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CHRISTIAN JOERGES (ED.)

European Product Safety,
Internal Market Policy and the New Approach
to Technical Harmonisation and Standards

Volume 4

EUI Working Paper **LAW** No. 91/13

**"Traditional" Harmonisation Policy,
European Consumer Protection Programmes
and the New Approach**

by

Josef Falke and Christian Joerges

European University Institute, Florence

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EUROPEAN UNIVERSITY INSTITUTE, FLORENCE

DEPARTMENT OF LAW

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BADIA FIESOLANA, SAN DOMENICO (FI)

This series of Working Papers is the translation of a study carried out on behalf of the Commission of the EC (Christian Joerges *et al.*, *Die Sicherheit von Konsumgütern und die Entwicklung der Gemeinschaft*, Baden-Baden: Nomos 1988). The Translation is – with the exception of Chapters I and V – by Iain Fraser.

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Editorial note

This Working Paper forms part of a series of five volumes dealing with the "Europeanisation" of product safety law. They are the result of a study carried out on behalf of the Commission of the EC which has so far been published only in German*. The publication of this English version has been made possible by a grant from Directorate General XI.

The five volumes of this series of Working Papers should thus be read in context. Volume 1 (Chapter I) aims to show why product safety law has given rise to extremely diverse regulation patterns and to provide an overview of the most important instruments for action.

Volumes 2 and 3 (Chapter II) are concerned with recent developments in the relevant legislation of the economically most important Community Member States and of the United States. Volume 2 (Chapter II, Parts 1 and 2) contains reports on France and the United Kingdom, Volume 3 (Chapter II parts 3 and 4) deals with the Federal Republic of Germany and the US Consumer Product Safety Act 1972, which is of crucial importance in the international debate.

Volume 4 (Chapters III and IV) analyses the development of the "traditional" policy of approximation of law and of efforts at a "horizontal" European product safety policy. In both policy areas it proved impossible to realise the Community's programmatic

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* Christian Joerges, Josef Falke, Hans-W. Micklitz, Die Sicherheit von Kosnumgütern und die Entwicklung der Gemeinschaft, Baden-Baden: Nomos 1988.

goals. As far as policy on achieving the internal market is concerned, the Commission itself has pointed out the reasons and called for, and implemented, a fundamental revision of traditional legal approximation policy. This reorientation of Community policy is dealt with in Chapters IV; it describes the most important precursors of the new internal market policy, namely ECJ case law on Articles 30 and 36 EEC since the Cassis de Dijon judgment, and regulatory technique for the Low Voltage Directive and then analyses the new approach to technical harmonisation and standards, whereby the Community will restrict itself in its directives to setting "essential safety requirements", leaving it to European and national standardisation bodies to convert these safety requirements into technical specifications.

Volume 5 (Chapters V and VI) evaluates the effects of the Community's new approach to technical harmonisation and standards on product safety policy. Chapter V diagnoses a new need for action in the area of product safety policy, including in particular the internal organisation of the standardisation process, and participation by consumer associations in European standardisation. Chapter VI continues a comprehensive discussion of alternatives open for co-ordinating internal market and product safety policy. It argues that a policy of "deregulating" Member States' product safety legislation would not be feasible, and opts for a "positive" supplementation of the new approach by a horizontal Community product safety policy. This option is elaborated in a number of recommendations.

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CHAPTER III:

The "traditional" harmonisation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy

The process of European integration affects the laws of product safety in many ways. Every law approximation policy measure, whereby the Community harmonises its legal and administrative provisions in the interest of the "functioning of the Common Market" (Art. 100 EEC, 1st paragraph), that also relates to the conditions for marketing products, necessarily contains substantive provisions that may in Member States act to promote or else to place restraints on product safety policy. These restraints may be preempted decisions at the choice of regulatory instruments and substantive definitions of the safety level to be aimed at. As well as law approximation policy, primary Community law restricts the Member States' field of action. While ECJ case law on Arts. 30 and 36 EEC has confirmed Member States' responsibility for product safety, it also subjects this responsibility to checks against principles of Community law. Finally, the Community has, following adoption of its Consumer Policy Programmes, developed approaches towards a "horizontal" European product safety policy of its own.

It nevertheless remains difficult to specify the nature of the Community's influence on product safety law more exactly, to recognise the consequences of the integration process for law in Member States and to find answers to the questions of what product safety policy tasks the Community should be responsible for and which instruments it ought to employ in so doing. Jurists are accustomed to approaching such questions by seeking to clarify and demarcate the competencies of the Community and

Member States. However apparent and inevitable this delineation of competencies may be, it rapidly emerges that the legal framework set by the EEC Treaty leaves the Community with enormous latitude, and can hardly define the priorities of Community policy (1.1 infra). Since Community law determines the process of Europeanisation of product safety policy only to a very limited extent, it is tempting to fall back on economic and politicalscience theories in explaining the actual course of this process. But attempts to date to reconstruct the process of European integration using economic models or political structural analyses have scarcely gone beyond the development of relatively abstract hypotheses on the effects of the general European policy framework conditions (1.2 infra). In view of this ambiguity not only in the law but also in sociological integration research, it is presumably justified in analysing Community practice to begin with long-term political programmes that the Community has taken as a guide in influencing product safety law: the 1969 General Programme on removing technical barriers to trade, and the programmes to protect and inform consumers (2 and 3 infra). It is the fate of political programmes, and not only where the Community is concerned, to never fully realise their original objectives. But the Community's responses to discrepancies between its original programmatic conceptions and the actual course of the integration process will be further analyzed in Chapters III and IV.

1. Framework conditions for the Europeanisation of product safety policy

The Community's competencies are by no means comprehensive. Its legislative acts in principle operate indirectly in Member States. The Community has genuine administrative

powers in only a few policy areas. All this influences both the orientation and the implementation of Community policy. All the same, these general framework conditions do not constitute insuperable legal barriers to the Community's possibilities of influencing product safety law.

1.1 The openness of the legal framework

A first indirect possibility for the Community to intervene in Member States' product safety law is offered by Art. 30 EEC. Although the ban on discriminatory import restrictions and all measures having an equivalent effect is by Art. 36 EEC for measures which, among other things, serve "the protection of health and life of humans", this has not prevented the ECJ from subjecting non-discriminatory marketing regulations to substantive verification[1]. Hopes or fears that the ECJ would use this supervisory possibility in order to "deregulate" product safety law in Member States have however not been realised[2].

Accordingly, the provisions of Arts. 100 et seq. EEC on approximation of laws remain the most important basis for Community policy. Art. 101 EEC even provides the possibility of adopting directives by qualified majority where legal differences are "distorting the conditions of competition in the Common Market". Significantly, the Community has refrained from attempting to clarify the conditions for applying this provision, which are controversial in the literature[3], thereby circumventing the difficulties of reaching consensus on law approximation mea-

1 Cf. esp. ECJ Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 — Cassis de Dijon; see Chapter IV, 1.1.

2 For more details see Chapter IV, 1.2.

sures under Art. 100 EEC. This cautiousness is hardly surprising. It is one of the indications that the limits to Community action in fact cannot be determined purely "legally"[4].

The Community's powers to take measures to approximate laws on product safety under Art. 100 EEC cannot *de facto* be limited by binding the Commission to particular integration policy objectives. There have of course been repeated attempts to derive the limits to Community competence specifically in areas of "social regulation" (chiefly health, consumer protection and the environment) from the requirement in Art. 100 EEC, stating that law approximation measures should have to do with the market[5]. But it cannot be denied that differences in product safety law constitute non-tariff barriers to trade and therefore "directly affect the establishment or functioning of the Common Market". This realisation leads directly to the position that in order to avert emergent regulatory differences the Community can exert a shaping influence "even in anticipation of the development of new legal areas"[6]. If as is the prevailing view today, the law-making competencies of Art. 100 EEC are taken in connection with the preamble and Art. 2 EEC[7], and further bearing in mind that in drafting directives the Community can lay claim to very wide discretion[8], then it is hard to identify any definitive legal bounds to product safety policy harmonisation at all. Moreover,

3 Cf. Röhling, 1972, 95 et seq., and more recently Collins/Hutchings, 1986, 197 et seq.

4 Cf. also the reports on the Commission's present consideration of activation of Arts. 101 et seq. EEC, in Collins/Hutchings, 1986, 198 et seq.; Pipkorn, Art. 101, No. 24.

5 From the German literature, see e.g. Kaiser, 1980, 102 et seq.; Börner, 1981.

6 Taschner, Art. 100, No. 23.

7 Cf. Close, 1978; Krämer, 1985, Nos. 6 et seq., 15 et seq., and for the analogous case of environmental policy Rehbinder/Stewart, 1985, 21 et seq., with other references.

8 Cf. only Langeheine, Art. 100, No. 13, with other references.

in addition to the instrument of the directive, the Community has by Art. 235 EEC a second and likewise very far-reaching power to act. This provision may, as the ECJ has confirmed[9], be taken advantage of where directives do not offer an "adequately effective means" to attain treaty objectives.

The demonstration that no clear limits to the Europeanisation of product safety law can be derived from the new Art. 100 a, Arts. 100 and 235 EEC does not explicitly respond to the questions of "dynamic" interpretation of these provisions. It may be very hard to derive clear criteria for the delimitation and control of European law-making activity from differences between the Community legal system and Member States' constitutions. But one indirect consequence, which is hard to grasp in formal legal terms, is definitely irrefutable: entry by the Community into areas of social regulation will lead to a conflict of objectives between a law approximation policy oriented merely towards market integration as such and a legislative policy oriented towards the substantive quality of regulations[10].

The Community's powers under Arts. 100, 100 a and 235 EEC compensate for the absence of genuine powers of direct action and administration by the Community. The most obvious way to reach uniform administrative practice is to harmonise the conditions for recognising national administrative acts[11]. The objective connection between approximation of laws and harmonisation of administrative practice is undeniable, particularly in the area of product safety law. Admittedly, such co-ordination is enormously complicated in practice, especially since, as M.

9 ECJ Case 8/73, Judgment of 12 July 1973, ECR [1973] 897 (907) — Massey-Ferguson.

10 Cf. Everling 1976, 170 et seq.; Langeheine, Art. 100, No. 54; Seidel, Künftige Regelungsprobleme, 1985, 170 et seq.; Bruha/Kindermann, 1986, 302 et seq.

Seidel rightly stresses[12], it affects the political "quality" of the integration process: it means an "approfondissement" of the integration process, legal reservations against which are not justified, but can at the same time be perceived by Member States as a threat to their sovereignty, and by national administrations as a restriction on their powers.

1.1 Excursus into integration theory

In practice, the potentially enormously broad legal framework for Community policy in product safety law could be used only extremely selectively and incompletely. The discrepancy between what is legally possible and what is politically feasible is a central theme of sociological integration research, which not only explains the difficulties of the integration process but looks to guide the choice of integration policy strategies. Recently in this area, the American economic theory of federalism has been taken up, and efforts at a political interpretation of the Community's legal order have been renewed.

1.2.1 The economic theory of federalism and conflicting economic interests in connection with the Europeanisation of product safety law

The economic theory of federalism seeks, in its normative part, to answer the question of what regulatory tasks can more rationally be handled ("economically") at a central level, and which better at a decentralised level. "Positive" federalism theory then tries to identify the factors that actually determine the ac-

11 Cf. Röhling, 1972, 156 et seq.

tions of those involved in politics, and bases recommendations for political strategies on this positive analysis[13]. Normative arguments for centralisation (federalisation) of regulatory activities apply where the costs and advantages of a measure cannot be confined to a particular jurisdiction ("externalities"), where regulatory differences can be strategically exploited by economic actors, starting off a regulatory "race to the bottom" ("prisoner's dilemma"), where duplication of administrative tasks (e.g. in the area of research) causes superfluous costs ("diseconomies of scale"), where the scale advantages of uniform regulation outweigh the chances of innovative product design and where federalisation weakens the influence of interest groups[14]. While such normative considerations can, *cum grano salis*, be transferred to the European situation notwithstanding the institutional differences between the Community and the US, this is much less true of the positive analysis. The current federalism debate presupposes an already economically integrated market, a parliamentary democratic constitution for the "central government" and the existence of a federal administration with a wide range of tasks and powers. It is on this institutional framework that the assumptions about interests and about the behaviour of industry, unions, consumers, and State and federal political actors are based, which in turn underlie hypotheses about the chances for a federal take-over of regulatory tasks from individual States or about the — at present more topical[15] — efforts at decentralisation. The Community situation differs from that of the US in several respects. This is primarily true as regards the process of political opinion-forming and decision-making. Political actors, who are according to the assumptions of economic theory oriented either to the expecta-

12 Seidel, Künftige Regelungsprobleme, 1985.

13 From the extensive literature, see Rose-Ackerman, 1981; Noam, 1982; Mashaw/Rose-Ackerman, 1984; Fix, 1984.

14 Mashaw/Rose-Ackerman, 1984, 115 et seq.

15 Fix, 1984.

tions of a particular clientele ("constituency politics"), or to more general regulatory attitudes and programmes ("electoral politics") lose part of their possibilities of self-presentation and influence, which are guaranteed only nationally, if they involve themselves in dealing with regulatory task at the European level[16]. European business maintains different interests and possibilites of influence . It has a degree of integration comparable with the US in only a few areas and therefore finds it enormously hard to develop a consistent position on uniformisation of product safety requirements. The two aspects mentioned are also connected with the different underlying assumptions of American federalism and of European integration. Explanations for the emergence of American federalism largely relate to situations concerning the introduction of new regulations or their generalisation, whereas the Community as a rule finds itself facing firmly established regulations that tend to differ in nature and intensity[17].

The differences between the American and European situations mentioned make it hard to transfer "positive" theorems of federalism theory. They do not, however, *a priori* preclude their adaptation to the specific conditions of European integration. For the area of environmental policy, which is related to the issue of Europeanising product safety law, E. Rehbinder and R. Stewart[18] have tried just that. In their modelling of the integration process, they conceive the Nation States as the sole political actors. For

16 For more details see Pelkmans, 1982, 116 et seq.; *idem*, 1984, 173 et seq. This fits the thesis developed by Scharpf in 1985 that willingness to convey powers of action to the Community was opposed by Member States' governments "own institutional interests".

17 Cf. Heller/Pelkmans, 1986, 245 et seq., esp. 397 et seq.; also Slot, 1975, 153. Scharpf, 1985, 34 et seq. calls the Community relationships with Member States a case of "policy overlap" that is closer to German federalism than to the American model.

18 Rehbinder/Stewart, 1985, 9 et seq.; Rehbinder/Stewart also apply their model as a starting point for analyzing the US federal system; however, they do not go any further into the state of American federalism

the integration policy behaviour of the States they assume on the one hand identification with the interests of the domestic economy, and on the other a loyalty towards protective standards valid in their own legal system. This hypothesis states that faced with a Europeanisation of legal standards the States will weigh up its advantages and drawbacks for the competitive position of their own industries, but that they cannot simply offer domestic comprises between economic and social interests. For so-called product regulation[19], the interest position for "protection States" and "risk States"[20] appears as such: as long as the protection States can exclude imports from risk States using Art. 36 EEC, the chances for harmonisation are good. The protection States will support it if the production costs caused by their domestic standards are higher, if setting up different production lines would not be economically sound and if foreign market opportunities are foreseen; the risk States will agree to the tightening up of standards where they expect advantages from access to markets in the protection States; finally, for pure "import States" the decision depends only on their own political calculations of the costs and benefits of a raised level of protection. Admittedly, the initial position changes where and to the extent that the restrictions of Art. 36 EEC have been lifted in favour of the principle of free market access in the protection State and/or products from the risk State merely need to be specifically marked. On such condi-

theory, and in the revisions of the model this necessitates (op. cit., 177 et seq., 277 et seq.).

19 Rehbinder/Stewart, as in American literature on the whole (cf. only Mashaw/Rose-Ackerman, 1984, 129 et seq.), distinguish between product regulations and process regulations (the third usual category of industrial safety regulations can be left out in considering environmental protection). For Rehbinder/Stewart, product regulation involves only the product requirements necessitated on grounds of environmental protection; but regulations motivated by consumer policy grounds also belong to this category. By "process regulations" one means environmental provisions relating to production processes; they may be neglected for our purposes.

tions, a risk State has in principle no longer any reason to agree to the tightening up of product regulations.

E. Rehbinder and R. Stewart themselves stress the limits to the explanatory capacity of their model[21]. These limits arise from the complexity of the economic interest situation, and are as a rule, not even homogeneous within the economy of a single Member State. The effects of harmonisation measure on firms involved in each case depend on the internationalisation of the economy, the size of the domestic market, their own competitive position, the costs involved in changing their output and expectations of the economic prospects — and it may, as the car industry shows, even pay to exploit different product standards in order to seal off regional sub-markets, and set up a sectorially differentiated price policy[22]. But not only the complexity of economic interests but also the "intrinsic logic" of political opinion-forming processes makes it hard to develop general hypotheses. In their negotiations at a European level, States need not concentrate on a particular product regulation, but can try to purchase gains in one sector through concessions in another. Political objectives within a government are just as unhomogeneous as business interests. The conduct of negotiations often depends on what department is responsible, how "high" the political value of the subject involved is rated and what influences the negotiators are exposed to. Awareness that a new regulation can, in any case, not be strictly monitored may facilitate acceptance. And last but not least, in agreements on product regulations, the object is often a uniformisation of regulatory methods, and therefore wishes for

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20 Since they are dealing with environmental protection, Rehbinder/Stewart talk about "environmental States" and "polluter States".

21 Rehbinder/Stewart, 1985, 9, 322 et seq.

22 Cf. Joerges/Hiller/Holzscheck/Micklitz, 1985, 345 et seq. and 2.4.1 and 2.4.3 infra.

change have to deal with administrative inertia even apart from their political and ideological content.

Up to now, integration of these viewpoints referred into a more differentiated economic model[23]. But this finding is not a merely negative statement. Bearing in mind the economic interest situation and political opinion forming processes in the Community it means that uniform behaviour patterns cannot be expected and the chances of carrying through broadly based integration strategies are slight. As regards the economic and political starting conditions, adapted fragmentary advance and pragmatism in negotiation, are to be expected. The difficult conditions of integration policy encourage an incrementalism which has a tendency to obstruct the development of a coherent European safety law[24].

1.2.2 Legal structures and political decision-making processes

Political research into integration has an ambitious past to consider. Looking back it is evident that the expectation of functionalism (and of neo-functionalism, too), i.e. that the political integration process would involve objective, functional interdependences and gradually extend to increasingly wider sectors, underestimated the contingencies of political developments[25]. The centre of interest in political research on Europe therefore shifted to the Community's decision-making structures[26] and

23 This is Rehbinder/Stewart's very surprising conclusion, given the nature of their presentation of the economic integration model as the starting point for their considerations: 1985, 315.

24 For the — relative — success of traditional harmonisation policy and on the heterogeneity of "vertical" and unsuccessfulness of "horizontal" European safety regulations see 2.7, 2.8 and 3 infra.

analyses of individual policy areas[27]. A repeatedly confirmed finding of political analysis is, as Joseph Weiler has shown[28], in striking contrast with the developments of the Community's legal structure: whereas in political decision-making processes a replacement of supranational elements by intergovernmental bargaining processes is inevitable, the supranational legal structures have developed into a European constitution which finds its expression specifically in the doctrines of direct effect, primacy and prior effect of European directives. The originality of Weiler's analysis is that he sees the presumed contradictions between the patterns of political decision-making and the legal structures as two characteristics of the European integration process that mutually determine each other. The discrepancies between the political and legal structures have not acted centrifugally, but rather as a balancing force that maintains the Community[29].

Weiler's theses are of equal importance for an understanding of the Community's legal structure and for advancing its policy programmes. They state that in order to stabilise and extend

25 See the literature survey in Behrens, 1981 and the references in Rehbinder/Stewart, 1985, 316 et seq. and Krislov/Ehlermann/ Weiler, 1986, 6 et seq.

26 As an example, see Bulmer, 1983.

27 Specifically on the programme for eliminating technical barriers to trade, see Dashwood, 1983, and on environmental policy the references in Rehbinder/Stewart, 1985, 265 et seq.

28 Weiler, 1981; *idem*, Community, Member States and European Integration, 1982; *idem*, Supranational Law and the Supranational System, 1982.

29 Scharpf's 1985 characterisation of the relationship between the Community and the Member States as a case of "policy overlap" very largely coincides with Weiler's analysis. Like Weiler, Scharpf, too, explains the unanimity rule on the basis of Member States' situations (and their governments "own institutional interests", see note 16 supra). However, Scharpf is interested only in the political conditions, which, despite the unanimity rule, impose constraints towards consensus formation at the European level (he specially mentions the density of regulation already attained, which excludes exit options and continually makes follow-up decisions unavoidable, 337 et seq.), whereas Weiler's

supranational legal structures, involvement of national political actors in the Community's political decision-making process is always necessary : the Community's precarious dual structure would be endangered by either neglecting Member States' political interests in making Community law or by neglecting principles of Community law in the Member States. These warnings coincide with the reservations against a purely formal legal treatment of the Community's powers under Arts. 100, 100 a or 235 EEC[30]. They have considerable practical implications for the connection between internal market policy and product safety policy that is of interest here. For if it is true that the adoption and implementation of Community legal acts must not, at any rate *de facto*, neglect to include political actors from the Member States, then a harmonisation policy oriented towards the objectives of realising the internal market must also bear in mind the effects of its measures in other policy areas, and cannot overextend the political consensus that underpins it. We shall return in more detail below to the consequences of these theses for the relationship between internal market policy and product safety policy in general, and to the legal significance of the "internal market to technical harmonisation and standards" in particular[31].

2. Traditional policy of approximating laws in order to break down technical barriers to trade

The manifestations and consequences of technical barriers to trade will be discussed in (2.1), the general programme for their removal in (2.2) and the methods of harmonisation it pro-

analysis centres around the relationship between the conditions for political agreement and the Community's legal structures.

30 Note 10 in 1.1 supra.

31 Chapter V infra.

vides in (2.3). Analysis of selected directives and proposals for directives shows that while this programme is primarily aimed at removing obstacles on the path to a common internal market, by way of negative integration, it also partly contains detailed regulations on product safety (2.4). Safeguard clauses are responses to reservations by Member States (2.5). With the proposal for a directive on construction products, the attempt to delegate powers to the Commission failed (2.6). Criticism of the production of directives overloaded with technical details (2.7) and the considerable difficulties in converting them into law in Member States (2.8) prepared the ground for a reorientation of integration policy; a policy that seeks in other ways to pursue the goals of free movement of goods on the one hand, and safety and health for the consumer along with industrial safety and environmental protection on the other (3).

2.1 Manifestations of technical barriers to trade and their consequences

Following the abolition of customs duties and quantitative restrictions between Member States, technical barriers to trade[32] attracted public attention. The General Programme to remove technical barriers to trade in goods was aimed at removing obstacles arising from differences in legal and administrative provisions in Member States relevant to product quality.

For many goods, special requirements on production, import, marketing or use exist that may, because of different national characteristics, hamper free movement of goods. Among these are all administrative measures by Member State authorities that ensure compliance with these regulations. Of particular importance economically are the numerous, often very detailed, intercompany technical standards, aimed at both raising the safety level of technical products, and especially at rationalising business processes and increasing productivity through mass production. Technical legal regulations are often based on decades of tradition; it is often not easy to separate the objective of protecting particular legal values on grounds of public safety and order from attempts to fence off markets. This is, however, not the place to examine attempts by particular industries to take advantage of industrial property rights and technical standards thereby avoiding price and quality competition[33].

Technical standards and trade regulations for a product that differ from one country to another may also unintentionally ham-

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32 In general on technical barriers to trade see esp. Nunnenkamp, 1983; Page, 1981 and Slot, 1975. See also OECD, Consumer Policy and International Trade, 1986.

33 Cf. Pelkmans, 1984, 175-8. For the pharmaceutical industry see Stuyck, 1983 and Reich, Parallelimporte, 184; for car spare parts cf. Joerges/Hiller/Holzscheck/ Micklitz, 1985.

per trade. These standards and regulations may have been deliberately created for protectionist reasons, but rather out of a desire to create uniformity, raise the safety of appliances or protect consumers, the environment or workers. Those particularly affected are foreign suppliers without enough economic strength to produce separate product lines to meet each set of national requirements. They are alleged to have their international competitivity notably cramped, in particular through insufficient possibility of exploiting the advantages of larger-scale mass production. Additionally, the price effects of non-tariff barriers and therefore the degree of protection for domestic suppliers are allegedly harder to estimate than for customs duties. The impenetrability and complexity of technical barriers to trade and the possibility of changing them rapidly are said to create considerable information costs and to hinder planning of production and investment. Domestic industrial firms are said to unavoidably have considerable influence on the shaping of technical standards.

A number of additional factors influence the extent to which differing technical standards and trade regulations lead to economic problems[34]. Flexibility in adaptation is greater in expanding markets and also in the early stages of a product cycle. Differences in standards hit harder as modificaton costs increase. Suppliers with the highest turnover on given markets play more or less the role of "standards leaders".

The economic effects of protectionist measures in general, including duties, levies, quotas and technical or administrative barriers to trades[35] havefrequently been discussed[36]. Among those repeatedly mentioned are higher prices for consumers, re-

34 Cf. Gröner, 1981, 153-155.

35 On 6 November 1978, in a letter to Member State governments, the Commission complained of the rising protectionism within the Community, mentioning as major examples the following restrictive mea-

striction of quality competition, loss of economic adaptability and medium- to long-term risks for jobs safeguarded in the short-term by protectionist measures.

2.2 The General Programme for the elimination of technical barriers to trade: a survey

The General Programme of 28 May 1969 for the elimination of technical barriers to trade resulting from disparities between the provisions laid down by law, regulation or administrative action in Member States[37] aims at harmonising national regulations regarding marketing and the use of particular important selected products, through directives under Art. 100 EEC. The mutual recognition of national regulations was out of the question as a procedure in principle, since it can be considered only for cases where regulations are more or less equivalent, particularly as regards objects of legal protection and production costs[38]. The programme consists of four Resolutions and a gentlemen's agreement. Two Council Resolutions contain a *timetable* for elimi-

sures that led principally to complaints about restrictions on free movement of goods:

- Documents on which imports or exports are dependent;
- Frontier checking procedures;
- Setting up minimum or maximum prices;
- Payments of equivalent effects for duties and inspection fees;
- Preference regulations in favour of national industry in the area of public supply contracts;
- National regulations laying down technical or quality conditions for marketing, e.g. technical standards.

Cf. EC Bulletin 10-1978, 24 et seq.

36 More recently, see OECD, Consumer Policy and International Trade, 1986; OECD, Costs and Benefits of Protection, 1985; Lorenz, 1985; Schultz, 1985; Gutowski, 1984; also Hasenpflug, 1976.

37 OJ C 76, 17 June 1969, 1.

nating barriers to trade in the industrial sector[39] and in foodstuffs[40]; the latter area will not further be discussed. According to this very ambitious but utterly unrealistic programme, the Council was to decide on 114 harmonisation directives for industrial products in three six-month periods between mid-1969 and the end of 1970[41]; the decisions were each to be taken within six months of presentation of the draft. Regulations were planned above all for motor vehicles, agricultural tractors and machinery, measuring instruments, electrical machinery and equipment, pressure vessels, fertilizers, dangerous preparations, lifting equipment and lifts, and other miscellaneous goods.

A further resolution[42] provided for the *mutual recognition of national inspections*, which are conditions for the marketing of many products. The principle of mutual recognition, applies, however, only in so far as national rules for marketing are equivalent or have been rendered so by Community harmonisation measures.

To *adapt directives to technical progress*, two simplified procedures are provided for[43]: in cases of particular importance, the Council will decide on a Commission proposal, by qualified majority. Otherwise the Commission will be empowered to enact amending provisions, but in doing so must call in a committee on which Member States are represented. Should the committee support the Commission's proposed regulation by qualified ma-

38 For detail on law approximation as a procedure for eliminating technical barriers to trade, see Seidel, 1969; *idem* 1971.

39 OJ C 76, 17 June 1969, 1.

40 OJ C 76, 17 June 1969, 5.

41 In March 1968, when the Commission proposed this programme (OJ C 48, 16 May 1968, 24), only 8 drafts of these were before the Council.

42 Council Resolution of 28 May 1969 on mutual recognition of tests, OJ C 76, 17 June 1969, 7.

jority, then it may be enacted; otherwise the Council will decide by qualified majority within three-months time. Should it not do so, the Commission itself may decide[44].

Finally, the Member State government representatives meeting in the Council agreed, by way of a "gentlemen's agreement", on *standstill arrangements*[45]. Governments were required for a particular period, in principle, to refrain from taking national legal or administrative measures for products covered by the programme, and to supply the Commission drafts of national legal and administrative measures. National measures "urgently required on ground of safety or of health" are excluded. This standstill arrangement has since been replaced by the directive laying down a procedure for the provision of information in the field of technical standards and regulations[46].

The Council Resolution of 21 May 1973[47] supplemented the General Programme for the elimination of technical barriers to trade in industrial products, because of the intensification of internal Community trade and the increasingly more pressing (or publicised) problems connected with environmental and health protection, adding such sectors as motorcycles, packaging, toys, equipment and machinery for building sites, petrol additives and fuel oil. Finally, in its Resolution of 17 December 1973 on industrial policy[48], the Council presented a thoroughly revised timetable for the elimination of technical barriers to trade in the

43 OJ C 76, 17 June 1969, 8.

44 For details on this see Zachmann, 1977.

45 OJ C 76, 17 June 1969, 9. Cf. the Commission's recommendations of 20 August 1965 to Member States on prior notification to the Commission of particular legal and administrative provisions at the drafting stage, OJ of 29 September 1976, 2611/65.

46 Directive 83/189/EEC of 28 March 1983, OJ L 109, 26 April 1983, 8. For details see Chapter IV, 3.1.

47 OJ C 38, 5 June 1973, 1.

field of industrial products. More than 100 additional directives were to be adopted in the four-year period which terminated at the end of 1977[49].

2.3 The methods of harmonisation provided for in the General Programme

In an annex to its original proposal for the General Programme, the Commission gave some fundamental indications on the harmonisation solutions still useful for understanding the new approach today. It distinguished the following five solutions[50]:

a) "Complete" solution: in this procedure, also known as *total harmonisation*, national regulations are completely replaced by Community ones. In complete harmonisation, only products that fully conform with directives may be marketed in the Community. The full harmonisation approach means the biggest loss of sovereignty for Member States, places particular requirements on political consensus formation and requires comprehensive detailed regulations at the Community level, but in the long-run results in the furthest-reaching harmonisation. This approach has so far been chosen, apart from the foodstuffs sector, in directives

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48 OJ C 117, 31 December 1973, 1, esp. Annex 2, 6-14.

49 It is noteworthy that the standstill arrangements are to apply to only 11 out of over 100 draft directives.

50 E.P. Doc. 15/68, VI, reprinted in BT-Drs. V/2743, 22 March 1968, 13 et seq.; for details on this see Slot, 1975, 80-89; cf. also Lauwaars, 1986, 2 et seq. Also very instructive on total and optional harmonisation is Part B of the agreement between CEN and the Commission on co-operation between CEN and the Commission of the European Communities as regards the Commission's work in the area of harmonisation of different technical legislation of Member States and the application of harmonised Community directives, DIN-Mitt. 53 (1974), 200.

on hazardous substances and preparations, cosmetics and pharmaceuticals.

b) "Alternative solution": this procedure, better known as *optional harmonisation*[51], leaves to suppliers, the freedom to choose between orienting their products to national law or to Community-law requirements. Products meeting the Community requirements cannot be refused access to the market in any Member State. This approach, the prevailing one in the area of industrial products, does ease political agreement, but has drawbacks from the viewpoints of harmonisation and also of product safety. The number of recognised rules is increased, so that it is harder to compare what is offered. Where safety standards differ, a manufacturer that avoids higher standards which in general mean higher costs, can secure competitive advantages[52]. Optional harmonisation thus tends, given significant differences in safety and a sizeable volume of cross-border trade in the products concerned, to promote a reduction in the safety level. The reasons adduced in favour of the Community regulation in cases of optional harmonisation — longer manufacturing series, better use of output, greater rationalisation — do not apply to many small- and medium-size firms that market their goods only domestically. In favour of optional harmonisation, it may be said that Member States have more leeway to take national peculiarities into account, and that national adaptation to technical progress is possible without amending the directive. Because the market is opened up for products that meet the Community standard, consumer choice is increased and competition among manufacturers stepped up.

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51 On optional harmonisation see Grabitz, 1980, 44-47; 1985, Nos. 78-80; Seidel, 1971, 742 et seq.; Eiden, 1984, 61 et seq.

52 On this see Krämer, 1985, No. 79 and Grabitz, 1980, 45.

c) "*Reference to technical standards*": On this method, directives refer, in order to specify safety requirements, to harmonised technical standards worked out by standardisation bodies[53]. This method of harmonisation has so far been applied only in the Low Voltage Directive[54], though the European Parliament[55] and the ESC[56] had selected it in their opinions on the draft general programme as the most promising of solutions. The Economic and Social Committee stressed that reference to technical standards was particularly suitable for sectors where there was experience in harmonising technical standards, and offered the greatest possibilities for elastic adaptation to the demands of technical progress and for the introduction of new technical ideas. Almost pre-empting the new approach to technical harmonisation and standards, the ESC states:

> "It would thus be conceivable for a Community directive first to list the safety objectives to be attained and then to state that these will be taken as having been attained where a particular standard, initially harmonised at Member State level, has been complied with. This provides an opportunity to demonstrate that the safety objectives can be met even without complying with the standard concerned"[57].

The legal literature had further defined this method of harmonisation by the early 70's, setting forth fairly clearly the out-

53 For more details on reference to technical standards see the chapter on Germany (Chapter II, 3), the discussion of the Low Voltage Directive (Chapter IV, 2) and that of the new approach (Chapter IV, 3).

54 Directive 73/23/EEC, OJ L 77, 26 March 1973, 29. The draft of the Low Voltage Directive was presented by the Commission on 12 June 1968 (OJ C 91, 13 September 1968, 19), only a few weeks after the General Programme for eliminating technical barriers to trade, which it had proposed to the Council on 7 March 1968 (OJ C 48, 16 May 1968, 24). On the Low Voltage Directive see Chapter IV, 2.

55 See point 5 of the European Parliament's Resolution, OJ C 108, 19 October 1968, 39 et seq.

56 See point VII (3) of the ESC's opinion, OJ C 132, 6 December 1968, 1 (4 et seq.).

line of the new approach[58]. While sliding reference to the successively newest version of a standard was rejected as inadmissible[59], conferring law-making powers to privately organised standardisation organisations, the preferred model was, for directives, only to prescribe compliance with basic requirements, with technical standards merely being cited to determine these basic requirements. Accordingly, manufacturers are not bound by the technical standards, but can show compliance with the basic requirements otherwise than by meeting standards[60]. The directive should lay down the basic requirements in a general clause embodying a rebuttable presumption that these requirements have been met by anyone who has complied with a particular technical standard in its latest version[61]. Where a manufacturer departs from the general clause, the onus is on him to prove that the generally formulated requirements of the general clause, which alone is *legally* binding, have nevertheless been met. Conversely, the authorities have the onus of showing that though technical standards referred to have been complied with, basic requirements set out in the general clause are not met[62]. In order that technical standards should not remain "merely a non-binding indication and aid to interpretation showing the specific content of the basic requirements in the individual case"[63] thereby bringing the success of harmonisation into question, Member States should "take all necessary measures to ensure that administrative authorities recognise goods as meeting the basic requirements if they comply

57 Op. cit. — Cf. also Seidel, 1971, 745 et seq.

58 Cf. esp. Starkowski, 1973, 104-118, 143-160. More recently, see also Grabitz, 1980, 82-91.

59 Starkowski, 1973, 111 et seq.; Grabitz, 1980, 72-75. Röhling, 1972, 112-132 rejects any form of reference to technical standards as unacceptable.

60 Starkowski, 1973, 115 et seq.

61 In the formulation by Grabitz, 1980, 82-91.

62 Cf. Grabitz, 1980, 88.

with the standards decided on by the Commission following consultation of the Standards Testing Committee"[64].

While its proponents presented as an advantage that standardisation in this procedure in principle remains a matter for industry[65], critics adduce constitutional reservations, complaining that

> "in view of the existential importance of environmental and consumer protection for our society today, a regulation can be tenable that leads to industrial organisations' wide-ranging powers of decision in determining the level of safety in manufacturing and utilising technical products"[66].

d) "*Conditional mutual recognition of tests*": Where harmonisation fails because Member States hold to their own safety regulations, products from one Member State should be exportable to another on the following two conditions:

— that the exported product complies with manufacturing provisions applying in the country of import;
— that competent authorities in the country of export carry out checks according to the methods applying in the country of import[67].

e) "*Mutual recognition of tests*": Here, checks carried out in one Member State are *automatically* recognised as valid by all Member States. This solution can be considered where in a given branch of industry there is very far-reaching correspondence between technical and administrative regulations in force, so that

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63 Starkowski, 1973, 116.

64 Op. cit., 151.

65 Op. cit., 152.

66 Röhling, 1972, 114.

67 BT-Drs. V/2743, 14.

prior harmonisation of national legal provisions seems superfluous[68].

2.4 Conversion into national law of the General Programme on elimination of technical barriers to trade

2.4.1 General survey

The programme to eliminate technical barriers to trade has to date been converted into law in only fragmentary fashion and with considerable delays[69]. Table 1 gives a picture of the number of Commission proposals for directives, Council directives and Commission directives on adjustment to technical progress for the years from 1968 to 1986.

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68 This solution should not be confused with the resolution on mutual recognition of tests (see the explanations in note 42 supra) since there harmonisation of legal provisions and equivalence of tests is assumed. Generally on the mutual recognition of certification and tests see Seidel, 1971, 748-750, who stresses that trust in other Member States' administrative actions is justified only where certification and tests are equivalent; see also Röhling, 1972, 142-160.

69 On this see also Pelkmans/Vollebergh, 1986.

Table 1: Programme to eliminate technical barriers to trade in industrial products — number of Commission proposals for directives, Council directives and Commission directives on adjustment to technical progress for the years from 1968 to 1986 (absolute and cumulative)(1)

Year	Commission proposals		Council directives		Difference between cols. 2+4	Commission adoption directives(2)	
	abs.	cum.	abs.	cum.		abs.	cum.
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
1968	18	18	—	—	18	—	—
1969	13	31	1	1	30	—	—
1970	5	36	9	10	26	—	—
1971	7	43	11	21	22	—	—
1972	12	55	3	24	31	—	—
1973	12	67	11	35	32	1	1
1974	33	100	14	49	51	2	3
1975	15	115	12	61	54	1	4
1976	13	128	21	82	46	4	8
1977	6	134	15	97	37	1	9
1978	11	145	15	112	33	5	14
1979	8	153	11	123	30	9	23
1980	25	178	10	133	45	1	24
1981	22	200	7	140	60	5	29
1982	5	205	7	147	58	14	43
1983	6	211	8	155	56	7	50
1984	8	219	16	171	48	7	57
1985	5	224	4	175	49	12	69
1986	11	235	19	194	41	5	74

(1) Determined from data on elimination of technical barriers in Community trade in the annual general reports, especially the tables in the annexes.

(2) Including four Commission directives on methods of analysis for verifying the composition of cosmetics and the Commission directives on sampling and analysis methods for fertilizers of 22 June 1977 (OJ L 213, 22 August 1977, 1) and on procedures for verifying the characteristics, threshold values and explosion resistance of ammonia fertilizers with high nitrogen content of 8 December 1986; OJ L 38, 7 February 1987, 1.

By the end of 1986 the Council had adopted 194 directives on the adaptation of Member States' legal and administrative provisions on trade of industrial products. Since 1974 it has had average "arrears" of some 50 Commission proposals for directives. By the end of 1970 only 10 directives had been adopted. According to the original 1969 Programme, the figure should have been over 100. It was not till June 1978 that adoption of the hun-

dredth directive on elimination of technical barriers to trade in industrial products could be hailed[70]. The directives adopted as a "package" in September 1984[71] had been awaiting decision before the Council for nine and a half years.

Most directives contain minutely detailed technically regulations[72] and do not differ significantly in content from technical standards. This entails long preparatory periods, considerable possibilities of external influence by the expert industrial circles involved, on overloading of the high-level political decision-making procedure in the Council with technical details and a pressing compulsion to adapt the directives to technical progress (or sometimes to advances in knowledge). By the end of 1986 the Commission had already adopted 74 directives on adaptation to technical progress[73].

Table 2 gives a survey of the sectors covered by the Council directives and the Commission directives on adaptation to technical progress.

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70 Bull. EG 6-1978, 7 et seq.

71 OJ L 300, 19 November 1984, 1-187.

72 A particularly obtuse example was the recent 80-page (!) long Commission proposal for a Council directive on the harmonisation of the legal regulations in Member States on "steering wheels placed in front of the driver's seat on narrow-gauge machinery with pneumatic tyres", OJ C 222, 22 September 1985, 1. Directives adopted in the automotive sector up to 1985 total — excluding the numerous amending directives and directives on adaptation to technical progress — 602 pages mainly containing technical specifications and testing instructions.

73 Including 4 Commission directives on the testing of constituents of cosmetics and Commission directives on testing and analysis methods for fertilizers of 22 June 1977 (OJ L 213, 22 August, 1977, 1) and on procedures for testing the characteristics, threshold values and explosion resistance of ammonia fertilizers with high nitrogen content of 8 December 1986, OJ L 38, 7 February 1987, 1.

Table 2: Programme to eliminate technical barriers to trade in industrial products — Number of Council directives and of Commission directives on adaptation to technical progress in individual areas (as at 31 December 1986)(1)

Area	Council directives	Commission adaptation directives
Vehicles	58	23
Chemical products(2)	33	16(3)
Measuring devices	30	10
Agricultural tractors	24	2
Construction machines and appliances	11	5
Electrical appliances	8	5
Textile products	5	1
Pressure vessels	5	0
Motorcycles	4	0
Lifts and lifting devices	3	2
Cosmetics	3	10(4)
Miscellaneous	8	0
TOTAL	192	74

(1) Derived from data on elimination of technical barriers in Community trade in the annual general reports, especially the tables in the annexes.

(2) Hazardous substances, lacquers and paints, pharmaceuticals, plant-health products, fertilizers, detergents; except for cosmetics.

(3) Including Commission directives on sampling and analysis methods for fertilizers of 22 June 1977 (OJ L 213, 22 August 1977, 1) and on procedures for verifying the characteristics, threshold values and explosion resistance of ammonia fertilizers with high nitrogen content of 8 December 1986; OJ L 38, 7 February 1987, 1.

(4) Including four Commission directives on methods of analysis for verifying the composition of cosmetics .

Of 192 directives, 145 are in the four areas of motor vehicles, agricultural and forestry vehicles, measuring devices and chemical products. The first three sectors mentioned are particularly favourable for approximation of laws. In the area of measuring devices, the Community can in its harmonisation work, call upon far-reaching international agreement regarding weights and measurement[74]. In the vehicle sector, it can largely refer back

to technical directives from the ECE in Geneva — the Economic Commission for Europe, a United Nations regional organisation. This not only signifies a saving of time for the Commission but a possibility for European vehicle manufacturers to offer their products on extra-Community market without special costly adaptations[75].

2.4.2 Total harmonisation — directives on hazardous substances

A special place is occupied by the directives that follow the principle of total harmonisation, hazardous substances with regard to fertilizers, and cosmetics. By contrast with most of the directives, they concern areas not normally regulated by technical standards. The directives in the area of classification, packaging and labelling of dangerous substances and preparations[76] were based on preliminary work done by the ILO, the Council of Europe and the OECD but not yet reflected in national legislation. Here the Community has given Member States a lead[77]. This is true particularly of the sixth amendment to Directive 67/548/EEC[78], which is the basis for chemicals laws in the Member States.

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75 Cf. Henssler, 1975, 175 et seq.; Lukes, 1985, 196.

76 Starting with Council Directive 67/548/EEC of 27 June 1967 on the classification, packaging and marking of hazardous substances, OJ L 196, 16 August 1967, 1. On this subject there were by the end of 1986, a total of 7 amending directives from the Council and 6 Commission directives on adjustment to technical progress. Additionally there were specific directives on the classification, packaging and marking of solvents, pesticides and paints, lacquers, print colors, adhesives etc.

77 Cf. Braun, 179 et seq.

78 OJ L 259, 15 October 1979, 10. This directive in turn follows the US Toxic Substances Control Act, Japanese chemicals legislation and relevant OECD proposals.

In contrast, the regulations restricting marketing and use of certain dangerous substances and preparations[79], much more detailed in application, almost always go back to initiatives by Member States barring dangerous substances on grounds of health protection or public safety, or introducing restrictions on their use. Quite clearly, these are ad hoc regulations, though adopted with considerable delays[80]: The underlying Directive 76/779 contains no criteria for including substances in the annex to the Directive. If hazards appear (and bans or restrictions are issued in Member States), a unanimous Council resolution, based on a Commission proposal, and following opinions from the European Parliament and the Economic and Social Committee, must be adopted. However, speedy mandatory measures should be required to avoid severe health risks[81]. A ban issued by one Member State and a Commission proposal for a ban give manufacturers and traders enough time to quickly sell off the dangerous sub-

79 Starting with Council Directive 76/769/EEC of 27 July 1976 on restrictions to the marketing and use of certain hazardous substances and preparations, OJ L 262, 27 September 1976, 201. Here by the end of 1986, there were a total of 7 amending directives, including those on PCB, PCT, Tris, PBB, particular substances in game articles, benzole in toys and asbestos.

80 For the seven amending directives, it took an average of 30 months between Commission proposal and Council Decision — quick as procedures for directives go, but far too slow considering the imminent risks.

81 Accordingly, the Commission undertook a new advance in 1983, in order to make amendments to the annex possible using the Regulatory Committee Procedure, COM (83) 556 final of 26 September 1983. In the meantime, with strengthening of the Commission's implementing powers by the Single European Act (for details see Chapter IV, 4.3 infra) it has proposed the even quicker and more flexible procedure of the Advisory Committee, which provides only for informative consultation of Member States' representatives, COM (87) 39 final of 30 January 1987. Cf. also the corresponding proposal for a directive on the classification, packaging and labelling of hazardous preparations, OJ C 41, 19 February 1987, 17 et seq. See also Krämer, 1985, Nos. 239-241.

stances in countries that have not yet applied the protective clause[82].

2.4.3 Optional harmonisation — Directives in the automotive sector

The most detailed regulations at Community level are for the vehicle market[83], which is also of paramount economic importance for internal trade[84]. All directives are based on the principle of optional harmonisation. In 1982, the Commission checked the extent to which Member States had bindingly prescribed compliance with Community standards domestically and to which manufacturers voluntarily followed Community provisions[85]. The finding was that except in Italy and The Netherlands, where Community standards are mandatory, manufacturers still largely have a choice between domestic provisions and Community directives. Manufacturers largely apply about half the directives, especially those on environmental protection and active safety. Otherwise, they apparently prefer national provisions. The Community standards have practically no effect where technical specifications are not legally regulated by national standards. Accordingly, manufacturers are only partly exploiting the oft- proclaimed advantages of longer production runs. The differing na-

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82 See the EAC's opinion on the proposal for a Council directive on the seven amendments to Directive 76/769/EEC, OJ C 112, 3 May 1982, 42 et seq. See also Written Question No. 650/79, OJ C 74, 24 March 1980, 6 et seq.

83 On this see Table 3 infra and Annex 13 to the Commission's Report on the European automobile industry, EC Bulletin, Supplement 2/81, 71-76, with a survey of the directives adopted for motor vehicles.

84 Automobile exports between Member States amounted in 1980 to almost 2.78 million units.

85 Commission activities and Community regulations for the automobile industry in 1981-3, COM (83) 633 final of 9 January 1984, 22 et seq.

tional provisions are apparently advantageous for dividing up and separating markets and preventing parallel imports[86].

Harmonisation directives in the vehicles sector are summarised in Table 3.

Even with the revised programme, considerable delays clearly emerge. The large number of directives can be explained by the fact that directives have been issued for practically all vehicle components. This concerns all the technical provisions that vehicles must meet, after securing EEC type approval in one Member State, in order to be marketed without further checks in other Community countries[87]. As Table 3 shows, since October 1978 all that remains to be done in order for EEC type approval to come into force is to produce directives for windscreens, tyres and the weights and dimensions of particular vehicle components.

The delays are attributed to the so-called "Third-Country" problem[88]; the fear that goods from third countries might take advantage of EEC-type approval to catch on easier to the Common Market. In the Council, even after adoption of 15 directives

86 In general on market delimitation in the automotive sector see Joerges/Hiller/Holzscheck/Micklitz, 1985. See also the report on behalf of the Committee for industry, currency and industrial policy on the automotive industry of the European Communities of 8 December 1986, EP-Doc. A2-171, 86, point 7. This product differentiation despite optional harmonisation should be separated from the "Third-Country problem" which arises particularly clearly in the automotive sector; on this see the references in notes 88-91 infra.

87 Directive 70/150/EEC on licences for motor vehicles and their trailers, OJ L 42, 23 February 1970, 1, as last amended by Council Directive of 25 June 1987 on the harmonisation of the legal provisions in Member States on licences for vehicle trailers, OJ L 192, 11 July 1987, 51.

88 See Commission activities (op. cit., note 85), 21; report on the Community automotive industry (op. cit., note 86), points 10 and 18; written questions No. 1498/81, OJ C 85, 5 April, 1982, 4; No. 1345/83, OJ C 52, 23 February 1984, 26; No. 1146/85, OJ C 341, 31 December 1985, 31 et seq.; No. 1291/85, OJ C 29, 10 February 1986, 13 et seq.

long-blocked because of this problem[89], and after adoption of the regulation on the strengthening of the common commercial policy (in particular, on protection against prohibited commercial practices[90]), it was not possible, in the same day, to overcome differences of opinion in the vehicle sector as to whether third-country products should secure access to the Community type-approval systems introduced by the harmonisation directives. By its international undertakings, the Community is obliged where reciprocity is guaranteed to give imported products equally favourable treatment with Community products[91].

While harmonisation work in the vehicle sector was initially and primarily aimed at the advantages of long-production runs, other aspects have become apparent for some time, since new production techniques allow flexible adaptation to different technical requirements. These aspects include noise levels, air pollution, fuel consumption and passenger safety. On 30 March 1984 the European Parliament adopted a resolution introducing a programme of Community measures to promote road traffic safety, and also called for an integrated programme including measures regarding vehicle construction and equipment, road construction and road signs, and road traffic regulations[92]. Among proposals are the obligatory equipping of all private cars with laminated windscreens, headrests and fog glass, anti-lock braking systems in all lorries and other safety devices, and the laying down of minimum standards on a large number of safety aspects. These

89 OJ L 300, 19 November 1984, 1-187. Cf. Bulletin EC 9-1984, points 2.1.9 and 2.1.70.

90 OJ L 252, 20 September 1984, 1.

91 Cf. the Council Decision of 15 January 1980 on provisions for applying technical regulations and standards, OJ L 14, 19 January 1980, 36, following approval of the GATT agreement on technical barriers to trade, OJ L 71, 17 March 1980, 29.

92 OJ C 104, 16 April 1984, 38; cf. also the report by the Committee on transport on the introduction of a programme of Community measures to promote road traffic safety, EP-Doc. 1-1355/83.

includes the quality of car tyres and rigidity of the passenger compartment, mandatory technical checks by independent test centres, and measures to remove vehicles with design faults from the market. It is clear that the originally largely commercially oriented policy to guarantee free movement of goods is gradually being overshadowed by an integrated policy on road traffic safety and aspects of environmental and consumer protection, even though the Council still remains closed to the idea of an integrated programme to promote road traffic safety[93].

Table 3: Directives on the approximation of Member States' legal provisions regarding vehicles

Regulatory object of directive	Date of proposal(1)	Adoption of directive planned(2) / achieved		Lag in months(3)
Type approval	7/68	1/70	2/70	1
Admissible noise level and exhaust equipment	7/68	1/70	2/70	1
Measures against air pollution by petrol engines	10/69	7/70	3/70	0
Containers for liquid fuel and its safe transport	7/68	1/70	3/70	3
Licence plate fixtures	unpublished	1/70	3/70	3
Steering equipment	2/69	7/70	6/70	0
Doors	12/68	7/70	7/70	1
Equipment for sound-level marking	8/68	1/70	7/70	7
Rear-view mirrors	8/68	1/70	3/71	14
Brakes	12/68	7/70	7/71	13

93 The Council merely took note of the Commission's plans, very modest by comparison with the European Parliament's ideas (OJ C 95, 6 April 1984, 2 et seq.); presentation of a programme is no longer being in question (OJ C 341, 31 December 1984, 1 et seq.). According to the time-table in the White Paper on the Completion of the internal market (COM (85) 310 final of 14 June 1985, 17), only three safety-related measures are listed in the automotive sector, as compared to five environment-related measures.

Radio interference removal for petrol-driven vehicles	unpublished	1/70	6/72	29
Measures against the emission of pollutants by diesel engines	12/71	7/70	8/72	25
Internal equipment	12/71	7/74 (7/70)	12/73	0 (42)
Security equipment against unauthorised use	7/72	new	12/73	-
Behaviour of steering gear in collisions	9/72	7/74 (7/70)	6/74	0 (48)
Strength and anchoring of seats	5/73	1/75	7/74	0
Projecting edges	12/73	1/75	9/74	0
Reverse gears and speedometers	8/74	1/76(1/70)	6/75	0 (66)
Licence plates	8/74	1/76	12/75	0
Safety belt anchorage	8/74	1/76	12/75	0
Lighting and signalling installations	6/74	1/75 (1/70)	7/76	19 (79)
Rear lamps	1/74	1/75	7/76	19
Contour lights, side lights, rear lights and brakelights	12/74	1/75	7/76	19
Direction indicators	12/74	1/75 (1/70)	7/76	19 (79)
Rear-numberplate lighting	12/74	1/75	7/76	19
Main-beam and dipped headlights	12/74	1/75	7/76	19
Fog lights	12/73	1/75	7/76	19
Towing equipment	12/74	1/77 (7/70)	5/77	5 (83)
Rear fog lamps	12/76	1/75	6/77	30
Reversing lights	12/76	1/77	6/77	6
Parking lights	12/76	1/77	6/77	6
Safety belts and restraints	12/74	1/76	6/77	18
Driver view field	12/75	1/77 (1/70)	9/77	9 (93)
Marking of starting equipment, telltale				

lights and indications	11/76	1/77	12/77	12
Defrosting and demisting equipment for glass surfaces	11/76	1/77	12/77	12
Windscreen wipers and washers	11/76	1/77 (1/70)	12/77	12 (96)
Internal heating	12/76	1/77	6/78	18
Wheel covers	12/76	1/77	6/78	18
Headrests	12/74	1/76	10/78	34
Fuel consumption	1/80	new	12/80	-
Engine performance	1/80	new	12/80	-
Safety windscreens(4)	9/71	7/74	(7/70)	
Pneumatic tyres(5)	12/76	1/76	(7/70)	not yet adopted
Weights and dimensions of particular vehicles(6)	12/76	1/77		

Notes to Table 3:

(1) Sometimes a directive was preceded by several drafts; the date here is that of the last draft.

(2) Determined from the timetables in the General Programme to eliminate technical obstacles to trade of 28 May 1969 (OJ L 76, 17 June 1969, 1) and the Council Resolution of 17 December 1973 on industrial policy (OJ C 117, 31 December 1973, 1). Figures in brackets are the earlier dates sometimes specified in the 1969 General Programme. In every case the implication is either 1 January or 1 July.

(3) Figures in brackets indicate the lag behind the original date in the 1969 General Programme.

(4) Commission proposal of 20 September 1971, OJ C 119, 16 November 1972, 21.

(5) Commission proposal of 31 December 1976, OJ C 37, 14 February 1977, 1.

(6) Commission proposal of 31 December 1976, OJ C 15, 20 January 1977, 4. This proposal relating to private cars should not be confused with the directive on the weights, dimensions and certain other technical characteristics of particular goods vehicles, OJ L 2, 3 January 1985, 14.

2.5 Safeguard clauses — response to Member States reservations

A number of directives contain safeguard clauses[94] allowing Member States to intervene should, despite compliance with Community standards, a hazardous situation suddenly arise calling for immediate action. Such safeguard clauses are essential to the extent that the Community provisions lay down rules for marketing and handling products Community-wide that take the right to appeal to Art. 36 EEC from Member States and adopt measures to protect the health and safety of persons[95]. The relevant provision usually runs:

> 1. Where a Member State has good grounds for believing that an EEC product, although satisfying the requirements of this Directive and the relevant implementing Directives, presents a hazard to safety or health, it may temporarily prohibit, or attach special conditions to, the marketing and use of that product. It shall immediately inform the Commission and other Member States thereof, giving the reasons for its decisions.
>
> 2. The Commission shall consult the Member States concerned within six weeks, then deliver its opinion without delay and take appropriate measures.
>
> 3. If the Commission considers that amendments to the relevant implementing Directives are needed, such amendments shall be adopted in accordance with the prodecure laid down in Art. 28; in this event the Member State which took the safeguard measures may retain them until these amendments come into force.[96]

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94 A comprehensive survey is given by Krämer, 1985, Nos. 242-246.

95 This is the ECJ's consistent case law; for more details on this see Chapter IV, 1.2.

96 Proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the construction of goods. OJ C 308, 23.12.1978, 10 et seq. Identical or similar formulations can be found in Art. 21 of Directive

The safeguard clauses are thus designed for cases where, after a Community provision has been enacted, a hitherto unknown or unrecognised hazard appears. The Member State, as responsible for the safety and health of its citizens and for other objects of legal protection, is allowed to take the necessary immediate action. At the same time, the notification of the Commission and other Member States and the involvement of the Committees to adapt the relevant directives to technical progress is aimed at securing amendment of the latter to cope with the hazard situation : this is to update Community law with regard to the hazardous situation that has emerged, so as to avoid obstacles to trade. A Member State that reacts more critically than others to hazardous situations can thus provide an impetus for the tightening up of Community standards. However, it must supply justification for temporary departure from Community law, and accept the fact that its intervention may not be lastingly confirmed by the Commission or in the committee procedure. Where, despite contrary decision by the relevant Community bodies, a Member State maintains its special measures, the Commission may bring it before the ECJ for infringement of Art. 30 EEC. Those who doubt that exercise of national police intervention powers is accessible to subsequent co-ordination through a binding Community procedure[97] have been refuted; Member States, in agreeing

84/530/EEC (common provisions for gas installations), OJ L 300, 19 November 1984, 95; Art. 24 of Directive 84/528/EEC (provisions for lifting and conveying equipment), OJ L 300, 19 November 1984, 72; Art. 23 of the sixth amendment to Directive 67/548/EEC on the classification, packaging and marking of hazardous substances, OJ L 259, 15 October 1979, 10; Art. 10 of Directive 78/631/EEC (pesticides), OJ L 206, 29 July 1978, 13; Art. 12 of Directive 75/117/EEC (electrical equipment for use in explosive atmospheres), OJ L 462, 30 January 1976, 45; Art. 12 of Directive 76/768/EEC (cosmetics), OJ L 262, 27 September 1976, 169. Member States' temporary measures are confined to a maximum duration of 6 months, unless the Commission finds adjustment of the Directive necessary, as with Art. 9 of Directive 73/173/EEC (solvents), OJ L 189, 11 July 1973, 7; Art. 9 of Directive 74/150/EEC (licences for agricultural and forestry tractors), OJ L 84, 28 March 1974, 10; Art. 9 of Directive 70/156/EEC (licences for motor vehicles), OJ L 42, 23 February 1970, 1. On the protection clause in the Low Voltage Directive, see Chapter IV, 2.3.3.

to the directive, have also agreed to verification of any further-reaching protective measures that may be necessary in accordance with the procedure laid down in the safeguard clause, so as to maintain already existing Community law. There is much to suggest that this question of principle remains obscured and that the safeguard clause procedure can be used pragmatically in a political negotiating process to adapt Community law to new hazard situations.

2.6 Proposal for a directive on construction products — a failed attempt to delegate powers to the Commission

With its proposal for a directive on construction products[98], the Commission embarked in 1978 on the since abandoned attempt to develop an alternative to the cumbersome policy of harmonisation through vertical, product-related Council directives[99]. A framework directive from the Council was to contain common definitions for all construction products and lay down general rules on the form of implementing directives; these implementing directives were, pursuant to Art. 155 EEC, fourth indent, to be enacted by the Commission, with feedback through a committee made up of Member State representatives (regulatory committee procedure). Implementing directives were to lay down more specific requirements for individual products or types of product,

97 Thus Seidel, 1971, 754.

98 OJ C 308, 23 December 1978, 3. For details on the basic problems raised by this proposal for a directive see Grabitz, 1980. See also Bub, 1979; *idem*, 1982; Blachère, 1982; Lindemann/Reihlen/Seyfert, 1984. Börner, 1973, 245 et seq., was already proposing basic directives from the Council with implementing directives from the Commission as a transitional solution until European standardisation bodies are in a position to produce recognised European standards.

99 The 1978 proposal has since been replaced by the proposal for a directive on construction products following the principles of the new ap-

and guarantee that buildings produced using materials complying with the implementing directives would meet the generally recognised requirements, including safety requirements. These requirements relate to reliability, safety, hygiene, comfort and economy of buildings, and to specific properties of products[100]. Conformity of construction products with implementing directives was to be verified and established through an EEC-type approval certificate (Art. 8-12), an EEC-type examination certificate (Art. 13-17), EEC-type conformity checks (Art. 18-21) or through EEC self-certification (Art. 22-26); procedures were to be laid down in the individual implementing directives[101].

The reasons for the failure of this ambitious project are not entirely clear. Besides Member States' reservations at such far-reaching transfer of powers to the Commission[102] and Parliament's mistrust of the excessive influence for Government representatives in the committee procedure[103], rejection of central bureaucratic detailed regulation by industrial circles involved was important, as well as special features of the construction industry which, by comparison with other technical areas, was and is relatively localised and characterised by special local and regional

proach to technical harmonisation and standards, OJ C 93, 6 April 1987, 1. On this proposal see Chapter IV, 3 infra.

100 Annex II to the 1978 proposal for a directive. Cf. the rather more detailed basic requirements formulated as performance requirements in Art. 2 and in Annex I in the 1987 proposal for a directive, relating to mechanical stability, fire protection, safety in use, durability, acoustic protection, energy saving, hygiene, health and the environment.

101 On conformity certificates, cf. Art. 13-15 and Annex IV in the 1987 proposal for a directive. According to this annex, the relevant standards or technical approvals should lay down the nature of the conformity certification (certification of product conformity, or quality control in the factory by an accepted office, manufacturer's own conformity declaration based on self-initiated personal checks or initial checks by a licensed testing centre), preference to be given in each case to the simplest procedure.

102 Cf. Braun, 1985, 181.

traditions. As well as these political reasons, there were legal reservations regarding the proposed delegation arrangements, since all essential basic decisions were not left to the Council, but would be given over to the Commission without its having any specific, detailed framework[104]. It is noteworthy that the Commission did not seek to follow the model of the Low Voltage Directive[105], but wanted to lay down the specific products standards itself in implementing directives. Here, however, it can always point to the fact, in contrast with the electrical sector, that only a few construction products are covered by international or European technical standards[106].

Aside from its failed attempt to secure far-reaching powers in implementing directives, the Commission is working on bringing out Eurocodes for the construction industry; these would be a set of European regulations based on the result of work by major international technical and scientific associations for the design, dimensioning and construction of buildings and engineering structures[107]. By contrast with the failed proposal for a directive on construction products of 1978, the 1987 proposal for a directive on construction products, with its strengthening of standardisation committees and the procedure of conformity certification, implies, above all, a strengthening of industrial circles involved. Because of the comprehensive competence of the pro-

103 Cf. the European Parliament's opinion on the proposal for a directive on construction products, points 4 and 5, OJ C 140, 5 June 1979, 28 et seq. (29).

104 In detail, see Grabitz, 1980, 48-55.

105 As for instance e.g. Bub, 1979, 673-675.

106 Cf. Lindemann/Reihlen/Seyfert, 1984, 184 et seq. See also point 11 of the explanatory statement on a proposal for a directive on construction products, COM (86) 756 final/3 of 17 February 1987, 6, according to which 15% of national draft standards reported under the information directive on standards and technical regulations related to construction products, but only 3% of existing international standards.

posed Standing Committee for the construction industry, the position of Member States ought, if anything, to be strengthened, even though from the purely legal point of view, they can assert their influence only through an advisory committee rather than a regulatory committee.

2.7 Criticisms of the classical concept of integration

Along the road towards the new approach to technical harmonisation and standards, criticism of the classical Community concept of integration was an important step. As described, the Community has for years pursued the aim of eliminating barriers to free movement of goods through vertical directives laying down uniform standards for particular products or groups of products, thereby providing firms with a broader area of action and at the same time creating uniform protective standards. By Art. 36 EEC, individual Member States may, as long as they comply with the principle of proportionality and non-discrimination, take measures to protect the health and life of people, and other objects of legal protection. These measures may have restrictive effects on free movement of goods. Harmonisation directives pursuant to Art. 100 EEC were intended to "communitarise" these protective policies, since if they continued to be on a national basis, market integration might be hampered. Along these lines, the Community, in its endeavour to create the internal market, pursued a highly fragmented product safety policy, structurally subordinated to internal market policy[108]. The

107 For more on this see Breitschaft, 1984. On European standardisation in the construction industry in general, see Kiehl, 1987.

108 On the uneven harmony between internal market and product safety policy cf. Reich, 1987, No. 116.

criticisms of the classical integration concept[109] related mainly to the following points:

— The results of harmonisation work concerned only a few areas of industry[110] and had in some sectors remained practically insignificant, considering the enormous number of technical regulations and standards in all Member States. For the Federal Republic of Germany, France, Britain and Italy alone, technical standards are estimated to total some 50,000[111]. In 1984 alone, 1,418 DIN standards[112] and 609 British Standards[113] appeared, while in the same year — one of the most successful — the Council, under the programme to eliminate technical barriers to trade, adopted 16 directives and the Commission a further 7 on adaptation to technical progress[114]. Clearly, the figures are not simply comparable, since some of the national standards served to take over international or European standards[115] and as a rule national standards have, at any rate by comparison with European standards and with the relevant directives, a much narrower area of application[116]. It is nevertheless clear that the Community cannot, even if it concentrates on a few industries of particular importance to Community internal trade, keep up with the speed and intensity of regulation in the Member

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109 A first comprehensive criticism can be found in the ESC's opinion on the issuing of barriers to movement of goods and harmonisation of relevant legal provisions, of 21 November 1979, OJ C 72, 24 March 1980, 8 et seq.; a balance sheet of the criticisms precedes the new approach, COM (85) 19 final of 31 January 1985, 3 et seq.; cf. also Pelkmans/Vollebergh, 1986, 25-27.

110 Cf. Table 2 supra.

111 Lukes, 1985, 198.

112 DIN in Zahlen, DIN-Mitt. 65 (1986), 314.

113 BSI, Annual Report, 1984 to 1985, 3.

114 Cf. Table 1 supra.

115 Of the 609 British standards adopted in 1984, for instance, 146 were identical to ISO standards, 49 to IEC ones and 37 to CEN or CENELEC ones; BSI, Annual Report, 1984 to 1985, 3.

116 To clarify this, in 1986 there were in the electrical engineering area 6, 463 DIN standards, but "only" 501 standards or harmonisation documents from CENELEC, and beside the 3 CEN standards on toy safety, 151 DIN standards for sport and leisure equipment; DIN-Geschäftsbericht 1986/87, 24-33.

States. This is particularly true where it tries to go into technical, detailed regulations, specific to particular products.

— Even where directives were adopted, they often, as in the automotive sector[117], regulated only particular aspects, whereas other aspects largely continued to get in the way of a genuine internal market.

— The procedure for developing and testing draft directives, and particularly the decision-making procedure, is extremely cumbersome and time-consuming. According to ESC indications[118], it takes more than three years between publication of a draft in the Official Journal and final adoption. The 15 directives adopted by the Council as a "package" on 17 September 1984 had been pending for decision for an average of nine years, much too long a period to be able to respond quickly and flexibly to new needs and to steadily accelerating technological advance. This criticism must of course be qualified by the observation that even at national or European level the conclusion of standardisation procedure often takes considerable time[119]. Conversion of directives in Member States takes at least another year and a half, and is often delayed still further[120].

— The frequently used procedure of optional harmonisation, while it facilitates compromise in the Council, is often not enough to bring about a genuine internal market. Here the ESC made the suggestion, apparently never taken up, that optional harmonisation solutions should in general be time-limited and be regarded as only a halfway house on the road to full harmonisation, in order to allow certain Member States and manufacturers enough time to adjust gradually[121].

— Only part of the barriers to trade that actually exist can be dealt with by directives, since Art. 100 EEC presupposes that legal or administrative provisions in the area exist in at least one Member State, or that there are plans likely to lead to the creation of a trade barrier. Harmonisation of inter-company technical standards by directives is pos-

117 See the comments under 2.4.3 supra.

118 OJ C 72, 24 March 1980, 9.

119 According to the procedure for producing DIN standards, some three years go by between application for standardisation and submission of finished DIN standard: DIN (ed.), Handbuch der Normung, Bd. 1, 2-5.

120 See the comments under 2.8 infra.

121 OJ C 72, 24 March 1980, 12.

sible only where technical norms are referred to by at least one Member State in legal or administrative provisions[122]. The Commission summarised the position in 1980 as follows[123]:

"All the national standards being drawn up by the national standardisation authorities at the rate of dozens per week are not in fact provisions of law, regulation or administrative action. These national standards are not designed deliberately in order to create obstacles but are generally meant to serve worthy aims: rationalisation of production, improvement of product quality, protection of workers, users, consumers or the environment, more economic use of energy and the like. Be that as it may, the way they are drawn up . . . gives the national manufacturers a twofold advantage over their competitors: they can be sure that in the preparation of these standards due consideration will have been given to their views and their manufacturing processes; they are aware of the intended pattern of development and modification in advance of their competitors, and therefore have time to prepare for it".

— If directives are not confined to setting forth results to be achieved, but rather bindingly prescribe detailed technical specifications of design, they may hamper technical progress[124].

— The unanimity requirement of Art. 100 EEC is indivisible, and therefore applies not only to the laying down of basic safety requirements in respect of the protective policies Member States may legitimately pursue under Art. 36 EEC, but also to the regulation of detailed technical requirements. The unanimity requirement is suspended only where adaptation of directives to technical progress has been entrusted to the Commission, in collaboration with a committee of Member State representatives. But is well-known that the attempt to give the Commission the power pursuant to Art. 155 EEC, fourth indent, to enact implementing regulations has failed[125]. This solution would have meant both gaining

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122 Langeheine, Art. 100, Nos. 18-23; Starkowski, 1973, 54-56.

123 Cited from the Commission communication to European Parliament and Council; extracts in EC Bulletin 1-1980, 12-13 (13).

124 Pelkmans/Vollebergh, 1986, 25.

125 This is provided for in the draft Directive on construction products, OJ C 308, 23 December 1978, 3; on this cf. the comments under 2.6 supra.

time and giving the Council the needed leeway to work out the underlying political principles more clearly. A prominent feature of work in the regulatory committees is the common endeavour of specialists and technicians represented not to let failure to agree in committee leave the decision to politicians and diplomats on the Council with no technical competence. In votes, there is a strikingly high proportion of concurring opinions, and in most cases even unanimity[126].

2.8 Difficulties with conversion into international law

The Commission's greater reluctance to enact new directives results in no small measure from the considerable difficulties in monitoring application of directives in Member States, and the amount of effort required to adapt them continually to technical progress[127]. Since the Commission intensified its monitoring activities in 1977[128], or one might say started paying more attention to implementation of Community law, it has often seen itself compelled to take action against several Member States simultaneously after expiring of the time-limit for conversion[129]. This is to preserve what has been accomplished and not to let the approximation of laws remain on paper, turning enactment of directives into purely symbolic politics.

This solution of delegation was once again suggested by the ESC, OJ C , 24 March 1980, 11.

126 For details see Schmitt von Sydow, 1980, 157-172.

127 Op. cit., note 123, 14.

128 For details see Ehlermann, 1981. On implementation of Community law using the breach of treaty procedure see supra all Krislov/Ehlermann/Weiler, 1986, 59-88 and Weiler, The European Community System. Legal Structure and Political Process, forthcoming. See also Hartley, 1981, 283-323; Everling, 1983, 105-109, 124; Evans, 1979; Ortlepp, 1987.

129 See the impressive list of actions for breach that appears monthly in the Community bulletins. It has even happened that the Commission has

Tables 4, 5 and 6 give a picture of the actions for treaty breaches brought by the Commission under Art. 169 EEC[130]. The actions start with a letter to the governments of the Member States concerned asking them to take a position on the non-conversion of a directive into national law, or else on an alleged breach of the EEC Treaty or of a regulation. The number of such letters grew from 97 in 1978 to 503 in 1985, that is to say they quintupled[131]. If the accusation is hereupon eliminated, the Commission presents a recent opinion; here the rise was threefold, from 68 in 1979 to 233 in 1985. Whereas on the long-term average, six out of ten cases were resolved in the initial clarificatory stage before presentation of the reasoned opinion, in approximately four out of ten cases the Court of Justice had to be called in because the Member State involved had not complied with the Commission's reasoned opinion. In all procedural stages, some 40% of cases concern the sector of the internal market and industry, i.e. the conversion of directives on elimination of technical barriers to trade or on infringement of free movement of goods. Table 5 shows that all Member States have been involved in actions for breach of treaty at all procedural stages, though to differing extents; Italy, France and Belgium are to the fore as well as Greece, considering its recent membership. Table 6 shows that just 70% of actions for breach of treaty relate to faulty conversion or non-conversion of directives[132]. The breach actions

had to take action simultaneously against all Member States for non-conversion of a particular directive.

130 Following H. Sieglerschmidt's report to the European Parliament on Member States' responsibility for application of Community law, EP-Doc. 1-1052/82, the Commission submits annual reports to Parliament on verification of the application of Community law, 1983: COM (84) 181 final of 11 April 1984, 1984: COM (85) 149 final of 23 April 1984, 1985: OJ C 220, 1 September 1986, 1, 1986: OJ C 338, 16 December 1987, 1.

131 The decline in 1983 can be traced to the fact, that, year the Commission terminated many old actions in order on grounds of legal security, to replace them with more specific notifications of time-limits.

132 In 81% of cases (1978-85) the conversion measure had not yet been notified — which primarily indicates that the directive was not yet

for 1985 relate to 219 different directives, 64 of them laying down standards for industrial products[133]. In recent years the number of actions concerning breaches of the EEC Treaty has risen very considerably. Singling out the area of the internal market and industry, these are almost always cases where the Commission complains of breach of Art. 30 ff. EEC[134].

Table 4: Actions for breach of treaty begun in the years from 1978 to 1985 by procedural stage, and specifically for questions of the internal market and industry(1)

Year	Letter of challenge		Reasoned opinions		Recourse to Court of Justice	
	Total	Internal Market	Total	Internal Market	Total	Internal Market
1978	97	60	68	49	15	9
1979	187	104	75	51	18	7
1980	227	140	68	41	28	25
1981	256	92	147	79	50	22
1982	335	97	157	92	45	21
1983	289	111	83	40	42	21
1984	454	172	148	46	54	23
1985	503	152	233	93	113	23
Total	2,348	928	979	491	365	162

(1) Source: Commission, Third Annual Report to the European Parliament on the Verification and Application of Community Law — 1985, OJ C 220, 1 September 1986, 15.

converted; in 9%, measures notified were not in line with a directive, and 10% of actions were brought for faulty application of directives, OJ C 220, 1 September 1986, 16.

133 See OJ C 220, 1 September 1986, 50-77. These figures covered only actions brought, recent opinions and letters setting time-limits because of failure to notify national conversion measures.

134 For 1983 see: COM (84) 181 final of 11 April 1984, 32-39, for 1984: COM (85) 149 final of 23 April 1985, 34-43, for 1985: OJ C 220, 1 September 1986, 33-40, for 1986: OJ 338, 16 December 1987, 41-47.

Table 5: Actions for breach of treaty begun between 1978 and 1985 (number of letters of challenge) by Member State(1)

Member State	Letters of challenge	Reasoned opinions	Recourse to Court of Justice
Belgium	285	134	62
Germany	173	81	29
Denmark	129	32	11
Greece	163	63	16
France	421	175	62
Ireland	190	64	21
Italy	420	235	112
Luxembourg	192	66	17
Netherlands	189	66	16
United Kingdom	186	63	19
Total	2.348	979	365

(1) Source: Commission, Third Annual Report to the European Parliament on the Verification and Application of Community law — 1985, OJ C 220, 1 September 1986, 14.

(2) Only after 1982.

Table 6: Actions for breach of treaty begun between 1978 and 1985, by legal bases (directives — non-notification, non-correspondence, improper application — or treaty/regulations) in total and specifically for questions of the internal market and industry(1)

Year	Total		Internal Market and Industry	
	Directives	Treaty/Regs.	Directives	Treaty/Regs.
1978	55	42	38	22
1979	150	37	82	22
1980	194	33	126	14
1981	196	60	75	17
1982	253	82	58	39
1983	186	103	65	46
1984	285	169	108	64
1985	301	202	92	60
Total	1,620	728	644	304

(1) Source: Commission, Third Annual Report to the European Parliament on the Verification and Application of Community law — 1985, OJ C 220, 1 September 1986, 16.

Between 1978 and 1985 the lion's share of Court of Justice rulings in treaty breach actions, 122 out of 135, were in the Commission's favour, with only 13 in favour of the Member State involved. The Commission boasts the same successful score sheet in the group of cases that is quantitatively by far the largest, and the one of interest here, namely the internal market and in-

dustry: 42 cases were decided in its favour, and 5 in favour of Member States involved[135].

2.9 The GATT agreement on technical barriers to trade

The trade-restricting effect of technical standards is the object of the GATT agreement on technical barriers to trade (the so-called GATT Standards Code) of 12 April 1979, which became effective on 1 January 1980 and was acceded to by the Community, as well as the most important industrial countries[136]. The agreement is aimed not only at bringing about a universal, equal level of safety, but at eliminating non-tariff barriers to trade caused by different technical requirements or different certification and monitoring procedures. Fair, open application of technical regulations and standards is to be secured through renunciation of mutual discrimination, increased transparency in standard-setting and certification systems, enhanced co-operation in the area of technical standardisation and a conciliation procedure. Goods from the territory of one contracting party may not be treated less favourably as regards technical standards and regulation or certification and control procedures, than similar goods from another contracting party or goods of domestic origin (Art. 1, 5.1, 7.2). The contracting parties undertake the use of relevant international standards, in so far as they exist, as a basis for their own standardisation work (Art. 2.2). This may be regarded as a

135 OJ C 220, 1 September 1986, 19-21.

136 The GATT agreement on technical barriers to trade is reprinted in OJ L 71, 17 March 1980, 29. By its resolution of 10 December 1979, on the conclusion of multilateral agreements negotiated as part of the trade negotiations from 1973 to 1979, the Council approved the agreement; OJ L 14, 19 January 1980, 36-37. To convert the GATT agreement, the Council decision of 15 January 1980 on the provisions for laying down and applying technical regulations and standards, OJ L 14, 19 January 1980, 36, was adopted. On the GATT standards code cf. esp. Middle-

reference to the international state of the art as embodied in international technical standards. However, the technical standards produced by the ISO and IEC are not explicitly mentioned. As with Art. 6 EEC, the contracting parties are allowed wide-ranging autonomy in the area of safety regulations: ". . . for reasons of national security, to prevent misleading practices, to protect the safety and health of the person, the life and health of animals and plants or the environment, because of significant climatic or other geographical factors or because of fundamental technological problems" (Art. 2.2).

The contracting parties undertake to take part in producing international standards (Art. 2.3.) and to lay down technical requirements where possible in relation to fitness for use and not in relation to design or descriptive characteristics (Art. 2.4). This leaves room for differing technical solutions as long as they meet the performance requirements. The contracting parties are obliged to publicise the introduction of technical standards departing from international standards, to allow their trading partners adequate time to comment and adjust, and to maintain an information office (Art. 2.5, 2.7, 2.8). Special importance can be attached to the attempt to arrive at mutual recognition of test results, conformity certificates or conformity marks. By Art. 5.2 the contracting parties guarantee that

> "their central government offices will recognise test results, conformity certificates or conformity marks from competent offices in the territories of other contracting parties, or accept certificates made out by manufacturers on the territories of other contracting parties even where test methods differ from their own, as long as they are convinced that the methods applied on the territory of the manufacturing contracting party are ade-

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ton, 1980 and Nusbaumer, 1984; also Sweeney, 1980 and Bourgeois, 1982, 7-11.

quately suitable for determining correspondence with relevant technical regulations and standards".

According to the GATT standards code, furthermore, each State that accedes to it guarantees that there is a central information office on technical regulations, standards and marking systems (Art. 10). Particularly in favour of developing countries, mutual technical support in producing technical standards and in setting up standards organisations and certification systems is provided for (Art. 11)[137].

By mid-1984, 37 signatories had acceded to the GATT standards code, including 14 developing countries. By then some 1,000 standardisation projects had been notified for which departure from relevant international standards was planned[138]. The importance of the GATT agreement on technical barriers to trade lies in the strengthening of international and regional standardisation, in the equal prominence given to certification besides standardisation, in the stress on the principle of mutual recognition of test results and conformity certificates and marks, in the setting up of an information system on technical standards and certification and in the consideration given to developing countries' special environmental, financial and commercial needs.

3. Approaches to a horizontally-oriented product safety policy

The programme to eliminate technical barriers to trade has seen its initial industrial policy orientation increasingly linked

137 In the interests of industrialised countries, performance-oriented standards, by comparison with design requirements, impede too speedy a transfer of technology. Cf. also Middleton, 1980, 207.

138 Nusbaumer, 1984, 542, 545.

with consumer policy objectives. The replacement of national product standards by the establishment of Community ones has always meant two things: removal of barriers to trade in goods (negative integration) *and* establishment of a more or less effective protective standard for the health and safety of consumers (positive integration). In addition to vertical product safety policy, aimed at individual products, Community consumer policy has developed horizontal approaches, embracing more than one product or group of products, for guaranteeing product safety.

3.1 Consumer protection and information programmes

The fundamental guidelines for a horizontally-based product safety policy can be found in the two action programmes on consumer protection and information[139], specifically in the section on protection of consumer health and safety. The principle set down there is:

> "Goods and services offered to consumers must be such that, under normal or foreseeable conditions of use, they represent no risk to the health and safety of consumers. There should be quick and simple procedures for drawing them from the market in the event of their presenting such risks"[140].

As well as many indications on the promotion of consumer safety and health in harmonising legal regulations for individual products, the second programme contains a basis for a horizontal

139 First and second programmes on consumer protection and information policy (OJ C 92, 25 April 1975, 1; OJ C 133, 3 June 1981, 1). For the survey see Krämer, 1983. An interim report can be found in: Commission of the European Communities, Zehn Jahre Verbraucherpolitik der Gemeinschaft. Ein Beitrag zum "Europa der Bürger", Luxembourg 1985.

140 First programme (op. cit., note 139), point 15.1; Second Programme (op. cit., note 139), point 12.1.

product safety policy which — against the background of increasing awareness of the limits to interventionist interference at the policy formation and programme implementation stage[141] — stresses informative guidance and the provision of incentives to co-operation over intervention. As regards product safety, in part to facilitate identification of priorities, two information systems are proposed: a Community system of information on accidents in connection with the use of particular products, other than in occupational activity or road traffic, and one for rapid exchange of information on hazards arising in the use of consumer goods[142].

To a large extent, Community consumer protection policy has had results that lag far behind its original programmatic intentions. This is due to economic decline, the view that consumer protection is part of Member State rather than Community competence, the unanimity requirement for law approximation pursuant to Arts. 100 and 235 EEC, and the concentration on vertical harmonisation[143]. For a long time successes were achieved essentially only where product-specific regulations were issued to guarantee free movement of goods that also involved protection of consumer health and safety[144]. The principle of pursuing con-

141 The first clear and portentous signal was given by the Commission at its Comblain-la-Tour meeting in 1978. In drawing up a balance sheet of its work and redefining its course, it made new harmonisation measures dependent on the following four conditions being met:

— Community action already requisite and not replaceable of measures by other actors;

— positive effects on Community internal trade;

— contribution to the economic and monetary integration of Europe;

— adequate staffing and financial resources.

On this see Bourgoignie, 1987, 178. On criticism of the production and implementation of directives in connection with the programme on eliminating technical barriers to trade cf. 2.7 supra.

142 Second Programme (op. cit., note 139), point 25-27.

sumer policy "piggyback" fashion to other policies cannot immediately be transferred to horizontal product safety policy. This is one explanation for why it was only fairly late that the Community developed systems to survey accidents and hazards in handling products, and adopted the Product Liability Directive.

As a continuation of the two consumer protection programmes of 1975 and 1981, the Commission, in its communication to the Council entitled "A new impetus for consumer protection policy", proposed the following four components of its future product safety policy[145]:

— Laying down of binding health and safety standards for manufacturers and suppliers, introduction of a general safety duty;

— co-operative action among national authorities responsible for consumer product safety;

— creation of Community institutions to monitor health and safety hazards arising in using consumer products;

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143 Commission communication to the Council on a new impetus to consumer protection policy, COM (85) 314 final of 23 July 1985, points 4-9. For an exhaustive analysis see Bourgoignie, 1987, 200-219.

144 Of the 28 most important texts adopted by the Council on consumer protection in the 10 years after 1975, not less than 24 under the programme to eliminate technical barriers to trade referred to very specific products (vertical product safety policy), with only 4 that could be regarded as constituting horisontal product safety policy (indication of prices for foodstuffs, pilot experiment on accident information, rapid exchange of information on hazards arising in the use of consumer products, misleading advertising). By contrast, of the 8 most important consumer protection proposals before the Council for discussion in early 1985, not less than 6 were on aspects of consumer protection applying to many products (product liability, "door-to-door salesmen", consumer credit, advertising, price indications, accident information system). Calculated from Zehn Jahre Verbraucherpolitik (op. cit., note 139), Annexes III and IV. For a critical account, specifically on product safety, see BEUC, Manifest für die Sicherheit in Europa, BEUC-Nachrichten 47/1985.

145 New impetus (op. cit., fn 143), points 19-28. On the Commission communication, cf. the Council resolution of 23 June 1986, OJ C 167, 5 July 1986, 1-2, and Stellungnahme von BEUC, BEUC-News, No. 46/1985, 7-10 and Héloire, 1987, 7-10.

— Community information and education on home and leisure product safety.

In pursuance of this new programmatic approach, explicitly identified as a complement to the new approach to technical harmonisation and standards, the Commission and Council have already adopted a number of measures:

— Amended proposal for a directive on the safety of toys[146];

— directives on products which appearing to be other than they are, endanger the health or safety of consumers[147];

— intensification of co-operation and information exchange with and among national authorities responsible for consumer product safety[148];

— interim report on the system for the rapid exchange of information on dangers arising from the use of consumer products, and initial proposals to extend the system[149];

— extension of the demonstration project on a Community accident information system[150];

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146 In OJ C 282, 8 November 1986, 4, on 2 October 1987 the Commission presented another amended version, COM (87) 467 final. See also the observations in 3.2 and in Chapter IV, 3.2.

147 OJ L 192, 11 July 1987, 49. See also the observations in 3.4.

148 The first conference took place in May 1984 in Montpellier, and dealt with national and Community provisions in force on implementation and monitoring of consumer product safety. The effects of Community directives on the conversion of standards and technical regulations and the monitoring of accidents caused by consumer products in the home were also discussed. Cf. Proceedings of the First European Conference on Inter-Administrative Co-operation in the Field of Consumer Product Safety in the Community, Montpellier, 28-30 May 1984, DG XI, -233-86. The second conference took place in June 1986 in The Hague, and dealt with the involvement of consumers in standardisation work, the development of a research programme on accidents in the private sphere, Community framework provisions on consumer product safety and the rapid information system on product hazards; cf. Bulletin EC 6-1986, No. 2.1.166. The third conference was held in September 1987 in Warwick.

149 COM (86) 562 final, 24 October 1986. For more on this see 3.4 infra.

150 For more on this see 3.3 infra.

— communication to the Council on the integration of consumer policy in the other common policies[151];

— communication to the Council on the safety of consumers in relation to consumer products[152];

— communication from the Commission on a Community information and awareness campaign on child safety[153].

3.2 Proposal for a directive on the safety of toys — search for product-specific integration of internal market and product safety policies

Some peculiarities are displayed by the 1983 proposal for a framework directive on toy safety [154], which replaced an initial proposal from 1980[155]. The toy industry is characterised by considerable international integration, and markets an extraordinarily varied range of products. Over 60,000 types of toys are marketed at present. These often have very short development periods, so that there is only a very limited time between development and marketing of a product, thus intensifying safety problems. Community-wide, some 2 million children per year have toy-related accidents.

What is aimed at is total harmonisation, since children's health and safety ought not to be protected to different extents in different Member States. Toys must meet a detailed catalogue of safety requirements which — in line with the variety of risks — relate to physical and mechanical risks, flammability, chemical

151 COM (86) 540 final, 24 October 1986. Cf. the Council resolution of 15 December 1986 on the integration of consumer policy in the other common policies, OJ C 3, 7 January 1987, 1-2.

152 COM (87) 209 final, 8 May 1987.

153 COM (87) 211 final, 11 May 1987.

154 OJ C 203, 29 July 1983, 1-11.

155 OJ C 228, 8 September 1980, 10-42.

hazards, explosion risks, electrical risks, hygiene and radioactivity (Annex II). It is not proper use that is to be taken as a basis, but the usual mode of use and foreseeable misuse by children under normal circumstances (Art. 2 (1)).

A notable feature of the proposal, now abandoned, was that it not only aimed at removing barriers to trade, but above all at protecting children's safety and health, for which it introduced some special legislative instruments. Thus, Member States were to report every three years on experience in safety checks carried out and in particular on accidents that had occurred when using toys (Art. 7 (3)). They had to ensure that toys not complying with the general safety principles and therefore hazardous to consumer safety and health were removed from the market without delay (Art. 9). Toy advertising was subject to minimum conditions to prevent consumers from being deceived as to the characteristics and safety level of toys, and to enable them to draw conclusions as to cautionary provisions in their use and as to the minimum age-limits applying to particular types of toys (Art. 10).

However, what makes the various proposals for directives on toy safety particularly interesting is that they document the regulatory shift from product-specific directives with detailed technical specifications up to the new approach, with its reference to technical standards[156]. The core of all the drafts is an annex containing general objectives on toy safety — or in the terminology of the new approach, the basic safety requirements.

According to the first 1980 draft[157], the technical standards to be observed for individual risks among those mentioned in the general safety objectives should be laid down in guidelines by the

156 For information on the various stages of this "regulatory odyssey" see the general explanatory statement to the proposal for a directive on toy safety, 1986, COM (86), 541 final, 16 October 1986, 2-4.

Council itself. The proposal for a directive contained general safety objectives and at the same time detailed annexes with Community technical safety standards, on testing of physical and mechanical properties and on the flammability of toys (Annexes V and VI); further directives on common technical standards concerning chemical, toxicological, electrical and other risks were contemplated (Art. 4 (1)). The initial attempt at broad reference to technical standards failed because no satisfactory technical standards for toy safety existed at a European level, and because European standardisation bodies did not get on with their work quickly enough, and were exposed to criticism from Member States regarding the quality of their work.

The European Parliament hoped for a specific reference to technical standards instead of a description of technical characteristics and test methods in the annexes to the directives[158]. The Commission thereupon split its proposal, bringing three variations before the Council in July 1983 for directives on toy safety. These included a framework directive containing general objectives for toy safety from all viewpoints[159], and two specific implementing directives on the mechanical and physical properties[160] and inflammability of toys[161]. The proposed implementing regulations referred — subject to particular amendments — to two European standards. Compliance with them was to be made binding (Art. 4 (1)). Departure was to be possible where toys were manufactured according to new technologies and the general safety regulations were complied with (Art. 5 (1)).

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157 OJ C 228, 8 September 1980, 10.

158 COM (86) 541 final, 16 October 1986, 2.

159 OJ C 203, 29 July 1983, 1-11.

160 OJ C 203, 29 July 1983, 12-14.

161 OJ C 203, 29 July 1983, 14-16.

The October 1986 proposal[162], fully adopts the regulatory concept of the new approach to technical harmonisation and standards. The safety requirements, taken over essentially unchanged, are (rebuttably) to be presumed compliant if their Community mark confirms that the toys meet particular harmonised technical standards converted into national standards or, in the case where the harmonised standards are not applied or only partially applied or no standard exists, meet the basic requirements of a Community design test. The proposal still contains a few features attributable to a general product safety policy: where toys jeopardise the safety and health of users or third parties, Member States are called on to take all appropriate measures to remove them from the market, forbid their marketing or restrict it (Art. 7 (!)). While initially there was explicit provision for an obligation on other Member States to withdraw toys from the market and prohibit their being marketed where such a measure proved justified, now all that is planned is information of other Member States by the Commission (Art. 7 (4)). Member States are instructed to ensure that random checks on toys marketed are carried out in order to verify their safety (Art. 12 (1)).

3.3 Pilot experiment for a Community accident information system

The first important foundation stone towards the establishment of a horizontal Community product safety policy was the Council's decision of 23 July 1981 on the "implementation of a pilot experiment relating to a Community system of information on accidents involving products outside the spheres of occupational activities and road traffic"[163]. The pilot experiment was

162 OJ C 282, 8 November 1986, 4 in the amended version of 2 October 1987, COM (87) 467 final. For more details see the comments in

carried out from 1 January 1982 onwards for a period of 30 months and was to cover accidents in the home and its immediate proximity requiring medical treatment, and supply information on identification of the accident, its location, products involved, type of accident, type of injury, activity in progress at time of accident, its outcome and arrangements relating to the victim. The intention was to cover 320,000 cases per year, distributed proportionately over Member States according to population, from hospitals, poison emergency centres and doctors. The object was to set up a Community system to collect information on home accidents in order to establish priorities for appropriate proposals to prevent accidents involving products[164]. All the States that have an information system for the systematic assessment of accidents in fact understood the setting-up of the system as a building-block towards a more comprehensive product safety policy[165].

The pilot experiment, which left Member States free as to the mode of their participation (Art. 2 (2)), ended in relative failure[166], because only Britain, the Netherlands and Denmark actually took part[167], the other Member States either did not partici-

Chapter IV, 3.2.

163 Council Decision 81/623/EEC, 23 July 1981, OJ L 229, 13 August 1981, 1.

164 Op. cit., note 162, 3rd and 4th recitals.

165 Cf. OECD, Data Collection Systems, 1978.

166 The final report on the results of the pilot experiment -published as an annex to the Commission's proposal for a Council decision introducing a Community system of information on accidents in which consumer products are involved, COM (84) 735 final, 7 January 1985 — rather complacently glosses over this. But see the report by the European Parliament Committee on the environment, public health and consumer protection on this Commission proposal, PE DOC A 2-183/85, 12 December 1985, 10.

167 That is, the Member States that already had a more or less developed system for monitoring accidents arising in product use; Britain has been running the "Home Accident Surveillance System" (HASS) since 1976 (cf. Chapter II, 2.5 supra), the Netherlands have been doing studies since 1981 for the "Privé Ongevallen Registratie Systeem" (PORS, in force since 1983), and Denmark has since 1978 been in-

pate at all[168] or supplied only fragmentary information[169]. Given the extremely limited financing, a representative data survey was never in question. Nevertheless, taking experience acquired in the US with the NEISS into account[170] and including data from Member States that have an appropriate survey system, the pilot experiment did allow a more or less well-founded estimate of home and leisure accidents. The study concluded that in the European Community annually more than 30,000 deaths and some 40 million injuries result from accidents not related to work and traffic. Hospital treatment and health insurance costs alone amount to more than 30 million ECU annually.

On the basis of experience with the pilot experiment, the Commission once again, on 7 January 1985, proposed the setting up of a "Community system of information on accidents in which consumer products are involved"[171]. Despite the favourable opinions from the Economic and Social Committee[172] and the European Parliament[173], all the Council managed to arrive at, with its decision of 22 April 1986 concerning a "demonstration project with a view to introducing a Community system of information on accidents involving consumer products"[174], was the introduction of a further demonstration project, this time limited to 5 years. Basic information is to be obtained from the casualty de-

volved in Scandinavian projects for surveying home and leisure accidents. A survey is provided by the Commission of the European Communities, Proceedings of the European Symposium on "Product Safety in European Community", Brussels, 17-18 May 1984, 60-120.

168 The Federal Republic, Greece and Luxembourg. For the justifications see the answer to written question No. 2194/84, OJ C 203, 12 August 1985, 3.

169 Belgium, France, Ireland and Italy.

170 Cf. Chapter II, 4.2 supra.

171 OJ C 117, 11 May 1985, 4.

172 OJ C 188, 29 July 1985, 9.

173 OJ C 68, 24 March 1986, 189.

partments of hospitals selected by Member States in agreement with the Commission; in full operation, between one (Luxembourg) and 13 (Federal Republic of Germany) hospitals per Member State are to be covered. The object is the involvement of 90 hospitals and collection of data on 400,000 to 900,000 cases per year, distributed over Member States in proportion to population[175]. In duly justified circumstances, the Commission may accept information from alternative sources of an equivalent value. Member States may also forward *additional* information from poison antidote centres, family doctors, insurance companies or other information sources. The Commission is responsible for assessing data from the whole Community, uniformly coded; it may carry out detailed studies on the most serious and/or most frequent accidents (Art. 4 (1)). A maximum amount of 7 million ECU is provided for implementing the demonstration project for the first three years[176].

The Council adopted the Commission's objective of using the information for "promoting improvements in product features, their standards, their proper use by consumers and consumer information and education aimed at preventing accidents"[177], but decided against the proposed documentation and information centre to make all non-confidential information accessible to those interested, which would have been important for achieving its goal[178], and instead of annual reports called only for a final report[179]. This decisively restricts the possibilities of

174 OJ L 109, 26 April 1986, 23.

175 Op. cit., note 105, Annex I.

176 This amount is regarded by the ESC (loc. cit., note 103), point 1.7, as utterly inadequate — understandably, since ignoring initial costs one arrives at less than 8 ECU per case, assuming coverage of only 300,000 cases per year on average, for data collection, evaluation and administration.

177 Council Decision 86/138/EEC, 22 April 1986 (op. cit., fn 173), sixth recital; cf. also Art. 1 (2).

arriving at any specific action during the again extended test period. The conveying of information to circles involved as quickly as possible, possible withdrawal of goods from the market, and in general, the urgency of action on an accident information system had been underlined by the European Parliament[180] and the Economic and Social Committee in their opinions, the latter putting it particularly emphatically:

> "Collecting statistics must not be an end in itself, and the Commission should set up procedures to ensure that action is taken in respect of products and features which cause accidents. Such action would involve for example product recall and redesigning of products and features and the setting of appropriate standards at Community and international level."[181]

Indeed, it has to be said that today the link-up between accident surveys and other areas of product safety policy has not yet been achieved. Priority ought to go not to the building-up of the most perfect possible accident information system in the 1990's, but to rapidly converting already available data into Community-wide action before completion of the demonstration project. This would mean making all non-confidential information collected available to interested circles, namely public authorities, manufacturers, traders, users, standardisation bodies and the Standing Committee on standardisation questions. Funds for the necessary in-depth studies on particularly hazardous areas found should already be made available.

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178 Art. 7 of the Commission proposal (loc. cit., note 170).

179 Cf. Art. 8 of the Council Decision (loc. cit. note 173) and Art. 8 of the Commission proposal (loc. cit. note 170).

180 Op. cit., note 172, points 4 and 9.

181 Loc. cit., note 171, point 1.6.

It is well known that only a small proportion of home and leisure accidents surveyed have causes attributable to the use of consumer products[182]. Such accident-causing products[183] ought to be recorded whenever possible: along with any marks the products might bear, their condition at the time of the accident and detailed information on how the accident occurred, if improvement of hazardous products on a voluntary basis, the establishment of suitable safety standards with priority in proven hazard areas, or where necessary, the publication of warnings or the commencement of recall campaigns shall be achieved. In designing the in-depth studies, representatives of standardisation workers should be brought in, to guarantee that information of importance to standard-setting is in fact collected[184].

The Commission intends as part of its research and development programme for 1987 to 1991 to coordinate and promote in-depth research work on the following priority areas: poisonous substances (especially child-proof seals), articles for children, playground devices and amusement parks, sport articles, do-it-

182 Even though the much played up finding of the HUK study for the Federal Republic (Pfundt, 1985, 190 — for more details see Chapter II, 3.1 supra), that 99% of home and leisure accidents result from more or less serious mistaken actions, is not entirely confirmed by the other information systems.

183 Cf. the list drawn up by the HASS of products, articles and characteristics in the household area with the most frequent involvement in accidents requiring hospital treatment, described in the Commission's preliminary draft, submitted in May 1986, for a multi-year action programme on consumer safety and on measures to prevent home and leisure accidents (1987-91), 20-21. For a comparison see Pfundt, 1985, 163-5.

184 On the supra see Falke, 1986, 19. On the connection between accident information systems and technical standardisation cf. also Micklitz, Perspectives 1984, 17.

yourself appliances, fire safety and products developed specially for the elderly and the handicapped[185].

3.4 Information exchange on product hazards — approach to Community follow-up market control

To date there is not at the Community level any "simple but effective system allowing products and services hazardous to consumer health to be removed from the market"[186].

The Community has contributed to the marketability of products in various ways: through its measures to eliminate technical barriers to trade, and still more through the new approach with its reference to standards and mutual recognition of certificates[187], and the ECJ case law on freedom of movement of goods — namely that a product legally manufactured and marketed in one Community country must in principle be admitted into all other Community countries, irrespective of contrary national regulations, which cannot be legitimated by Art. 36 EEC[188]. However, with a few exceptions[189], it is not taking

185 Commission, preliminary draft multi-year action programme on consumer safety and measures to prevent home and leisure accidents (1987-91), Brussels, May 1986, 29-30.

186 Thus the European Parliament's proposed amendment to the proposed system for information exchange on product hazards, OJ C, 19 July 1982, 116 et seq. (117); it takes up a formulation from the first and second programmes on consumer protection and information. On the legal position in the Community and the individual Member States cf. Stuyck, Withdrawal, 1984; Krämer, Zum Rückruf von Produkten, 1982; *idem*, Product Recalls, 1982. On the legal position in the OECD countries and the OECD's position, cf. OECD, Recall Procedures, 1981.

187 For details see the comments in Chapter IV, 3.2.

188 More details in Chapter IV, 1.

189 Cf. the directives restricting the marketing and use of certain hazardous substances and preparations, on which see 2.4.2 supra, esp. note 79; cf. also the Directive on products which, being other than they appear to

any measures for Community-wide intervention against product hazards. It is in most cases left up to Member States to restrict or prohibit trade in suitable fashion on their territory when serious hazards arise from a product. For products to which Community safety standards apply, the safeguard clause procedure must be used[190].

The reverse side of the Cassis de Dijon principle, according to which anything legally manufactured and marketed in one Member State may be marketed without restriction everywhere in the Community, leads to the political maxim that a product must be removed from the market in all Member States when serious risk has been found in one Member State, leading to a recall or marketing ban[191]. Behind this lies the general idea that free movement of goods should benefit only products that do not constitute a hazard to consumer safety or health[192]. If a product could be recalled or banned from the market in one Member State but simultaneously freely marketed in others, this would be incompatible with the objective of creating a Community-wide level of comparable product safety and of guaranteeing free movement of goods only when this does not adversely affect the rightful protection of consumer safety and health[193]. A common market for products necessitates, if new border controls are not to be introduced because of the possibility of resale and parallel imports, a

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be, endanger consumer health and safety, OJ L 192, 11 July 1987, 49. See also Krämer, 1985, Nos. 239-241.

190 Cf. 2.5 supra.

191 For details on this, discussing it as a legal principle, see Krämer, 1985, Nos. 247-251. See also Kögler/Krämer, 192; Domzalski, 1984, 28.

192 The present position is bitterly described by Domzalski (1984, 30) as follows: "If there is one field in which the Community principle of `free movement' is fully implemented, then it is without a doubt that of dangerous products".

193 Krämer (1985, No. 250) describes examples where recalls remain restricted to individual Member States. On the related problem of banning particular hazardous substances, cf. 2.4.2 supra.

Community instrument for eliminating products hazards arising from it[194].

The Council decision of 2 March 1984 "introducing a Community system for the rapid exchange of information on dangers arising from the use of consumer products"[195] does not aim at introducing this sort of Community follow-up market control. Instead, all Member States are to be informed as rapidly as possible of urgent steps taken by one Member State (if possible only after consulting the producer, distributor or importer)[196] to prevent, restrict or attach particular conditions to the marketing or use of a product on its territory, or product group, because of a serious and immediate risk which that product or product group presents for the health or safety of consumers when used in normal and foreseeable conditions (Art. 1 (1)). The information system applies to all products intended for use by consumers except those intended exclusively for professional use or those subject under other Community instruments to equivalent notification procedures (Art. 2). It has since been clarified that only medical specialties falling under Directives 75/319/EEC and 81/851/EEC, and notifications on animal diseases and residues in foodstuffs and fresh meat pursuant to Directives 64/432/EEC and 82/894/EEC have an equivalent Community notification proce-

194 For details on this see Chapter VI, 3.4 infra.

195 OJ L 70, 13 March 1984, 16-17. For details on this see Milas, 1984. See also Pauli, 1984; Falke, 1986, 20-21. The European Parliament, which initially took a negative attitude to the Commission proposal (OJ C 172, 13 July 1981, 135-36), indicated its agreement only once the existing informal information exchange among European countries under OECD auspices proved to be inadequate in the case of the denatured Spanish oil, from which hundreds of people died and thousands were poisoned in the summer of 1981. See the European Parliament resolutions on the Commission proposal, OJ C 182, 19 July 1982, point 3. In July 1985 the Commission, pursuant to Art. 4 of the decision, decided the details of its implementation, communicated as Annex II to the interim report on the system for the rapid exchange of information on dangers arising from the use of consumer products, COM (86) 562 final, 24 October 1986.

dure[197]. The safeguard clause procedure contained in many product-related directives[198] cannot be regarded as an equivalent notification procedure, as it is not aimed at equally rapid exchange of information, applies only to products complying with the harmonised standards, and finally is intended, over and above urgent temporary intervention, to lead to revision of the Community standards themselves. The point of the system is to facilitate a rapid exchange of information in the case of a serious, immediate danger requiring immediate action, not long-term risks in the case of which the adjustment of product-specific requirements has to be considered[199]. For foodstuffs, which formally fall under the scope of the decision, the informally introduced and, according to report, well-functioning system has been retained and not administratively integrated in the non-food area[200].

The Commission, under which an advisory committee is set up to implement the decision (Art. 7), is the central relay station for information. It receives notification of emergency measures taken, verifies it and telexes it to the competent authorities of the other Member States (Art. 1 (3)). These have to inform it without delay of any measures they may have taken following receipt of the information; the Commission in turn forwards this information to the competent authorities of other Member States (Art. 3). At the request of authorities supplying the information, it may in justified cases be treated as confidential (Art. 6). By March 1988 the Council was to decide in the light of experience obtained

196 Cf. point 4 of the detailed description of the procedure.

197 See interim report (op. cit., note 194), section VI.

198 Cf. 2.5 supra.

199 See interim report (op. cit., note 194), section IV and point 2 in the detailed description of the procedure.

200 See interim report (op. cit., note 194), section II.

whether to continue or revise the system, initially restricted to 4 years (Art. 8 (2)).

Between March 1985 and September 1986, 34 cases were reported in the foodstuffs area and 33 in the non-foodstuffs area. In the latter area, communications overwhelmingly concerned electrical appliances, but also toys, and were concentrated almost exclusively in the last half-year period[201]; now that initial difficulties have been overcome, a further increase in notifications is to be expected. It is at present being considered whether and to what extent European consumer organisations should be given the information received and whether information should be exchanged on a voluntary basis even before such a decision is taken[202]. The Commission has commendably announced its intention to include information for third countries in the early warning system, so as to prevent export of hazardous products or substances banned in the Community[203].

One point that should be verified is whether the information exchange should remained confined to sovereign governmental urgent measures. It is likely that voluntary recall or warning campaigns by manufacturers and importers, not infrequently in response to pressure from government agencies[204] or consumer organisations or the media, are commoner than governmental marketing bans or restrictions. Government agencies more often act in an advisory capacity rather than with repressive police

201 Cf. the lists of cases notified since March 1985, printed as an annex to the interim report (op. cit., note 194).

202 See interim report (op. cit., note 194), section VIII.

203 New impetus (op. cit., note 143), point 25. Cf. also the European Parliament resolution instructive in this context, on the export of pesticides to third countries, OJ C 307, 14 November 1983, 109 et seq.

204 In this connection, cf. the cooperation between manufacturers and the Institute for Research and Standards in Ireland and the Consumer Safety Unit of the Department of Trade and Industry in Britain, and

measures in monitoring the safety of technical consumer products[205]. Agencies responsible for monitoring product safety in Member States ought to exchange information regularly on their experience in this area of their work. Whether other Member States in turn act when they have received the information and what functionally equivalent measures they take after how long a time is an important preliminary question for the setting up of Community follow-up market controls[206].

Important supplementary functions or initiatives, correction and information are results of the efforts of consumer associations to set up information networks on product hazards[207]. All too often the authorities merely react to public pressure, or else keep important information from the public by minimising hazardous situations. Since 1981 the BEUC has, with its BEUC Communications, set up a sort of Interpol system for hazardous products. By mid-1985 some 140 different products had been indicated as hazardous, though without distinction as to whether the case concerned a ban or warning from a public body, a voluntary recall by a manufacturer or a comparative test of goods[208]. In view of the practice by multinational concerns of selling off hazardous products and chemicals in Third World countries that have been banned in industrialised countries, the worldwide ac-

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supra all the British Code of Practice on action concerning vehicle safety defects.

205 Thus in the German Land of North Rhine-Westphalia in 1984 tests under the GSG showed 5,393 defects out of 18,997 appliances tested; in only 27 cases (i.e. 0.5% of the appliances found defective) was marketing or exhibiting prohibited; Jahresbericht 1984 der Gewerbeaufsicht des Landes Nordrhein-Westfalen, 232.

206 More details in Chapter VI, 3.4.

207 On the activities of BEUC and IOCU, see Domzalski, 1984.

208 Cf. Krämer, 1985, No. 154.

tivities of the IOCU (International Organisation of Consumers' Unions)[209] deserve particular attention.

3.5 The Product Liability Directive

Almost a decade after submission of the Commission's first proposal[210], the Council arrived on 25 July 1985 at adoption of the Directive on Defective Products[211].

The main lines of the Directive can be summarised as follows[212]: the manufacturer[213] of a product — except for primary agricultural products (Art. 2) — is liable, even without fault, for damages caused by a defect in the product (Art. 1). The requirements as to proof are strict: the injured person has to prove the damage, the defect and the causal relationship between defect and damage (Art. 4)[214]. Liability cannot be excluded by contractual

209 A particular strongpoint of IOCU's activities is in the area of pharmaceuticals (Health Action International — HAI) and pesticides (Pesticide Action Network — PAN).

210 OJ C 241, 14 October 1976, 9. Following opinions from the ESC (OJ C 114, 7 May 1979, 15) and the European Parliament (OJ C 127, 21 May 1979, 61), the Commission submitted an amended version in September 1979 (OJ C 271, 26 October 1979, 3).

211 OJ L 210, 7 August 1985, 29.

212 On the product liability directive in general see Taschner, Kommentar, 1986; Schmidt-Salzer, Kommentar, 1986; Taschner, Die künftige Produzentenhaftung in Deutschland, 1986; Hollmann, 1985; Brüggemeier/Reich, 1986; Reich, 1986; Reich, 1987, Nos. 86-112; Krämer, 1985, Nos. 320-330; Schmidt-Salzer, Die EG-Richtlinie Produkhaftung, 1986; Schlechtriem, 1986; Storm, 1986; Pauli, 1986; Lorenz, 1987; Frietsch, 1987; Budde/Reihlen, 1987; Whittaker, 1985.

213 By Art. 3 of the directive, a "producer" is the manufacturer of the final product, a raw material or a partial product, or any person describing himself or herself as a producer, the so-called quasi-producer, and importers bringing products, from "Third Countries" into the territory of the Common Market. If the producer of a product cannot be established, then any supplier may be liable on certain conditions.

214 This distribution of the onus of proof is called by Taschner in Die künftige Produzentenhaftung in Deutschland, 1986, 613-14, a "Magna

provision and is unlimited in extent, although Member States may set a limit, of at least 70 million ECU for a given producer, for deaths or personal injuries caused by identical items with the same defect (Art. 16 (1)). The Directive does not apply to property damage in the industrial sphere; even property damage to non-commercial consumers is not compensated for fully, but only above a limit of 500 ECU (Art. 9 (b)). Member States' provisions relating to non-material damage remain unaffected (Art. 9, last sentence). Manufacturers are not liable where the product complies with mandatory regulations issued by the authorities (Art. 7 (d)). Liability does not extend to development hazards, that is, to defects that could not be discovered given the stage of scientific and technical knowledge at the time of its manufacturing (Art. 7 (e)), unless a Member State explicitly so provides (Art. 15 (1)(b)). Liability is extinguished 10 years after marketing of the specific product in question (Art. 11). As to the latency period of up to 30 years between the action of chemicals and other harmful substances such as asbestos and the manifestation of damage and other after-effects, this is a very significant exclusion of liability, since in this sort of situation, the conditions for tortious liability should normally not exist.

The central provision for the directive's safety concept, Art. 6 (1), affirms[215]:

Charta to protect industry against unjustified claims". For criticism see Brüggemeier/Reich, 1986, 153-54; Krämer, 1985, No. 328, with references to the potentially considerable effects in the area of regulatory practice outside the Courts.

215 Cf. the tenor of Art. 1 of the French law No. 83-660 of 21 July 1983 on consumer safety: "Products and services must under normal conditions of use, or any other conditions of use reasonably foreseeable by the expert, offer the level of safety that can legitimately be expected, and may not endanger the health of persons". — Cf. the comments in Chapter II, 1.2 supra.

"A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

a) the presentation of the product;

b) the use to which it could reasonably be expected that the product would be put;

c) the time when the product was put into circulation".

Accordingly, defectiveness of a product follows not from its lack of fitness for use, but from a lack of the safety that the public is entitled to expect[216]. The use of the "informed public" as a reference point provides courts in Member States with considerable leeway in putting the norm into practice. "The relevant safety expectations within the meaning of Art. 6 (1)", conclude Brüggemeier and Reich[217], "are precisely what the courts find to be necessary in the individual case in terms of hazard protection, in the interest of protecting the integrity of the citizens of the Common Market".

Different definitions of safety expectations by courts in individual States cannot be ruled out[218]. In view of the differing legal traditions and divergent safety philosophies in Member States, any farther-reaching attempt at harmonisation would probably be in vain. Consideration should however be given as to whether an information system on relevant decisions by national courts[219] might not restrain excessive divergence. Such an information system would also help with deciding in 1995 on a secure

216 As the sixth recital in the Product Liability Directive explicitly states.

217 Brüggemeier/Reich, 1986, 150.

218 Taschner, Kommentar, 1986, Art. 6, Nos. 5-7, regards the danger of divergent decisions by the courts of different Member States as rather a theoretical one. He bases himself not only on the possibility of preliminary rulings from the ECJ, which favours uniform practice (op. cit., No. 7), but also on an exhaustive list of examples of product defects from Member States' case law (op. cit., 88-96).

basis of knowledge as to the inclusion of agricultural products and development risks, and as to the liability restrictions for damage resulting from deaths or personal injury (cf. Art. 15 (3) and Art. 16 (2)). Even before this second stage of the harmonisation process, it would also provide further indications of product hazards, possibly useful for setting standards.

The directive's concept of defect is, even though this terminology[220] is not used, oriented towards foreseeable misuse. Accordingly, a manufacturer cannot escape liability with the defence that the specific use of the product did not correspond with proper use; otherwise, by restrictively defining use he could decide as to the defectiveness of his product and thus as to his own liability. Conversely, not every misuse counts against the manufacturer, but only misuse that could be foreseen[221].

A product which met ordinary safety expectations at the time it was marketed does not subsequently become defective because an improved product is marketed later (Art. 6 (2)). Accordingly, tighter technical standards do not make a previously marketed product meeting all safety standards defective.

Among the grounds for exclusion of liability, the provisions of Art. 7 (d) are significant for our purposes. A manufacturer of a defective product that has caused damage can exculpate himself by showing that the defect is due to compliance of the product with mandatory regulations issued by the authorities. This does not include technical standards from private standardisation organisations, since they are not issued by the public authorities and compliance is not mandatory. Nor does this change where

219 Brüggemeier/Reich, 1985, 150-51.

220 Cf. Chapter I, 2.1 supra.

221 Cf. Taschner, Kommentar, 1986, Art. 6, Nos. 16-18; Schmidt-Salzer, Kommentar, 1986, Art. 6, Nos. 141-148; Hollmann, 1985, 2393-94.

technical standards have by way of sliding reference, been made an integral part of a product safety regulation such as under the German Appliances Safety Act or the Low Voltage Directive or the new approach to technical harmonisation and standards. In this case all that is legally relevant for the manufacturer are the basic safety requirements, or the general safety obligation of the Appliances Safety Act[222]; compliance with the relevant technical standards merely justifies the rebuttable assumption that the binding safety requirements have been met. In order not to hamper technical progress, departure from technical standards is allowed, sometimes explicitly, if the same level of safety is achieved in other ways when sliding reference is used[223]. In this case, the onus of proof that products meet the basic safety requirements is on the manufacturer[224]. In other words, compliance with particular European or national technical standards to which the Community or Member State legislator has referred does not allow the manufacturer to apply the exclusion of liability under Art. 7 (d)[225]. As an argument for this, Taschner[226] adds:

> "Manufacturers in a particular industry, normally the authors of such technical standards, may not, by issu-

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222 § 3 (1) (1) GSG.

223 Thus § 3 (1) (2) GSG.

224 On the supra cf. the 3rd and 4th basic principles in the new approach to technical harmonisation and standards, OJ C 136, 4 June 1985, 1 et seq. (3). See further the comments in Chapter IV, 3.2.

225 See also Taschner, Kommentar, 1986, Art. 7, Nos. 24-35; Brüggemeier/Reich, 1986, 152-53; Reich, 1987, Nos 95a; Krämer, 1985, No. 325; Frietsch, 1987, 137; Hollmann, 1985, 2394-95; Schlechtriem, 1986, 1036-37; Lorenz, 1987, 12. The only divergent view as far as can be seen is from Budde/Reihlen, 1987, 66, who, however, generously overlook the characteristic of the bindingness of standards and Schmidt-Salzer, Kommentar, 1986, Nos. 99-104, for the case where interpenetration or statutory regulation with various intercompany sets of regulations and administrative practice put manufacturers concerned into a position that is identical with a mandatory statutory norm.

226 Taschner, Kommentar, 1986, Art. 7, No. 26.

ing standards that exclude liability, make themselves the masters of their own liability".

The ground of exculpation in Art. 7 (d) applies only where statute or ordinance has bindingly prescribed one particular method of production, to which the product defect is causally to be attributed. Compliance with a statutorily prescribed minimum standard is not enough, since nothing prevents the manufacturer from going beyond this minimum standard and increasing the safety of his product. Compliance with the basic safety requirements under the new approach to technical harmonisation and standards is not automatically enough to free the manufacturer from liability[227].

Positive and negative lists issued by the authorities do not constitute grounds for exclusion from liability under Art. 7 (d). Use of an admissible food additive (in the case of positive lists), or of a non-prohibited additive in the case of cosmetics (in the case of negative lists) is freely open to the manufacturer, but not bindingly prescribed; positive and negative lists are aimed merely at ruling out the use of particular hazardous substances, but not at bindingly prescribing a particular way of producing a product[228].

According to Art. 7 (e), a manufacturer is not liable where he shows that the "state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered". The manufacturer cannot exculpate himself by showing that he complied with the state of scientific and technical knowledge[229]. The state of scientific and technical knowledge is in Art. 7 (e) a criterion

227 Taschner, Kommentar, 1986, Art. 7, Nos. 25 and 33.

228 Particularly incisive is Krämer, 1985; No. 325; see also Taschner, Kommentar, 1986, Art. 7, No. 31; Brüggemeier/Reich, 1986, 153; Reich, 1987, No. 95.

not for the manufacturer's action but for the recognisability of the defect. What is decisive is not the individual manufacturer's actual possibilities of knowledge, but whether anyone at all could have possibly recognised the defect because the scientific and technical aids objectively existed[230]. Since scientists and technologists exchange information worldwide, it is not the scientific and technical expertise available in the manufacturer's country that counts[231]. Nor is it relevant whether the science and technology are generally recognised and generally available[232]. Science lives on the methodical encouragement of doubt, and constantly re-defines technical risks; to see it as the administration of presumably established stocks of knowledge is to misunderstand it. Accordingly even potential hazards expressed in outsider views but scientifically justified are to be taken into account[233]. Before marketing a hazardous substance — development risks are relevant above all for the chemical and pharmaceutical industries — all investigations into the state of science and technology that may provide information to determine side-effects and after-effects are to be employed, or to be considered. This does not of course eliminate the dilemma that the research laboratories of industry, which frequently have a monopoly on knowledge, do not

229 But see Kretschmer, 1986, 35; by contrast Taschner, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie, 1986, 55.

230 Taschner, Kommentar, 1986, Art. 7, No. 44; Brüggemeier/Reich, 1986, 153.

231 Taschner, Kommentar, 1986, Art. 7, No. 45.

232 But see Taschner, Kommentar 1986, Art. 7, No. 45. Cf. also Schmidt-Salzer, Kommentar, Art. 7, Nos. 133-148, who wishes to go further and focus on whether knowledge of the relevant hazard has become general knowledge among experts in the area concerned. He however takes it that the legal meaning and purpose of Art. 7 (e) is to clarify that, in principle, tortious liability should continue to apply to development risks (op. cit., Art. 7, Nos. 139-142).

233 Cf. Brüggemeier/Reich, 1986, 153; Reich, 1987, No. 106.

necessarily see their task as being the publication of scientific knowledge and the advancement of science[234].

All in all, this probably means that the Product Liability Directive's contribution to harmonising the level of product safety will remain limited[235]. Important questions of liability law are not harmonised; apart from the non-material damages and development risks already mentioned, and property damage in the commercial area, this also applies to recalls and to product monitoring. This means that the harmonisation of product liability aimed at in the Directive has hardly been achieved; it was regarded as necessary because "existing divergences may distort competition and affect the movement of goods within the Common Market and entail a different degree of protection of the consumer"[236]. The exclusion of compensation claims for damage to commercially used property means, in view of the fact that the major proportion of product liability cases handled through insurance companies falls into the commercial sector[237], that the differing cost burden on manufacturers in individual Member States because of differing liability regulations remains unaffected. In the case of damage to non-commercial users, too, the goal of harmonisation has been achieved only in embryo. In the case of property damage, the injured person will, in order to have access to excluded personal damages, which is anything but a petty

234 Instructive examples in Krämer, 1985, No. 326.

235 On this see Brüggemeier/Reich, 1986, 155; Schmidt-Salzer, Die EG-Richtlinie Produkthaftung, 1986, 1103-04; Schlechtriem, 1986, 1043; Storm, 1986, 116-218; Pauli, 1986, 154-55; Lorenz, 1987, 36-37. The limited success of the harmonisation is explicitly admitted in the second-last recital to the Directive: "Whereas the harmonisation resulting from this cannot be total at the present stage, but opens the way towards greater harmonisation".

236 First recital to the Product Liability Directive.

237 According to a letter from the HUK Association to the Federal Minister of Justice of 15 November 1979, 3, 75% of damage involving liability for industrial products is accounted for by claims from industrial

amount, have recourse to the general law of tort. In the case of personal injury as well, in order to assert claims to a solatium, he will likewise have to proceed under the relevant general law of tort[238]. One should not, however, lose sight of the fact that the Product Liability Directive ought to lead to an improvement in consumer safety especially in countries where product liability is still regulated on a pure basis of tortious liability, with a corresponding burden of proof on the injured person.

contractual partners, mainly because of subsequent damages arising due to defects in preliminary products supplied.

238 Brüggemeier/Reich, 1986, 155.

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 integration[1]. The general economic and social policy consequences of achievement of an integrated internal market can hardly be overestimated, and the issues of the relationship between internal market and product safety policies, on which this study concentrates, cover only a small range of the questions that will have to be thought through in order to "complete the internal market". But even this range is wide enough. The far-reaching integration policy 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 trade[2] 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 directives[3], the collapse of

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.

initiatives in the area of construction materials[4], the lack of success in efforts to supplement harmonised product standards in the automotive sector with an integrated safety policy programme[5] and the general resistance to a "horizontal" European product safety policy[6]. The problems with internal market policy can clearly not be explained exclusively by the fact that Member States seek to assert their own economic interests in negotiations on legal approximation measures; they point at the same time to the fact that the issue of product safety is felt as a politically sensitive area where political actors resist delegating powers of action and decision to the Community.

The documents in which the Commission explained its interpretation of the stagnation of legal 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 developments[7]. This diagnosis is in line with the therapy recommended by the White Paper on completion of the Internal Market[8]: the Community should in 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

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.

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 preconditions 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 1973[9], 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).

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8 Op. cit. (note 1), 14 et seq.

9 OJ L 77 of 26 March 1973, 29.

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

The relationship between marketability of goods and product safety requirements is fundamentally regulated in Articles 30 and 36 EEC. In recent years extensive ECJ case law has developed here, meeting with an extremely strong response in the literature[10]. As *Table 1* shows, of 140 judgments delivered by the ECJ by 31 March 1987 on free movement of goods, only a little over a quarter (42) were based on an action for breach of treaty brought by the Commission; such actions occurred in 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 Judgments per year	
From 1968 (2) until Dassonville judgment (3)	8	1	91.8	
From Dassonville judgment until Cassis judgment (4)	25	3	28	6.2

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 Dauses, 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.

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" judgment[11] that the ECJ undertook a comprehensive definition of the central concept of measures having equivalent effect. This basic rule has been repeated by the Court in large numbers of later judgments, and continues to be the basis for the case law; the Commission, too,

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.

observes it in bringing actions for breach of treaty against Member States. It says:

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

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

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

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 comprehensive[15]. With this as a starting point, the ECJ faced a dilemma if it did not want to subject the general power of Member States to regulate production and marketing or to control economic policy completely to the verdict of Art. 30 EEC. Either it could give an expansive interpretation to the object of legal protection in Art. 36 EEC or it could restrict the concept of measures having equivalent effect, at any rate for the area of measures applicable without distinction, by contrast with the Dassonville formulation[16]. With the well-known judgment in the "Cassis de Dijon" case of 20 February 1979[17], the Court of Justice took the latter path, thereby laying the foundations for a new approach to harmonisation policy in the area of free movement of goods and for systematic monitoring by

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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.

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 effect[19].

The list of binding requirements is not exhaustive: others that enter in are environmental protection and measures to improve working and living conditions[20]. This must, though,

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.

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 protection[21].

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

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 Dauses, 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.

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 exceptions[24].

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 policy[25]. 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 «suitably and satisfactorily» 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

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.

that the way it fulfills the objectives is different from that imposed on domestic products"[26].

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

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.

tion, it simultaneously determines the extent to which measures on approximation of laws are necessary in order to eliminate barriers to trade[29].

The Cassis judgment (and the Commission communication) were on the one hand welcomed as, in principle, allowing marketing of the most diverse local specialties throghout the Community, thereby increasing consumer choice[30], 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 denominator[31]. The latter standpoint was represented particularly strongly by the government of the Federal Republic of Germany in the Cassis case:

> "Ultimately, the regulation binding in all Member States would be that of the country setting the lowest requirements; since this legal conclusion would be based on the directly applicable provision of Art. 30, these legal changes will have to have been effected already, at latest by 1 January 1970. Because of the automatic effect of Art. 30, in 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

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.

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 unwarrented[33]. 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 endangered[34]. Above all, however, it goes much farther to meet Member States interests in protection, especially as regards the very frequently mentioned protection of health[35], than the Commission with its rigid scheme of rule and exception and its stress on "very strict criteria" and on the possibility of 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 differentiated[36].

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 requirements[37]. However, a few restrictions should be mentioned: the Commis-

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,

sion'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 level[38]. Elimination of barriers to trade through Art. 30 EEC presupposes unless Member States voluntarily refrain from asserting particular domestic standards for imported products, an initiative by manufacturers, importers or the Commission, and can come about only reactively and case by case; law approximation can act preventively and much more comprehensively[39]. Furthermore, pronouncements of the Court of Justice can act only by way of quashing, in the sense that rules may be abolished without substitution, but not replaced by new requirements under the Community Treaty[40]. Finally, overstressing negative harmonisation through Art. 30 EEC would mean transferring to the Court evaluative tasks that normally fall within the province of the legislator[41].

There is agreement that application of Art. 30 EEC cannot be made dependent on prior harmonisation of laws. This was unmistakably stated by the Court of Justice in case 193/80[42],

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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.

when it also stressed the different objectives of Articles 30 and 100 EEC[43]:

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

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

Technical standards drawn up by private institutions and therefore not legally binding, do not count as measures having equivalent effect within the meaning of Art. 30 EEC. There is a

43 Roth, 1977, 24-30; Dauses, 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 proce-

different case, however, where compliance with them is mandatorily prescribed *de jure* or *de facto* by government action[45]. 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 addresses. It arrived at this conclusion, against the Advocate General's opinion, in the case of the "Buy Irish" publicity campaign by the Irish Goods Council, an association of leading representatives of the business world set up as a company limited by guarantee, without investment of capital, to promote the sale of Irish products. It attributed the campaign as a whole to the Government, which had established the programme, made the major staffing decisions and borne the overwhelming share of the financing[46]. Comparable circumstances are not present in the case of technical standardisation by private standardisation bodies[47].

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

On the conditions set out in Art. 36, Member States may break the prohibition in principle on quantitative restrictions and measures having equivalent effect and maintain or introduce regulations or practices restricting free movement of goods, in order to protect the objects of legal protection listed. These measures may not, however, constitute a means of arbitrary discrimination

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dures, 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.

or a disguised restriction on trade between Member States (Art. 36 EEC, second sentence).

With its underlying pro-integration approach, the Court has given this exceptional provision a narrow interpretation in several respects. Among the principles that can be taken as established are: Art. 36 covers only situations of a non-economic nature and cannot be understood as an escape clause against the economic effects of the opening up of markets[48]; the list of objects of protection in Art. 36 EEC is exhaustive and cannot be extended by conclusions from analogy, Art. 36 EEC is not intended to reserve particular fields for the exclusive competence of Member States[49].

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

Only where Community directives provide for *complete* 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 regulation[50]. Here verification is required as to whether a Community provision consti-

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 [3883 at 3904 - van Bennekom; Case 28/84, Judgment of 3

tutes a definitive regulation or was introduced only as a minimum measure, not ruling out additional national provisions[51]. Moreover, the content of the individual Community regulations and harmonisation programmes must be looked at to see whether all relevant objects of protection under Art. 36 EEC are already covered[52]. In other words, Community regulations have a blocking effect on Member States only to the extent that they actually meet the individual interests in protection under Art. 36 EEC. Should, for instance, a Community regulation take account of the mechanical hazards of a product but not the toxic ones, to that extent Member States' competence will remain.

This applies, too, where hitherto 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.

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.

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 available[54]. The Court of Justice has frequently stressed that it is in the interest of free movement of goods to carry out sanitary controls in the country of manufacture, and that it is appropriate for the sanitary authorities of the Member States concerned to co-operate in order to avoid duplication of checks[55]. This leaves untouched the power to carry out random checks. The Court has also concluded from the proportionality principle that the aim of reducing the burden on the administration or reducing public expenditure does not justify any stronger intervention, and that administrations are bound to make reasonable efforts to

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.

secure the necessary indications by active administrative efforts[56].

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

In recent years voluminous case law has developed on the question of health protection within the meaning of Art. 36 EEC[57]. It amounts to allowing Member States to engage in preventive health policies of their own where a Community regulation is absent, with the objective of keeping foodstuffs as free as possible from hazardous substances. National regulations may take account 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,

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; Dauses, 1987, 252-256.

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 people[59]. 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 nutrition[60].

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 97/83[61]. The

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.

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 foodstuffs[62]. While this judgment found a policy for preventing pesticide residues in foodstuffs to be compatible with Community law, another judgment found a policy to limit additives in food preparation to be permissible. Imported foodstuffs can accordingly be subjected to national licensing procedures which test not only whether the colouring agent used may be dangerous to human health, but also whether there is a technological, economic or psychological need for colouring the foodstuffs concerned. In assessing hazards, Member States must here take account of the findings of international scientific research, especially the work of the Community's Scientific Committee on Foodstuffs, but may in evaluating them into account take specific eating habits in the importing Member State[63].

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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,

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 effect[64]. On the basis of these criteria, the German beer purity law proved incompatible with Community law, on the grounds that it was disproportionate to rule out all additives admissible in other Member States on grounds of preventive health protection, instead of adducing proof of health risk for each substance[65]. The submission of the German government, the defendant, 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 possible[66], was rejected as insufficient. It was necessary to justify the exclusion of particular substances on grounds of specific hazards.

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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 - Eyssen (Nisin).

A judgment of direct relevance for technical safety law is the one in case 188/84 on the licensing of woodworking machines in France[67]. The French conception of industrial safety starts from the idea that users of machinery must be protected against their own mistakes, so that machines must be designed in such a way that they can be used, mounted and maintained without risk (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 regulation[69]. The Court of Justice accepted this principle but arrived at a different conclusion:

> "Moreover, it may not prevent the marketing of products originating in another Member State which, in respect of 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

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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.

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 training[71].

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 Directive[72] — with its new harmonisation technique of

70 Loc. cit., paras. 16-17.

sliding reference to harmonised standards, became the model for the new approach to technical harmonisation and standards[73]. For many years it had been regarded by many officials in governments and the Commission as an original sin that ought not to be repeated[74]. With annual output worth some 80,000 million ECU in 1981, Community internal trade in electrical appliances amounted to some 35,000 million ECU; an estimated 70% of turnover in the electrical sector comes under the Low Voltage Directive[75].

2.1 Peculiarities of the electrical sector

There are good reasons why, for 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 applied[76]. These reasons also indicate that experience with the Low Voltage Directive can be transferred only to a limited extent to other areas of industry[77]. Electrical 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

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.

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 standards[78].

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 postive 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

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.

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 atmosphere[79], 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 excluded[80].

Art. 2 lays down the basic requirements for marketable electrical products. Electrical equipment may be marketed only if

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.

"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 Act[81]. The affirmative statement that in the event of a differing level of safety technology in individual Member States, all ought to apply the highest level[82], does not fully bring out the graded 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 exactly[83]. The safety objectives contain, among others, the following statements:

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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/Nöthlichs, Kennz. 1610, 9.

83 Cf. Winckler/Cassassolles/Verdiani, 1974, 28.

— Instructions on proper, risk-free use must appear on the electrical equipment.

— Manufacturers' or brand-names or trademarks should appear on the electrical equipment.

— The electrical equipment should be made in such a way as to ensure that it can be safety and properly assembled and connected.

— For protection against hazards that might arise from the electrical equipment, technical measures are to be prescribed, 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 standards[84], products not complying with the technical standards

mentioned but meeting the general safety objectives are also admitted to free movement (Art. 8 (1)). Conformity with the safety objectives may be shown by an expert report (Art. 8 (2)). The free movement of electrical products meeting the safety objectives on the terms just set out may not be impeded on safety grounds (Art. 3).

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

2.3 *Individual questions on the Low Voltage Directive and its application*

For years there was considerable uncertainty as to the interpretation of the Low Voltage Directive. This resulted not least from the regulatory technique, which was unusual for many Member States, and was not cleared up until the ECJ ruling of 2 December 1980 in preliminary ruling procedure 815/79-Cremonini v. Vrankovich[86]. On the basis of this ruling, the Commission once again summarised the legal framework of the Directive and its application in a explanatory communication to all concerned[87]. Further clarifications emerged from the meeting of the

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.

working group on elimination of technical obstacles to trade in the electrical sector held on 20 December 1983, on application of the Low Voltage Directive[88]. The following observations on individual provisions of the Low Voltage Directive are based essentially on the Commission communication and the findings of that working session.

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 CENELEC[89].

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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.

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

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

The results of CENELEC's work may be adopted by majority vote, effective for outvoted committees too, though in principle unanimity is aimed at and almost always obtained[93]. This procedure of unanimous voting by the national committees accords with Art. 5 of the Directive, which says that harmonised standards are to be drawn up by "common agreement"[94]. This is justified on the basis that the Community legislator has left the

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,

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 bodies[95].

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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.

Following the ruling in the Cremonini v. Vrankovich case, it was clarified[96] that type B departures are not admissible, since no discrepant national standards apply alongside the 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 concerned[97]. Indeed, it explicitly notifies Member States of the possibility of affecting the production of harmonised standards through the various standardisation bodies[98]. K. Fitting has the following to say about a remarkable practice by the German authorities of securing for themselves a right of participation in European standards[99]:

> "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

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.

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 requirements[100].

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

100 Cf. Chapter IV, 3.3 infra.

bility 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 minimum[103].

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 Directive[104]. 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

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.

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 I[105].

Art. 7 also makes it clear that Member States may not link the marketing of electrical equipment that meets the prescribed safety objectives, to the condition of complying with particular provisions regarding quality or performance[106].

2.3.3 Safeguard clause procedure

A Member State which for safety reasons prohibits the marketing of electrical equipment or restricts its free movement, need only, but must always, employ the safeguard clause procedure of Art. 9, if conformity with the general safety objectives is to be presumed because a conformity mark, certificate of conformity from an 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 measures has been taken because of a shortcoming in a technical standard, the Commission sees itself as obliged to act in order to maintain a

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.

uniform safety standard in the Community even where other Member States have no objections to the national measures[107], though the Directive does not provide for any action in this case. In its details, the safeguard clause procedure is rather unclearly and awkwardly constructed as regards 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 1983[108] (CCA) facilitates the acquisition of such marks

107 COM III/1412/83 — Rev. 3, para. 2.5.2.2.

without needless repetition of tests. A manufacturer who has already secured a conformity mark on the basis of the prescribed tests may, by submitting the tests result on a form, secure the mark of another office too, in a rapid, informal procedure[109]. There are agreements between the test centres on initial inspection of the place of manufacture and on monitoring of the manufacturing process and of marketing. Where a manufacturer so desires, he can on the basis of *one* test acquire national conformity marks for all Member States more or less automatically. The Commission energetically supports this agreement, which it regards as an advance on the system of mutual recognition of conformity marks and certification in the Low Voltage Directive and as making introduction of a Community mark practically superfluous[110]. What is ultimately decisive is the initial test which does not necessarily have to be done in the manufacturer's country.

> The HAR agreement describes a procedure for issuing and using a jointly agreed marking for cables and insulated wires meeting the harmonised standards[111]. National test centres mark the cables and wires not only with the national test mark but also with the CENELEC test mark HAR. Accordingly, in the area of cables and wires, 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].

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.

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 IEC[113]. Since 1963, its predecessor organisation[114], which until 1981 had also issued standards in the electrical sphere, had provided a system of certification, the CB procedure[115]. 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

113 Details in Warner, 1983, 88-9; *idem*, 1984, 38, 46-7.

114 CEE — International Commission for rules on approval of electrical products.

is made of certification by manufacturers even outside the industrial use of products, and what precautionary measures ought to or can be taken against misuse[116].

2.4 Inadmissible delegation of public tasks to private 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 Directive[117]. The possible criticism has been brought out very succinctly by E. Röhling[118], in specific reference to the Low Voltage Directive, and can be 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

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.

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 detail[119]. The Low Voltage Directive and the new approach have carefully been designed so as to leave the following legal fallback position open[120]: 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

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

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 provisions[121] and permit the generalisation of the reference technique first practised in the 1973 Low Voltage Directive[122]. But the political impulses and preliminary conceptual date much further back[123]. Both the European Parliament[124] and the Economic and Social Committee[125] had already recommended the reference method in their resolutions or opinions on the 1969 General Programme to eliminate technical bar-

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.

riers to trade, as an alternative to the "traditional" method of approximation of laws[126]. In the early 70's, these suggestions were taken up in the German literature, and the outlines of the new approach were formulated[127]: Directives should lay down "basic requirements", and conformity with technical standards should justify a presumption of compliance with these requirements[128]. In accordance with this presumption, Member States ought to take "all necessary measures to ensure that administrative authorities 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 standards[130].

But these proposals were by no means unanimously accepted. As suggested notably by Röhling[131], the regulatory technique of reference to standards substantively meant delegation of legislative powers, inadmissible according to the EEC Treaty[132]; if the Community wished to take advantage of the expert knowledge of standardisation organisations, it ought first

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.

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 standardisation[133].

This already brings out the major legislative policy problems to be overcome in working out the new approach. The following survey will however give legal assessment second place to the solutions or proposed solutions developed by the Commission[134], in order 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 standards[136]. The directive was also innovative because of the measures by which it sought to oppose the emergence of technical barriers to trade. Art. 8 obliges Member States (and Art. 4 national standardisation bodies) to "immediately communicate to the Commission any technical draft regulation" (and national standards programmes and draft standards)[137]. This information is to

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.

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 doctrine[138], which replaces the "Gentlemen's Agreement" of 28 May 1969[139]. The Commission or a Member State can cause adoption of technical regulations to be delayed for six months (Art. 9 (1)) and the Commission even by 12 months, if it announces an intended directive (Art. 9 (2)). Art. 7 (1) obliges Member States to ensure that standards are suspended for a period of six months if production of a European standard is intended. It is noteworthy that the Information Directive "institutionally" restricts the supremacy claim of European law by taking Member States' interests into account and giving standards institutions a possibility of collaboration[140]. These opportunities of influence are guaranteed by the Standing Committee of Member States' representatives set up by Art. 5, which shall be consulted on all important matters and may deal with any questions it finds important (cf. Art. 6 (5) and (6)). National and European 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

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.

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 cases[141].

Evidently, however, the "information ethics" documented in these figures is still not enough. At any rate, the Commission pointed out in a communication of 1 October 1096 that failure by Member States to comply with their information and postponement obligations was an infringement of Community law from which citizens of the States concerned could derive a right to non-application of provisions enacted in contradiction with the provisions of the Information Directive[142]. The Commission can base its legal position on ECJ case law on the direct effect of secondary Community law. However, the expectation that the postponement periods provided for in the Information Directive could allow European solutions for the 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 Commu-

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.

nity level and the involvement of the Member States and their standardisation organisations in the process of Europeanisation of technical regulations and standards[143].

This assessment is confirmed by the proposals submitted by the Commission on 20 February 1987. By these, the scope of the Information Directive is to be considerably expanded, extending in future to farm products, foodstuffs and fodder, pharmaceuticals and cosmetics[144]; at the same time, it is intended that the Standing Committee set up by Art. 5 of the Information Directive should be involved in working on 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 1987[145] 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.

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.

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 three[146] strategies to reduce its burden. All are to be continued under the new approach. In accordance with the extensive interpretation of Art. 30 EEC[147] advocated by the Commission following the Cassis de Dijon decision[148], in areas where reliance can be placed on mutual recognition of national regulations and standards, harmonisation of laws is to be avoided where possible; existing regulations and standards are instead to be checked for proportionality[149]. The scope of this strategy is, however, limited[150]. 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 indent[151]. The White Paper mentions the success of this method[152], which however cannot easily be reconciled with efforts at increasing involvement of standardisation organisations in harmonisation policy[153]. The third method of allievation, the reference technique first practised in the Low Voltage

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.

Directive of 19 February 1973[154], 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 organisations[155]. 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 technique[156], does describe the mandatory safety objectives comprehensively, but only by vague general clauses[157]. Descriptions of this nature, as the literature on the Low Voltage Directive brings out, allow only preliminary assessments; they become "practically applicable. . .only by actually adducing the standards"[158]. It is 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 cer-

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/Nöthlichs, Nos. 1610, 11, 13, cf. 17-18.

159 Op. cit. (note 1), 11.

tify products as being in conformity, having regard to those requirements in the absence of standards"[160].

This addition has led to considerable hesitation and controversies. Pelkmans, for instance, warns[161] that it 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 product[162]. In its report on technical harmonisation and standards in the Community[163], 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 MEP[164] suggested that it be treated as non-mandatory. The answer to this question, communicated by Lord Cockfield on behalf of the Commission[165], makes the legal position clear and yet seems to dodge the issue:

> As far as the requirements on the precision of safety objectives are concerned, the addition is "only a comment intended to define the relationship between the essential safety requirements (point B III) and the means of proof of conformity and effects (point B V

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.

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 «new approach».
The Commission in no way takes the view that this principle will necessarily lead the Council to adopt directives laying down very detailed essential safety requirements, since the testing bodies appointed by the Member States to check the conformity of manufactured products with the essential requirements, normally have expertise based on lengthy experience. 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 vessels[166], with its descriptions of the essential safety requirements, is not comparable with the general clauses of the Low Voltage Directive. The characteristics of the materials to be used are laid down in detail in Annex I[167];

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

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 toys[169]. Art. 2 (1) lays down a general safety obligation whereby manufacturers must bear in mind the foreseeable use of toys and the "normal behaviour of children". This general safety obligation is specified in Annex II, initially in "general principles", according to which children are to be protected not only against risks due to the construction and composition of the toy, but also, where design measures are not possible, against those inherent in its use[170]. The lengthy Annex II establishes requirements on physical and mechanical properties, flammability, chemical properties, explosion, electrical properties, hygiene and radioactivity. Annex IV additionally

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.

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 1980[171] Draft Directive, from which they were taken over into the proposal for a framework Directive of 23 June 1983[172]. The 1980 draft dealt in Annexes V and VI with Community standards for physical and technical properties and the flammability of toys, but in 1983 corresponding standards were incorporated into separate directives[173]. A simplified procedure for amending these mandatory standards had been provided for both in 1980 (Art. 17) and in 1983 (Art. 13). The regulatory technique of the draft as now submitted thus builds on preliminary work already done. This continuity emerges particularly clearly from the fact that the binding standards in the 1980 and 1983 drafts merely took over provisions from the European 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 binding[174].

The Commission's most recent project to date[175], the proposal for a directive on construction products[176], is likewise the resumption of a long-discussed project[177]. The development is

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

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 buildings[178]. 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 saving[179]. The Commission explicitly stresses that it would not, in general, be possible on the basis of these requirements "to directly establish a

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.

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 Directive[181]. It also corresponds to the pragmatically sibylline statements by its leading supporters[182]. 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 approach[183] and now specifically

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.

stressed in the proposal for a directive on construction products[184]: the abandonment of detailed design specifications in favour of "performance" standards. The distinction between "performance" and design is evidently intended not merely to paraphrase the difference between "safety objectives" and their "specifications", but at the same time to refer to a more general competition-policy dimension of the debates on the regulatory technique of product safety law. The preferability of performance standards is because as repeatedly asserted in the 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 competition[185].

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 conceivable[186]. Accordingly, the Draft Toy Directive, to the extent that it deals with chemical properties of toys, contains threshold values for particular substances and references to relevant prohibitions in Community law[187]. The explanatory statement on the proposal for the Directive on simple pressure vessels points out, in connection with restrictions relating to materials, a further problem with performance standards[188]: the development of suitable certification procedures and mutual recognition of confor-

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.

mity certifications becomes more urgent and at the same time more difficult as the manufacturer's leeway is broadened.

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

The retreat from approximation of laws to the harmonisation of essential safety requirements is motivated by internal market and competition policy concerns. Following these objectives, the new approach envisages a variety of alternatives for manufacturers in order to comply with the mandatory requirements of directives and a range of ways of showing the safety conformity of their products which are patterned on the Low Voltage Directive[190]. Section B VIII and V of the Model Directive of 7 May 1985[191] provides the following alternatives:

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

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

Conformity is attested by

— certificates, marks of conformity or reports of results of tests by a "third party" (Section B VIII (1) (a) and (b)),

— a declaration of conformity issued by the manufacturer, in which case a surveillance system may be required (Section B VIII (1) c).

Self-certification by manufacturers was also accepted in principle by the Low Voltage Directive, though for products not conforming to standards, the submission of an expert report was

189 A general survey is given by Volkmann, 1987.

190 See 2.2 supra, text accompanying note 84.

191 Note 160.

required[192]. The Model Directive correspondingly draws a distinction: "when the product is not in conformity with a standard", its safety conformity must be "declared by the means of an attestation delivered by an independent body" (Section B V (3) (2)).

3.3.1 Recognition of national standards

Reference to national standards is explicitly termed a "transitional measure" in the Model Directive (Section B V (1) (b)). Nevertheless, this recognition of national standards is of fundamental importance. It corresponds to the assumption, contained in the Commission's White Paper[193] and repeated in the explanatory material on the new approach[194], that the objects of national safety provisions mostly coincide and that one may therefore take the equivalence of differing mandatory provisions and voluntary standards as a basis. It is far from clear, where this confidence derives from and why the statements in the General Programme on elimination of technical barriers to trade of 28 May 1969 that harmonisation measures are indispensable[195] have since been superseded. The technical safety development in the electrical sector, which the regulatory technique of the Low Voltage Directive could take as a basis[196], has, after all, not taken place in other sectors. This is amply confirmed by the difficulties

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

193 Op. cit. (note 1), para. 65.

194 Loc. cit. (note 160), 2 and in the relevant Commission Communication (note 122), 6.

195 Cf. Chapter III, 2.2, text accompanying note 38.

196 2.1 supra.

in delimiting the "essential safety objectives" from mere "manufacturing specifications" in the Commission's new proposals for directives[197]; and the proposal on construction materials shows that a basic pattern of "equivalent" safety objectives that merely have to be specified by standards cannot be achieved without further action.

In its provisions on mutual recognition of national standards, the Model Directive is more cautious than the thesis of the equivalence of national safety provisions would imply. The Model Directive thus provides for a special procedure that must be gone through before national standards are recognised. National standards which in the view of Member States meet the safety objectives of Directives are to be communicated to the Commission, which forwards them to the other Member States and consults the Standing Committee before allowing official publication[198]. Even though the description of the Committee's remit states that consultation is aimed more at providing "a framework . . . for discussion of any reservations on the part of the Commission or a Member State" than at "carrying out a systematic check on the whole content of the standards", the Model Directive does basically take account of the perception that there can be an obligation on Member States to mutually recognise national standards only within a context of harmonisation of the legal provisions underlying these standards[199]. There is certainly a reduction from the requirements of the first paragraph of Art. 100 EEC if the Commission is to have a right of ultimate decision on inclusion of national standards in the "standards catalogue" of Community law. But this power is compensated for by Member States' right of objection in administering the standards catalogue (and also by the fact that conformity to standards can

197 3.2 supra.

198 Sections V 2, VI 2 of the Model Directive (note 160).

always justify only a presumption of compliance with the safety objectives)[200].

3.3.2 Mutual recognition of conformity certificates and certification procedures

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

The Model Directive largely ignores the thorny question of how equivalence of national safety certificates can be guaranteed. It merely lists a number of different means of attestation[201] (certificates and marks of conformity issued by a third party, results of tests by a third party, manufacturer's declarations of conformity and surveillance systems), but does not specify the requirements that these certification bodies have to meet[202]. It is

199 Cf. Chapter III, 1.1, text accompanying note 11.

200 Cf. Sections VI (2), VII and VIII (3) of the Model Directive (note 160), and for more details on the safeguard procedure 3.4 infra.

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

202 Loc. cit. (note 160), Section VIII.

only with the directives and proposals for directives submitted on the basis of the new approach that we come upon more precise regulatory proposals, meant as examples, on the certification issue.

The Directive on simple pressure vessels, following numerous predecessors[203], distinguishes between design testing to verify the safety conformity of the manufacturer's designs (EC type-examination) and monitoring of the production process relating to actual compliance with the accepted designs (EC verification)[204]. The Commission favours the setting up of quality guarantee systems under official control in factories themselves, through which manufacturers would assume primary responsibility for monitoring their production processes[205]. Arrangements of this type are provided for in the Draft Toy Directive. Here, too, a distinction is drawn between type-examination (Articles 8 (2), 10) and surveillance of the manufacturing process, for which again the manufacturer himself is to be primarily responsible (Art. 8 (1)).

Both design checks (type-examination) and surveillance of quality control systems are incumbent on national bodies. Accordingly, the new directives must seek to guarantee the equivalence of the administrative practice of these bodies. For this purpose, requirements are established for the independence, technical competence and requisite equipment of those bodies[206]. The administrative sovereignty of Member States, however, re-

203 In particular following the Pressure Vessels Directive of 1976 (note 166); cf. also, among the directives adopted as a package in 1984, the Directive on lifting and conveying equipment (note 192), Chapters III, VI and V, VI.

204 Loc. cit. (note 166), Arts. 10-15.

205 Cf. in the explanatory statement cited in note 167 supra, point I (9) and Art. 12 of the Directive.

206 Directive on simple pressure vessels (note 166), Annex III (and with the same wording, Annex III of the 1976 directive, note 166); proposal for a directive on toys (note 169) Annex III; cf. also ISO guideline 24-

mains unaffected, since they alone decide whether the bodies they have designated meet the Community requirements[207].

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

This summary of a perusal of the new directives and draft directives is in line with the outcome of Community endeavours hitherto to clarify the relationship between safety objectives and design specifications. Regulatory conceptions based on the new approach contain clear guidelines for future Community policy,

1978 (D) on the recognition of testing and monitoring marks by certification centres, printed in DIN-Mitt. 59 (1980), 613-14 and for more details on the situation regarding electrical appliances, 2.3.4 supra.

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

208 Note 176 supra.

but at the same time must yield to needs for differentiation[210]. Ultimately it will be only the practical application of the new directives that will show how far Member States are really prepared to trust the test practices of foreign agencies, and whether they will be able to come to terms with the system of manufacturer self-certification favoured by the Community, which can only indirectly be controlled by national or independent bodies. The primary competence of Member States' administrations in interpreting safety objectives, implementing control measures and applying certification programmes can at any rate be exploited openly or indirectly to bring to bear reservations against the new policy or objections to the practice of other Member States.

3.4 Safeguard clause procedure and follow-up market controls

Even in directives adopted in accordance with the "traditional" harmonisation policy, safeguard clauses have become usual. These cut into the supremacy claim of European law by allowing Member States to appeal to their safety policy interests within the meaning of Art. 36 EEC and initiating a procedure to amend the directives[211]. The Model Directive

209 Cf. 3.2 supra, text at notes 175 et seq. and the bilateral "special procedure" provided for in Art. 16 of the Directive.

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

(Section VII), and following it all new directives and proposals for directives[212], contain corresponding provisions.

Incorporation of safeguard clauses is in fact inevitable for a variety of reasons: The new harmonisation policy lays down only basic safety objectives bindingly, and is in principle here confined to "performance" standards; the specification of safety objectives by private standardisation organisations is to imply only a presumption of safety conformity; the European standardisation organisations can decide by qualified majority; last but not least, Member States agencies may autonomously verify the Community requirements. It is easy to conceive of a large number of conflicts in which Member States might assert their safety policy interests. Member States may in particular, even where products have a certificate of conformity, prohibit their marketing, referring to the inadequacy either of autonomous conformity certification or even of European and national standards[213]. The solution of such conflicts is referred by the Model Directive initially to the Standing Committee, which has to take a position on objections to European or national standards. On the basis of the Committee's opinion, the Commission then has to decide. If it finds the objection justified and revokes recognition of a standard, a State finding itself disadvantaged by this may proceed in accordance with Art. 173 EEC. If instead, the Commission finds the objection unjustified, the rejected State has the same possibility. Conversely, procedure according to Art. 169

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5 and 6) are intended to make superfluous the checks by national agencies on manufacturer self-certification.

211 Cf. Chapter III, 2.5, and specifically on the Low Voltage Directive 2.3.3 supra.

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

213 Section VI (1) of the Model Directive (note 160).

EEC is open to the Commission where a Member State keeps to its measures contrary to the Commission's decision[214].

However, the possibilities of safety-motivated action open to Member States not only concern the recognition of standards and conformity certificates, but could also directly affect the marketability of products. By Section VII (2) of the Model Directive, the Commission shall, where it finds the action taken by a Member State justified, "point out to the other Member States that (all else being equal) they are also obliged to prevent the product in question from being placed on the market". No legal basis for this Community-wide applicability of a measure by a single Member State is contained in the Model Directive itself. Even if the Commission manages to assert its interpretation of the basic safety objectives, there is no means of action available to it whereby it could compel active intervention by the administrative bodies of Member States.

The new directives or proposals for directives respond differently to this regulatory lacuna in the Model Directive. The Directive on simple pressure vessels[215] contains provisions on review of the recognition of standards (Art. 6) and on information of the Commission on unilateral measures (Art. 7), but in no way guarantees their applicability Community-wide. The safeguard clause in the proposal for the Directive on construction materials[216] likewise deals only with the need to amend standards and approve decisions, without making it clear how a justifiably adopted protective measure by one Member State can be made applicable Community-wide. By contrast the proposal for a toy directive[217] aims at Europeanising follow-up market controls.

214 Cf. Weber, 1982, 321 et seq.

215 Loc. cit. (note 166).

216 Loc. cit. (note 176), Art. 21.

Article 7 (1) obliges all Member States to take "all appropriate measures to withdraw" unsafe toys "from the market and prohibit their placing on the market" and to inform the Commission of such measures. This information is aimed not only at revision or supplementation of standards; the Commission is instead to verify the justifiability of national measures and inform other Member States, while according to the 1986 proposal it should if national measures prove justified, remind other Member States of the need to take similar action (Art. 7 (4))[218]. The Directive on airborne noise emitted by household appliances[219] likewise "walks on two legs": Art. 9 regulates the procedure for reviewing European standards and national standards or technical regulations[220], while Art. 7 obliges Member States to take steps to secure correction of faulty information from manufacturers[221].

Visualising the number of potential conflict situations that are supposed to be dealt with through the safeguard clause procedure, one is forced to conclude that this procedure has been overloaded; on the one hand, through the twofold load of perfecting standards, approval criteria and certification procedures

217 Note 169.

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

219 Note 210.

220 On this differentiation see 5.3 infra.

221 The most detailed regulations on follow-up market control to date are contained in the proposal for a directive of 8 October 1986 on "products which, seeming to be other than they are, endanger the health or safety of consumers" (OJ C 272, 28 October 1986, Art. 3). In the Directive since adopted (OJ L 192, 11 July 1987, 49) these propos-

and on the other, through having to cope with emergency decisions because of newly recognised dangers. This point and its consequences will be returned to[222].

3.5. Improving the position of European standards

All documents on the new harmonisation policy treat reference to national standards as merely a transitional solution[223]. Co-ordination of future directives with corresponding work by the European standardisation organisations is therefore a key feature of the new approach, or conversely, the new approach means a "rather fateful challenge" to European standardisation[224].

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

als are withdrawn; all that is still provided for is an "exchange of views" on national measures (Art. 4).

222 Cf. Chapter V, 3 and Chapter VI, 3.4.

223 Cf. only Section V (1) of the Model Directive (note 160).

224 Anselmann, 1986, 993.

225 Technical barriers to trade: A new Commission approach, EC Bull. 1-1980, 12, 15-16.

226 Loc. cit., 15.

information procedure in the area of technical regulations and standards[228].

The starting position for European standardisation is clearly precarious. "Disorientation and remoteness from reality", as R. Winckler was warning as long ago as 1980[229], characterise the situation of European standardisation organisations. The reasons for this judgement are multifarious. Orientation of standardisation work to the internal market of the Community does not *a priori* correspond to the interests of standardisation organisations (nor of their supporters), which have always regarded international standardisation under ISO and IEC as having priority[230]. The stagnation and shortcomings in implementation of traditional harmonisation policy and legal establishment of standards to date are hardly likely to help increase their attractiveness or involvement in European standardisation work[231]. The new approach to technical harmonisation and standards is now intended to create

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

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

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

228 On this see 3.1 supra.

229 Winckler, 1980, 85; see also Winckler, 1978, 59 et seq.

230 Cf. Reihlen, 1984.

fundamentally improved co-operation conditions for both the Community and the standards organisations. Standards organisations gain additional importance from the reference technique itself and from the now essential co-ordination between policy on directives and standardisation work, while the Commission expects the concentrating of harmonisation policy on the laying down of essential safety objectives to unburden political decision-making processes in the Community. The "general guidelines on co-operation"[232] agreed to by the Commission and the European standards organisations CEN/CENELEC on 13 November 1984, laid the foundations for future co-operation. Four elements in this document should be stressed:

— The Commission recognises the "competence" of CEN/CENELEC for producing European standards; it will in principle support these organisations through orders for standards, and also support their work financially.

— CEN and CENELEC for their part guarantee that they will take account of the safety requirements specified in Community directives and in the Commission's orders for standards.

— Co-operation between the Commission and the standardisation organisations starts from the preparatory stage of directives; the Commission will also bring the standardisation organisations in for general issues of "common interest"; on the other hand, Commission representatives will take part in meetings of the technical boards and technical committees of the standardisation organisations.

— CEN and CENELEC guarantee that "interested circles, in particular government authorities, industry, users, consumers and trade unions will if they wish, be able to be genuinely involved in the development of European standards".

All these elements of co-operation call for further clarification. Thus, the safety policy importance of future standardisation

231 See also the figures in Reihlen, 1984.

work depends essentially on the specific form of the "basic safety objectives" in the new directives — at the CEN annual meeting in 1985 the fear was already being expressed "that individual debates on the boundary between governmental stipulation and standardisation are clearly unavoidable"[233]. But particularly now that European standardisation organisations are being assigned the substantive tasks that result from a reticent formulation of safety objectives, they must redefine their relationship to national and international standardisation. They will increasingly be taking over the functions of safety standardisation hitherto handled by national and international standardisation bodies. It remains to be seen, whether the European organisations will be able to overcome the considerable reservations that in the past have been voiced against the usefulness of establishing a new organisational level between national and international standardisation[234].

The desired "functional shift" in European standardisation is unlikely to ease an arrival at consensus among national delegations at the European level. Even in the past, a voting procedure applied in CENELEC for members from the Community that was patterned on Art. 148 EEC, and that required member organisations to transpose European into national standards within six months[235]. CEN likewise had a qualified majority rule, but here outvoted members were not obliged to adopt the European standard[236]. Following the agreement of 13 November 1984 between Commission and CEN/CENELEC, the voting rules of CENELEC were taken over in CEN and the incorporation of European stan-

232 Reprinted in DIN-Mitt. 64 (1985), 78 -79.

233 See the report by Mohr, 1986 and note 175 supra.

234 Cf. Seidel, 1981, 1121; Seidel, 1985.

235 Cf. Mohr, 1980; Schulz, 1984.

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

dards into national ones was also guaranteed[237]. The now unified voting rules differ markedly from the unanimity rules of Art. 100 (1) EEC. On the other hand, economic conflicts of interest among Member States continue to exist[238], and one shall in other respects have to wait and see how the voting rules in the standardisation organisations will impinge on Member States' behaviour in the Council when adopting new directives, and then in any recourse to the safeguard clause. Finally, it is hard to see how the participation rights for "interested circles" are to be structured and implemented[239].

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

The restructuring of legal harmonisation policy not only leads to a "functional" involvement of private organisations in the Community's law-making process, but also affects the relationship between Member States, Council and Commission. The Council's role will, according to the ideas of the Model Directive, be confined to laying down the basic safety requirements. This means that Member States are no longer to be involved directly ("in legislative policy") in transposing the new directives. This limitation of their possibility of influence explains the setting up of a Standing Committee pursuant to Section IX of the Model Directive, identical with the one set up by the 1983 Information Directive. Pursuant to Art. 6 of the Information Directive, it is to be involved in discussion of standardisation projects[240] and may

237 Cf. Mohr, 1986. The new draft Directive on toys (note 169) already assumes these changes.

238 Cf. Chapter III, 1.2.1.

239 Chapter V, 6 infra.

be brought into the standstill procedure under Art. 8 (2) of that Directive. The Standing Committee is now also concerned with administering the list of recognised standards (Section VI (2)); it is to be consulted in the safeguard clause procedure (Section VII (2)) and furthermore "any question regarding the implementation of a Directive may be submitted to the Committee" (Section X (2)). Nevertheless, the Commission's legal prerogative remains clear. As regards the Committee's function in managing the list of standards, Section X of the Model Directive states in sibylline fashion that "the object of the consultation of the Committee . . . is more to provide for a forum for the discussion of the objections . . . than to carry out a systematic examination of the entire contents of the standards". Its formal powers are clearly limited. The Committee cannot, by contrast with "management" and "regulatory" committees, compel the Council through its vote to reformulate its decision, but is a mere consultative body, an "advisory committee" therefore, as the final conference on the Single European Act recommended, in the area of application of Art. 100 a[241]. The comprehensive formal powers of the Commission are supposed to make the decision-making procedure effective. But having regard to the legal-policy explosiveness of the questions that might arise, particularly in the safeguard clause procedure, it is to be expected that the practical importance of the Standing Committee (and the sub-committees) will be greater than the legal status assigned to it suggests. And quite irrespective of how the actual decision-making process develops, the question still has to be asked whether the shape given to the Commission's formal powers can be maintained legally at all[242].

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240 See also point 4 of the "general guidelines on co-operation" between Commission and CEN/CENELEC (note 232) and Art. 1 (2) of the proposal for amending the Information Directive (note 144).

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

242 Cf. 5.2 infra.

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

The Single European Act (SEA)[243] provides for some important changes to the framework conditions for a policy that will bring about the internal market and guarantee product safety. Art. 8 a[244] contains the central objective of progressively establishing the internal market by 31 December 1992, and lists the additions to the Treaty that are to permit the accomplishment of the ambitious political programme contained in the White Paper on completing the internal market[245]. The supplementations of the Treaty relate essentially to harmonisation measures, leaving unaffected the existing rules on free movement of goods before approximation of laws. The internal market, on the realisation of which the new instruments are to be employed, is defined as an "area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty" (Art. 8 a, second sentence). It is the

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243 Signed on 17 February 1986 in Luxembourg and on 28 February 1986 in The Hague, published as supplement 2/86 to the EC Bulletin. An exhaustive survey on this can be found in EuR 21 (1986), 199 et seq. ; Ehlermann, 1987; Jacqué, 1986 and Lodge, 1986, and sharp criticism in Pescatore, 1986. See also Arnull, 1986; Ehlermann, 1986; European Consumer Law Group, 1987; Gulmann, 1987; Hrbek/Läufer, 1986; Reich, 1987, Nos. 173-180; Sedemund/Montag, 1987, 546-47; Zuleeg, 1987. Specifically on the connection between the SEA and free movement of goods or achievement of the internal market, see Forwood/Clough, 1986; Hirsch, 1987; Meier, 1987; Rögge, 1986; Scharrer, 1986; Seidel, 1986. On the background to and the emergence of the SEA see de Zwaan, 1986; see also the comprehensive reports in EC Bull. 11-1985, 7-22 and EC Bull. 12-1985, 7-16.

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

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

core of the more comprehensively treated measures to set up and operate the Common Market (cf. Articles 2, 3, 100, 235 EEC).

4.1 Article 100 a — majority principle and reservations by Member States

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

It is questionable whether legal harmonisation measures to bring about the internal market will continue in the future to be possible in accordance with Art. 100 EEC. The majority principle is aimed at facilitating arrival at a political consensus; a single Member State is no longer to have the possibility of vanifying or delaying the further building of the internal market by a veto. It is therefore to be presumed that measures of legal approximation for the creation and operation of the internal market should in the future no longer be possible under Art. 100 EEC, which *requires* unanimous decision[247]. In the interest of accelerated realisation of the internal market, it is specifically the veto position allowed individual Member States by the unanimity principle, that is to be

246 This means the overcoming of the extra-legal 1966 Luxembourg Compromise, which allowed a Member State to prevent a Council decision by appealing to vital interests.

overcome. The derogation and safeguard clauses of Art. 100 a (4) and (5) constitute only a very restricted form of compensation for the veto right of Member States resulting from the unanimity principle. The individual Member State cannot prevent a Community regulation which in any case will have the effect of abolishing some of its powers. The derogation clause in Art. 100 a (4) provides no protection against failure of a measure adopted by the Community legislator to meet regulatory policy concepts of an outvoted Member State, or against a measure in which one Member State's view brings in excessive protection of the objects legally protected by Art. 36 EEC, thus disproportionately restricting the freedom of economic activity[248].

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

Restrictions on use, such as restrictions on distribution, speed limits or conditions for utilisation, indirectly interfere with intra-Community trade if they differ from one Member State to another. A ticklish question of demarcation arises, namely whether a Community regulation of restriction on use is to be counted as part of a realisation of freedom of movement of goods, and can therefore in accordance with Art. 100 a be made. Seidel denies this, on convincing grounds[249]. In attempts at legal harmonisation so as to remove technical barriers to trade, such

247 Cf. Ehlermann, 1987, 382. Many proposals for directives mentioning Art. 100 EEC as a legal basis are being converted to Art. 100 a.

248 Seidel, 1986, 63-64.

arrangements have to date been included only where at least one Member State has met the regulatory object by design requirements, thus raising a technical barrier to trade. He further points out that restrictions on use have not been classified by the ECJ as measures having equivalent effect to quantitative restrictions within the meaning of Art. 30 EEC[250]. Accordingly, harmonisation of restriction on use could be brought about only from the viewpoint of harmonising competition conditions, and therefore not according to the procedure of Art. 100 a. The danger that restrictions on use may be used as an indirect instrument for market restriction, though not the walling off of markets, cannot be entirely ruled out.

Since completion of the internal market cannot be brought about through directives that merely lay down minimal standards and allow Member States to make further-reaching requirements[251], but undercutting of higher protected levels reached in individual Member States is politically undesirable, Art. 100 a (3) provides that the Commission shall, in its proposals for legal harmonisation in the areas of health, safety, environmental protection and consumer protection, take as a basis a high level of protection. The Commission's proposals and the resulting Council decisions need not necessarily meet the highest existing level of protection in one of the Member States. The compromise lies in "setting the level of protection in such a way that the burden on Member States that so far had a low level of protection remains acceptable and on the other hand, the reduction of a high level of

249 Seidel, 1986, 61. See also Reich, 1987, No. 176 on the economic interests of consumers.

250 Cf. ECJ, Judgment of 31 March 1982, ECR [1982] 1211 (1229) - Blesgen; Judgment of 14 July 1981, ECR [1981, 1993] 2009 — ban on night baking. See also Skordas, 1986, 23-28.

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

protection in one Member State does not lead to political problems"[252]. An additional procedural guarantee against removal of a high level of protection is that the Council can by Art. 149 (1) EEC decide on amendments to the Commission proposal only unanimously, so that each Member State has a veto on going below a high standard proposed by the Commission. What is wanted, then, is the levelling of protective standards at a high but not necessarily the highest level[253].

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

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

252 Glaesner, EuR 21 (1986), 131. See also Rögge, 1986, 461.

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

cept and uniform technical safety provisions for all appliances, machines and installations[254].

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

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

By contrast, Art. 100 a (4) means a considerable innovation. If a directive has been adopted by qualified majority[257], a Member State can by appealing to compelling concerns within the meaning of Art. 36 EEC or relating to protection of the environment or of the working environment, unilaterally apply different national provisions. This right of "opting out" is open to all Member States, not only outvoted ones[258]. The view that consent by a Member State necessarily means abstaining from national special regulations pursuant to Art. 100 a (4)[259] is not supported

254 Cf. Jahresbericht 1985 der Bundesanstalt für Arbeitsschutz 1985, 22. See also Budde, Vorschlag, 1987; Dey, EG-Richtlinie, 1987.

255 Cf. on this concept Scharrer, 1981; *idem*, 1984; Langeheine, 1984; Ehlermann, 1984; Eiden, Abgestufte Integration, 1984.

256 Cf. Chapter III, 2.5 supra.

257 Only Gulmann, 1987, 37-38 regards appeal to Art. 100 a (4) as possible even in the case of unanimous decisions; Ehlermann, 1987, 391 is convincing in the opposite direction.

by the tenor of that provision, and creates a risk that Member States may endanger a decision by qualified majority because they abstain as a precautionary measure, in order to retain their possibilities of action pursuant to Art. 100 a (4). Art. 100 a (4) and (5) should be considered in the light of German desires for vehicles with clean exhausts and "are to guarantee that insistence on legal approximation once attained does not prevent the further development of environmental or health protection"[260].

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

It can be expected that Member States' powers deriving from Art. 100 (4) will be restricted by the principle of propor-

258 So also Ehlermann 1986, 104. But cf. by contrast Ehlermann, 1987, 394-95.

259 Meier, 1987, 540; see also Seidel, 62-63.

260 Steindorff, 1986, 702.

261 Another opinion is held by Glaesner, EuR 21 (1986), 134.

262 Cf. Meier, 1987, 540.

tionality developed in the case law. This is that a measure taken must be suitable for securing the object of protection adduced, and be necessary without being disproportionate; that is, it must be the measure that least hampers free movement of goods[263]. To limit the danger of the Common Market being split by measures of individual Member States under Art. 100 a (4), the Commission has to ensure that national measures that continue to apply one-sidedly do not constitute a means of arbitrary discrimination or a disguised restriction on trade among Member States. These two criteria are derived from Art. 36 EEC, second sentence. The ECJ has, in delimiting Member States' rights of reservation vis-à-vis free movement of goods, undertaken comprehensive verification of proportionality, referring not only to the ban on arbitrary discrimination and disguised restrictions on trade. If it takes the same line in the case of the safeguard clause of Art. 100 a (4), the Commission should acquire further-reaching powers of verification and prohibition than would appear from the wording of Art. 100 a (4), second sentence[264]. In order to permit rapid judicial control where necessary, the Commission and the other Member States are exempted from the procedures laid down in Articles 169 and 170 EEC when they wish to impugn unilateral action by a Member State under Art. 100 a (4). This indicates that a determination by the Commission, that a Member State's provision is in conformity with Community law or not, does not constitute law-making[265]. If refusal of confirmation constituted law-making, the deviant Member State could bring an action for avoidance pursuant to Art. 173 EEC[266], and no provision on simplified

263 In detail see the account in Chapter IV, 1.2.2 supra. See also Glaesner, EuR 21 (1986), 135; Seidel, 1986, 66-67; Rögge, 1986, 461.

264 Cf. Seidel, 1986, 67.

265 For details on this see Seidel, 1986, 64-66. By contrast Meier, 1987, 540, with his unconvincing reference to the confirmation provisions of Art. 93 (3) EEC, which are not taken over into Art. 100 a (4). This reference is also found in Forwood/Clough, 1986, 403.

266 But this is said by Glaesner, EuR 21 (1986), 135.

appeal to the Court, by the Commission or another Member State, would have been required.

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

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

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

Legal conclusion	not a measure having equivalent effect	measure having equivalent effect is justified	
Communication to the Commission	not required	not required	required
Judicial control	The Commission and other Member States may resort to the ECJ only once they have first presented the Member State concerned with a reasoned opinion and given it a chance to react; Preliminary ruling procedure		Commission or other Member States may resort directly to the ECJ; Preliminary ruling procedure

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

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

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267 Explicitly stated by Reich, 1987, No. 176; see also Ehlermann, 1986, 104. BEUC, Actualités No. 51 (2/1986), 9 criticises these restrictions. For the admissibility of introducing tighter national legislation once the Council has adopted the harmonisation measure see Miller, 1987, 503-04.

268 See Case 148/78, Judgment of 5 April 1979, ECR [1979] 1629 (1645) - Ratti.

This still leaves unanswered the general question, not specific to Art. 100 a (4), as to whether and under what conditions unilateral action by a Member State remains permissible when new risks come to light following harmonisation[269]. In just those areas where the Community has replaced Member States' powers by its activities, the Commission is obliged not only to set up and properly operate the Common Market, but also to protect such objects of legal protection as those listed in Art. 36 EEC. If it has not responded to newly emerging hazardous situations not yet covered by harmonisation measures, there is *ipso facto* no Community regulation, and Member States are, if the Community does not act, not prevented from taking protective measures themselves in response to the new risk. If the case is one of intensification of a hazardous situation already covered by Community law, Member States must aim at raising the Community level of protection[270].

A manageable distinction is required between harmonisation measures under Art. 100 a to complete the internal market on the one hand, and environmental protection and industrial safety arrangements on the other, since Articles 118 a and 130 t allow Member States to introduce or maintain higher protection even in a harmonised area without further substantive or procedural restrictions[271]; in contrast Art. 100 a (4) appeals to industrial safety or environmental protection dependent on the conditions described. The relevant point is the primary object of the measure[272]. If it is concerned primarily with creating the internal market, that is, with the free movement of goods, persons, ser-

269 On this see Skordas, 1986, 152-177.

270 On this issue, in connection with vehicle catalysers and lead-free petrol, see Steindorff, Umweltschutz, 1984 and Ress, 1985.

271 See the statements by Zuleeg, 1987, 283-286 on the principle of best possible protection of the environment.

vices and capital in the various Member States with as little restriction as possible from different standards, then appeal to increased industrial safety or environmental protection is possible only under the restrictive conditions of Art. 100 a (4). If instead, a measure has to do primarily with the working environment within the meaning of Art. 118 a or with environmental protection within the meaning of Art. 130 r, that is, so to speak, with raising the "quality of life" in the Community, then Member States are not subject to any further restrictions if they wish to bring in higher levels of protection relative to industrial safety or the environment.

The simplified decision-making by qualified majority in the Council may ultimately have a disintegrative effect. This might occur because of the possibility of more than temporary derogation pursuant to Art. 100 a (4) not only by outvoted Member States, irrespective of an acute hazardous situation, The Commission and Council will therefore have to consider whether they wish to push forward decisions by qualified majority and put up with the uncertainty, deriving particularly from Art. 100 a (4), for harmonisation already attained, or else strive as previously for unanimity, providing safeguard clauses specific to each directive[273].

4.2 Art. 100 b — mutual recognition

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

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272 See Reich, 1987, No. 176. On the practical significance of this allocation, see the instructive example in Reich, 1987, No. 180.

273 See Reich, 1987, No. 174; Seidel, 1986, 71.

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

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

It seems doubtful whether Member States that have not managed to arrive at harmonising their laws will be ready to decide on the step of bringing about the internal market by mutual recognition of legislation. After all, this would mean leaving aside all the substantive criteria, such as taking a high

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

275 Skepticism would seem appropriate. On the delay already accumulated by comparison with the ambitious programme, see the Commission's first report to the Council and the European Parliament on implementation of the Commission White Paper on completing the internal market, COM (86) 300 final of 26 May 1986 and the answer to written question No. 2758/85, OJ C 202, 11 August 1986, 3-6, according to

level of protection as a basis (Art. 100 a (3)), and taking differing levels of individual economic development into account (Art. 8 c)[276], quite irrespective of the fact that here, too, unilateral rejection of mutual recognition is possible by Art. 100 a (4). Finally, it remains unclear as to whether only provisions adopted by the Commission in the course of 1992 can be the object of Council decision on mutual recognition; in that case the principle would be enumerative, requiring recognition of a precisely defined set of provisions. The alternative to this narrow interpretation would be to read Art. 8 c as establishing the principle of mutual recognition generally and *a priori*, even for provisions in non-harmonised areas, that is, where there is no Community law to exert a preemptive effect.

In view of these ambiguities, one is inclined to favour the further application of Articles 30 *et. seq.* in non-harmonised areas. They, too, lead, where Member States cannot exceptionally appeal to the objects of protection of Art. 36 EEC or to mandatory requirements within the meaning of the Cassis de Dijon case law, to mutual recognition as the outcome in practice. Mutual recognition that would no longer presuppose a careful evaluation of Member States' interest in protection and proceed on a case-by-case basis, would overstrain the consensus achieved among Member States in their acceptance of the internal market objective.

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which, of the 59 proposals in the Annex to the White Paper that the Council should have adopted in 1985, only 16 were adopted in time.

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

4.3 Conferment of implementing powers on the Commission

Finally, the Single European Act provides for a supplement to Art. 145 EEC[277]. According to this the Council has, apart from certain exceptional cases not mentioned in detail, to confer upon the Commission powers to implement regulations adopted. By its Decision of 13 July 1987, the Council laid down the procedures for the exercise of implementing powers conferred on the Commission[278], thereby limiting the number of different committee procedures to which the Council may resort in the future in conferring these powers. According to Art. 4 of that decision, the existing structure of some 300 committees is to remain unaffected. In its original 1986 proposal[279], the Commission had, referring back to practice to date[280], provided for only three different types of committees, namely "advisory committees" as purely consultative bodies, "management committees", brought in so far particularly in the area of agricultural regulations for products coming under a common organisation of the market, and "regulatory committees", previously used primarily in the area of adapting directives to technical progress. The European Parliament, in its endeavours to strengthen the Community's executive powers while concomitantly expanding its own control powers, recommended only the procedures of the Advisory Committee (preferred in the context of Art. 100 a) and the Management Committee)[281]. The Council Decision, now heavily attacked by

277 Art. 10 SEA. On this subject see Bruha/Münch, 1987 and Glaesner, EuR 21 (1986), 145-46.

278 OJ L 197, 18 July 1987, 33.

279 OJ C 70, 25 March 1986, 6-7.

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

the European Parliament[282], provides for no less than seven different Committee procedures. The details of the four basic procedures and their variants are contained in the following table.

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

282 EP Resolution of 8 July 1987, OJ C 246, 14 September 1987, 42-43 and EP complaint against the Council submitted on 2 October 1987, Case 302/87, OJ C 321, 1 December 1987, 4.

Procedures for exercise of implementing powers conferred on the Commission

Type of Committee	Procedure I "Advisory Committee"	Procedure II "Management Committee"	Procedure III "Regulatory Committee"	"Safeguard Clause Committee"
Committee	Advice	Majority decision pursuant to Art. 148 (2) EEC	Majority decision pursuant to Art. 148 (2) EEC	Advice
Commission	may depart from it without further consequences; informs the Committee of the measures taken	in the case of agreement with the Committee, the measure applies directly	in the event of agreement with the Committee the measure intended enters into force	may without further consequences depart from the Commission's opinion; informs the Council and Member States of every decision on protective measure; prior consultation by Member States may be provided for any Member State may bring the Commission's decision before the Council
Council	no powers	may take another decision by qualified majority var. a) 1 month var. b) within..... 3 months (period to be laid down in each act to be approved by the Council), otherwise the Commission's postponed measure applies	within a period of the most 3 months (period to be laid down in every legal act to be adopted by the Council) var. a) can decide by qualified majority var. b) can decide by qualified majority, or rejects the proposed measure by simple majority, otherwise the Commission adopts the proposed measures	may decide by qualified majority within a time limit to be laid down in the legal act concerned var. a) to take a different decision var. b) to confirm, amend or reject the Commission's decision; the Commission's decision shall be taken as .rejected where the Council takes no decision

The main novelty is the "safeguard clause committee procedure", which most strongly restricts the Commission's powers. It has to inform the Council and Member States of any decision on protective measures; prior consultation of Member States may be provided for. Irrespective of whether the Commission agrees with a committee, which in the overall context is not explicitly mentioned but is usually set up in the case of safeguard clause procedures, each Member State can bring the Commission's decision before the Council within a set period. The Council may then, within a set period and by qualified majority, take a different decision (variant a) or (variant b) confirm, amend or abrogate the Commission's decision; where the Council does not take a decision within the set period, the Commission's decision is treated as abrogated. In the latter case, and with variant (b) in the regulatory committee procedure, a block on the application of Community law is possible where the Council cannot arrive at a majority for a decision.

The Conference had called on the Council in the Final Act of the SEA to give preference to the "advisory committee" procedure as regards the Commission's powers of implementation, in order to bring about the internal market; emphasis was placed on the rapidity and effectiveness of the decision-making process; this would have considerably increased the weight of the Commission vis-à-vis the Council and thus vis-à-vis the Member States. The Council Decision of 13 July 1987 makes no mention of preference for using advisory committees.

In the procedure of management and regulatory committees, the Council was hitherto able to take the delegated power on itself again in the event of unresolvable disagreement of the Commission with the Committee, i.e. with the majority of Member States' government representatives. These powers of recourse for the Council have so far been of a theoretical nature. The real influence on the Commission takes the shape of prior pressure to

adapt, and of a more or less diffuse basic consensus of national experts and the relevant Commission officials among themselves. This explains why the committees, which have in some cases been operating for many years now, have only rarely rejected Commission proposals, fairly rarely abstained from an opinion and often even voted unanimously[283]. This "filter of expert consensus" is not provided for in the case of the safeguard clause procedure, which is usually highly controversial politically or at any rate, a very sensitive issue for the protection policies of Member States concerned.

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

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

283 Schmitt v. Sydow, Art. 155, No. 52; more fully, *idem*, 1980, 160-166.

284 On this see Chapter V,3.; on the significance of Art. 100 a (4) of the SEA cf. 4.1 supra.

5.1 Inclusion of standardisation organisations in the Community's law-making process

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

The proponents of the Low Voltage Directive referred above all to the legally non-binding nature of standards; the prohibition on delegation would not be infringed if and because the specification of safety objectives laid down in the Directive would ultimately be under the control of governmental bodies, and because the safeguard clause procedure of Art. 9 did not rule out emergency measures[287]. Yet this argument has two weak points. First, the structure of the Low Voltage Directive gives harmonised, international and national standards (and conformity certificates issued by a national body) considerable legal importance, merely because conformity with the standards is a basis for presuming compliance with the safety objectives in the Directive and thus a right to access to Member State markets[288]. This legal effect can

285 OJ L 77, 26 March 1973, 29.

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

287 Cf. esp. Starkowski, 1973, 115 et seq.

be removed only through the apposite safeguard procedure. A second, graver objection is directed against the merely formalistic interpretation of the prohibition on delegation. Especially in the case of the Low Voltage Directive, it is indisputable that its safety objectives open up very considerable leeway for standardisation organisations[289] and that the level of safety is, in practice, essentially determined by private standards[290].

The Model Directive modified the reference technique of the Low Voltage Directive. The safety conformity of European and national standards is continually checked through the "management of the list of standards", though there is no such preliminary control in the case of national certificates of conformity; to that extent, Member States are solely responsible for the reliability of their certification bodies. With all these provisions, the Model Directive presupposes that safety requirements be more precisely formulated than in the Low Voltage Directive[291].

These changes take the force away from the objections raised against the Low Voltage Directive, but do not remove the problem of delegation. By contrast with what has often been asserted in the literature[292], the controversy that broke out over the Low Voltage Directive has not been clarified even by the ECJ judgment in case 815/79[293]. While in its decision the ECJ urged

288 Cf. Lauwaars, The Model-Directive on Technical Harmonisation, EUI-Colloquium Papers, DOC IUE 169/86 (COL 82), 12.

289 Cf. 3.2 supra at note 158.

290 Cf. esp. Röhling, 1972, 114 et seq. and more details in 2.4 supra; the European Parliament's Committee for economic and mandatory affairs and industrial policy (note 163 supra) arrives at an answer to this objection that is as contradictory as it is legally untenable. The Committee categorically rejects involvement with "technical details" (loc. cit., point 2) and alleges that there is no "abandonment of legislative powers" because technical regulations secure general bindingness and legal force (sic!) only "where the Community legislator confers it upon them in the prescribed procedure" (loc. cit., 11).

291 3.2 supra at notes 160 et seq.

Member States to comply with the Low Voltage Directive[294], it did not explicitly address itself to the issue of the prohibition on delegation. The sole relevant decision of the ECJ, as far as we can see, is from long ago. It concerned the delegation of decision-making powers of the High Authority on private institutions set up pursuant to Art. 53 ECS. The ECJ drew a distinction: "clearly defined executive powers" are unobjectionable; "discretionary powers" instead "bring about an actual transfer of responsibility", "since it replaces the choices of the delegator by the choices of the delegate"[295]. But these statements do not offer much help in deciding either. By contrast with the situation in Art. 53 ECSC, co-operation between the Community and European standards organisations is based not on a particular provision of the EEC Treaty but only on the Council resolution of 16 July 1984[296]. Above all, however, it is hard to draw a line between mere "executive powers" and inadmissible "transfers of discretionary powers"[297]; and in the case of the delegation issue with reference to standards, where what counts is the relationship between formal decision-making powers and actual possibilities of influence, it can only be applied in the form of a description of general trends. The more precisely safety objectives are set forth in

292 Cf. most recently Bruha, 1986, 25.

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

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

295 ECJ, 4, 13 June 1958, Case 9/56, ECR [1958] 9, at 43-44.

296 OJ C 136, 4 June 1985, 2.

directives, and standardisation mandates to European standardisation organisations are formulated, and the more intensivy the follow-up supervisions of standards in recognition and safeguard clause procedures and those regarding conformity certificates from national bodies are exercised, the easier it is to throw out the objection that the new approach means impermissible delegation of legislative powers[298].

5.2 The institutional balance between Council and Commission

The Model Directive strengthened the Commission's position not only in managing the list of standards but also in administering the safeguard clause procedure[299]. This makes it easier to defend the reference technique against the objection on delegation of powers, but at the same time raises the further question as to whether the Commission's strong legal position is compatible with the principle of institutional balance. The Treaty basis for delegating "implementing powers" of the Council to the Commission is Art. 155 EEC, fourth indent. A widespread extensive interpretation of this provision in the literature states that the extent and procedures for conferring decision-making powers on the Commission is within the Council's discretion[300]. Delegation without any criteria or bounds would be incompatible with the

297 See Hilf, 1982, 317 et seq.

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

299 3.4 and 3.6 supra.

principle of institutional balance, to which the term "implementing regulations" refers, and which is not even at the disposal of the Council, especially since delegation restricts the European Parliament's powers of involvement in the Community law-making process[301]. Following the European Parliament's censure, demarcation formulas were developed requiring that the Council itself should take the "essential basic decision" and the Commission's leeway in decision be limited in such a way that "the political, economic and legal effects of the Treaty are determined by the Council's measure and are not affected by the Commission"[302].

The ECJ has not directly taken a position on these problems of interpretation. Admittedly, there is a statement in the judgment of 17 December 1970 that application of Art. 155 EEC is "at the discretion of the Council"[303]. But the matter at dispute in this judgment was the admissibility of a management committee procedure that restricted the Commission's decision-making autonomy. Accordingly, the ECJ's pronouncement cited has to be read along with its recognition of the possibility for the Council, provided for in the management committee procedure, to "delegate to the Commission an implementing power of considerable scope, subject to its power (specifically where the management Committee rejects Commission measures) to take the decision itself where necessary"[304]. The same approach has been followed in Cases 23 and 37/75[305], concerning a conferment of

300 Cf. Schindler, 1972, 152 et seq. ; Schmitt von Sydow, 1980, 64 et seq.

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

302 According to Grabitz, 1982, 50; see also Ehlermann, Note on ECJ Judgment of 31 March 1971, Case 22/70, EuR 1971, 242-43., 250 et seq., 252 and Chapter III, 2.6 supra.

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

304 Loc. cit., 1173.

"comprehensive implementing powers" with broad room for discretion" in cases where the transfer of powers by the Council was compensated by involvement of Member State representatives in the Commission's decision-making process and by corrective powers for the Council. This is in line with the political meaning of the management committee and regulatory committee procedure, but is at the same time an objectively obvious consequence of the delegation of implementing powers that include discretion.

The wide-ranging debate on shifting decision-making powers to "non-Treaty" bodies, which always concerned the admissibility of restrictions on the Commission's autonomy of decision[306], ignored the consequences of extensive delegation of "implementing powers" for the political legitimation of Community law. But now that the practice of delegation has become established, and at the same time highly articulated machinery to protect Member States' influence has been developed, employment of these controls must also be in line with the nature of the delegation concerned. A normative interpretation of the principle of "balance", which sees this principle as one of maintaining Member States' possibilities of influence, can be combined with the analytical observation that the Community, wherever it creates supranational legal structures, has to allow Member States possibilities of involvement in its decision-making process[307]. But now the Final Act of the governmental conference on the Single European Act has explicitly asked the Council "to give the Advisory Committee procedure in particular a predominant place", specifically "for the exercise of the powers of implementation . . . within the field of Art. 100 a"[308], and the European

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

306 Apart from the authors' mentioned in note 297, see also e.g. Bertram, 1967.

Parliament has firmly supported this proposal[309]. Even these statements were already lagging behind the Commission's original intentions on amendment of Art. 145 EEC[310], and also presuppose the powers of action remaining to Member States pursuant to Art. 100 a (4). Now the Council decision of 13 July 1987[311] has politically (even if not legally) strengthened the position of Member States in the "advisory committee" procedure, and above all abandoned the favouring of this type of committee in connection with activities oriented towards bringing about the internal market. This development quite meets the legal reservations regarding the Council's depriving itself of its powers by transferring decision-making powers in extremely sensitive questions of legislative policy to the Commission, under the title of mere "implementing powers".

5.3 Future perspectives

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

307 Chapter III, 1.2.2 supra.

308 Cf. 3.6, note 241 and 4.3 supra.

309 See the European Parliament's opinion, printed in OJ C 227, 8 September 1986, 54, concerning the Commission's proposal on the exercise of implementing powers transferred to the Commission, OJ C 70, 25 March 1986, 6.

310 Cf. Glaesner, EuR 1986, 146-47.

practice, this proposal has little chance of being realised, if only because the whole setup of the new approach offers alternative ways out, which have already in part been taken.

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

311 OJ C 197, 18 July 1987, on this see 4.3 supra.

312 Loc. cit. (note 281); on the conditions for this sort of foundation see Lauwaars, 1979, and Hilf, 1982, 322 et seq.

313 See Chapter V, 6 infra.

314 Note 232 supra.

tion IX (9) of the Model Directive to the patterns of the Management Committee or to the general Regulatory Committee procedure.

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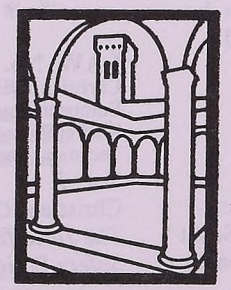

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