

CHAPTER IV:

The new approach to technical harmonisation 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

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 integration¹. 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 expectations 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 the Europeanisation of product safety law.

The description of law approximation policy under the 1969 General Programme to remove technical barriers to trade² has repeatedly confirmed the notion that internal market policy must always include coverage of product safety policy implications of legal harmonisation measures. Let us only recall the broad use of escape clauses in relevant Community directives³, the collapse of initiatives in the area of construction materials⁴, the lack of success in efforts to supplement harmonised product standards in the automotive sector with an integrated safety policy programme⁵ and the general resistance to a "horizontal" European product safety policy⁶. 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 harmonisation policy and the need for a new approach to harmonisation did not clearly address the connections between internal market policy and product safety policy. 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 harmonisation and the quantity of national standardisation material and the need for flexible adaptation of harmonised provisions to technical developments⁷. This diagnosis is in line with the therapy recommended by the White Paper on completion of the Internal Market⁸: the Community should in the 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 harmonising binding safety and health requirements, to be specified by the European standardisation organisations, supplemented by mutual recognition of national standards. The following description begins with 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 harmonisation 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 1973⁹, the first to apply the technique of harmonisation of safety objectives and reference to standards at Community level, can be generalised, will likewise be shown to be highly problematic, since the regulatory technique of the Low Voltage Directive presupposed 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 harmonisation 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 applicability of the new approach (4 below). Finally, the new harmonisation 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 literature¹⁰. 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 significant quantity only with the case law following-up the Cassis judgment.

Table 1: ECJ judgments on free movement of goods over particular periods, by type of proceedings (1)

Period of time	Preliminary Ruling (Art. 177)	Breach of Treaty (Art. 169)	Total per year	Judgments
Preliminary				
Breach of Total				
Judgments				

From 1968 (2) 8 1 91.8 until Dassonville judgment (3)	8	1	9	1.8
From Dassonville judgment until Cassis judgment (4)	25	3	28	6.2
From Cassis judgment until March 1987 (5)	65	38	103	12.7
Total	98	42	140	7.8

(1) Calculated from the European Court reports and communications regarding the ECJ's work.

(2) Case 7/68, Judgment of 10 December 1968, ECR [1968] 634.

(3) Case 8/74, Judgment of 11 July 1974, ECR [1974] 834 (Dassonville).

(4) Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 (Cassis de Dijon).

5. Case 178/84, Judgment of 12 March 1987, published in NJW 1987, 1133 (Beer Purity Ordinance).

In the period after the Dassonville judgment the number of judgments handed down triples annually, 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 to develop its case law on free movement of goods. Outside the foodstuffs sector, there is a strikingly high proportion of judgments concerning medicines, 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
Pharmaceuticals 17
Technical products 8
Publications 7
Fuels, used oil 7
Foodstuffs 5
Pesticides 4

Animals 4
Tobacco 3
Plants 3
Other products 12
Not product-specific 9

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 harmonisation and standards and to the need for a horizontal Community product safety policy. The case law on Art. 30 EEC and its impact on harmonisation policy will first be dealt with (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 harmonisation policy

Art. 30 EEC prohibits quantitative restrictions on imports and measures having an equivalent effect between Member States; 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" judgment¹¹ 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/EEC¹³. 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 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 by 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 the flow of goods between States is here 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 is to be treated as comprehensive¹⁵. 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 formulation¹⁶. With the well-known judgment in the "Cassis de Dijon" case of 20 February 1979¹⁷, the Court of Justice took the latter path, thereby laying the foundations for a new approach to harmonisation 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 regulations on manufacture and 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, however, 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 in Art. 36 EEC; instead, their presence makes a regulation or proceeding no longer describable as a measure having equivalent effect¹⁹.

The list of binding requirements is not exhaustive: others that enter in are environmental protection and measures to improve working and living conditions²⁰. This must, though,

involve a non-economic objectives in the general interest, which take 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 protection²¹.

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 possible²². 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 suffice²³. In testing the binding requirements, the principle of the second sentence of Art. 36 EEC should be applied, with the result that no primacy can be assigned to national regulatory powers when these are used as a means of arbitrary discrimination or as 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 regulatory interests of Member States, not a rigid scheme of rules and exceptions²⁴.

1.1.2 The consequences of the Cassis Case Law for legal 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 harmonisation 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 legal approximation policy²⁵. It summarises 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 **Errore. L'origine riferimento non è stata trovata.** 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 provisions²⁷. Above all, however, efforts at harmonisation are to be concentrated in 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 trade²⁹.

The Cassis judgment (and the Commission communication) were on the one hand welcomed as, in principle, allowing marketing of the most diverse local specialties throughout the Community, thereby increasing consumer choice³⁰, but on the other hand criticised as facing the national legislature with the dilemma of either discriminating against domestic industry or giving up higher quality standards in favour of adaptation to the lowest common denominator³¹. 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 the future further amendments to national legal provisions could be adopted 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 co-operation or information of other Member States, determine legislation for the whole Community. The outcome would be that the minimum requirements would, without the harmonisation 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 that the new jurisprudence will lead to a levelling down to the lowest common denominator has proved unwarranted³³. This is partly because Member States can defend themselves against undermining of standards by appealing to mandatory requirements, where a legitimately pursued general object of protection of a non-economic nature is endangered³⁴. Above all, however, it goes much farther to meet Member States interests in protection, especially as regards the very frequently mentioned protection of health³⁵, than the Commission with its rigid scheme of rule and exception and its stress on "very strict criteria" and on the possibility of non-compliance "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 generalised the interpretive principles, which the ECJ, particularly in its subsequent case law, has still more finely differentiated³⁶.

It is plain that harmonisation remains indispensable only in areas where Member States can base themselves on objects of protection under Art. 36 EEC or on mandatory requirements³⁷. 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 appropriate; 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 level³⁸. 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 preventively and much more comprehensively³⁹. Furthermore, pronouncements of the Court of Justice can act only by way of quashing, in the sense that rules may be abolished without substitution, but not replaced by new requirements under the Community Treaty⁴⁰. Finally, overstressing negative harmonisation through Art. 30 EEC would mean transferring to the Court evaluative tasks that normally fall within the province of the legislator⁴¹.

There is agreement that application of Art. 30 EEC cannot be made dependent on prior harmonisation of laws. This was unmistakably stated by the Court of Justice in case 193/80⁴², when it also stressed the different objectives of Articles 30 and 100 EEC⁴³:

"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 Commission⁴⁴.

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, however, where compliance with them is mandatorily prescribed *de*

jure or *de facto* by government action⁴⁵. To date, the Court of Justice has found a measure of equivalent effect in only one case where the measure was neither a sovereign one nor binding on its addressees. 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 the major staffing decisions and borne the overwhelming share of the financing⁴⁶. Comparable circumstances are not present in the case of technical standardisation by private standardisation bodies⁴⁷.

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 markets⁴⁸; 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 States⁴⁹.

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

Only where Community directives provide for *complete* harmonisation of *all* measures necessary to safeguard 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 regulation⁵⁰. 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 provisions⁵¹. Moreover, the content of the individual Community regulations and harmonisation programmes must be looked at to see whether all relevant objects of protection under Art. 36 EEC are already covered⁵². 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 unrecognised 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 harmonisation 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 less restrict internal Community trade. 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 available⁵⁴. 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 it is appropriate for the sanitary authorities of the Member States concerned to co-operate in order to avoid duplication of checks⁵⁵. 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 efforts⁵⁶.

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 EEC⁵⁷. 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 of climatic conditions, the population's eating habits and their state of health, and therefore differ 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.

When complete harmonisation has not been achieved, Member States remain free to take action if uncertainties still exist at a given stage of research. Both the eating habits of their population and the needs of free movement of goods must be taken into account to determine the extent to which they wish to guarantee protection of the health and life of people⁵⁹. Accordingly, the Dutch ban on adding vitamins was declared to be compatible with Community law on the grounds that, although an health-endangering effect was not proven, it could not be ruled out given excessive consumption in the whole diet in its unforeseeable, unverifiable composition; the Court added, however, that marketing is to be permitted where the addition of vitamins corresponded to a genuine need, in particular in regard to technology or nutrition⁶⁰.

A particularly illuminating judgment regarding the far-reaching powers that the Court allows Member States in the area of preventive health protection was given in Case 97/83⁶¹. The Court held 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 the storage of milk products between the moment of purchase and consumption.

Member States may also prohibit pesticide residues in foodstuffs entirely, leading to a trade block 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 foodstuffs⁶². 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 into account take specific eating habits in the importing Member State⁶³.

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, parties concerned 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 effect⁶⁴. 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 on grounds of preventive health protection, instead of adducing proof of health risk for each substance⁶⁵. The submission of the German government, the defendant, stating that beer was a foodstuff consumed in considerable quantities by the German people and that on general preventive health protection grounds, it was advisable to restrict the quantity of additives consumed as far as possible⁶⁶, 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 France⁶⁷. 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 (design safety)⁶⁸. In Germany, by contrast, the principle is that the worker must, through thorough vocational training and further education, learn to handle any problem that might arise in machine operations. The Commission expressed the view that Member States ought not to block the import of machines based on other conceptions of industrial safety, but that have proven to be just as safe as appliances in accordance with the national regulation⁶⁹. 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 the 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 detail 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 ruled 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 levels of employee training⁷¹.

Lacking 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 recognised as equivalent, so as to exclude in the harmonised area the sealing-off of markets by appeals to different ones.

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

Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits - the Low Voltage Directive⁷² - with its new harmonisation technique of sliding reference to harmonised standards, became the model for the new approach to technical harmonisation and standards⁷³. For many years it had been regarded by many officials in governments and the Commission as an original sin that ought not to be repeated⁷⁴. 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 Directive⁷⁵.

2.1 Peculiarities of the electrical sector

There are good reasons why, for many years, it was specifically only in the electrical sector that the general-clause method of reference to the European state of safety technology was applied⁷⁶. These reasons also indicate that experience with the Low Voltage Directive can be transferred only to a limited extent to other areas of industry⁷⁷. Electrical standardisation has for decades occupied a special place in all industrial countries. The rapid pace of development in the electrical field 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 systematised and intermeshed than in other areas. This is because despite an almost limitless variety of products, there are comparable modes of 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, at least internationally compatible provisions are essential for the numerous points of intersection, 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 standards⁷⁸.

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

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

Level of standardisation	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

(1) 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 appliances in which there

is great public interest, covered by specific directives (electrical equipment for use in an explosive atmosphere⁷⁹, electrical equipment for radiology and medical purposes, electrical parts for goods and passenger lifts, electricity meters) nor to electric fence controls 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 excluded⁸⁰.

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 recognised rules of art" in the German Appliances Safety Act⁸¹. The affirmative statement that in the event of a differing level of safety technology in individual Member States, all ought to apply the highest level⁸², does not fully bring out the graded harmonisation machinery of the Directive, developed because the desired success in harmonisation at an enhanced safety level could not be ensured simply by having product requirements 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 exactly⁸³. 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 safely and properly assembled and connected.
- For protection against hazards that might arise from the electrical equipment, technical measures are to be prescribed, so 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 the insulation is suitable for foreseeable conditions.

- Technical 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 when the equipment:

- complies with harmonised standards (Art. 5), i.e. those produced by CENELEC;
- where harmonised 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 harmonised 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 standards⁸⁴, 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 body⁸⁵, 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. Vrankovich⁸⁶. On the basis of this ruling, the Commission once again summarised the legal framework of the Directive and its application in a explanatory communication to all concerned⁸⁷. Further 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 Directive⁸⁸. 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.

2.3.1 Harmonised standards

The pillars of the Low Voltage Directive are the harmonised standards within the meaning of Art. 5. They definitively replace other categories of technical standards mentioned in the Directive. They are to be laid down by the standards organisations 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 harmonised standards. Harmonised 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 harmonisation document to be incorporated verbatim, without change, in their national standards by all national committees of CENELEC⁸⁹.

The Commission publishes the harmonised standards in the Official Journal; this publication is for purposes of information and thus has a purely declarative function⁹⁰. The list published in September 1984 summarised harmonised standards agreed on up to that date⁹¹. The 94 harmonisation documents⁹² 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 obtained⁹³. This procedure of unanimous voting by the national committees accords with Art. 5 of the Directive, which says that harmonised standards are to be drawn up by "common 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 standardisation bodies. Moreover, compliance with harmonised 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 harmonised 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 the comparison between CEN and CENELEC specifically shows how much the adoption of harmonised 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 standardisation committee, has the safeguard clause procedure of Art. 9 open to it.

In the case of many harmonisation 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 standardisation bodies⁹⁵.

Following the ruling in the Cremonini v. Vrankovich case, it was clarified⁹⁶ that type B departures are not admissible, since no discrepant national standards apply alongside the harmonised standards. Nor could type A divergences continue to claim any validity alongside a harmonised standard, since compliance with discrepant national safety provisions operates as a presumption of compliance with the general safety objectives only where no harmonised 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 are found in informal ways by removing national discrepancies or incorporating them in the standard concerned⁹⁷. Indeed, it explicitly notifies Member States of the possibility of affecting the production of harmonised standards through the various standardisation bodies⁹⁸. 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 standards⁹⁹:

"Following adoption of a harmonisation 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 harmonised 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 harmonised 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 harmonised norms with the general safety objectives. The new approach provides for a procedure of its own, though a Community one, in order to test harmonised standards adopted by the European standardisation bodies, or else the national standards that for the moment continue to apply, for compliance with the essential safety requirements¹⁰⁰.

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 "special national conditions"¹⁰¹.

Publication of safety requirements of international standardisation 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 organisations cannot manage to agree on harmonised 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. Note should, however, above all be taken of the CENELEC mode of procedure: it takes up work of its own only when 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 minimum¹⁰³.

2.3.2 Equivalence of safety level

Art. 7 has raised severe problems of interpretation. It says that where harmonised 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 harmonised standards have not yet been established for the whole area of application of the Low Voltage Directive¹⁰⁴. It is conceivable that in this transitional period national standards which lag behind the requirements of Art. 2 taken together with Annex I, that is, the general safety objectives, will in one Member State or another continue to apply. 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 that required by Art. 2 and Annex I¹⁰⁵.

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 performance¹⁰⁶.

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 authorised 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 measure 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 measures¹⁰⁷, 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 its conditions, course and consequences. Its main function is in preventing Member States from 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, formulate recommendations or statements.

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 authorised centers in Member States must, as the *Cremonini v. Vrankovich* judgment explicitly states, be recognised 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 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 1983¹⁰⁸ (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 procedure¹⁰⁹. 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 superfluous¹¹⁰. 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 harmonised standards¹¹¹. 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, a European test mark does exist which all certification centres have to recognise. A further special procedure exists for construction components in electronics, regulated by the CENELEC Committee for Electronic Components (CECC)¹¹².

Internationally, however with a restriction mainly to Europe, the certification of electrical products is organised by the International Commission for Conformity Certification of Electrical Products (CEE), recently integrated into the IEC¹¹³. Since 1963, its predecessor organisation¹¹⁴, which until 1981 had also issued standards in the electrical sphere, had provided a system of certification, the CB procedure¹¹⁵. Under this system, tests by any member organisation are mutually recognised. 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. Besides the necessary cross-co-operation among certification centres, an international certification system ought to require that certification be centralised 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 when defining 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, it would be useful to examine 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 misuse¹¹⁶.

2.4 Inadmissible delegation of public tasks to private standardisation 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 standardisation 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 Directive¹¹⁷. The possible criticism has been brought out very succinctly by E. Röhling¹¹⁸, in specific reference to the Low Voltage Directive, and can be summarised as follows:

Sliding reference to technical standards in their current version is alleged to constitute inadmissible delegation of sovereign powers to non-sovereign organisations, 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 grounds 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 standardisation bodies are viable. The standard-setting bodies are 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 environmental protection, safety). Finally, there is an objection on grounds of democratic legitimation, namely that the however weak control over Council members by national parliaments is still undermined.

These massive objections will not be gone into any further here in connection with the Low Voltage Directive. They arise in dealing with the new approach, in part with modified parameters, and will there be discussed in detail¹¹⁹. The Low Voltage Directive and the new approach have carefully been designed so as to leave the following legal fallback position open¹²⁰: products need meet only the essential safety requirements laid down by the Council. Harmonised 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 harmonisation 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 renewed efforts to bring about the internal market. The new approach to harmonisation 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 require mutual recognition of national provisions¹²¹ and permit the generalisation of the reference technique first practised in the 1973 Low Voltage Directive¹²². But the political impulses and preliminary conceptual date much further back¹²³. Both the European Parliament¹²⁴ and the Economic and Social Committee¹²⁵ had already recommended the reference method in their resolutions or opinions on the 1969 General Programme to eliminate technical barriers to trade, as an alternative to the "traditional" method of approximation of laws¹²⁶. In the early 70's, these suggestions were taken up in the German literature, and the outlines of the new approach were formulated¹²⁷: Directives should lay down "basic requirements", and conformity with technical standards should justify a presumption of compliance with these requirements¹²⁸. In accordance with this presumption, Member States ought to take "all necessary measures to ensure that administrative authorities recognise as conforming with the basic requirements, such goods as meet standards laid down by the Commission, following consultation of the Standardisation Committee"¹²⁹. Manufacturers can furthermore declare, and where necessary prove, the basic conformity of products not complying with standards¹³⁰.

But these proposals were by no means unanimously accepted. As suggested notably by Röhling¹³¹, the regulatory technique of reference to standards substantively meant delegation of legislative powers, inadmissible according to the EEC Treaty¹³²; if the Community wished to take advantage of the expert knowledge of standardisation organisations, it ought first to guarantee the Commission's influence on the standardisation procedure in any such co-operation, and then adopt the procedure of Art. 155, fourth indent, for the legal "ratification" of the results of standardisation¹³³.

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 Commission¹³⁴, in order 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 harmonisation 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 harmonisation policy to the legal and administrative provisions mentioned in Art. 100 (1) EEC to cover also their non-governmental appendage, namely national technical standards¹³⁶. 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 standardisation bodies) to "immediately communicate to the Commission any technical draft 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 given by the Information Directive for this purpose is a time-limited anticipation of the primacy doctrine¹³⁸, which replaces the "Gentlemen's Agreement" of 28 May 1969¹³⁹. 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 supremacy claim of European law by taking Member States' interests into account and giving standards institutions a possibility of collaboration¹⁴⁰. 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 standardisation organisations may themselves be represented on the Committee directly through experts or through advisers; in other respects they are recognised 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 Europeanisation 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 imposes in the first place a very considerable burden of work upon the Commission. 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 cases¹⁴¹.

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 1986 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 Directive¹⁴². 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 pertaining technical regulations and standards to be found and applied would be unrealistic. The most important effect of the Information Directive is no doubt instead that the creation of an information system at the Community level and the involvement of the Member States and their standardisation organisations in the process of Europeanisation of technical regulations and standards¹⁴³.

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, pharmaceuticals and cosmetics¹⁴⁴; 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 standardisation contracts (Art. 1 (2)). The postponement periods in Art. 9 of the Directive are not extended. However, in the 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 1987¹⁴⁵ stresses that the various 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 combined.

3.2 Harmonisation 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 testing of three¹⁴⁶ strategies to reduce its burden. All are to be continued under the new approach. In accordance with the extensive interpretation of Art. 30 EEC¹⁴⁷ advocated by the Commission following the Cassis de Dijon decision¹⁴⁸, in areas where reliance can be placed on mutual recognition of national regulations and standards, harmonisation of laws is to be avoided where possible; existing regulations and standards are instead to be checked for proportionality¹⁴⁹. The scope of this strategy is, however, limited¹⁵⁰. Another way of unburdening the cumbersome procedure of adopting new directives is through the delegation of power to enact implementing provisions to the Commission pursuant to Art. 155, fourth indent¹⁵¹. The White Paper mentions the success of this method¹⁵², which however cannot easily be reconciled with efforts at increasing involvement of standardisation organisations in harmonisation policy¹⁵³. The third method of alleviation, the reference technique first practised in the Low Voltage Directive of 19 February 1973¹⁵⁴, is unambiguously and emphatically favoured in the new approach.

This means, in the White Paper's terms, that harmonisation 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 standardisation organisations¹⁵⁵. The allaying effect of this inclusion of standardisation organisations in harmonisation policy depends in the first place on the demarcation between the "basic safety requirements" and the "technical specifications". The Low Voltage Directive, explicitly emphasised in the explanatory memorandum on the new approach as a model for the new regulatory technique¹⁵⁶, does describe the mandatory safety objectives comprehensively, but only by vague general clauses¹⁵⁷. 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 particularly 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, warns¹⁶¹ that it threatens to endanger the whole planning of the new approach and ought therefore to be understood merely as a call for involvement of national certification centres in cases where neither European or national standards guarantee the safety of a product¹⁶². In its report on technical harmonisation and standards in the Community¹⁶³, the European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy called for the deletion of this addition, and an April 1986 question by one MEP¹⁶⁴ suggested that it be treated as non-mandatory. The answer to this question, communicated by Lord Cockfield on behalf of the Commission¹⁶⁵, 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 B V 3). An essential aspect of the harmonisation 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. There is therefore a choice that makes it possible to retain the voluntary nature of standards, which is the basic feature of the **Errore. L'origine riferimento non è stata trovata.**

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. This ensures 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 co-operation 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, in any event, 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 essential safety requirements. The Directive for simple pressure vessels¹⁶⁶, 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 Annex I¹⁶⁷; 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 standardisation bodies"¹⁶⁸.

The second draft directive submitted on the basis of the new approach concerns the safety of toys¹⁶⁹. 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 use¹⁷⁰. The lengthy Annex II establishes requirements on physical and mechanical properties, flammability, chemical properties, explosion, electrical properties, hygiene and radioactivity. Annex IV additionally contains differentiated requirements as to warnings concerning the age of children, nature of the toys, and risks involved. All categories of risks and warnings were contained in the Commission's 3 July 1980¹⁷¹ Draft Directive, from which they were taken over into the proposal for a framework Directive of 23 June 1983¹⁷². The 1980 draft dealt in Annexes V and VI with Community standards for physical and technical properties and the flammability of toys, but in 1983 corresponding standards were incorporated into separate directives¹⁷³. 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 standardisation organisations, seeking to make them mandatory even though not yet formally adopted at the time by the national standards organisations. 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 binding¹⁷⁴.

The Commission's most recent project to date¹⁷⁵, the proposal for a directive on construction products¹⁷⁶, is likewise the resumption of a long-discussed project¹⁷⁷. 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 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 materials, and the multiplicity of existing national standards referring to them relates to differing national statutory provisions on buildings¹⁷⁸. In these circumstances, the Commission's proposal cannot apply the new approach in the way the Model Directive assumes. The safety requirements in the Directive on construction materials 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 saving¹⁷⁹. The Commission explicitly stresses that it would not, in general, be possible on the basis of these requirements "to directly establish 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 authorised by Member States should, "on the basis of common approval guidelines for the product", in co-ordination 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 feasibility in practice of the Model Directive¹⁸¹. It also corresponds to the pragmatically sibylline statements by its leading supporters¹⁸². These were to the effect that, when delimiting "essential safety requirements" in need of harmonisation from mere specifications of those requirements which need not to be uniform, 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 standardisation, 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 approach¹⁸³ and now specifically stressed in the proposal for a directive on construction products¹⁸⁴: 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 U.S., such provisions leave room for technical innovation and make it harder to turn the standard-setting process into a way of warding off competition¹⁸⁵.

The theoretically clear distinction between performance and design standards in the practice of standard setting has repeatedly lead to wellnigh unsolvable problems of demarcation. It may, moreover, prove questionable from a safety policy viewpoint where and in so far as alternative design solutions are not conceivable¹⁸⁶. 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 law¹⁸⁷. The explanatory statement on the proposal for the Directive on simple pressure vessels points out, in connection with restrictions relating to materials, a further problem with performance standards¹⁸⁸: the development of suitable certification

procedures and mutual recognition of conformity certifications becomes more urgent and at the same time more difficult as the manufacturer's leeway is broadened.

CONTINUE

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. Chapter III, 2.
3. Chapter III, 2.5.
4. Chapter III, 2.6.
5. Chapter III, 2.4.3 end.
6. Chapter III, 3.
7. For more details see Chapter III, 2.7, and references.
8. Op. cit. (note 1), 14 et seq.
9. OJ L 77 of 26 March 1973, 29.
10. From the already enormous literature, mention should be made especially of Gormley, 1985 and Oliver, Free Movement, 1982. See also the commentaries on Art. 30-37 EEC by Colliard/Herzog, Matthies and Wägenbaur. A review of individual groups of cases is given also by Dausès, 1984, 201-206; Masclet, 1986, 253-267; Mattera, 1983; *idem*, 1984; Moench, 1982 and Rabe, 1984. On the connection between the case law on Art. 30 et seq. EEC and consumer protection see Reich, 1987, Nos. 11-26; Bourgoignie, 1987, 159-172; Stuyck, Free Movement, 1984; Grabitz/Borchardt/Klippstein, 1983.
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, Judgement of 11 July 1974, ECR [1974] 837 at 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, 1977; Ehlermann, 1977; Timmermans, 1981, 285-290, Wägenbaur, Art. 30, Nos. 5-31.
14. In the elastic formulation of Steindorff, 1986, 697.
15. Continuing case law: cf. Case 7/61, Judgment of 19 December 1961, ECR [1961] 695 at 720 - Commission v. Italy; Case 13/68, Judgment of 19 December 1968, ECR [1968] 679 at 694 - Salgoil; Case 113/80, Judgment of 17 June 1981, ECR [1981] 1625 at 1637 - Commission v. Ireland.
16. Ehlermann, 1977, 589.
17. Case 120/78, Judgment of 20 February 1979, ECR [1979], 649 - Cassis de Dijon. Cf. on this judgment also Barents, 1981, 271 at 291-299; Capelli, 1981; Masclet, 1980; Mattera, 1980; Micklitz, 1983, 485-487; Millarg, 1979; Oliver, CMLR 19 (1982), 227-237; Rabe, 1984; Seidel, 1984; VerLoren van Themaat, 1982; Wägenbaur, 1983; *idem*, Art. 30, Nos. 32-41.
18. Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 at 662 - Cassis de Dijon.

19. Explicitly clarified in Case 113/80, Judgment of 17 June 1981, ECR [1981], 1625 at 1638 - Commission v. Ireland; Case 220/81, Judgment of 22 June 1982, ECR [1982] 2349 at 2360 - Robertson.
20. Cf. answer to written question No. 749/81, OJ C 309, 30 November 1981, 7.
21. Cf. Reich 1982, 455; *idem* 1987, Nos. 25. Two particularly instructive examples are Case 120/78, Judgment of 20 February 1979, ECR [1979], 649 at 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., Nos. 32). On this judgment see Dausies, 1987, 256-263; Funck-Brentano, 1987; Moench, 1987; Rabe, 1987; Zipfel, 1987.
22. Cf. Steindorff, 1984, 346; Wägenbaur, Art. 36, Nos. 68-72; Case 104/75, Judgment of 20 May 1976, ECR [1976] 613 at 635-36 - de Peijper; Case 35/76, Judgment of 15 December 1976, ECR [1976] 1871 at 1885 et seq. - Simmenthal.
23. Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 at 664 - Cassis de Dijon; Case 788/79, Judgment of 26 June 1980, ECR [1980] 2071 at 2078 - Gilli & Andres; Case 27/80, Judgment of 16 December 1980, ECR [1980] 3839 at 3854 - Fietje; Case 130/80, Judgment of 19 February 1981, ECR [1981] 527 at 536 - Kelderman; Case 261/81, Judgment of 10 November 1982, ECR [1982] 3961 at 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, 1987, No. 25; *idem*, 1982, 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, 2-3. See Barents, 1981, 296-299; Gormley, 1981; Mattera, 1980; Oliver, CMLR 19 (1982), 234 et seq.; Welch, 1983, 63-68; Micklitz, 1983, 486-87.
26. OJ C 256, 3 October 1980, 2-3.
27. The corresponding proposal was submitted to the Council on 25 August 1980, OJ C 253, 1 October 1980, 2 et seq.
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 1987, 51-53.
29. Cf. Steindorff, 1986, 689-699.
30. Cf. Mattera, 1980, 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, 1984, 87; Micklitz, 1983, 483.

32. Case 120/78, Judgment of 20 February 1979, ECR [1979], 649 at 656 - Cassis de Dijon.
33. See Stuyck, Free Movement, 1984, 95-96.
34. See Matthies, Art. 30, No. 24; Welch, 1983, 66.
35. This will become clear from the analysis of individual cases in Chapter IV, 1.2.
36. Micklitz, 1983, 487; and with particular clarity Barents, 1981, 298. On the tendency in the Commission communication to overshoot, see also Bourgoignie, 1987, 171 f.; Welch, 1983, 64; Reich, 1987, No. 25; Steindorff, 1984, 347.
37. On the new approach to approximation of laws see New Roads for Harmonisation of Legislation?, CMLR 17 (1980), 463 et seq.; Masclet, 1980, 622-630; Mattera, 1980, 510 f.; Sedemund, 1987; Wägenbaur, Art. 30, No. 41.
38. See Rabe, 1983, 63.
39. Wägenbaur, 1983, 906-7.
40. Seidel, 1984, 81.
41. See the preliminary remark on the new approach to technical harmonisation and standards, COM (85), 19 final, 31 January 1985, 5.
42. Case 193/80, Judgment of 9 December 1981, ECR [1981] 3019 at 3033 - Commission v. Italy.
43. Roth, 1977, 24-30; Dausies, 1984, 206; Wägenbaur, preliminary observation on Arts. 30-37, Nos. 68-73; Matthies, Art. 30, No. 25.
44. Cf. in Table 1 supra 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, 1-2. - Buy Irish; and Mattera, 1984, 286-87.
46. Case 249/81 Judgment of 24 November 1982, ECR [1982] 4005 at 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, 1985, 12-23. Cf. also Röhling 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 at 1886 - Simmenthal; Case 5/77, Judgment 5 October 1977, ECR [1977] 1555 at 1576 - Tedeschi; Case 153/78, Judgment 12 July 1979, ECR [1979] 2555 at 2564 - Commission v. Germany.
50. Case 5/77, Judgment of 5 October 1977, ECR [1977] 1555 at 157 - Tedeschi; Case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 at 3388 - Denkavit; Case 227/82, Judgment of 30 November 1983, ECR [1983] 3883 at 3904 - van Bennekom; Case 28/84, Judgment of 3 October 1985, ECR [1985] 3097 at 3123 - Mischfuttermittel; Case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 at 3903-04 - Léon Motte. See also Wägenbaur, Art. 36, Nos. 12-17.
51. As in Case 4/75, Judgment of 8 July 1975, ECR [1975] 843 at 859 - Rewe-Zentralfinanz.
52. Very instructive on this is Case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 at 3389-90 - Denkavit, which also contains an indication that the

- Council should in harmonisation use the method of gradual advance covering individual points.
53. Case 272/80 Judgment of 17 December 1981, ECR [1981] 327 at 3291 - Biologische Producten. Cf. answer to the Written Question No. 1928/84, OJ C 233, 12 September 1985, 5.
 54. For details cf. Gormley, 1985, 154-174.
 55. Cf. Case 73/84, Judgment of 27 March 1985, ECR [1985] 1013 at 1025 - Mischfuttermittel.
 56. Case 104/75, Judgment of 20 May 1976, ECR [1976] 613 at 634-35 - de Peijper.
 57. Cf. Kommers/Waelbroeck, 1986, 203-206; Gormley, 1985, 139-181; Dausés, 1987, 252-256.
 58. Case 53/80, Judgment of 5 February 1981, ECR [1981] 409 at 422 - Eyssen (Nisin).
 59. Case 272/80, Judgment of 17 December 1981, ECR [1981] 3277 at 3290 - Biologische Produkten; Case 174/82, Judgment of 14 July 1983, ECR [1983] 2445 at 2463 - Sandoz; Case 227/82, Judgment of 30 November 1983, ECR [1983] 3883 at 3905 - van Bennekom; Case 97/83, Judgment of 6 June 1984, ECR [1984] 2367 at 2386 - Melkunie; Case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 at 3904 - Léon Motte; Case 54/85, Judgment of 13 March 1986, published in NJW 1987, 565-66, para. 15 - Maleinsäurehydrazid; Case 304/84, Judgment of 6 May 1986, published in RIW 1986, 1002-03, para. 21 - Muller. In general on the alleviation of the requirement of proof in favour of a State acting against previously and recognised hazardous situations, see Skordas, 1986, 122-127.
 60. Case 174/82, Judgment of 14 July 1983, ECR [1983] 24445 at 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.
 61. Case 97/83, Judgment of 6 June 1984, ECR [1984] 2367 at 2386 - Melkunie.
 62. Case 94/83, Judgment of 10 September 1984, ECR [1984] 3263 at 3280 - Heijn. Cf. answer to Written Question No. 1581/84, OJ C 176, 15 July 1985, 4-5. Cf. also Case 54/85, Judgment of 13 March 1986, published in NJW 1987, 565 f., para. 15 - Maleinsäurehydrazid.
 63. Case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 at 3904 - Léon Motte. Cf. also Case 304/84, Judgment of 6 May 1986, published in RIW 1986, 1002-03, 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 at 2463-64 - Sandoz; Case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 at 3905-06 - Léon Motte; Case 304/84, Judgment of 6 May 1986, published in RIW 1986, 1002-03, paras. 23-26 - Muller.
 65. Case 178/84, Judgment of 12 March 1987, paras. 47-53, published in NJW 1987, 1133 et seq. - Beer Purity Law.

66. Loc. 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 at 414-416 - Eysen (Nisin).
67. Case 188/84, Judgment of 28 January 1986, ECR [1986] 419 - Woodworking machines. On this Judgment see also Chapter II, 1.10.1 supra 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. Loc. cit., paras. 16-17.
71. Loc. cit., paras. 17-22.
72. OJ L 77, 26 March 1973, 29. Cf. Winckler/Cassassolles/ Verdiani, 1974; Orth, 1984; Tronnier, 1986.
73. Cf. Garvey, 1984, 46; Braun, 1985, 182; Bruha, 1986, 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, 1985, 34; Schloesser, 1976, 27.
75. Cf. the communication on the application of the Low Voltage Directive (op. cit., note 73), 2.
76. On this see Leber/Oehms/Winckler/Orth, 1983.
77. Also skeptical is Mertens, 1985, 616-17.
78. Accordingly, in view of a manifest overlap of interests, the statement (Leber/Oehms/Winckler/Orth, 1983, 827) that electrical standards are as a rule neutral as regards interests, since organised 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.
79. OJ L 43, 20 February 1979, 20. This Directive works with the technique of rigid reference to standards.
80. Cf. Winckler/Cassassolles/Verdiani, 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, Gerätesicherheitsgesetz, 146-161.
82. Op. cit., 149. Schmatz/Nöthlich, Kennz. 1610, 9.
83. Cf. Winckler/Cassassolles/Verdiani, 1974, 28.
84. Communication on the application of the Low Voltage Directive (loc. cit., note 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., note 73).
88. COM/III/1412/83 - Rev. 3.
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 harmonisation 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 affected only with very considerable delay. This is complained of by Winckler, 1985, 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, 2-3, OJ C 199, 5 August 1980, 2-3.
 92. This does not take the numerous amendments to harmonised 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.
 94. On this see the Communication on application of the Low Voltage Directive (op. cit., note 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 at 1466-1468.
 95. Cf. CENELEC Memorandum No. 5, "Document of principle for national departures from harmonisation 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 harmonised standards were affected by departures of type A because of differing statutorily prescribed requirements regarding the extent of safety.
 96. Cf. the Communication on application of the Low Voltage Directive (loc. cit., note 73), point 6.2.1; COM III/1412/83 - Rev. 3, point 2.3.3.; CENELEC Memorandum No. 10 (loc. cit., note 89), points 3.3 to 3.5.
 97. Cf. COM III/1412/83 - Rev. 3, point 2.3.3 end.
 98. Loc. cit., point 2.3.1.
 99. Fitting, 1976, 87.
 100. Cf. Chapter IV, 3.3 infra.
 101. CENELEC Memorandum No. 10 (loc. cit., note 89), point 3.3.
 102. Winckler/Cassassolles/Verdiani, 1974, 16.
 103. Cf. Winckler, Europäische Normung in CENELEC, 1983; Leber, 1976, 65.
 104. According to industry figures, harmonised standards already existed for over 90% of turnover in equipment covered by the Low Voltage Directive; cf. COM III/1412/83 - Rev. 3, para. 2.4.1.
 105. On the foregoing cf. the closing speech by Advocate-General J.-P. Warner in Case 815/79, ECR [1980] 3583 at 3624-25; cf. also Hartley 1982, 59.
 106. Communication on application of the Low Voltage Directive (loc. cit., note 73), point 6.3.

107. COM III/1412/83 - Rev. 3, para. 2.5.2.2.
108. Which replaces similar agreements of 2 May 1968, 1 April 1971 and 11 September 1973.
109. For details see Warner, 1983, 87-88; *idem*, 1984, 36-37. 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, 1983, 87-88; *idem*, 1984, 37-38, 50-51.
112. For more details see Bier, 1983.
113. Details in Warner, 1983, 88-9; *idem*, 1984, 38, 46-7.
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.
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, 1972, 122-127. Reservations are also expressed by Grabitz, 1980, 78-79.
119. Cf. Chapter IV, 5.
120. See COM III/1412/83 - Rev. 3, point 2.3.1 and Winckler/Cassassolles/Verdiani, 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 (at 2-3). The legal conception was early worked out in basic outline by Starkowski, 1973, 143-160.
121. Cf. in the Commission's White Paper on Completion of the Internal Market (note 1) in particular points 63 and 77, and for qualifications to this principle cf. *supra* 1., esp. 1.2.3.
122. The White Paper (*loc. cit.*, note 1), point 63, is able to point in this connection to the Council Resolution on conclusions regarding standardisation of 16 July 1984 (OJ C 136, 4 June 1985, 2); see also the Commission communication "Technical Harmonisation and Standards: a new approach", COM (85) 19 final of 31 January 1985, 6.
123. Cf. Chapter III, 2.3 (c).
124. OJ C 108, 19 October 1968, 39-40.
125. OJ C 132, 6 December 1968, 1, 4-5.
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 harmonised at the level of the Member States, is 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, 1973, 104 et seq., 143 et seq.; more recently, also Grabitz, 1980, 82-91 and earlier Seidel, 1969, 960 et seq. and *idem*, 1971, 745-46.
128. Cf. Grabitz, 1980, 82 et seq.
129. Starkowski, 1973, 151.
130. Starkowski, 1973, 115-16; Grabitz, 1980, 88.
131. Röhling, 1972, 114 et seq.
132. See 2.4 *supra*, as well as 5.1 *infra*.
133. Röhling, 1972, 132 et seq.; on this more at 5.2 *infra*.
134. On this cf. 5 *infra*.
135. OJ L 109, 26 April 1983, 8.
136. Cf. Macmillan, 1985; Lecrenier, 1985.
137. The information from national standards organisations is collected by the European standards organisations CEN/CENELEC and passed on to the Commission; see Anselman, 1986, 937.
138. Cf. Rehbinder/Stewart, 1985, 331.
139. OJ C 76, 17 June 1969, 9.
140. On the general context, see Chapter III, 1.2.2.
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, 12-13. 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.
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 1986, 937, on the adoption of national standards.
143. Cf. also Pelkmans, 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 harmonisation (Chapter III, 2.3 (b) *supra*), which is however not mentioned in the White Paper and is critically commented on in the explanatory memorandum on the new approach (*op. cit.*, note 122, 4).
147. Cf. 1.1.2 *supra*, text on note 26.
148. Case 120/78, Judgment of 20 February 1979, ECR [1979] 649.
149. See point 65 in the White Paper (note 1).
150. See 1.2.3 *supra* and point 64 in the White Paper (note 1).
151. Cf. the proposal for a directive on construction products, OJ C 308, 23 December 1978, 3 and Chapter III, 2.6 *supra*, and the ESC's opinion on problems

- of barriers to trade and the harmonisation of relevant legal provisions, OJ C 72, 24 March 1980, 8.
152. Op. cit. (note 1), point 70.
 153. Cf. Chapter III, 2.6.
 154. OJ L 77, 26 March 1973, 29.
 155. Op. cit. (note 1), points 65, 68.
 156. Op. cit. (note 1), 5.
 157. Cf. 2.2 supra.
 158. Schmatz/Nöthlich, Nos. 1610, 11, 13, cf. 17-18.
 159. Op. cit. (note 1), 11.
 160. Council Resolution of 7 May 1985, OJ C 136, 4 June 1985, 2.
 161. Pelkmans, 1985, 115, says that this is "de dood in de pot" (see also Pelkmans, 1987, 265 et seq.). See further Hartlieb/Krieg, 1987, 127 as well as the interesting opinion in Dey, EG-Richtlinie, 1987, 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 harmonising the legal provisions of Member States for machines, OJ C 29, 3 February 1988, 1.
 162. Cf. 3.3 infra.
 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 harmonising 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.
 167. In the explanatory statement to the "proposal for a Council directive harmonising 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 utilised.
 168. Op. cit., 6; by contrast, the EP Committee for Economic and Monetary Affairs and Industrial Policy, loc. cit. (note 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 harmonising 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 often be deduced only by considering the versions in 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. Chapter III, 3.2 supra.
 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 *infra*.
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, 1987, EG-Richtlinie 233 *et seq.*). How the relationship here between legally binding safety objectives and legally non-binding standardisation 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 standardisation organisations, the more comprehensive the scope of a machine directive is supposed to be - this is decidedly the view of Dey, *Status Europäischer Normen*, 392-93. 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 harmonising the legal and administrative provisions of Member States on construction products, OJ C 93, 6 April 1987, 1.
177. Cf. Chapter III, 2.6; 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. *Loc. cit.* (note 178), point 10.
181. See Joerges, 1986, Section III 1 b.
182. See note 165 *supra* and accompanying text.
183. *Loc. cit.* (note 122), 5.
184. *Loc. cit.* (note 176), Art. 5 (2).
185. See Klayman, 1982, 104 *et seq.*
186. *Op. cit.*, 105 *et seq.*
187. *Loc. cit.* (note 169), Annex II (3).
188. *Loc. cit.* (note 167), 9.