indirectly to bring reservations against the new policy or objections to the practice of other Member States to bear.

3.4. Safeguard clause procedure and follow-up market controls

Even in directives adopted in accordance with the "traditional" harmonization policy, safeguard clauses have become usual. These cut into the primacy claim of European law by allowing Member States to appeal to their safety policy interests within the meaning of Art. 36 EEC and making possible commencement of a procedure aiming at amending the directives.[211] The model directive (Section VII), and following it all new directives and proposals for directives,[212] contain corresponding provisions.

Incorporation of safeguard clauses is in fact inescapable given the whole setup of the new approach. Since the new harmonization policy lays down only basic safety objectives bindingly, and is in principle here confined to "performance" standards, and since the specification of safety objectives by private standardization organizations is to imply only a presumption of safety conformity, and since the European standardization organizations can decide by qualified majority, and finally since nation states autonomously verify the Community requirements at their test centres, a large number of conflict situations is conceivable in which Member States might assert their safety policy interests against the outcome of the procedures introduced by the model directive. These possibilities are explicitly allowed them by the model directive. Member States may in particular, even where products have a certificate of conformity, prohibit their marketing, referring to the inadequacy either of autonomous conformity certification or even of European and national standards.[213] The solution of such conflicts is referred by the model directive initially to the Standing Committee, which has to take a position on objections to European or national standards. On the basis of the Committee's opinion, the Commission then has to decide. If it finds the objection justified and revokes recognition of a standard, a State finding itself disadvantaged by this may proceed in accordance with Art. 173 EEC. If instead the Commission finds the objection unjustified, the rejected State has the same possibility. Conversely, procedure according to Art. 169 EEC is open to the Commission where a Member State keeps to its measures contrary to the Commission's decision.[214]

However, the possibilities of safety-motivated action open to Member States not only concern the recognition of standards and conformity certificates, but could also directly affect the marketability of products. By section VII (2) of the Model Directive, the Commission shall, where it finds the action taken by a Member State justified, "point out to

[211] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.5. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf, and specifically on the low-voltage Directive 2.3.3 above.

[212] Art. 2 of the Directive on simple pressure vessels (fn. 166); Art. 7 of the proposal on toys (fn. 169); Art. 21 of the proposal on construction products (fn. 176).

[213] Section VI (1) of the Model Directive (fn. 160).

[214] Cf. *Weber, A.*, Schutznormen und Wirtschaftsintegration, Baden-Baden 1982., 321 et seq.

the other Member States that (all else being equal) they are also obliged to prevent the product in question from being placed on the market". No legal basis for this Community-wide applicability of a measure by a single Member State is contained in the Model Directive itself. Even if the Commission manages to assert its interpretation of the basic safety objectives, there is no means of action available to it whereby it could compel active intervention by the administrative bodies of Member States.

The new directives or proposals for directives respond differently to this regulatory lacuna in the Model Directive. The Directive for simple pressure vessels[215] contains provisions on review of the recognition of standards (Art. 6) and on information of the Commission on unilateral measures (Art. 7), but in no way guarantees their applicability Community-wide. The safeguard clause in the proposal for a directive on construction products[216] likewise deals only with the need to amend standards and approvals decisions, without making it clear how a justifiably adopted protective measure by one Member State can be made applicable Community-wide. By contrast the proposal for a toy directive[217] aims at Europeanizing follow-up market controls. Article 7 (1) obliges all Member States to take "all appropriate measures to withdraw" unsafe toys "from the market and prohibit their placing on the market" and to inform the Commission of such measures. This information is aimed not only at revision or supplementation of standards; the Commission is instead to verify the justifiability of national measures and inform other Member States, while according to the 1986 proposal it should if national measures prove justified remind other Member States of the need to take similar action (Art. 7 (4)).[218] The Directive on airborne noise emitted by household appliances[219] likewise "walks on two legs": Art. 9 regulates the procedure for reviewing European standards and national standards or technical regulations,[220] while Art. 7 obliges Member States to take steps to secure correction of faulty information from manufacturers.[221]

Visualizing the number of potential conflict situations that are supposed to be dealt with through the safeguard clause procedure, one is forced to the conclusion that this procedure has been overloaded, on the one hand through the twofold load of perfecting standards, approval criteria and certification procedures and on the other through having to cope with emergency decisions because of newly recognized dangers. This point and its consequences will be returned to.[222]

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[215] Op. cit. (fn. 166).

[216] Op. cit. (fn. 176), Art. 21.

[217] Op. cit. (fn. 169).

[218] The 1983 preliminary draft (fn. 171) was still clearer; Art. 10 obliges Member States to recall dangerous toys, though "subject to Community provisions, and failing them national ones". The 1983 preliminary draft (fn. 172) provided in Art. 9 for a general obligation for recalls on the authority. The EP has since, in its opinion on the Commission draft (OJ C 246, 14 September 1987, 85) called for "mitigation" of these control provisions, but the ESC (OJ C 232, 31 August 1987, 22) for their extension. The amended Commission proposal (COM (87) 467 final) now provides only for information to Member States.

[219] Op. cit. (fn. 210).

[220] On this differentiation see 5.3 below.

[221] The most detailed regulations on follow-up market control to date are contained in the proposal for a directive of 8 October 1986 on "products which, seeming to be other than they are, endanger the health or safety of consumers" (OJ C 272, 28 October 1986, Art. 3). In the Directive since adopted (OJ L 192, 11 July 1987, 49) these proposals are withdrawn; all that is still provided for is an "exchange of views" on national measures (Art. 4).

[222] Cf. *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 251, 3. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf and *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, Hanse Law Review 2010, 383, 3.4. Online available at:

3.5. Improving the position of European standards

All documents on the new harmonization policy treat reference to national standards as merely a transitional solution.[223] Coordination of future directives with corresponding work by the European standardization organizations is therefore a key feature of the new approach – or conversely, the new approach means a "rather fateful challenge" to European standardization.[224]

The Commission's efforts at intensifying European standardization work go back to 1980. Even then the Commission recognized that all efforts at approximation of laws and at application of Community law would not be enough to bring about the internal market unless the barriers to trade resulting from national standards were simultaneously brought down.[225] The ambitious goal of preparing European standards "without 'deviations'" (and "at the rate of several hundred a year"[226]) could admittedly not be achieved.[227] The most important positive outcome of this early initiative was instead the Directive of 28 March 1983 on an information procedure in the area of technical regulations and standards.[228]

The starting position for European standardization is clearly precarious. "Disorientation and remoteness from reality", as R. Winckler was warning as long ago as 1980,[229] characterize the situation of European standardization organizations. The reasons for this judgement are multifarious. Orientation of standardization work to the Community economic area does not *a priori* correspond to the interests of standardization organizations (nor of their supporters), which have always regarded international standardization under ISO and IEC as having priority.[230] The stagnation and shortcomings in implementation of traditional harmonization policy and legal establishment of standards to date are hardly likely to help

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http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf.

[223] Cf. only section V (1) of the Model Directive (fn. 160).

[224] *Anselmann, N.*, Die Rolle der europäischen Normung bei der Schaffung des europäischen Binnenmarktes, RIW 1986, 936 et seq., 993.

[225] Technical barriers to trade: A new Commission approach, EC Bull. 1-1980, 12, 15 et seq.

[226] Op. cit., 15.

[227] This is made clear by the following table on growth of the body of standards under CEN/CENELEC, ISO/IEC and DIN in the years from 1980 to 1986:

Year	*CEN/CENELEC*	*ISO/IEC*	*DIN*
1980	492	5,909	18,739
1981	537	6,273	19,430
1982	568	6,756	19,970
1983	625	7,210	20,299
1984	668	7,757	20,732
1985	747	8,275	20,566
1986	829	8,726	19,937

Source: DIN-Jahresbericht 1982/83, 2; DIN-Mitt. 65 (1986), 314; DIN-Geschäftsbericht 1986/87, before p. 1. The figures given for CEN/CENELEC also include CENELEC harmonization documents and Euro-standards for iron and steel.

[228] On this see 3.1 above.

[229] *Winckler, R.*, Harmonisierung technischer Regeln in Europa auf dem Gebiet der Konsumgütersicherheit und des Verbraucherschutzes aus der Sicht der Industrie, in: DIN-Normungskunde, Heft 15, Harmonisierung technischer Regeln in Europa, Berlin/Köln 1980, 85 et seq., 85; see also *Winckler, R.*, Normungs- und Harmonisierungsbestrebungen der Europäischen Gemeinschaft, in: DIN-Normungskundeheft 14, Technische Normung und Recht, Berlin/Köln 1978, 59 et seq., 59 et seq.

[230] Cf. *Reihlen, H.*, Europäische Normung - eine Bilanz und eine Vorschau, DIN-Mitt., 63 (1984), 4 et seq.

increase their attractiveness or involvement in European standardization work.[231] The new approach to technical harmonization and standards is now intended to create fundamentally improved cooperation conditions for both the Community and the standards organizations. Standards organizations gain additional importance from the reference technique itself and from the now essential coordination between policy on directives and standardization work, while the Commission expects the concentrating of harmonization policy on the laying down of essential safety objectives to unburden political decision-making processes in the Community. The "general guidelines on cooperation"[232] agreed by the Commission and the European standards organizations CEN/CENELEC on 13 November 1984 laid the foundations for future cooperation. Four elements in this document should be stressed:

- The Commission recognizes the "competence" of CEN/CENELEC for producing European standards; it will in principle support these organizations through orders for standards, and also support their work financially.
- CEN and CENELEC for their part guarantee that they will take account of the safety requirements specified in Community directives and in the Commission's orders for standards.
- Cooperation between the Commission and the standardization organizations starts from the preparatory stage of directives; the Commission will also bring the standardization organizations in for general issues of "common interest"; on the other hand, Commission representatives will take part in meetings of the technical boards and technical committees of the standardization organizations.
- CEN and CENELEC guarantee that "interested circles, in particular government authorities, industry, users, consumers and trade unions will if they wish be able to be genuinely involved in the development of European standards".

All these elements of cooperation call for further clarification. Thus, the safety policy importance of future standardization work depends essentially on the specific form of the "basic safety objectives" in the new directives – at the CEN annual meeting in 1985 the fear was already being expressed "that individual debates on the boundary between governmental stipulation and standardization are clearly unavoidable".[233] But particularly now that European standardization organizations are being assigned the substantive tasks that result from a reticent formulation of safety objectives, they must redefine the relationship to national and international standardization. The task will increasingly go to them of themselves taking over the functions of safety standardization hitherto handled by national and international standardization bodies. On the other side, there had been considerable reservations in the past at the idea of increasingly giving standardization tasks to European organizations.[234]

The "functional shift" in European standardization being aimed at is unlikely to ease arrival at consensus among national delegations at European level. Even in the past a voting procedure applied in CENELEC for members from the Community that was based on Art. 148 EEC, results of which were to be transposed into national standards within six

[231] See also the figures in *Reihlen, H*., Europäische Normung - eine Bilanz und eine Vorschau, DIN-Mitt., 63 (1984), 4 et seq.
[232] Reprinted in DIN-Mitt. 64 (1985), 78 et seq.
[233] See the report by *Mohr, C.*, CEN-Generalversammlung 1985, DIN-Mitt. 65 (1986), 47-48. and fn. 175 above.
[234] Cf. *Seidel, M*., Regeln der Technik und europäisches Gemeinschaftsrecht, NJW 1981, 1120 et seq., 1121; *Seidel, M.*, Grundsätzliche Regelungsprobleme bei der Verwirklichung des Gemeinsamen Marktes, in: Magiera, S. (Ed.), Entwicklungsperspektiven der Europäischen Gemeinschaft, Berlin 1985, 169 et seq.

months.[235] CEN likewise had a qualified majority rule, but here outvoted members were not obliged to adopt the European standard.[236] Following the agreement of 13 November 1984 between Commission and CEN/CENELEC, the voting rules of CENELEC were taken over in CEN and the incorporation of European standards into national ones was also guaranteed.[237] The now unified voting rules differ markedly from the unanimity rules of Art. 100 (1) EEC. On the other hand, economic conflicts of interest among Member States continue to exist,[238] and one shall in other respects have to wait and see how the voting rules in the standardization organizations will impinge on Member States' behaviour in the Council when adopting new directives and then in any recourse to the safeguard clause. Finally, it is hard to see how the participation rights for "interested circles" are to be structured and implemented.[239]

3.6. The decision-making powers of the Commission and the powers of the Standing Committee

The restructuring of legal harmonization policy not only leads to a "functional" involvement of private organizations in the Community's law-making process, but also affects the relationship between Member States, Council and Commission. The Council's role will according to the ideas of the model directive be confined to laying down the basic safety objectives. This means that Member States are no longer to be involved directly ("in legislative policy") in transposing the new directives. This limitation of their possibility of influence explains the setting up of a Standing Committee pursuant to Section IX of the Model Directive, identical with the one set up by the 1983 information Directive. Pursuant to Art. 6 of the information Directive, it is to be involved in discussion of standardization projects[240] and may be brought into the standstill procedure under Art. 8 (2) of that Directive; it is now also brought into managing the list of standards (Section VI (2)), is to be consulted in the safeguard clause procedure (Section VII (2)) and furthermore, "any question regarding the implementation of a Directive may be submitted to the Committee" (Section X (2)). But for all that, the Commission's legal prerogative remains clear. As regards the Committee's function in managing the list of standards, Section X of the Model Directive says in sybilline fashion that "the object of the consultation of the Committee ... is more to provide for a forum for the discussion of the objections ... than to carry out a systematic examination of the entire contents of the standards". Its formal powers are described unambiguously. The Committee cannot, by contrast with "management" and "regulatory" committees, compel the Council through its vote to reformulate its decision,

[235] Cf. *Mohr, C.*, Kurzinformation über Organisation, Arbeitsweise und Arbeitsergebnisse von CEN/CENELEC, in: DIN-Normungskunde, Heft 15, Harmonisierung technischer Regeln in Europa, Berlin/Köln 1980, 9 et seq.; *Schulz, K.-P.*, Aufbau und Arbeitsweise internationaler Normungsorganisationen, DIN-Mitt. 63 (1984), 365 et seq.

[236] For more details, see point 3.5 and 3.6.1 in the CEN rules of procedure (Part 1. Basic provisions, 2nd. ed. 1982).

[237] Cf. *Mohr, C.*, CEN-Generalversammlung 1985, DIN-Mitt. 65 (1986), 47-48. The new draft toy Directive (fn. 169) already assumes these changes.

[238] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 1.2.1. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[239] *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 251, 6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf.

[240] See also point 4 of the "general guidelines on cooperation" between Commission and CEN/CENELEC (fn. 232) and Art. 1 (2) of the proposal for amending the information Directive (fn. 144).

but is a mere consultative body, an "advisory committee" therefore, as the final conference on the Single European Act recommended, in the area of application of Art. 100a.[241] The comprehensive formal powers of the Commission are supposed to make the decision-making procedure effective. But having regard to the legal-policy explosiveness of the questions that might arise, particularly in the safeguard clause procedure, it is to be expected that the practical importance of the Standing Committee (and the sub-committees) will be greater than the legal status assigned to it suggests. And quite irrespective of how the actual decision-making process develops, the question still has to be asked whether the shape given to the Commission's formal powers can at all be maintained legally.[242]

4. The change in the legal framework conditions for European product safety policy brought about by the Single European Act

The Single European Act (SEA)[243] provides for some important changes to the framework conditions for a policy to bring about the internal market and guarantee product safety. Art. 8 a[244] contains the central objective of progressively establishing the internal market by 31 December 1992, and lists the additions to the Treaty that are to permit the accomplishment of the ambitious political programme contained in the White Paper on completing the internal market.[245] The supplementations of the Treaty relate essentially to harmonization measures, leaving the existing rules on free movement of goods before approximation of laws unaffected. The internal market, on the realization of which the new instruments are to

[241] EC Bulletin, supplement 2/86, 23; for more details see 4.3 below.

[242] Cf. 5.2 below.

[243] Signed on 17 February 1986 in Luxembourg and on 28 February 1986 in The Hague, published as supplement 2/86 to the EC Bulletin. An exhaustive survey on this can be found in EuR 21 (1986), 199 et seq.; *Ehlermann, C.-D.*, The International Market Following the Single European Act, CMLR 24 (1987), 361 et seq.; *Jaqué, J.-P.*, L'Acte unique européen, RTDE 22 (1986), 575 et seq. and *Lodge, J.*, The Single European Act: Towards a New Euro-Dynamism?, JCMSt 24 (1986), 203 et seq., and sharp criticism in *Pescatore, P.*, Die Einheitliche Europäische Akte. Eine ernste Gefahr für den Gemeinsamen Markt, EuR 21 (1986), 153 et seq. See also *Arnull, A.*, The Single European Act, ELR 11 (1986), 358 et seq.; *Ehlermann, C.-D.*, Die einheitliche Europäische Akte: Die Reform der Organe, Integration 9 (1986), 101 et seq.*; European Consumer Law Group*, Consumer Protection After Ratification of the Single Act, JCP 10 (1987), 319 et seq.; *Gulmann, C.*, The Single European Act - Some Remarks from a Danish Perspective, CMLR 24 (1987), 31 et seq.; *Hrebek, R./Läufer*, Th., Die Einheitliche Europäische Akte. Das Luxemburger Reformpaket: eine neue Etappe im Integrationsprozeß, Europa-Archiv 1986, 173 et seq.; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 173-180; *Sedemund, J./Montag, F.*, Europäiches Gemeinschaftsrecht, NJW 1987, 546 et seq,, 546 et seq.; *Zuleeg, M.*, Vorbehaltene Kompetenzen der Mitgliedstaaten der Europäischen Gemeinschaft auf dem Gebiet des Umweltschutzes, NVwZ 1987, 280 et seq. Specifically on the connection between the SEA and free movement of goods or achievement of the internal market, see *Forwood, N./Clough*, M., The Single European Act and Free Movement. Legal Implications of the Provisions for the Completion of the Internal Market, ELR 11 (1986), 383 et seq.; *Hirsch, V.*, Marché intérieur: une nouvelle grace à l'acte unique, RMC 1987, 1 f.; *Meier, G.*, Einheitliche Europäische Akte und freier EG-Warenverkehr, NJW 1987, 537 et seq.; *Rögge, K.*, Binnenmarktrealisierung 1982 auf der Grundlage der Einheitlichen Europäischen Akte, WRP 1986, 459 et seq.; *Scharrer, H.E.*, Die Einheitliche Europäische Akte: Der Binnenmarkt, Integration 9 (1986), 108 et seq.; *Seidel, M.*, Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986. On the background to and the emergence of the SEA see *de Zwaan, J.W.*, The Single European Act: Conclusion of a Unique Document, CMLR 23 (1986), 747 et seq,; see also the exhaustive reports in EC Bull. 11-1985, 7-22 and EC Bull. 12-1985, 7-16.

[244] Below the amendments or supplementations to the EEC Treaty proposed by the SEA are indicated as articles with no indication of law or treaty.

[245] COM (85) 310 final of 14 June 1985.

be employed, is defined as an "area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty" (Art. 8 a, second sentence). It is the core of the more comprehensively treated measures to set up and operate the Common Market (cf. Articles 2, 3, 100, 235 EEC).

4.1. Article 100 a – majority principle and reservations by Member States

Departing from the unanimity principle of Art. 100 EEC for adopting directives, Art. 100 a (1) provides that the Council should adopt measures for the approximation of the legal and administrative provisions of Member States, having as their object the establishment and functioning of the internal market, by qualified majority.[246] Apart from this facilitated decision-making, there are also provisions on taxes, freedom of movement and the rights and interests of employed persons (Art. 100 a (2)), areas where to date fundamental political agreement has been lacking.

It is questionable whether legal harmonization measures to bring about the internal market will continue in future to be possible in accordance with Art. 100 EEC. The majority principle is aimed at facilitating arrival at political consensus; a single Member State is no longer to have the possibility of vanifying or delaying the further building of the internal market by a veto. It is therefore to be presumed that measures of legal approximation for the creation and operation of the internal market should in future no longer be possible under Art. 100 EEC, which requires unanimous decision.[247] In the interest of accelerated realization of the internal market, it is specifically the veto position allowed individual Member States by the unanimity principle that is to be overcome. The derogation and safeguard clauses of Art. 100 a (4) and (5) constitute only a very restricted form of compensation for the veto right of Member States resulting from the unanimity principle. The individual Member State cannot prevent a Community regulation which in any case will have the effect of abolishing some of its powers. The derogation clause in Art. 100 a (4) provides no protection against failure of a measure adopted by the Community legislator to meet regulatory policy concepts of an outvoted Member State, or against a mesure which in one Member State's view brings in excessive protection of the objects legally protected by Art. 36 EEC, thus disproportionately restricting the freedom of economic activity.[248]

By the procedure of Art. 100 a, regulations too may be adopted. Since regulations limit Member States' room for manoeuvre even more than directives, the Commission has made a declaration in the Final Act that it will give precedence to the instrument of the directive in its proposals pursuant to Art. 100 a, where the harmonization will in one or more Member States involve the amendment of legal provisions.

Restrictions on use, such as restrictions on distribution, speed limits or conditions for utilization, indirectly interfere with border-crossing trade if they differ from one Member State to another. A ticklish question of demarcation arises, namely whether a Community regulation of restriction on use is to be counted as part of realization of freedom of

[246] This means the overcoming of the 1966 Luxembourg compromise, which could in any case only be located outside the EEC Treaty, which allowed a Member State to prevent a Council decision by appealing to vital interests.

[247] Cf. *Ehlermann, C.-D.*, The International Market Following the Single European Act, CMLR 24 (1987), 361 et seq., 382. Many proposals for directives mentioning Art. 100 EEC as a legal basis are being converted to Art. 100a.

[248] *Seidel, M.*, Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 63 et seq.

movement of goods and can therefore in accordance with Art. 100a be made. Seidel denies this, on convincing grounds.[249] In measures on approximation of laws so as to remove technical barriers to trade such arrangements have to date been included only where at least one Member State has met the regulatory object by design requirements, thus raising a technical barrier to trade. He further points out that restrictions on use have not been classified by the ECJ as measures having equivalent effect to quantitative restrictions within the meaning of Art. 30 EEC.[250] Accordingly, harmonization of restriction on use could be brought about only from the viewpoint of harmonizing competition conditions, and therefore not according to the procedure of Art. 100 a. The danger that restrictions on use may be used as an indirect instrument for market restriction, though not the walling off of markets, cannot be entirely ruled out.

Since completion of the internal market cannot be brought about through directives that merely lay down minimal standards and allow Member States to make further-reaching requirements,[251] but undercutting of higher protected levels reached in individual Member States is politically undesirable, Art. 100 a (3) provides that the Commission shall, in its proposals for law approximation measures in the areas of health, safety, environmental protection and consumer protection, take as a base a high level of protection. The Commission's proposals and the resulting Council decisions thus need not necessarily meet the highest existing level of protection in one of the Member States. The compromise lies in "setting the level of protection in such a way that the burden on Member States that so far had a low level of protection remains acceptable and on the other hand the reduction of a high level of protection in one Member State does not lead to political problems".[252] An additional procedural guarantee against removal of a high level of protection is that the Council can by Art. 149 (1) EEC decide amendments to the Commission proposal only unanimously, so that each Member State has a veto on going below a high standard proposed by the Commission. What is wanted, then, is the levelling of protective standards at a high but not necessarily the highest level.[253]

It should be borne in mind in this connection that the Commission has by Art. 8 (c) to take account in its proposals for realizing the internal market of the extent of the effort that certain economies showing differences in development will have to sustain during the period of establishment of the internal market. The objective of attaining as high a level of protection as possible is thus limited by the political objective of promoting harmonious development of the Community as a whole, to strengthen its economic and social cohesion (cf. also Art. 130 a and 130 b).

[249] Seidel, M., Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 61. See also *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987., para. 176 on the economic interests of consumers.

[250] Cf. ECJ judgment of 31 March 1982, ECR [1982] 1211 (1229)/Blesgen; judgment of 14 July 1981, ECR [1981, 1993] 2009 - ban on night baking. See also *Skordas, A.*, Umweltschutz und freier Warenverkehr im EWG-Vertrag und GATT, Steinbach 1986, 23-28.

[251] By contrast Member States are explicitly allowed in the area of environment protection and in order to promote the safety and health of workers to retain or adopt stronger protective measures (Art. 130 t and 118 a (3)); Art. 118 a (2) explicitly mentions minimum provisions.

[252] *Glaesner, H.J.*, Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq., 131. See also *Rögge, K.*, Binnenmarktrealisierung 1982 auf der Grundlage der Einheitlichen Europäischen Akte, WRP 1986, 459 et seq., 461.

[253] One may well doubt whether a more or less laboriously reached common protective level may still make it possible to adapt to technical progress or to advancing awareness of safety, the environment or health.

Doubts admittedly remain as to whether differing conceptions of safety in areas where safety levels cannot be expressed by numerical threshold values can be brought under a simple linear ranking. Here harmonization of basic technical safety standards at European level could be of assistance. In June 1985, a month after the Council decision on a new approach to technical harmonization and standards, CEN set up a new technical committee (CEN/TC 114) with the task of creating, as with the German standard DIN 31000/VDE 1000, a common safety concept and uniform technical safety provisions for all appliances, machines and installations.[254]

Art. 8 c allows exceptional arrangements in favour of less developed economies. They must be of a temporary nature and must cause the least possible disturbance to the functioning of the common market. This introduces the ground rules for a "multi-speed Europe" or for "graded integration"[255] into the Treaty system.

According to Art. 100 a (5), harmonization measures adopted may be combined with a safeguard clause authorizing Member States to take, for one or more of the non-economic reasons referred to in Art. 36 EEC, provisional measures subject to a Community control procedure. Safeguard clauses of this nature were already usual.[256]

By contrast, Art. 100 a (4) means a considerable innovation. If a directive has been adopted by qualified majority,[257] a Member State can by appealing to major needs within the meaning of Art. 36 EEC or relating to protection of the environment or of the working environment, unilaterally apply different national provisions. This right of "opting out" is open to all Member States, not only outvoted ones.[258] The view that assent by a Member State necessarily means abstaining from national special regulations pursuant to Art. 100 a (4)[259] is not supported by the tenor of that provision, and creates a risk that Member States may endanger a decision by qualified majority because they abstain as a precautionary measure, in order to retain their possibilities of action pursuant to Art. 100 a (4). Art. 100 a (4) and (5) should be considered in the light of German desires for vehicles with clean exhausts and "are to guarantee that insistence on legal approximation once attained does not prevent the further development of environmental or health protection".[260]

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[254] Cf. Jahresbericht 1985 der Bundesanstalt für Arbeitsschutz 1985, 22. See also *Budde, E.*, Vorschlag für eine EG-Richtlinie über die Sicherheit von Maschinen, DIN-Mitt. 66 (1987), 390-391.; *Dey, W.*, EG-Richtlinie über die Sicherheit von Maschinen, DIN-Mitt. 66 (1987), 233 et seq.

[255] Cf. on this concept *Scharrer, H.E.*, Abgestufte Integration - Eine Alternative zum herkömmlichen Integrationskonzept?, Integration 4 (1981), 123 et seq.; *idem*, 1984; *Langeheine, B.*, Rechtliche und institutionelle Probleme einer abgestuften Integration in der Europäischen Gemeinschaft, in: Grabitz, E. (Ed.), Abgestufte Integration. Eine Alternative zum herkömmlichen Integrationskonzept?, Kehl/Straßburg 1984, 47 et seq.; *Ehlermann, C.-D.*, How Flexible is Community Law? An Usual Approach to the Concept of Two Speeds, Michigan L. Rev. 82 (1984), 1274 et seq.; *Eiden, Ch.*, Abgestufte Integration in der EG. Risiken für Rechtsangleichung und Gemeinsamen Markt, Europa-Archiv 1984, 365 et seq.

[256] Cf. *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.5. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[257] Only *Gulmann, C.*, The Single European Act - Some Remarks from a Danish Perspective, CMLR 24 (1987), 31 et seq, 37 et seq. regards appeal to Art. 100a (4) as possible even in the case of unanimous decisions; Ehlermann, C.-D., The International Market Following the Single European Act, CMLR 24 (1987), 361 et seq., 391 is convincing in the opposite direction.

[258] So also *Ehlermann, C.-D.*, Die einheitliche Europäische Akte: Die Reform der Organe, Integration 9 (1986), 101 et seq., 104. But by contrast *Ehlermann, C.-D.*, The International Market Following the Single European Act, CMLR 24 (1987), 361 et seq, 394 et seq.

[259] *Meier, G.*, Einheitliche Europäische Akte und freier EG-Warenverkehr, NJW 1987, 537 et seq, 540.

[260] *Steindorff, E.*, Gemeinsamer Markt als Binnenmarkt, ZHR 50 (1986), 687 et seq., 702.

The derogation clause of Art. 100 a (4) also applies in cases where a directive adopted by qualified majority contains a safeguard clause within the meaning of Art. 100 a (5).[261] These safeguard clauses usually allow only temporary departure from the harmonized law in order to respond to a newly apparent hazardous situation, and are aimed at allowing appropriate adaptation, in order to restore the harmonization already reached. Art. 100 a (4) is not confined only to temporary measures and narrowly limited hazardous situations and should, unlike the safeguard clause in Art. 100 a (5), on certain conditions allow a Member State to make a lastingly deviant regulation. However, a Member State's recourse to autonomous national exceptional regulations might prove improper within the meaning of Art. 100 a (4), third sentence, if a safety interest could also be adequately taken into account through the safeguard clause procedure of Art. 100 a (5).[262]

It can be expected that Member States' powers deriving from Art. 100 (4) will be restricted by the principle of proportionality developed in the case law. This is that a measure taken must be suitable for securing the object of protection adduced, and be necessary without being disproportionate, that is, it must be the measure that least hampers free movement of goods.[263] To limit the danger of the Common Market being split by measures by individual Member States under Art. 100 a (4), the Commission has to ensure that national measures that continue to apply one-sidedly do not constitute a means of arbitrary discrimination or a disguised restriction on trade among Member States. These two criteria are derived from Art. 36 EEC, second sentence. The ECJ has, in delimiting Member States' rights of reservation vis-å-vis free movement of goods, undertaken comprehensive verification of proportionality, referring not only to the ban on arbitrary discrimination and disguised restrictions on trade. If it takes the same line in the case of the safeguard clause of Art. 100 a (4), the Commission should acquire further-reaching powers of verification and prohibition than would appear from the wording of Art. 100 a (4), second sentence.[264] In order to permit rapid judicial control where necessary, the Commission and the other Member States are exempted from the procedures laid down in Articles 169 and 170 EEC when they wish to impugn unilateral action by a Member State under Art. 100 a (4). This indicates that a determination by the Commission that a Member State's provision is in conformity with Community law or not does not constitute law-making.[265] If refusal of confirmation constituted law-making, the deviant Member State could bring an action for

[261] Another opinion is held by *Glaesner, H.J.,* Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq., 134.

[262] Cf. *Meier, G.,* Einheitliche Europäische Akte und freier EG-Warenverkehr, NJW 1987, 537 et seq., 540.

[263] In detail see the account in 1.2.2 above. See also *Glaesner, H.J.,* Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq 135; *Seidel, M*., Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 66 et seq.; *Rögge, K*., Binnenmarktrealisierung 1982 auf der Grundlage der Einheitlichen Europäischen Akte, WRP 1986, 459 et seq., 461.

[264] Cf *Seidel, M*., Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 67.

[265] For details on this see *Seidel, M.,* Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 64-66. By contrast *Meier, G*., Einheitliche Europäische Akte und freier EG-Warenverkehr, NJW 1987, 537 et seq., 540, with his unconvincing reference to the confirmation provisions of Art. 93 (3) EEC, which are not taken over into Art. 100a (4). This reference is also found in *Forwood, N./Clough, M*., The Single European Act and Free Movement. Legal Implications of the Provisions for the Completion of the Internal Market, ELR 11 (1986), 383 et seq., 403.

avoidance pursuant to Art. 173 EEC,[266] and no regulation on simplified appeal to the Court by the Commission or another Member State would have been required.
Over and above the objects of protection of Art. 36 EEC, a Member State may appeal to protection of the working environment or of the environment, but not to other binding requirements developed in the Cassis de Dijon case law as implicit reservation of Art. 30 EEC. It has no legal significance that the case law on the implicit reservation of Art. 30 EEC speaks of "mandatory" requirements whereas Art. 100 a (4) only mentions "major" ones. Both measures under the implicit reservation of Art. 30 EEC and steps justified by Art. 36 EEC must, like departures justified by Art. 100 a (4), meet the criteria of the proportionality principle, which has been handled strictly by the ECJ. The accompanying comparative table shows what departures Art. 100 a (4) brings in by comparison with the implicit reservation of Art. 30 EEC and Art. 36 EEC.

Comparative Table of the implicit reservation of Art. 30 EEC, Art. 36 EEC and Art. 100 a (4) of the Single European Act

<table>
<tr><th>Points of comparison</th><th>Implicit reservation of Art. 30</th><th colspan="2">Art. 36</th><th>Art. 100a (4)</th></tr>
<tr><td>Scope</td><td colspan="2">where no Community regulation exists</td><td colspan="2">where a directive has been decided by qualified majority</td></tr>
<tr><td>Justified measures</td><td>only measures applicable without differentiation to imported goods</td><td colspan="3">even measures applicable not without differentiation between domestic and imported goods</td></tr>
<tr><td rowspan="2">Object of protection</td><td rowspan="2">mandatory requirements, in particular for effective fiscal control, protection of public health, the integrity of trade and consumer protection, but also other objects of protection (e.g. industrial safety, environment protection) - not an exhaustive catalogue</td><td colspan="3">grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value or the protection of industrial and commercial property</td></tr>
<tr><td>exhaustive catalogue</td><td>with additional reference to protection of the working environment and of the environment - exhaustive catalogue</td></tr>
<tr><td>Proportionality principle</td><td colspan="4">The regulation must be suitable to secure the mandatory requirements or the objects of protection adduced and be necessary without being disproportionate (the means that least hampers free movement of</td></tr>
</table>

[266] But this is said by *Glaesner, H.J.,* Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq. 135.

	goods); no means of arbitrary discrimination or of disguised restriction on trade between Member States		
Legal conclusion	not a measure having equivalent effect	measure having equivalent effect is justified	
Communication to the Commission	not required	not required	Required
Judicial control	The Commission and other Member States may resort to the ECJ only once they have first presented the Member State concerned with a reasoned opinion and given it a chance to react; Preliminary ruling procedure		Commission or other Member States may resort directly to the ECJ; Preliminary ruling procedure

It is hard to answer the question whether Art. 100 a (4) allows only appeal to already existing national provisions, ruling out the possibility of adopting new and further-reaching national requirements in an already harmonized area, contrary to the doctrine of the blocking effect.[267] In favour one may adduce the fact that Art. 100 a (4), first sentence, allows only the application of national provisions, but for the area of industrial safety and environment protection the comparable Art. 118 a (3) and 130 t explicitly allow further-reaching measures to be "maintained or introduced". There are, though, grounds for doubting this position too: the doctrine of the blocking effect derives its legitimation largely from the fact that all Member States have agreed to a particular measure; it is just this full consensus that is lacking here. With a restriction to the application of already existing measures, a Member State with no relevant national provisions would be unilaterally disadvantaged.

For many types of cases there could be a pragmatic compromise by focusing on the date when the time-limit for transposing a particular harmonization directive expires, not the date when a harmonization directive was decided by majority. As long as the transposition period has not expired, Member States would be allowed to regulate a matter freely.[268] This would give a Member State the possibility of deciding on a further-reaching national measure during the time-limit for transposition and continuing to apply it after expiry of that period following the procedure provided for in Art. 100 a (4).

This still leaves unanswered the general question, not specific to Art. 100 a (4), whether and under what conditions unilateral action by a Member State remains permissible when new risks come to light following harmonization.[269] In just those areas where the Community has replaced Member States' powers by its activities, the Commission is obliged not only to set up and properly operate the Common Market, but also to protect

[267] Explicitly stated by *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 176; see also *Ehlermann, C.-D.*, Die einheitliche Europäische Akte: Die Reform der Organe, Integration 9 (1986), 101 et seq., 104. BEUC, Actualités No. 51 (2/1986), 9 criticizes these restrictions. For the admissibility of introducing tighter national legislation once the Council has adopted the harmonization measure.

[268] See case 148/78, judgment of 5 April 1979, ECR [1979] 1629 (1645)/Ratti.

[269] On this see *Skordas, A.*, Umweltschutz und freier Warenverkehr im EWG-Vertrag und GATT, Steinbach 1986, 152-177.

such objects of legal protection as those listed in Art. 36 EEC. If it has not responded to newly emerging hazardous situations not yet covered by harmonization measures, there is *ipso facto* no Community regulation, and Member States are, if the Community does not act, not prevented from taking protective measures themselves in response to the new risk. If the case is one of intensification of a hazardous situation already covered by Community law, Member States must aim at raising the Community level of protection.[270]
A manageable distinction is required between harmonization measures under Art. 100 a to complete the internal market on the one hand, and environment protection and industrial safety arrangements on the other, since Art. 118 a and 130 t allow Member States to introduce or maintain higher protection even in a harmonized area without further substantive or procedural restrictions,[271] whereas Art. 100 a (4) makes appeal to industrial safety or environment protection dependent on the conditions described. The relevant point is the primary object of the measure.[272] If it is concerned primarily with creating the internal market, that is, with the free movement of goods, persons, services and capital in the various Member States with as little restriction as possible from different standards, then appeal to increased industrial safety or environment protection is possible only under the restrictive conditions of Art. 100 a (4). If instead a measure has to do primarily with the working environment within the meaning of Art. 118 a or with environmental protection within the meaning of Art. 130 r, that is, so to speak, with raising the "quality of life" in the Community, then Member States are not subject to any further restrictions if they wish to bring in higher levels of protection of industrial safety or of the environment.
The simplified decision-making by qualified majority in the Council may, because of the possibility of more than temporary derogation pursuant to Art. 100 a (4) not only by outvoted Member States and irrespective of an acute hazardous situation, ultimately have a disintegrative effect. The Commission and Council will therefore have to consider whether they wish to push forward decisions by qualified majority and put up with the uncertainty, deriving particularly from Art. 100 a (4), for harmonization already attained, or else strive as previously for unanimity, providing safeguard clauses specific to each directive.[273]

4.2. Art. 100 b – mutual recognition

The internal market is to be set up by 31 December 1992. As regards the legal effect of this date, the conference made the following declaration in the Final Act:

[270] On this issue, in connection with vehicle catalysers and lead-free petrol, see *Steindorff, E.*, Umweltschutz in Gemeinschaftshand?, RIW 1984, 767 et seq. and *Ress, G.*, Luftreinhaltung als Problem des Verhältnisses zwischen europäischem Gemeinschaftsrecht und nationalem Recht. Überlegungen zu einem Alleingang der Bundesrepublik Deutschland bei der Einführung des Katalysatorautos und des bleifreien Benzins, FS Hundertfünfzig Jahre Landgericht Saarbrücken, Köln 1985, 355 et seq.
[271] See the statements by *Zuleeg, M.,* Vorbehaltene Kompetenzen der Mitgliedstaaten der Europäischen Gemeinschaft auf dem Gebiet des Umweltschutzes, NVwZ 1987, 280 et seq., 283-286 on the principle of best possible protection of the environment, applied by him.
[272] See *Reich, N*., Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 176. On the practical significance of this allocation see the instructive example in *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 180.
[273] See *Reich, N*., Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 174; *Seidel, M*., Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 71.

> *The Conference wishes by means of the provisions in Article 8a to express its firm political will to take before 1 January 1993 the decisions necessary to complete the internal market defined in those provisions, and more particularly the decisions necessary to implement the Commission's programme described in the White Paper on the Internal Market.*
>
> *Setting the date of 31 December 1992 does not create an automatic legal effect.*

This declaration should be understood as a response by the conference to the Commission's original proposal whereby after 1 January 1993 every Member State will automatically be obliged to recognize the equivalence of non-harmonized provisions of other Member States in respect of persons, goods, services and capital.[274] Now Art. 100 b empowers the Council to decide by qualified majority before the end of 1992 that non-harmonized provisions relating to the function of the internal market are to be recognized as equivalent in all Member States. But Art. 100 a (4) should also apply here as appropriate. At the moment one cannot really say how successful the efforts at legal harmonization by 1992 will really be by comparison with the White Paper's ambitious programme.[275]

It is questionable whether Member States that have not managed to arrive at approximating their laws will be able to decide on the step of bringing about the internal market by mutual recognition of legislation. After all, this would mean leaving aside all the substantive criteria, such as taking a high level of protection as a basis (Art. 100 a (3)), and taking differing levels of development of individual economies into account (Art. 8 (c))[276], quite irrespective of the fact that here too unilateral rejection of mutual recognition is possible by Art. 100 a (4). Finally, it remains unclear whether only provisions adopted by the Commission in the course of 1992 can be the object of Council decision on mutual recognition, which would then more or less be a substantively precisely defined, enumerative mutual recognition, or whether the principle of mutual recognition can additionally be established generally and *a priori*, even for provisions in non-harmonized areas decided only later, that is, where there is no Community law to exert a blocking effect.

In view of these problems and unclarities, the question arises whether Art. 30 ff. EEC may not be enough in the future too in non-harmonized areas. They too lead, where Member States cannot exceptionally appeal to the objects of protection of Art. 36 EEC or to mandatory requirements within the meaning of the Cassis de Dijon case law, to mutual recognition as the outcome in practice. Mutual recognition that would seek to go beyond this automatically affects legitimate interests of Member States in protection, without there being a substantive consensus, since otherwise there could have been an approximation of laws.

[274] But see the declaration on Art. 100 b in the Final Act, whereby Art. 8 c applies also to proposals submitted by the Commission pursuant to Art. 100 b.

[275] Skepticism would seem appropriate. On the delay already accumulated by comparison with the ambitious programme, see the Commission's first report to the Council and the European Parliament on implementation of the Commission White Paper on completing the internal market, COM (86) 300 final of 26 May 1986 and the answer to written question No. 2758/85, OJ C 202, 11 August 1986, 3-6, according to which, of the 59 proposals in the annex to the White Paper that the Council should have adopted in 1985, only 16 were adopted in time.

[276] But see the declaration on Art. 100 b in the Final Act, according to which Art. 8 c also applies to proposals to be submitted by the Commission pursuant to Art. 100 b.

4.3. Conferment of implementing powers on the Commission

Finally, the Single European Act provides for a supplement to Art. 145 EEC.[277] According to this the Council has, apart from certain exceptional cases not mentioned in detail, to confer upon the Commission powers to implement regulations adopted. By decision of 13 July 1987, the Council laid down the procedures for the exercise of implementing powers conferred on the Commission,[278] thereby limiting the number of different committee procedures to which the Council may in future resort in conferring implementing powers, with the existing structure of some 300 committees remaining unaffected (see Art. 4 of the decision). In its proposal[279] the Commission had, referring back to practice to date,[280] provided for three different types of committees of national experts, namely "advisory committees" as purely consultative bodies, "management committees", so far brought in particularly in the area of agricultural regulations for products coming under a common organization of the market, and "regulatory committees", till then used mainly in the area of adapting directives to technical progress. The European Parliament, in its endeavours to strengthen the Community's executive powers while concomitantly expanding Parliament's control powers, recommended only the procedures of the Advisory Committee (preferred in the context of Art. 100 a) and the Management Committee).[281] The Council decision, now heavily attacked by the European Parliament,[282] provides for no less than seven different Committee procedures. The details of the four basic procedures and their variants are contained in the following table.

Procedures for exercise of implementing powers conferred on the Commission

Type of Committee	***Procedure I "Advisory Committee"***	***Procedure II "Management Committee"***	***Procedure III "Regulatory Committee"***	***"Safeguard Clause Committee"***
Committee	Advise	Majority decision pursuant to Art. 148 (2) EEC	Majority decision pursuant to Art. 148 (2) EEC	Advise
Commission	what may depart from it without further consequences; informs the	in the case of *agreement* with the Committee, the measure applies directly	in the event of agreement with the Committee the measure intended enters	may without further consequences depart from the Commission's

[277] Art. 10 SEA. See on this *Bruha, Th./Münch*, W. Stärkung der Durchführungsbefugnisse der Kommission. Anmerkungen zu Art. 10 der Einheitlichen Europäischen Akte, NJW 1987, 542 et seq. and *Glaesner, H.J.*, Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq., 145 et seq.

[278] OJ L 197, 18 July 1987, 33.

[279] OJ C 70, 25 March 1986, 6 et seq.

[280] On the various committees see Commission, list of committees of Council and Commission, EC Bulletin, supplement 2/80; *Schmitt von Sydow, H.*, Organe der erweiterten Europäischen Gemeinschaften - Die Kommisssion, Baden-Baden 1980, 131-185; Die Beratenden Ausschüsse, 1979; *idem*, 1983, Art. 155, para. 48-54. In the Community budget for financial 1987, 244 committees of the Commission were listed, OJ L 86, 30 March 1987, 372-380. The expenditure on their work has approximately quintupled in the course of ten years.

[281] OJ C 297, 24 November 1986, 54 et seq.

[282] EP resolution of 8 July 1987, OJ C 246, 14 September 1987, 42 et seq. and EP complaint against the Council submitted on 2 October 1987, case 302/87, OJ C 321, 1 December 1987, 4.

	Committee of the measure taken	in the event of *disagreement* with the Committee the Council is immediately notified other measure adopted and its implementation is postponed for a particular period	into force in the event of *disagreement* with the Committee or where its opinion has not been given the Commission submits proposal to the Council for the measure to be adopted	opinion; informs the Council and Member States of every decision on protective measure; prior consultation by Member States may be provided for *any Member State* may bring the Commission's decision before the Council
Council	no powers	may take another decision by qualified majority var. a) 1 month var. b) within 3 months (period to be laid down in each act to be approved by the Council), otherwise the Commission's postponed measure applies	within a period of the most 3 months (period to be laid down in every legal act to be adopted by the Council) var. a) can decide by qualified majority var. b) can decide by qualified majority, or rejects the proposed measure by simple majority, otherwise the Commission adopts the proposed measures	may decide by qualified majority within a time limit to be laid down in the legal act concerned var. a) to take a different decision var. b) to confirm, amend or the Commission's decision; the Commission's decision shall be taken as where the Council takes no decision

The main novelty is the "safeguard clause committee procedure", which most strongly restricts the Commission's powers. It has to inform the Council and Member States of any decision on protective measures; prior consultation of Member States may be provided for. Irrespective of whether the Commission agrees with a committee, which in the overall

context is not explicitly mentioned but is usually set up in the case of safeguard clause procedures, or not, each Member State can bring the Commission's decision before the Council within a set period. The Council may within a set period and by qualified majority take a different decision (variant a) or (variant b) confirm, amend or abrogate the Commission's decision, with the Commission's decision been taken as abrogated where the Council has not taken a decision within a set period. In the latter case, and with variant (b) in the regulatory committee procedure, a block on the application of Community law is possible where the Council cannot arrive at a majority for a decision.
The Conference had called on the Council in the Final Act of the SEA to give preference to the "advisory committee" procedure as regards the Commission's powers of implementation in order to bring about the internal market, with a view to the rapidity and effectiveness of the decision-making process; this would have considerably increased the weight of the Commission vis-à-vis the Council and thus vis-à-vis the Member States. The Council decision of 13 July 1987 makes no mention of preference for using advisory committees.
In the procedure of management and regulatory committees, the Council was hitherto able to take the delegated power on itself again in the event of unresolvable disagreement of the Commission with the Committee, i.e. with the majority of Member States' government representatives. These powers of recourse for the Council have so far been of theoretical nature. The real influence on the Commission takes the shape of prior pressure to adapt and of a more or less diffuse basic consensus of national experts and the relevant Commission officials among themselves. This explains why the committees, which have in some cases been operating for many years now, have only rarely rejected Commission proposals, fairly rarely abstained from an opinion and often even voted unanimously.[283] This "filter of expert consensus" is not provided for in the case of the safeguard clause procedure, which is in the main highly controversial politically or at any rate very sensitive for the protection policies of Member States concerned.

5. Compatibility of the new harmonization policy with the EEC Treaty

In legally evaluating the new approach, two group of questions should be distinguished: those of its compatibility with the EEC Treaty, and the legal problems with implementing the individual new directives patterned on the model directive.[284] Both sets of questions can, as long as important elements in the new harmonization policy have not been definitively conceived, in the main be dealt with only hypothetically. Nevertheless, it is sensible to discuss these questions in practical terms too, when and in so far as they illustrate the limits to political room for manoeuvre and thus give purely legal considerations additional weight.

[283] *Schmitt von Sydow, H.,* Organe der erweiterten Europäischen Gemeinschaften - Die Kommisssion, Baden-Baden 1980, Art. 155, para. 52; more fully, idem,, 160-166.
[284] On this see *Joerges, C./Micklitz, H.,* The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 251, 3. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf; on the significance of Art. 100 a (4) of the SEA cf.point 4.1 above.

5.1. Inclusion of standardization organizations in the Community's law-making process

In the course of preparing the low-voltage Directive[285] the advocates and opponents of the reference technique had exhaustively discussed the pros and cons of including standards organizations in the Community's legislative process. The uncontroversial starting points for these debates were the principle of limited individual empowerment whereby the Community could exercise only the powers allocated to it in the EEC Treaty, and the related principle of institutional equilibrium which in particular requires observance of the relationship depicted in the Treaty between Commission and Council.[286] Both principles have to do with the upholding of the rule of law and of democracy, from which it also follows that these principles prohibit the assignment elsewhere of Community legislative tasks.

The proponents of the low-voltage Directive referred above all to the legally non-binding nature of standards; the prohibition on delegation would not be broken if and because the specification of safety objectives laid down in the Directive would ultimately be under the control of governmental bodies, and also because the safeguard clause procedure of Art. 9 did not rule out emergency measures.[287] But this argument has two weak points. Firstly, the structure of the low-voltage Directive gives harmonized, international and national standards (and conformity certificates issued by a national body) considerable legal importance, merely because conformity with the standards is a basis for presuming compliance with the safety objectives in the Directive and thus a right to access to Member State markets.[288] This legal effect can be removed only through the safeguard procedure provided for the purpose. A second, graver objection is directed against the merely formalistic interpretation of the prohibition on delegation. Especially in the case of the low-voltage Directive, it is indisputable that its safety objectives open up very considerable leeway for standardization organizations[289] and that the level of safety is in practice essentially determined by private standards.[290]

The model directive modified the reference technique of the low-voltage Directive. The safety conformity of European and national standards is continually checked through the "management of the list of standards", though there is no such preliminary control in the case of national certificates of conformity; to that extent, Member States are primarily solely responsible for the reliability of their certification bodies. In all of this the model

[285] OJ L 77, 26 March 1973, 29.

[286] For a recent description see Hilf, 1982, 310 et seq.

[287] Cf. esp. *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 115 et seq.

[288] Cf. *Lauwaars, R.H.*, The Model-Directive on Technical Harmonization, EUI-Colloquium Papers, DOC IUE 169/86 (COL 82), 12.

[289] Cf. 3.2 above at fn. 158.

[290] Cf. esp. *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 114 et seq. and more details in 2.4 above; the European Parliament's Committee for economic and mandatory affairs and industrial policy (fn. 163 above) arrives at an answer to this objection that is as contradictory as it is legally untenable. The Committee categorically rejects involvement with "technical details" (loc. cit., point 2) and alleges that there is no "abandonment of legislative powers" because technical regulations secure general bindingness and legal force (sic!) only "where the Community legislator confers it on them in the prescribed procedure" (op. cit., 11).

directive takes it as a basis that safety requirements be more precisely formulated than in the low-voltage Directive.[291]

These changes take the force away from the objections raised against the low-voltage Directive, but do not remove the problem of delegation. By contrast with what has often been asserted in the literature,[292] the controversy that broke out over the low-voltage Directive has not been clarified even by the ECJ judgment in case 815/79.[293] While in its decision the ECJ urged Member States to comply with the low-voltage Directive,[294] it did not explicitly address itself to the issue of the prohibition on delegation. The sole relevant decision, as far as we can see, of the ECJ is from long ago. It concerned the delegation of decision-making powers of the High Authority on private-law "financial arrangements" set up pursuant to Art. 53 ECS. The ECJ drew a distinction: "clearly defined executive powers" are unobjectionable; "discretionary powers" instead "bring about an actual transfer of responsibility", "since it replaces the choices of the delegator by the choices of the delegate".[295] But these statements do not offer much help in deciding either. By contrast with the situation in Art. 53 ECSC, cooperation between the Community and European standards organizations is based not on a particular provision of the EEC Treaty but only on the Council resolution of 16 July 1984.[296] Above all, however, it is hard to draw a line between mere "executive powers" and inadmissible "transfers of discretionary powers";[297] and in the case of the delegation issue with reference to standards, where what counts is the relationship between formal decision-making powers and actual possibilities of influence, it can be applied only in the form of a description of general trends. The more precisely safety objectives are set forth in directives and standardization orders to European standardization organizations are formulated, and the more intensive the substantive checking of standards in recognition and safeguard clause procedures and those regarding conformity certificates from national bodies, the easier is it to throw out the objection that the new approach means impermissible transfer of legislative powers.[298]

[291] 3.2. above at fn. 160 et seq.

[292] Cf. most recently *Bruha, Th.*, Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft, Deregulierung durch "Neue Strategie"?, ZaöRV 1986, 1 et seq., 25.

[293] Judgment of 2 December 1980, ECR [1980] 3583/Cremonini v. Vrankovich.

[294] See also judgment of 14 July 1977, case 123/76, ECR [1977] 1449/Commission/Italy. In this procedure the Republic of Italy, the defendant, further asserted that the legal effects attributed to European standards in Art. 5 of the low-voltage Directive could at any rate not arise where they have been adopted only by (qualified) majority. This was opposed at the time by the Commission and Advocate General Warner (loc. cit., 1470) with the thesis that all Member States had by their agreement to the low-voltage Directive accepted CENELEC's decision-making procedure and were therefore now bound by its outcome. Understandably, the ECJ avoided adopting this position as its own (loc. cit., 1458, para. 8). Possibly the tighter version of the recognition procedure in the Model Directive was motivated in part by this problem.

[295] ECJ, 4, 13 June 1958, case 9/56, ECR [1958] 9, 43 et seq.

[296] OJ C 136, 4 June 1985, 2.

[297] See *Hilf, M.*, Die Organisationsstruktur der Europäischen Gemeinschaften, Berlin/Heidelberg/New York 1982, 317 et seq.

[298] An additional objection to the reference technique is derived by *Lauwaars* (op. cit., fn. 285), from the fact that privately set standards are not subject to any judicial review (see also Avocate-General Roemer's opinion in case 10/56, judgment of 13 June 1958, ECR [1958] 177 - Meroni. Member States can now secure judicial verification that standards are in conformity with respect to safety and firms can defend themselves against refusal of conformity certificates by certification centres.

5.2. The institutional balance between Council and Commission

The model directive strengthened the Commission's position not only in managing the list of standards but also in the safeguard clause procedure.[299] This makes it easier to defend the reference technique against the objection about delegation, but at the same time raises the further question whether the Commission's strong legal position is compatible with the principle of institutional balance. The Treaty basis for delegating "implementing powers" of the Council to the Commission is Art. 155 EEC, fourth indent. A widespread extensive interpretation of this provision in the literature says that the extent and procedures for conferring decision-making powers on the Commission is within the Council's discretion.[300] Delegation without any criteria or bounds would be incompatible with the principle of institutional balance, to which the term "implementing regulations" refers and which is not even at the disposal of the Council, especially since delegation restricts the European Parliament's powers of involvement in the Community law-making process.[301] Following the European Parliament's censure, demarcation formulas were developed requiring that the Council itself should take the "essential basic decision" and the Commission's leeway in decision be limited in such a way that "the political, economic and legal effects of the Treaty are determined by the Council's measure and are not affected by the Commission"[302]. The ECJ has not directly taken a position on these problems of interpretation. Admittedly, there is a statement in the judgment of 17 December 1970 that application of Art. 155 EEC is "at the discretion of the Council".[303] But the matter at dispute in this judgment was the admissibility of a management committee procedure that restricted the Commission's decision-making autonomy. Accordingly, the ECJ's pronouncement cited has to be read along with its recognition of the possibility for the Council, provided for in the management committee procedure, to "delegate to the Commission an implementing power of considerable scope, subject to its power (specifically where the management Committee rejects Commission measures) to take the decision itself where necessary"[304].

The same line is taken by the judgments in cases 23 and 37/75,[305] concerning a conferment of "comprehensive implementing powers" with broad room for discretion in cases where the transfer of powers by the Council was compensated by involvement of Member State representatives in the Commission's decision-making process and by corrective powers for the Council. This is line with the political meaning of the management committee and

[299] 3.4 and 3.6 above.

[300] Cf. B. *Schindler, P.*, Delegation von Zuständigkeiten in der Europäischen Gemeinschaft, Baden-Baden 1972, 152 et seq.; *Schmitt von Sydow, H.*, Organe der erweiterten Europäischen Gemeinschaften - Die Kommisssion, Baden-Baden 1980, 64 et seq.

[301] On the European Parliament's position see the references in Schindler, 1972, 149 et seq.

[302] According to *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 50; see also *Ehlermann, C.-D.*, Institutionelle Probleme der Durchführung des abgeleiteten Gemeinschaftsrechts. Institutionelle Probleme zum Urteil des EuGH in der Rs. 22/70 v. 31.3.1971, EuR 6 (1971), 250 et seq., (note on ECJ judgment of 31 March 1971, case 22/70, EuR 1971, 242 et seq., 250 et seq.), 252 and *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 2.6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.

[303] Case 25/70, ECR [1970] 1161, 1172/Köster.

[304] Op. cit., 1173.

[305] Case 23/75, judgment of 30 October 1975, ECR [1975] 1279, 1302/Rey Soda; case 37/75, judgment of 11 November 1975, ECR [1975] 1339, 1346/Bagusat.

regulatory committee procedure, but is at the same time an objectively obvious consequence of the delegation of implementing powers that include discretion.
The wide-ranging debate on shifting decision-making powers to "non-Treaty" bodies carried on in connection with the development of committee procedures, which always concerned the admissibility of restrictions on the Commission's autonomy of decision,[306] ignored the consequences of extensive delegation of "implementing powers" for the political legitimation of Community law. But now that both the practice of delegation has become established and at the same time highly articulated machinery to protect Member States' influence has been developed, employment of these controls must also be in line with the nature of the delegation concerned. A normative interpretation of the principle of "balance", which sees this principle as one of maintaining Member States' possibilities of influence, can be combined with the analytical observation that the Community, wherever it creates supranational legal structures, has to allow Member States possibilities of involvement in its decision-making process.[307] But now the Final Act of the governmental conference on the Single European Act has explicitly asked the Council "to give the Advisory Committee procedure in particular a predominant place", specifically "for the exercise of the powers of implementation ... within the field of Art. 100 a"[308], and the European Parliament has firmly supported this proposal.[309] Even these statements were already lagging behind the Commission's original intentions on amendment of Art. 145 EEC,[310] and also presuppose the powers of action remaining to Member States pursuant to Art. 100 a (4). Now the Council decision of 13 July 1987[311] has politically (even if not legally) strengthened the position of Member States in the "advisory committee" procedure, and above all abandoned the favouring of this type of committee in connection with activities oriented towards bringing about the internal market. This development quite meets the legal reservations regarding the Council's depriving itself of is powers by transferring decision-making powers in extremely sensitive questions of legislative policy to the Commission, under the title of mere "implementing powers".

5.3. The way forward

A precise formulation of safety objectives can not only fend off the delegation issue but also clearly limit the "implementing powers" of the Commission. But this reaction would put the practical advantages which the new harmonization policy is all about in question again. In order to make the new harmonization policy legally unassailable R.M. Lauwaars has suggested setting up a European standards institute on the basis of Art. 235 EEC, with the power to decide on adoption of standards through decisions within the meaning of Art. 189 EEC.[312] In practice this proposal has little chance of being realized, if only because the

[306] Apart from the authors' mentioned in fn. 297, see also e.g. *Bertram, Ch*., Das Verwaltungsausschußverfahren, Diss. jur. Bonn 1967.
[307] *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 1.2.2. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf.
[308] Cf. 3.6, fn. 241 and 4.3 above.
[309] See the European Parliament's opinion, printed in OJ C 227, 8 September 1986, 54, on the Commission's proposal on the exercise of implementing powers transferred to the Commission, OJ C 70, 25 March 1986, 6.
[310] Cf. *Glaesner, H.J.*, Die Einheitliche Europäische Akte, EuR 21 (1986), 119 et seq, 146 et seq.
[311] OJ C 197, 18 July 1987, on this see 4.3 above.
[312] Op.cit. (fn. 281); on the conditions for this sort of foundation see *Lauwaars, R.H*., Auxiliary Organs and Agencies in the E.E.C., CMLR 17 (1979), 367 et seq, and *Hilf*, M., Die Organisationsstruktur der Europäischen

whole setup of the new approach offers alternative ways out, which have in part already been taken.

The legal systems of Member States that allocate functions in the law-making process directly or indirectly to standardization organizations restrict this function by powers of influencing the standardization organizations, by requirements on the transparency of standardization work and on guarantees of "balanced" rights of participation and through governmental checks on the outcome of standardization.[313] The general guidelines on cooperation between the Commission and European standardization organizations,[314] though no doubt in need of further clarification, and the form of the recognition procedure in the model directive point in the same direction. By using these guidelines, however, the Commission can secure transparency in the standardization procedures and possibilities for participation by "interested circles" vis-à-vis only the European standardization organizations. If the principles of the general guidelines are meant as an answer to the delegation issue, then compliance with them ought consistently to be made binding also on all national standardization organizations seeking recognition of their standards, or recognition of national standards made dependent on corresponding requirements. Community-law requirements on standardization procedure would, however, not take account of the objections to the Commission's formal position in the recognition and safeguard clause procedure arising out of the principle of institutional balance. It might therefore be an idea to harmonize the rules of procedure of the Standing Committee mentioned in Section IX (9) of the Model Directive with the patterns of the Management Committee or with the general regulatory committee procedure.

Gemeinschaften, Berlin/Heidelberg/New York 1982, 322 et seq.

[313] See *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 251, 6. Online available at: http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf.

[314] Fn. 232 above.