EUI Working Paper RSC No. 96/9

Integrating Scientific Expertise into Regulatory Decision-Making.

The Role of Non-governmental Standardization Organizations in the Regulation of Risks to Health and the Environment

JOSEF FALKE

EUI WORKING PAPERS

EUROPEAN UNIVERSITY INSTITUTE

EUI Working Paper RSC No. 96/9

Falke: *Integrating Scientific Expertise into Regulatory Decision-Making. The Role of Non-governmental Standardization Organizations in the Regulation of Risks to Health and the Environment*

The Robert Schuman Centre was set up by the High Council of the EUI in 1993 to carry out disciplinary and interdisciplinary research in the areas of European integration and public policy in Europe. While developing its own research projects, the Centre works in close relation with the four departments of the Institute and supports the specialized working groups organized by the researchers.

EUROPEAN UNIVERSITY INSTITUTE, FLORENCE

ROBERT SCHUMAN CENTRE

Integrating Scientific Expertise into Regulatory Decision-Making

The Role of Non-governmental Standardization Organizations in the Regulation of Risks to Health and the Environment

JOSEF FALKE

A Working Paper written for the workshop *Integrating Scientific Expertise into Regulatory Decision-Making*, organized by Christian Joerges and Karl-Heinz Ladeur, held with the support of the Robert Schuman Centre at the European University Institute on 5-7 October 1995.

EUI Working Paper **RSC** No. 96/9

BADIA FIESOLANA, SAN DOMENICO (FI)

Printed in Italy in March 1996
European University Institute
Badia Fiesolana
I – 50016 San Domenico (FI)
Italy

TABLE OF CONTENTS

The Role of Non-governmental Standardization Organizations in the Regulation of Risks to Health and the Environment

JOSEF FALKE*/**

1. THE NEW APPROACH TO TECHNICAL HARMONIZATION AND STANDARDS

1.1. Preliminary Remarks

The 'New Approach to Technical Harmonization and Standards'[1] has proven to be a decisive step towards the effective dismantling of technical barriers to trade within the policy on the completion of the internal market. Tied in with this new approach is the strengthening of European standardization and the development of a complementary global approach to certification and testing[2], which are being used as a central instrument in other areas such as the environment, energy, foodstuffs quality, health and safety at work and trans-European networks[3]. Reference to harmonized standards has led to a noticeable relief of Community legislation and has replaced the harmonization of laws, the

* Dr. Jur. Researcher at Centre for European Legal Policy Universitätsallee, GW 128359 Bremen.

** The paper draws on a report for a research project on 'The Hierarchy and Sources of EC Law', directed by Prof. Dr. Gerd Winter, Center for European Legal Policy at the University Bremen, and financed by the European Parliament, forthcoming in: Gerd Winter (ed.), 'Reforming the Categories and Hierarchy of EC Legal Acts', Baden-Baden 1996: Nomos.

An elaborated version of this paper will be published in: Joerges, Ch./ Ladeur, K.-H. in collaboration with E. Vos (eds.), 'Integrating Scientific Expertise into Regulatory Decision-Making -National Experiences and European Innovations', Nomos (forthcoming).

[1] OJ C 136 of 4.6.85, 1-9.

[2] Initiated by the Commission Communication of 15.6.1989, A Global Approach to Certification and Testing. Quality Measures for Industrial Products, OJ C 267 of 19.10.89, 3-27; finished by the Council Decision of 22.7.1993 concerning the modules for the various phases of the conformity assessment procedure and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives, OJ L 220 of 30.8.93, 23-39.

[3] Cf., Commission Communication to the Council, "Making the Most of the Internal Market": Strategic Programme, COM (93) 632 final of 22.12.93, 38.

progress of which has been extremely sluggish in the past due to the tendency towards detailed perfectionism[4].

As a consequence of the judgment in the leading case *Cassis de Dijon*[5], the imposition of binding Community requirements in directives or regulations is to remain restricted to cases in which Member States can invoke mandatory requirements of the common good. This includes, besides those goods already protected under Art. 36 EEC, the requirements of effective tax control, public health, the integrity of trade, and consumer and environmental protection[6]. The Community thus responded to the now obvious shortcomings of its work in implementing the 'General Programme for the elimination of technical barriers to trade in goods' dating from 1969[7]. It had become evident that the race with technical development and the protective fantasy of Member States was not to be won, and that the political decision-making process of the Community would have been overtaxed if they had continued to lay down binding market requirements for individual product categories in the directives themselves[8]. The attempt at detailed sovereign control of technology at the Community level had failed[9].

1.2. Basic Principles

The failure of a detailed public supervision of technology was officially conceded to with the introduction of the new approach to technical harmonization and standards[10]. This new approach is oriented towards the use of references to standards, used for the first time at the Community level in the

[4] A particularly blatant example is the Council Directive of 25.6.1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, OJ L 220 of 8.8.87, 1-43, with a length of 43 printed pages.

[5] ECJ, Case 120/78, Judgment of 20.2.1979, ECR [1979], 1449.

[6] Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 (*Cassis de Dijon*); OJ C 256 of 3.10.80, 2-3. Cf. on this, Joerges, Falke, Micklitz, Brüggemeier 1988: 313-318.

[7] OJ C 76 of 17.6.69, 1-6.

[8] A first comprehensive criticism can be found in the opinion of the Economic and Social Committee on the problems of trade barriers and the alignment of laws in this area of 21.11.1979, OJ C 72 of 24.3.80, 8-13; a balance sheet of the criticisms precedes the new approach to technical harmonization and standards, COM (85) 19 final of 31.1.1985, 3 *et seq.* See also, Pelkmans, Vanhenkelen 1986: 25-27.

[9] See also Eichener, Heinze, Voelzkow 1993: 396 f.

[10] OJ C 136 of 4.6.85, 1-9 — Cf. on this, Anselmann 1986; Anselmann 1991a; Vieweg 1991; Pelkmans 1987; Joerges 1988; Joerges, Falke, Micklitz, Brüggemeier 1988: 341-365; Falke 1989.

Low Voltage Directive[11] in 1973, and on the common tie between State law and technical standards found in most Member States[12]. It is based on the following basic principles[13]:

a) The harmonization of legal provisions is to restrict itself to laying down essential safety requirements which the products put on the market must satisfy. The harmonization is generally left to those areas in which Member States can, according to the jurisprudence of the ECJ, invoke national reservations for reasons of the common good where harmonized provisions are lacking: areas not reached by the principle of mutual recognition, according to which a product which is legally produced and put onto the market in one Member State must be permitted on the market in another Member State, even if it does not comply with the rules applicable to domestic products.

b) The European standardization bodies, the CEN *(Comité européen de normalisation)*, the CENELEC *(Comité européen de normalisation electrotechnique)*, and since 1988 the ETSI (European Telecommunications Institute) for the field of telecommunications[14], are assigned the task of making, always taking the 'state of the art' into account, the technical specifications which the economic circles involved need in order to produce and put on the market goods which meet those essential requirements laid down in directives.

c) These technical specifications are in no way binding, but rather remain voluntary standards; they can be deviated from, only on the condition that the essential safety requirements are otherwise met[15].

---

[11] OJ L 77 of 26.3.73, 29-33 — Cf. on this, Winckler, Cassassolles, Verdiani 1974; Joerges, Falke, Micklitz, Brüggemeier 1988: 326-340.

[12] For the Federal Republic of Germany and for the European Community see the comparative analysis of Breuer 1989.

[13] OJ C 136 of 4.6.85, 2-3.

[14] The ETSI was established in March 1988, acting on a proposal of the EC Commission, and represents a radical change in European standardization to the extent that all interested circles (postal and telecommunications authorities, operators of public networks, manufacturers, users and other organizations) can participate directly in the standardization work at the European level, with more than just a representation in national delegations under direction of the national standardization institutes taking place. Cf. on the ETSI, Quander 1989; Baragiola 1991.

[15] It is exceptionally provided for in the case of telecommunications terminal equipment that the Commission is to transpose, in a multistage procedure bringing in the Approvals Committee for Terminal Equipment, harmonized standards for the satisfaction of certain essential requirements into binding technical provisions which are to be complied with, cf., Art. 6 and 14 of the Council Directive of 29.4. 1991 on the approximation of the laws of the

d) The administrations of Member States must abide by a refutable presumption that the appropriate essential requirements are met in the case of goods which are produced according to a declaration of the manufacturer or a certificate of a controlling body (or temporarily, within the range of application of a number of directives, according to national standards which meet the essential requirements). Should a manufacturer not produce according to the standards referred to, the burden of proof is on him to show the compliance of his goods with the essential requirements.

1.3. Accelerating Effect

The New Approach has overcome the traditional concept to regulate all product-specific details at the highest political level in Community directives. Together with the majority principle introduced in Art. 100a EEC, it has led to a considerable growth and acceleration of EC rule-making activities. Using the old method, six years were required in order to determine the permissible sound level of lawnmowers[16], whereas using the new approach it only took 18 months to adopt a general directive for machines[17]. This directive covers everything from 'hobby' tools to machines for professionall uses, all the way to entire industrial plants, thus taking in beaters, hairdryers and drills as well as large chemical plants; the production value of the entire mechanical engineering sector in the EC is estimated at more than 200 billion ECU. One of the main goals of the new approach is 'to make it possible to settle at a stroke, with adoption of a single Directive, all the problems concerning regulation for a very large number of products, without the need for frequent amendments or adaptations to that Directive. Consequently in the selected areas there should be a wide range of products sufficiently homogeneous to allow common "essential requirements" to be defined'.[18]

In just a few years, far-reaching directives for many and highly heterogeneous product areas have been adopted, with an average consultation

---

Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 128 of 23.5.91, 1-18.

[16] Council Directive of 17.9.1984 on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers, OJ L 300 of 19.11.84, 171-178.

[17] Council Directive of 14.6.1989 on the approximation of the laws of the Member States relating to machinery, OJ L 183 of 29.6.89, 9-32. — Cf. on this Zachmann 1988; Reuter 1990; Fritze 1989/1990.

[18] Criterion d) for choosing the priority areas, in which the new approach could initially be applied, OJ C 136 of 4.6.85, 9.

period of only 18 months. These include simple pressure vessels[19], safety of toys[20], construction products[21], electromagnetic compatibility[22], machines[23], personal protective equipment[24], non-automatic weighing instruments[25], active implantable medicinal devices[26], appliances burning gaseous fuels[27], telecommunications terminal equipment[28], hot-water boilers[29], explosives for civil uses[30], medicinal devices[31], satellite earth station equipment[32], equipment and protective systems intended for use in potentially explosive atmospheres[33], and recreational crafts[34]. In doing so, the initial methodical concept of a 'model-directive' was continually refined and specified, in particular through a complex system of rules for certification. The abandonment of detail perfectionism has led to a considerable acceleration and growth in Community rule-making, as well as to greater transparency of Community law with regard to the marketing requirements of technical products. In comparison, in the motor vehicle sector no less than 78 Council directives and 40 Commission adaptation directives were adopted at the end of 1994.

1.4. Essential Safety Requirements – Technical Specifications

The Commission has managed to tie into the model for regulating technology predominant in most Member States its new approach to technical harmonization and standards, not however leaving it completely unaltered. Reference is not simply made to the 'generally accepted rules of the art' (as in

[19] OJ L 220 of 8.8.87, 48-59.

[20] OJ L 187 of 16.7.88, 1-13.

[21] Council Directive of 21.12.1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products, OJ L 40 of 11.2.89, 12-26 — Cf. on this Molkenbuhr 1991a: 68-89; Molkenbuhr 1991b; Kiehl 1990.

[22] OJ L 139 of 23.5.89, 19-26.

[23] OJ L 183 of 29.6.89, 9-32, amended for the purpose of integrating mobile equipment and lifting equipment by the Directive 91/368/EEC, OJ L 198 of 22.7.91, 16-32 and by the Directive 93/44/EEC, OJ L 175 of 19.7.93, 12-20.

[24] OJ L 399 of 30.12.89, 18-38. — Cf. on this, Fritze 1990.

[25] OJ L 189 of 20.7.90, 1-16.

[26] OJ L 189 of 20.7.90, 17-35.

[27] OJ L 196 of 26.7.90, 15-29.

[28] OJ L 128 of 23.5.91, 1-18. — Cf. on this, Fangmann 1991.

[29] OJ L 167 of 22.6.92, 17-28.

[30] OJ L 121 of 15.5.93, 20-36.

[31] OJ L 169 of 12.7.93, 1-43 — Cf. on this, Anselmann 1993.

[32] OJ L 290 of 24.11.93, 1-8.

[33] OJ L 100 of 19.4.94, 1-29.

[34] OJ L 164 of 30.6.94, 15-38.

the German Federal Appliances Safety Act) or to the 'state of the art' or to the 'state of science and technology' – the most advanced reference formula in the form of a general clause. In the EC at the moment there is no such professional consensus, inherent in these 'hinge terms' *(Scharnierbegriffe)* between science and technology, on the technical requirements for the composition of technical appliances. The differences in the individual regions of the Community with regard to the awareness of politicians and the population as to risk, the philosophy of technicians as to safety, the traditional approaches to technical solutions, and in economic performance, are all too great to grant European standardization bodies such a wide general power of attorney.

The political preconditions for European standards must be that they cover all Member State goals with regard to the assertion of the common good which might be legitimately invoked according to the jurisprudence of the ECJ on the acceptability of goods for the market. In the case of the Low Voltage Directive, a brief reference to the state of safety technology in the Community and 11 generally formulated clarifications of the essential safety goals were exceptionally found to be sufficient for the electrotechnical area[35]. There has long been a large amount of work on international standardization here, arising from a high degree of international consensus on the necessary requirements in this area, as well as from the necessity of preferably international or at least internationally compatible fixings for the numerous interfaces and the interchangeability of parts due to the reliance on certain utility and transmission networks and the strong international trade in goods.

The New Approach to Technical Harmonization and Standards laid down the following as a political maxim for the delineation of those fundamental decisions reserved for the Council and those technical specifications to be transferred to the European standardization bodies[36]:

> 'The essential safety requirements which must be met in the case of products which can be put on the market shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced. They should be so formulated as to enable the certification bodies straight away to certify products as being in conformity, having regard to those requirements in the absence of standards'.

This principle, which was subsequently added on, met with considerable reservations from the advocates of a more extensive retreat of public organs

[35] Cf., Art. 2, Para. 1 and Annex I of the Low Voltage Directive (OJ L 77 of 26.3.73, 29-33).

[36] Model-Directive (OJ C 136 of 4.6.85, 1-9), B, III, 1.

from product safety law; they regarded this as a relapse to the old method of harmonization[37]. In the meantime there ought to be unanimity that the essential safety requirements alone are not suitable for attaining examination results which are capable of reproduction. They do, however, contain a relatively detailed agenda for the setting of harmonized standards.

> The example of the Machine Directive shows clearly how the work of the standardization bodies and the political definitions in the essential safety requirements occur in close coordination with one another[38]: in July 1986 the Commission presented its first working paper on the Machine Directive with an extensive catalogue of essential safety requirements. In October 1986 the CEN decided on the establishment of a programme committee 'Safety of Machines'. As a continuation of the work commenced by the CEN/TC 114 in June 1985 on a common European safety philosophy for the basis and general rules of the safety standards for machines, appliances and plants, it worked out a hierarchical standardization agenda for the safety of machines, which it completed with the draft directive presented in December 1987. The Commission oriented itself on the working agenda of the CEN in allocating standardization tasks. According to a study of the CEN agenda for the concretion of the Machine Directive through European standards which was instigated by the Commission, the standardization work on technical safety of machines included around 620 standardization projects at the beginning of 1994[39]. CEN has turned to applying for the assignment of mandates after often lengthy preparation by the Commission, rather than passively waiting for such a mandate.

The Community is a participant in a cooperative network and even takes the ideas of the European standardization bodies into consideration as early as in the detailed setting of the essential safety requirements. It must use 'perfectly fitting' guiding impulses in the necessary coordination with the standardization bodies, because they are not in an instructing relationship to the Community. The European standardization bodies accept the challenge presented by the new approach, at least partially in order to protect the area left to them for autonomous regulation from 'encroachments' by the State.

> The Council Directive on construction products shows peculiarities in relation to the delineation of the spheres of influence of political requirements and technical standards. The essential requirements with regard to mechanical resistance and stability, safety in case of fire, hygiene, health and the environment, safety in use, protection against noise, energy economy and heat retention of construction sites are kept very brief and general[40]. The Commission has, after treatment by the Standing Committee on Construction Products and the bringing in of technical committees in which the Member States participate, concretized

[37] Cf., Pelkmans 1987: 265 *et seq.*; Hartlieb, Krieg 1987: 127.

[38] On the following cf., Dey 1987; Dey 1988; Dey, Sälzer 1989; Dey 1990.

[39] Cf., Dey 1993; Dey 1994.

[40] Cf., Annex I of the Council Directive on construction products (OJ, L 40 of 11.2.89, 12-26).

these goals in very detailed interpretative documents in the course of the regulatory committee procedure[41]. The main aim of the interpretative documents is to establish the links between the essential requirements and the mandates which the Commission assigns the European standardization organizations for the making of harmonized standards[42]. Besides the essential requirements of the Construction Products Directive, they are based on the state of the art concerning construction products, on the intended use of construction products as well as the knowledge of existing national regulations for construction products and take into account possible differences in geographical or climatic conditions or in ways of life as well as possible different levels of protection[43]. They thus respond to a political subprogramming of technical standards in the Directive and ensure that Member States have considerable influence in the subsequent rectification of this shortcoming.

The catalogues of essential safety requirements provide a standard for undertakings and controlling bodies as long as harmonized technical standards are lacking or a more advanced state of technical development has not yet been inserted into the network of technical rules. In order to leave room for further technical development, they must restrict themselves to performance standards and may not lay down binding detailed design standards.

1.5. Safeguard Clauses

All directives adopted in implementing the new approach to technical harmonization and standards contain so-called safe-guard clauses[44]. They allow Member States to take products off the market, to prohibit them from being put on the market, or to restrict their free circulation if they do not satisfy the essential requirements despite certified conformity. This deviation can be *inter alia* based on the technical specification being insufficiently applied, the conformity being certified despite non-compliance with the appropriate harmonized standards, or a harmonized standard not satisfying the essential requirements. The immediate notification of the Commission, consultation with the affected parties, and the speedy notification to other Member States, all of which are foreseen in such cases, are aimed at allowing the competent authorities in the entire Community to adjust to newly recognized changes. In the case of insufficient standards, a speedy rectification of the technical

[41] Communication of the Commission with regard to the interpretative documents of Council Directive 89/106/EEC, OJ L 62 of 28.2.94, 1-163.

[42] Cf., Art. 12 Para. 2 of the Council Directive on construction products. — Until the end of 1991 the Commission already had assigned mandates for the making of 484 harmonized standards in the sector of construction products.

[43] Cf., No. 6 of the general introduction to the interpretative documents, OJ C 62 v. 28.2.94, 2. Cf. also, Art. 3 Para. 2 of the Council Directive on construction products.

[44] For more on this, Europäische Kommission 1994: 43-48; Joerges, Falke 1991: 179-182.

standards according to the newest knowledge is to be initiated through recourse to the Standing Committee on Standards and Technical Rules. Member States which respond more critically than others to dangers can thus provide the necessary push for the control and tightening up of harmonized standards.

Safeguard clauses emphatically confirm that the declaration of conformity is only a refutable presumption of compliance with the appropriate essential safety requirements; the Member States or the competent authorities in each Member State remain responsible for the protection of personal health and safety and for environmental protection or other non-economic goods in need of protection. Safeguard clauses are necessary since Member States lose the right to invoke unilateral safeguard measures under Art. 36 to the extent that Community provisions lay down product requirements.

1.6. Control of Harmonized Standards

No system for the substantive control of harmonized standards is provided for with respect to their conformity to essential safety requirements. Where a Member State or the Commission is of the opinion that a harmonized standard which is cited in the *Official Journal* does not conform to the essential requirements, the Commission can have it struck out of the *Official Journal* after consulting the Standing Committee on Standards and Technical Rules. Conformity thereto thus no longer leads to the refutable presumption of the satisfaction of essential requirements; the effect of this presumption can be extinguished by means of such a formal procedure for challenging it.

A paper containing the position of the Directorate General for the internal market and commercial economy[45] makes it clear how the Commission wishes to fulfil its task of controlling the conformity of harmonized standards to the essential requirements. It reads as follows:

> 'If all parties which are interested in standardization adequately use the possibilities to raise their objections which are entailed in the procedural rules of the European standardization organizations, and if these rules were really observed, one has to conclude that the achieved standard fulfils the respective essential requirements. On that reason, the offices of the EC Commission are convinced that it is not possible to add further procedures to those which are already valid in the European standardization

[45] The paper of 22.6.1990 on the "compatibility of harmonized standards with the directives following the 'new concept'" is printed in DIN-Mitteilungen 70 (1991), 106 f. — The quoted text is translated from the German version.

organizations, and in particular, that a formal approval of an orderly accepted standard is not to be taken into consideration'.

The Commission announces its intent:

'(...) in certain sectors to meet the expenses for technical qualified personnel which is to subordinate to the central secretary office of the CEN and to the EC Commission. (...) These experts would have the duty to pursue the current standardization work and to report each recognized illegality to the central secretary office of the CEN and to the EC Commission, especially in those cases in which an incompatibility between the standard in preparation and the essential health and safety requirements is developing. As far as possible, such cases should be decided informally between the respective Technical Committee of the CEN and the competent office of the EC Commission which is orderly informed by the expert'.

Instead of exercising a subsequent external control, the Commission thus wishes to participate in the ongoing standardization process, to make personnel available for the European standardization bodies and to use informal opportunities for negotiations and early warning.

The competent national authorities are also told in this paper to actively participate in the harmonization activities, to put forward to the technical committee responsible for the setting of a certain standard any objection raised during the public survey after the publication of the draft standard. This is to be done through each national standardization institute. Should the objections not be considered, they may notify the Commission or the competent committee directly.

The Council Directive on construction products shows several noteworthy peculiarities with regard to the Commission's standardization mandate and its consultation with experts – or more accurately that of the Member States – in the examination of harmonized standards: the Commission can assign standardization mandates only after consulting the existing Standing Committee for Construction Products, which is made up of representatives from Member States; these must take interpretative documents into account and are to be drafted as far as possible in the form of performance requirements for the products[46]. The committee referred to is to submit an opinion if the Commission or a Member State objects that a harmonized standard or a standardization mandate does not satisfy the essential requirements or the interpretative documents adopted for their concretion[47][48].

[46] Art. 7 of the Council Directive on construction products.

[47] *Ibid.*, Art. 5, Para. 1. — The Council Directive on construction products is the sole directive taking the new approach to technical harmonization and standards which expressly grants Member States the right to examine the assignment of standardization mandates.

[48] The Council Directive on telecommunications terminal equipment has a comparable provision that the Approvals Committee for Terminal Equipment is to be brought in, if it is

The Commission approves – after consultation of the Approval Committee for Terminal Equipment – the harmonized standards relating to electromagnetic compatibility, protection of the public telecommunications network from harm, effective use of the radio frequency spectrum, interworking of terminal equipment with public telecommunications network equipment, interworking of terminal equipment via the public telecommunications network, in justified cases; if they are transformed into common technical regulations, compliance with them is mandatory[49].

2. New Structures of the European and of National Standardization

2.1. Transfer from the National to the European Level

The orientation of the Community policy on standards has led to a fundamental and very rapid transfer of priorities from the national to the European level with respect to technical standards. This can be seen in *Table 1* in the increase in standardization activity of the DIN *(Deutsches Institut für Normung)* at the European level from 10 per cent in 1984 to 45 per cent in 1994, and the even greater decline in the share of activity covered by national projects from 60 to 18 per cent between 1984 and 1994. In the same period the proportion of work in this area which went to worldwide standardization projects increased from 23 to 32 per cent.

	1984	1986	1988	1990	1992	1994
national	60	50	40	30	27	18
bilateral	5	5	5	5	5	5
European	10	15	25	35	38	45
worldwide	25	30	30	30	30	32

Source: DIN Annual Report 1992/93, 21

Table 1: Share of standardization activity of the DIN at different regional levels, 1984 - 1994 (in %)

The presidency of the DIN declared that from 1991 onward all standardization committees had to have new standardization initiatives approved by its advisory councils, unless the project was identical to an actual

objected that the harmonized standards do not completely satisfy the essential requirements or go beyond these. Cf. Art. 7 of the Council Directive on telecommunications terminal equipment (OJ L 128 of 23.5.91, 1-18).

[49] Art. 6 Para. 2 of the Council Directive on telecommunications terminal equipment. — This is the only directive under the new approach, which entails such an urgency of an approval.

or planned project of the CEN, CENELEC, ISO (International Standardization Organization) or the IEC (International Electrotechnical Commission). The advisory council is in any case to determine whether an equivalent application to the ISO or CEN might not be more appropriate[50].

As *Table 2* shows, the total of European standards[51] increased from 1,116 to 3,255 between 1988 and 1993, just about tripling in a period of only five years. An annual increase of 1,000 European standards is expected up to the year 2000[52]. In comparison, the number of national standards has almost stagnated, although one must take into account that European standards are to be included unaltered in the total of national standards. In this five-year period, international standards also show a clear increase by almost a third. Reflecting the precedence of international standards for reasons arising from the opening of the market, 40 per cent of the European standards of the CEN are identical to international standards of the ISO, with the CENELEC showing a 95 per cent degree of conformity[53]. The current dynamic of European standardization is seen in particular in the number of standards and draft standards. The revival of European standardization, which, with the exception of electrotechnical standardization by the CENELEC, had a somewhat uncertain existence between worldwide and national standards until the working out of the new approach to technical harmonization and standards, is also reflected in the number of working committees; it practically doubled in 1993 in comparison to 1988, and almost increased eightfold in comparison to 1980. The number of working committees of the DIN and of the ISO and IEC has by comparison shown a relatively small increase.

[50] Reihlen 1991: 5.
[51] Including harmonization documents and ETS (European Telecommunication Standards).
[52] DIN Annual Reports 1992/93, 8.
[53] Bestel 1994.

	1980	1988	1989	1990	1991	1992	1993
DIN standards, total	18739	20450	20510	20988	21257	21655	22002
of these newly published	1655	1379	1272	1425	1150	1453	1337
DIN Working committees	3865	3709	3768	3960	3973	4296	4300
International standards (ISO/IEC)	5978	9928	10461	10778	11471	12183	13168
of these newly published	591	823	742	928	904	1021	1114
Working Committees (ISO/IEC)	2880	3360	3400	3700	3470	3510	3652
European standards	496	1116	1376	1648	1870	2440	3255
of these newly published	47	213	306	311	400	603	939
European draft standards	250	850	1300	1462	2940	2032	2691
Working Committees CEN/CENELEC/ETSI	280	1260	1500	1620	1700	2004	2138

Source: DIN Annual Reports

Table 2. National, European and international standardization activities, 1980 - 1993

Until the end of 1991 the Commission assigned the European standardization bodies, CEN, CENELEC and ETSI, with the making of 1,939 European standards in the area of the internal market, information technology and telecommunications; and made 60.42 million ECU were made available for this purpose. Of these, 938 standards were left to directives in accordance with the new approach: in particular, construction products (484), machines (189) and personal safety equipment (102). In 1991 alone the tasks assigned to CEN, CENELEC and ETSI encompassed 828 standards for approximately 28 million ECU[54]. The payments of the EC and EFTA countries for the standardization work accounted about 70 per cent of the CEN annual budget in 1990 and around 55 per cent of the annual budget of the CENELEC[55].

[54] Cf. Commission Communication "Standardization in the European Economy (Follow-up to the Commission Green Paper of October 1990)", OJ C 96 of 15.4.92, 2-18 (18).

[55] Cf., Commission Communication on the Development of European Standardization — Action for Faster Technological Integration in Europe ("Green Paper"), OJ C 20 of 28.1.91, 1-35, No. 66. — The budget of the European standardization organizations constitutes only a small part of the total costs of the European standardization work.

2.2. Strengthening of the Central National Standardization Institutes

The importance of the central national standardization institutes grew parallel to the revaluation of European standards. Only they have a vote and right to negotiate in the preparation and adoption of European standards. The interested circles (including manufacturers, appliers, consumers, certification bodies, scientists, authorities, environmental associations) are not directly involved in European standardization, rather they can only participate via national standardization organizations in so-called 'mirror committees' *(Spiegelausschüsse)*. There is also no participation of the (expert or interested) public through direct Europe-wide hearings on draft European standards; these go through an opinion procedure limited to six months, which is coordinated by the national standardization institutes[56]. Environmental, consumer and employee interests can be represented to a limited degree (principle of 'functional representation') in the national standardization bodies. However, according to the principle of national delegation, the standardization institutes must take part in European standardization according to the conditions of 'territorial representation'[57]: the national delegates have only one vote in the voting on a European standard[58]. Normally no more than three delegates from one Member State organization are to take part in a meeting of the Technical Committees, the actual working groups of European standardization. In putting together and preparing its delegation, the national standardization bodies must 'ensure that the delegation represents a uniform national position which takes into consideration the opinion of all circles affected by the work'[59]. In this manner the large scope of the regulated aspects cannot be covered in a representative way. There is the danger that particularly those aspects articulated in the interests of environmental protection, occupational safety and consumer protection might go missing 'on the road to Brussels'[60]. The admissions monopoly of national standardization bodies on European standardization thus leads to a depluralization of the standardization process; it is uncertain whether this organizational principle can improve the chances of small and medium-sized undertakings[61] going up against large undertakings.

[56] Para. U.3.4 and U.3.5 of the Joint Rules of CEN and CENELEC.

[57] Cf., Voelzkow, Eichener 1992: 272.

[58] Para. V.1.3 of the Joint Rules of CEN and CENELEC.

[59] Para. S.3.2. of the Joint Rules of CEN and CENELEC.

[60] Cf., Voelzkow, Eichener 1992: 280.

[61] The associations of the tradesmen and of small and medium-sized undertakings defend the national delegation principle with particular emphasis, because in their mind they would be overcharged to participate directly in the European standardization work.

2.3. Precautions for the Protection of Public Interests within the DIN

Considerable attempts are being made at the level of national standardization organizations to draw together the activities of the different bodies for technical rule-making and to take institutional precautions for the assertion of public interests[62]. This can be demonstrated by the example of the DIN:

2.3.1. Environmental Concerns

Since March 1990 authoritative rule-making committees of the Union of German Engineers *(Verein Deutscher Ingenieure – VDI)* in the areas of noise and air pollution have been integrated into the organization of the DIN in order to include the German state of the art described in the relevant VDI guidelines in European standards and to thus influence European technical rule-making in the areas of noise and air pollution[63].

The Coordinating Office for Environmental Protection *(Koordinierungsstelle Umweltschutz)* was created within the DIN in 1983, aided by the Federal Ministry for the Environment *(Bundesunweltministerium)* and the Federal Environment Office *(Umweltbundesamt)*, with the aim of fostering greater and more systematic consideration of environmental concerns[64]. It is *inter alia* to put forward environmentally relevant requirements for technical rules, to examine DIN standards at the draft stage with respect to environmentally relevant fixings, to compile and maintain an index of environmentally relevant technical rules and to aid groups interested in the protection of the environment in participating in the making of technical rules. With this in mind, guidelines were prepared for the consideration of environmental aspects in product development and standardization[65].

A specialist advisory council made up of representatives of the Federal Ministry for the Environment and the Federal Environment Office, environmental, consumer and industrial associations, trade unions and the DIN was formed in November 1990 as a political management committee for environmentally relevant questions in technical harmonization. Its tasks include

---

[62] According to the pointing formulation of Voelzkow, Eichener 1992: 278, the originally economic-oriented standardization organizations should be transformed by state interventions into an arena of social decisions on technology.

[63] Cf., Grefen 1991.

[64] Cf., Lehmann, Graßmann 1990; Schiffer 1991; Lamb 1991; Troge 1991.

[65] Printed in DIN-Mitteilungen 73 (1994), 356-358.

determining the main issues for product-related environmental standardization and directive work, giving opinions on the drafts of technical rules with regard to their environmental relevance, and representing the demands of environmental protection to those making the rules[66]. In January 1994 it presented guidelines for the consideration of environmental aspects in product development and standardization as an aid to the standardization committees[67].

In October 1992 the Federal Ministry for the Environment concluded an agreement with the DIN on the consideration of environmental concerns in standardization[68]. In implementing it the DIN established the DIN Standardization Committee for the Foundations of Environmental Protection *(Normenausschuß Grundlagen des Umweltschutzes – NAGUS)* as the competent working committee of the DIN for the standardization of interdisciplinary foundations of environmental protection at the national, European and international level[69].

The agreement between the DIN and the Federal Ministry for the Environment contains noteworthy determinations for the consideration of environmental concerns in European and international standardization: to the extent that environmentally relevant determinations are being met in European and international standardization bodies, the appropriate representatives of the coordination office for environmental protection and/or the Standardization Committee for the Foundations of Environmental Protection are to be included in the formation of the German position and are to provide the expertise for the German delegation. In the setting of European and international standards, the mirror committees established in the standardization committees of the DIN and the representatives named by them are to work towards the German standard of environmental protection which is laid down *inter alia* in legal provisions, DIN standards or self-imposed obligations of the industry not being undercut in the European and international standardization work. The DIN also obliges itself to work towards a strengthening of the weight of environmental concerns in European and international standardization from an organizational point of view.

[66] Cf., Troge, 1991: 284; Schiffer 1991: 371; Lehmann, Graßmann, 1990: 77-78.
[67] Printed in DIN-Mitteilungen 73 (1994), 356-358.
[68] Printed in Umwelt, No. 1/1993, 8-9.
[69] Cf., Feldhaus 1994.

2.3.2. Other Public Interests

Since 1975 the DIN Consumer Council[70], situated at the head of the DIN and financed by the Federal Government, has been in charge of the collective assertion of consumer interests in the DIN. It now plays a substantive role in the coordinated assertion of consumer interests in European standardization. The Consumer Council connects the scene of consumer protectors with that of technical standardization, and thereby also of associations of engineers specialized in questions of standards. It thus ensures the inclusion of consumer aspects in the usual course of standardization work. It is a 'partner-ship-like in-house solution' *('partnerschaftliche Im-Hause-Lösung')*[71] to the representation of certain interests, which is more accurately described as State-ordered as opposed to being achieved by consumer associations; it seems very difficult to transfer this model to other sectors and countries.

The DIN and the occupational health and safety agencies concluded an agreement[72] as early as 1982, according to which the latter are to restrict themselves to laying down general protective goals and safety standards in making and reviewing standards and are to refer to DIN standards in the concrete filling in with regard to constructive solutions and specific product requirements. Legally binding requirements for the composition of pharmaceuticals in the collection of rules of the health and safety agencies which go beyond the applicable directives would not be permissible under European law, although rules for use and for the protection of employees do remain permissible to the extent that they do not involve any deviations from the harmonized composition requirements[73]. Representatives of the occupational health and safety agencies are trying to introduce the contents of accident prevention regulations into European standardization work in numerous standardization committees[74]; the equal influence on the making of these central rules for industrial protection of the employee side which had been assured until now is to this extent lost forever.

---

[70] Rules of procedure of the DIN Executive of October 1975, No. 4.2.2. For more on this cf., Bosserhoff 1980; Bosserhoff 1987; Kypke 1982; Joerges, Falke, Micklitz, Brüggemeier 1988: 185-189.

[71] Schatz 1984: 199.

[72] Printed in DIN-Mitteilungen 62 (1983), 92-94.

[73] So explicitly Art. 2 Para. 2 of the Council Directive relating to machinery, Art. 2 Para. 2 of the Council Directive on personal protective equipment and Art. 2 Para. 4 of the Council Directive on construction products.

[74] Cf., Leichsenring 1987.

The very complex Technical Rules for plants in need of monitoring, made by long tradition by the committees under § 24 of the Industrial Code *(Gewerbeordnung – GewO)* and published by the Federal Ministry for Employment and Social Order *(Bundesministerium für Arbeit und Sozialordnung)*, are affected by the structural change in the German law on technical safety which was brought about by the European standardization policy. A Standardization Committee for Plants in Need of Monitoring *(Normausschuß überwachungsbedürftige Anlagen)* was set up by the DIN in 1989 in order to offensively introduce their substance into European standards. It coordinates the making of appropriate draft norms and the cooperation of the existing committees[75].

The extensive collection published by the Federal Ministry for Health *(Bundesgesundheitsamt)* of procedures for trial and examination under § 35 of the law governing trade in foodstuffs, tobacco and cosmetic products, and other articles of daily use *(Lebensmittel- und Bedarfsgegenständegesetz)* is to be included in the European work on standards for the analysis of foodstuffs[76].

2.4. General Principles for the Cooperation and Participation of Interested Parties in European Standardization

2.4.1. General Remarks

The newly strengthened corporatistic networks in the field of standardization and certification (at the European level) are not equipped to assert the interests of employees and consumers as well as other public interests with similar effectivity to the supplying market. There is the danger that the 'entry monopoly' of the DIN and other national standardization organizations on European standardization might lead to a distortion of the national balance of individual affected interests, which is necessary for the preparation of national positions on the individual projects[77]. The following not unfounded conclusion was drawn herefrom: 'With the transfer of standardization competences to the EC level (...) the relative and absolute opportunities of small and middle-sized undertakings and their associations, of consumers and citizens, of employees and for individual regions for the organization, articula-

[75] Agreement between the Federal Minister for Labour and Social Affairs and the DIN on the introducing of technical rules under Para. 24 of the Industrial Code into the European standardization work, Bundesarbeitsblatt 1990, 133-134; cf. on this, Doktor 1990.

[76] For details Großklaus 1991.

[77] Cf., Welsch 1990: 658.

tion and assertion of their specific conditions and requirements have decreased'[78]. The difficulties, already existing at the national level, in organizing diffuse interests become more acute at the European level[79].

The attempts of the Commission to influence the process of setting standards and the organization of cooperation has increased in number with the growth in importance of European standardization[80]. These are on the one hand aimed at increasing the effectiveness of working methods, as the desired relief in the area of rule-making will only come about if the required harmonized standards are provided in the given time period. On the other hand, these attempts are striving for minimal constitutional guaranties for the consideration of public interests and the avoidance of unilateral assertion of interests by the supplier side.

2.4.2. 'General Provisions Concerning Cooperation'

In the 'General Provisions Concerning Cooperation' agreed on by the Commission and the European standardization organizations, CEN and CENELEC, in November 1984[81], the Commission obliges itself to make reference to European standards in its proposals on technical harmonization and to delegate their preparation to the European standardization organizations, as well as to further the spread and application of European standards. CEN and CENELEC oblige themselves to maintain the necessary infrastructure for the fulfilment of standardization mandates, to unify their procedure for coordination and to encourage Member State organizations in the EC area to transpose the appropriate harmonized standards in national standards; they invite the Commission to take part in the meetings of the technical committees. They wish to ensure that the standards satisfy the essential requirements for the protection of citizens in accordance with the directives and the standardization assignments. The General Provisions read as follows[82]:

> 'In order to provide the foundation for a far-reaching acknowledgement of the European standards and their significance, CEN and CENELEC will assure that the interested parties, especially administrative authorities of the state, the industry, users, consumers, trade unions could, if they wish, really participate in the elaboration of European standards. If necessary,

[78] Eichener, Heinze, Voelzkow 1990: 633.

[79] On the connection between the protection of interests and the contradictory orientation of European economic, consumer and environmental policy cf., Reich 1987.

[80] In general on the European standardization, Nicolas, Repussard 1994; Eichener, Heinze, Voelzkow 1990; Reihlen 1989.

[81] Printed in DIN-Mitteilungen 64 (1985), 78 -79.

[82] *Ibid.*, No. 5, third indent — The quoted text is translated from the German version.

the Commission will contribute to the determination of suitable procedures'.

Despite this impressive principle, no appropriate solution for the participation of consumer representatives[83] and other guardians of the public interest has as of yet been found. One of the main difficulties is that each national standardization organization can, under the Joint Rules of CEN and CENELEC, only take a uniform national position in voting[84]. Consumers must therefore, as other interested circles, attempt to exercise their influence via the national standardization work and as members of national standardization organizations. The Council has thus called for greater participation of consumers in the standardization process at the national level[85]. The search for a suitable organizational form of participation in standardization continues.

2.4.3. Participation of Consumers

The participation of consumers in European standardization is developing hesitantly[86]. Since 1983 representatives of consumers have at least been admitted as observers to those meetings of technical committees of the CEN and CENELEC which are addressing standardization initiatives of consumer relevance, on the grounds of an agreement between the EC Commission and CEN and CENELEC. A coordination office, SECO *(Secrétariat Coordination pour la Normalisation)*, in the BEUC *(Bureau Européen des Unions des Consommateurs)* tries to coordinate the contributions of the individual national consumer agencies, to obtain qualified experts and to compile preparatory expert opinions. The incentive was the positive experience had with consumer councils in national standardization in Denmark, Germany and Great Britain. In June 1991 a management committee for standardization policy was established in the consulting consumer council to process political requirements. The CEN had proposed the establishment of a European consumer council along the lines of the DIN consumer council, which was to be completely integrated into the structure of the CEN. The European consumer representatives finally agreed at the beginning of 1994 on the establishment of a European Consumer Council, ANEC *(Association de Normalisation Européenne pour les Consommateurs)*, outside of the European standardization institutes. Besides coordination of the

[83] On the participation of consumers in the European standardization work cf., Joerges, Falke, Micklitz, Brüggemeier 1988: 401-429; Micklitz 1989; Bosserhoff 1992.

[84] Cf., Joint Rules of CEN and CENELEC, Para. S.3.2. and V.1.3., which are valid for the total standardization work since 1.1.1987.

[85] Council Resolution of 4.11.1988 on the improvement of consumer involvement in standardization, OJ C 293 of 17.11.88, 1.

[86] Cf. in detail, Maier 1994.

national representation of consumer interests in standardization matters, its tasks include participating in European standardization initiatives of consumer relevance and influencing appropriate directives and standardization mandates. For the moment a full right to vote in all standardization committees is being sought, and not merely the right to appear as observers, as well as the financing needed to enable participation in all consumer-relevant standardization work. The Community budget supported the participation of consumers in standardization in 1995 with 0.75 million ECU.

2.4.4. Participation of the Trade Unions

The European Confederation of Trade Unions has established, with the support of the Commission, a 'Technical Board for Industrial Safety Rule-making and Standards' *(Technikbüro für die Arbeitsschutzrechtsetzung und -normung)*[87]. It belongs, together with the European Construction Association, to the first associated members of the CEN. The CEN has, as a compromise to the many further-reaching proposals for the direct participation of interested circles in European standardization, created a possibility for organized groups at the European level to participate in standardization activities as associated members with consultation rights, but no vote[88]. The Technical Board of the European Confederation of Trade Unions was supported by 1.05 million ECU from the Community budget in 1995.

In the area of industrial safety, the Machine Directive, the Directive on Personal Safety Equipment and the Directive on Safety Systems in Explosion Endangered Areas impose a duty on Member States to take the appropriate measures 'to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonized standards'[89]. To this aim, the Commission of Industrial Safety and Standards was established in Germany in February 1994[90]. This honorary committee is made up of 5 representatives of the social partners, 2 representatives of the Federal Ministry for Employment *(Bundesarbeitsministerium)*, 3 representatives of the supreme Industrial Safety Authorities *(Arbeitschutzbehörden)* of the Länder, 1 representative of the DIN and 1 representative of the Main Association of the Occupational Health and Safety Agencies *(Hauptverband der gewerblichen Berufsgenossenschaften)*. Its tasks include examining the contents of standards

[87] Cf., Sapir 1992; Pickert, Köpcke 1992. See also Green Paper on European Standardization, No. 33; Partikel, 1989: 147.

[88] Cf. also, Para. S.3.5 of the Joint Rules of CEN and CENELEC.

[89] Cf. respectively, Art. 5 Para. 3 of the directives mentioned.

[90] Cf., Sozialpolitische Umschau, No. 471/1994 v. 7.11.1994, 7-9.

as to their compliance with the German industrial safety requirements, giving consideration to the protective goals laid down in European directives. Upon ascertaining deficits, they intervene in the European standardization in the appropriate manner through the DIN. Furthermore, it is, when possible, to exercise influence via the Federal Ministry of Employment over the contents of standards at the stage of assignment of standardization mandates by the Commission.

2.4.5. Consideration of Environmental Concerns – Status Quo and Proposals

An infrastructure for a systematic consideration of environmental concerns and for the participation of European environmental associations in European standardization is at present in its initial stages. In 1989 the technical sectorial board 'Health and Environmental Protection' was established within the CEN, and in April 1991 an ad-hoc group 'Environmental Protection' was set up with a working group for the measurement of environmental parameters and a working group for specifically environmental aspects of the standardization activities of the CEN. In September 1993 the CEN held the first meeting of the programme committee 'Environment', with the participation of representatives of greatly differing industrial branches, trade unions and scientific organizations, as well as the European Environmental Board. It appears a priority to set up within the CEN and CENELEC a parallel organization to NAGUS[91], and to grant the European Environmental Board an official observer status with consultation rights in the actual standardization committees.

The CEN Working Group 'Environment' classified the following areas as 'direct environmental standardization tasks'[92]: environmental measurement methods, measurement methods for environmental properties of chemical substances and chemical products, pollution control methods and equipment, environmental management tools, and methods for the evaluation of environmental effects of products. The setting of limit values and the kind of procedure for testing compliance with those values was explicitly declared as a task of the legal authorities. In order to concentrate the efforts of CEN on those subjects needing most attention, the following system for priority-setting was proposed[93]:

1. standardization needs as a result of existing or draft EX legislation (demands from especially DG XI, DG III and DG VI);

[91] Cf., Rühl 1994: 156.

[92] Cf., CEN Consultation Document, Environmental Standardization by CEN. A Proposal for a General Outline of Activities, Brussels 1992, No. 2.1.

[93] *Ibid.*, No. 2.2.

2. standardization needs as a result of market demands (demands from industry and consumer organizations)[94];

3. standardization needs as a result of EC environmental programmes (demands from the European Environmental Agency, DG XII and the Joint Research Unit Ispra);

4. standardization needs as a result of environmental programmes of other organizations (demands from UNEP, OECD, etc.);

5. standardization needs caused by the fact that in existing standards environmental aspects are not dealt with adequately.

The Working Group 'Environment' should advise the Technical Board of CEN on environmental standardization and should have the possibility and task of monitoring all environment-relevant activities in CEN. It was proposed that it should initiate the following indirect standardization actions that are important to facilitate and support progress in environmental standardization within the CEN standardization system in general[95]:

- development of recommendations and a guidance document for non-environmental orientated Technical Committees for dealing with environmental subjects;
- initiation of environmental activities by non-environmental orientated Technical Committees;
- monitoring of the compatibility of existing standards with generally accepted environmental policy and monitoring of the progress of the work on environmental standardization.

But the Technical Board of CEN has rejected the proposed establishment of an institution within the structure of CEN, comparable to the Coordinating Office for Environmental Protection within the DIN, and which would coordinate all environment-relevant activities of CEN. The reason for this rejection was a potential delay in the standard-setting process.

It remains uncertain, whether there is a chance to realize the proposal of establishing a Working Group on Environmental Aspects in Product Standards (ENAPS)[96]. This proposal was developed under the responsibility of the Coordinating Office for Environmental Protection within the DIN.

---

[94] Environmental associations are not mentioned explicitly.

[95] CEN Consultation Document, Environmental Standardization by CEN, No. 5.2.

[96] Cf., Annex 2 of the report of the Coordinating Office for Environmental Protection within the DIN for the period from July 1993 to December 1994, Bonn 1995.

Guidelines could support the inclusion of environmental aspects in product-related standards[97]. Their purpose is:

- to set forth some general considerations that should be taken into account when developing product standards that balance the need to achieve the intended product performance while reducing adverse environmental effects;
- to outline ways in which provisions in product standards may affect the environment during the stages of a product's life cycle: planning and development, production (incl. raw materials, energy, transportation), distribution (incl. packaging), use, reuse, recycling, disposal;
- to provide an overview of recognized scientific methodologies in identifying and assessing the environmental effects of provisions in product standards; and
- to highlight some strategies for improving environmental performance.

An Advisory Council within CEN could function as a political management committee for environmentally relevant questions in the European standardization work[98]. Social interests should be represented in a (well-) balanced manner, especially the European environmental associations. In order to facilitate the adjustment with the existing or draft EC regulations, representatives of the European Commission and of the European Environmental Agency should participate without voting rights.

In the Technical Committees of CEN, the core of the European standardization work, the European environmental associations should be awarded official observer status with consultation rights. The prospect of influencing the content of standards only by raising protest at the very late stage of the public hearing is a fruitless one; on the contrary, an early active and intensive participation in the relevant working groups of the European standardization organizations is necessary[99]. The working group or office that coordinates the environmentally relevant aspects of the European standardization work has to inform all interested circles, which are represented in the political management committee for environmentally relevant questions in the

[97] Cf. the proposed ISO Guide for the inclusion of environmental aspects in product standards, Annex 3 of the report of the Coordinating Office for Environmental Protection within the DIN for the period from July 1993 to December 1994, Bonn 1995.

[98] Corresponding to the Advisory Council of the Coordinating Office for Environmental Protection within the DIN.

[99] Cf., report of the Coordinating Office for Environmental Protection within the DIN for the period from July 1993 to December 1994, Bonn 1995, 56.

European standardization work, about new proposals for European standards as early as possible.

2.5. Green Paper on the Development of European Standardization

In October 1990 the Commission presented a 'Green Paper' on the development of European Standardization with the title 'action for Faster Technological Integration in Europe'[100]. It discusses a number of questions in relation to the organizational structure, financing, policy and activity of standardization organizations at the European as well as the national level, and proposes changes in order to increase the use of standards for the European market. A key point reads as follows[101]:

> 'Standards have now become too important to be the exclusive preserve of technical experts. The European standards developed over the next decade will have a decisive influence on the technical structure of the entire European market'.

The most important recommendations of the Commission for the division of work between State regulation and self-regulation by associations can be summarized as follows:

- The European industry is asked to give European standardization much higher priority than hitherto and to show greater financial and scientific commitment[102].
- The standardization organizations are called upon to accelerate the setting of standards, to use majority votes more systematically, to further branch specific standardization committees and to achieve direct application at the national level of harmonized standards without an implementing act[103].
- New committees are proposed for the coordination and structuring of European standardization: a European Standardization Council, in which the most important economic interest groups are represented, is to be responsible for the strategic orientation. A European Standardization Board is to coordinate the activities of the individual standardization organizations which are responsible for certain areas according to common rules[104].

---

[100] OJ C 20 of 28.1.91, 1-35. Cf. on this, the resolution of the European Parliament, OJ C 240 of 16.9.91, 208-212, and the opinion of the Economic and Social Committee, OJ C 120 of 6.5.91, 28-33, of the German Bundesrat, BR-Drs. 766/2/90; of the German Federal Government, DIN-Mitteilungen 70 (1991), 369 f. and of the DIN, DIN-MItteilungen 70 (1991), 265-268.

[101] Green Paper on European Standardization, No. 29.

[102] *Ibid.*, Nos. 28-32.

[103] *Ibid.*, Nos. 34-40.

[104] *Ibid.*, Nos. 41-45 and Annex 2.

- Individual members are to be able to directly participate in the work of technical committees. Organizations such as trade unions and consumer associations are to be given an observer status for the entire technical work. The most important economic interest groups and agencies are to be represented on the boards of the European standardization organizations[105].

- European standardization is to receive long-term financial support from the Member States and the Community without dependency on industry[106].

In its recommendations, the Commission follows goals which tend to contradict one another. The aim of accelerating standardization work wished in line with the ambitious programme for a single market runs against the opening for additional interested groups and for guardians of public interests. It endangers the orientation towards consensus now present in setting standards, and which has been kept on with good reason despite the introduction of qualified majority decisions[107]: technical standards must be professionally convincing, they cannot be inevitably carried through. As long as no veto opportunities exist, the principle of consensus makes it more difficult to attain the unilateral assertion of interests in the limits set in the composition of standard committees. A consensus is not to be found at the Community level without lengthy and thorough wading through of the different traditions and economic conditions. The direct applicability of European standards of their own right without formal transposition in the corresponding national standards would lead to a stock of 'real' European standards within the foreseeable future, which would allow the extent of technological integration to be recognized. However, it would not reflect the still, and for a while yet, very fragmental nature of the European standards structure and would endanger the unity of national standard structures.

In the opinions on the Green Paper on the Development of European Standardization[108], the national delegation principle is in particular defended and the creation of further sector-specific standard organizations rejected. All affected groups are to work with the national standardization committees and to

[105] *Ibid.*, Nos. 33, 61-65.

[106] *Ibid.*, Nos. 66-73, 96, 98.

[107] Cf., the Joint Rules of CEN and CENELEC, Para. 3.3.: "The Chairman must do everything in his power to maintain unanimous decisions of the Committee. If unanimity cannot be achieved on an issue then the chairman should try to bring about a consensus instead of merely relying on a majority decision." and Para. V.I.I.: "In all cases in which a decision must be made, unanimity is to be aimed at most emphatically."

[108] The Commission has got more than 250 opinions of interested parties.

participate in the wide national formation of opinion in all phases of standard setting. The working results aimed at must reflect the wide consensus of the expert groups; the formation of such a consensus would, however, need sufficient time. Instead of a political committee with wide participation of companies, a non-binding European standardization forum is to be created that would observe the work agenda of the European standardization organizations, advise on important, long-term topics related to standardization policy and further the participation of all affected groups in the national standardization institutions[109].

After extensive discussion with the affected groups the Commission dropped most of its proposals for the new structuring of European Standardization[110]. It no longer adheres to its proposal to create, besides the CEN, CENELEC and ETSI, further sector specific European standardization committees. It has dropped the model of direct financing of European standardization through the sale of European standards, but rather proposes to distribute them at market prices to spread them more widely[111]. The idea that European standards are to apply of their own right, that is without transposition in national standards, is no longer being pursued[112]. Instead of establishing the proposed European standardization committee, the Commission regards it as sufficient that the Joint Presidents Group of CEN, CENELEC and ETSI coordinates the work agenda of the three European standardization committees and develops a joint concept for tasks of common interest[113]. It regards a European forum for standardization giving mere recommendations as to the basic direction of European standardization – rather than the proposed European Standardization Council – as sufficient for the continued dialogue between the European standardization committees and the most important economic and social partners involved in standardization work[114].

---

[109] Cf. on the last topic, the opinion of the DIN on the Green Paper on the development of the European standardization, DIN-Mitteilungen 70 (1991), 265-268 (266-267).

[110] Cf., Commission Communication, Standardization in the European Economy (Follow-up to the Commission Green Paper of October 1990), OJ C 96 of 15.4.92, 2-18; cf. also, the Council Resolution of 18.6.1992 on the role of European standardization in the European economy, OJ C 173 of 9.7.92, 1-2.

[111] Commission Communication, Standardization in the European Community, OJ C 96 of 15.4.92, 14 (Nos. 59-61).

[112] The Commission has as of yet not carried through its announcement (cf., *ibid.*, No. 53) to make direct references to harmonized standards in future proposals of directives and not, as until now, to the national standards made in implementing them.

[113] *Ibid.*, No. 40.

[114] *Ibid.*, Nos. 41-43. The following composition is proposed: one delegate from each Member State and from each EFTA State to be appointed by the national authorities, 5 representatives of the Joint Presidents Group, 12 representatives of the European processing

In light of the massive defence of the national delegation principle, the Commission recognizes the 'primacy of the national route to European standards-making', which however is not to be developed into a monopoly[115], although it demands:

> 'For these reasons the European standardization bodies must allow the direct participation of representative European-level organizations in their work. Such participation, even in the form of non-voting observership, must be possible at every stage of the standardization process and at every level of the standardization body concerned, from working group to General Assembly. In the case of the social partners (...) such direct participation is a political precondition for the acceptability and further development of European standardization'[116].

It adheres to the financial support of European trade union and consumer associations for their participation in European standardization and announces the same for small and medium-sized undertakings[117].

It is interesting to note that the Commission did not expressly mention some possibilities for participation. The participation of European associations in the laying down of the essential safety requirements[118] and the assignment of standardization mandates would be put before the setting of harmonized standards. To allow such associations to express themselves in the hearing procedure to the published draft standards and to prompt the making of certain standards directly at the European level without national standardization bodies acting as go-betweens belongs to the key areas of standardization[119].

---

and service trades, 3 representatives each from the consumer, trade union and professional standard users as well as one representative each from the European Organization for certification and examination, the EC Commission and the EFTA Office.

[115] *Ibid.*, No. 33.

[116] *Ibid.*, No. 34. — Cf. also, the Resolution of the European Parliament of 11.7.1991 on European standardization, certification and testing, OJ C 240 of 16.9.91, 208-212 (No. 15), where for the first time also environmentalists are called, and the opinion of the Economic and Social Committee on the Green Paper on the development of European standardization, OJ C 120 of 6.5.91, 28-33 (No. 5 and 6).

[117] Cf., Commission Communication, Standardization in the European Economy, Nos. 36 and 37.

[118] But cf. to that extent, No. 6.5. of the opinion of the Economic and Social Committee on the Green Paper on European Standardization.

[119] On the latter cf., Para. U.1.2. of the Joint Rules of CEN and CENELEC, according to which besides the members of CEN and CENELEC, the EC Commission and the EFTA Secretariat, European economic, occupational, specialist and scientific organizations may make proposals for new standardization projects.

3. Reference to Technical Rules

3.1. Function and Principles of Reference to Technical Rules

'The interaction of public legal standards and private technical standards set by specialist technical associations in a complex system of standards' is characteristic for the German product safety law as well as for the whole of the law on technical safety[120]. The resolution of 2 December 1966 of the Common Committee for Technology[121] is very telling in stating the following:

> 'Technical knowledge and its application are subject to rapidly, steadily advancing development. (...) The usual procedure of governmental law-making, aimed at codifying an area as exhaustively as possible, is therefore not suitable for keeping up with accelerating technical development through legal rules. (...) Governmental law-making should therefore confine itself in the technical area to setting the necessary requirements and criteria for the general good, leaving it to the organized, representative knowledge of experts from theory and practice to determine how precisely these requirements and criteria can be met in technical rules to be drawn up by the technical and scientific bodies in voluntary self-regulation'.

The goals of technical rule-making are, besides providing uniformity for goods and services (rationalization and rendering compatible function) and the industry-wide assurance of quality (quality assurance function), technical safety for the protection of life, health and property (protection function) and environmental protection (environmental protection function)[122].

Coordinative and regulative standards might be distinguished from a social science point of view[123]. *Coordinative standards* serve to ensure the compatibility and interoperability of individual technical units in the context of larger systems and to decrease transaction costs; they standardize interfaces and ensure that even products of different manufacturers fit together in vertically interwoven markets. *Regulative standards* are to prevent dangers to safety, health and environment (in short, negative externalities) arising from the production, distribution and use of technical products or plants. They are the reason for the political supervision of standardization with the aim of the assertion of public interests in technical development, namely technical and industrial safety, consumer protection, rationalization and furtherance of technology as well as socially compatible technical development[124].

---

[120] Marburger 1979: 111.
[121] Published in VDI Information, No. 14, April 1967.
[122] Cf., Marburger, Gebhard 1993: 3.
[123] Cf., Werle 1993: 130-133.
[124] Cf., Eichener, Heinze, Voelzkow 1993: 394-395.

Since the legislator or regulator in general cannot refer to sufficient expertise of their own in order to make the required detailed scientific or technical regulations themselves[125], statutes and regulations often paraphrase the requirements of the composition of technical appliances, plants or materials in general clauses and undefined terms such as 'generally recognized rules of the art', 'state of the art' or 'state of science and technology'.

> The choice among the referred measures[126] determines the lag in adapting legal requirements to technical or scientific advances. The legally indefinite expression 'generally recognized rules of the art' focuses on the prevailing view among technical practitioners, on what is generally regarded as tried and tested in professional practice. The formula 'state of the art' shifts the legal criterion for what is permitted or commanded to the front line of technical development, the decisive point is not what is generally recognized or established in practice, but what is technically necessary, appropriate and possible, even if commercial practice is not yet in line with it. If a requirement mentions the 'state of science and technology', those precautionary measures regarded as necessary according to the latest scientific findings must be used; the limit to the requirement is not set by what is currently technically achievable.

The indefinite legal terms are often filled in through references to technical rules or standards, which have been made by public expert committees or private standardization bodies. The exact profile of requirements for technical goods or plants is regularly first defined in an applicable manner for manufacturers and plant operators as well as for licensing authorities or examining bodies through the detailed technical rules. The manufacturers or users as well as operators of potentially dangerous technical goods are not legally bound by the standards, rather they may choose deviating solutions if at least the same safety standard is achieved thereby (deviation clause). The development dynamic of modern technology is to be thereby taken into account and loss of topicality and hindrance of progress avoided.

A number of advantages are named in favour of the principle of filling in binding requirements of the State and Community legislator through technical rules made by expert committees or technical standards adopted by private standard associations[127]:

- mobilization of expertise from greatly differing areas of knowledge and activity; stimulation of the 'involved circles' own interests;

[125] See Eichener, Heinze, Voelzkow 1993: 396-398 for a summary of the possibilities and restrictions of State-controlled technology development.

[126] Fundamental to the reference trial is the so-called Kalkar Decision of the German Constitutional Court of 8.8,1978, BVerfGE 49, 80 (135-136).

[127] Marburger, Gebhard 1993: 40-42.

- relief of the State legislator and regulator or the Community legislator of rule-making tasks, for which they do not usually have adequate expertise and/or which quantitatively exceed the performance capability of the usual legislative procedures;

- relief of binding legal texts (statutes and regulations as well as directives and regulations) and the corresponding consultation and decision-making procedure from extensive detailed technical provisions;

- quick adaptation of technical rules to the advanced state of science and technology with consequences for the referring binding legal act without having to alter the text;

- solutions close to practice as a consequence of the cooperation of specialists from the professional practice;

- compensation of conflicting interests in the pluralistic composition of the respective committees and as a consequence of the consensus principle;

- increased willingness to comply with the standards as a consequence of the participation of the affected circles in the adoption of technical rules and standards.

3.2. Legislative Reservation and Reference to Technical Rules

The constitutional requirements discussed assume the inevitability of the delegation of tasks to technical rule-makers in wide areas of technological and environmental law. They are not to decrease the described advantages of reference to technical standards, but are rather to compensate for the loss of constitutionality, democratic legitimation, procedural protection of fundamental rights and publicity[128]. For the attachment of legal provisions and technical rules, the German legal literature has discussed the constitutionality of the rigid reference, sliding reference in supplementation of legal norms, and the sliding reference in specifications of legal norms[129]. An important point is that the legislator and regulator are to make the 'essential decisions' on the respective technical risks themselves; the legislative authority must not be transferred to private organizations.

[128] This compensation thinking is found in particular in Lübbe-Wolff 1991: 242-244. Cf. also, Roßnagel 1993: 178, who will transfer adequately the requirements of democratic rule-making to associational standard setting.

[129] Cf., Marburger 1979: 379-407; Marburger 1991: 38-45; Ernst 1973: 27-41; DIN (ed.) 1982; Ossenbühl 1967; Karpen 1970; Karpen 1976; Staats 1978; Schwierz 1986: 63-99; Denninger 1990: 130-147; Lübbe-Wolff 1991: 237-248.

The permissibility of the *rigid reference*, in which the statute or regulation refers to a version of a technical rule clearly determined by the date of publication, is not disputed. It is actually an abbreviation of the binding normative text; the legislator or regulator is adopting an established rule for itself. The contents of the technical rule referred to obtain the same legal application as the referring legal norm. This form of reference is constitutionally sound, it avoids a delegation of rule-making powers and also satisfies the constitutional principle of legal certainty. It does, however, presuppose an appropriate technical rule and might only be considered where a technical development has reached a certain end and where significant changes are not to be expected so quickly or are irrelevant for the protection of legal goods.

The permissibility of the *sliding or dynamic reference*, which refers to one or more technical rules in their respectively applicable version, was disputed for a long time; in the case of a change in the technical rule, no amendment of the referring legal text is necessary. Great constitutional doubts have been put forward against its permissibility[130]: it is a hidden transfer of rule-making power to private parties, violates the principles of democracy, a constitutional state, namely the principle of the certainty and clarity of the law, as well as the principle of separation of powers.

These doubts are maintained in relation to the permissibility of *sliding reference in supplementation of legal norms*, which, in supplementing the legal text, makes direct obligatory reference to technical rules in their respective version. The referring legal norm is incomplete and the rule being referred to in its respectively applicable form becomes an integral part of the legal rule which is binding on the citizen and the administration. The legislator or regulator hands over the determination of the state of duties of the addressees of the norm to private standardization bodies within the extent of the reference. In reality, it is a blanket law, the contents of which can be set and altered at the discretion of private rule-makers.

It has been proposed that the sliding reference in supplementation of legal norms ought to be permitted when the referring legal norm, in accordance with the requirements of an empowering provision enabling the making of regulations (Art. 80, Para. 1, Sentence 2 of the German Basic Law), is put into such concrete terms that the contents, purpose and extent of the technical rules being referred are largely defined[131]. In order to do this, the legislator or regulator would have to lay down binding authoritative safety goals, the

[130] Cf. Ossenbühl 1967; Karpen 1970: 131 *et seq.*; Karpen 1976: 232 *et seq.*; Arndt 1979.
[131] In detail on this, Veit 1989: 57 *et seq.*

essential safety principles and, in the case of complex technical plants, the system components of significance to technical safety, and, due to the technical details, it would have to refer to technical rules. In such a legally binding framework, only insignificant detailed rules are left for the technical rule. In comparison to the existing legal situation, a large part of the technical rules would have to be laid down in statutes and regulations. This would not only exceed the expertise of the legislature in relation to new technologies, but would also endanger the necessary flexibility for dynamic legal protection, unless one is prepared to take continuous novelties into account[132].

The *sliding reference in specification of legal norms* always appears in connection with an undefined legal term, which it helps to concretize. It would, for example, be legally laid down to conform to the 'generally recognized rules of technology'; it would then be determined that certain technical standards are to be taken as generally recognized rules of technology. Mere conformity with the legal standard is legally binding on the manufacturer of a product. The referring legal norm itself conclusively determines the requirements to be satisfied, although not in detail, rather with the aid of more or less undefined terms. The abstract qualitative predetermination of goals at the legal norm level must be 'translated' into concrete technical rules, which can be monitored and which can be coherently integrated into the existing network of technical rules in order for them to be relevant for undertakings and authorities and their behaviour. There is regularly not only one 'correct' solution, rather the standardization bodies make a selection from several possible solutions. This connection with valuations and an open competition of interests are in the end inevitable[133].

In order not to hinder technical progress, technical standardization is generally not set on definite technical solutions, for which details of construction and make-up are given *(design standards)*, It is instead far more aimed at results; in other words, it lays down product requirements *(performance standards)*, which can be conformed to through concurrent technical solutions. In the end these technical rules are decisive for the construction of products and the composition of plants as well as for the standard of industrial safety and health and environmental protection. The additional reference to technical rules is on the one hand to point the way to the addressees of standards, showing how they can satisfy the legal requirements, and on the other hand to bind the competent authorities to tolerating those products or plants which satisfy the technical rules referred to. The market

[132] Cf., Marburger 1991: 41.

[133] In detail on this, Lübbe-Wolff 1991: 235-237.

preference for conform products and plants produces an effective force to follow, even when it is legally open to a plant operator or a manufacturer to choose a solution other than provided for in the technical rule, provided that this satisfies the binding legal requirements.

In conforming to the technical rules referred to, a refutable presumption speaks in favour of the legally binding requirements being satisfied. Conformity with technical standards only fulfils an indicatory function for conformity with the legal safety duty; it is still left to the competent au-thorities to take steps against a product produced to standard or against a plant operated according to standard where there is a concrete danger for the protected legal objects.

As far as can be seen, no one doubts that the sliding reference in specification of legal norms which makes use of 'hinge terms' such as 'state of the art', also satisfies the principle of legislative reservation, as long as a complete regulation is made in the referring legal norm. The directives taking the new approach to technical harmonization and standards go beyond this required minimum with their more or less comprehensive and precise catalogues of essential safety requirements. In the case of a lacking stock of assured and Community-wide applicable harmonized standards, these basic requirements represent at the same time extensive and evaluating standards for making harmonized technical standards and until their adoption the decisive criteria for the acceptability of products for the market and the suitability of applicable national technical standards.

> Roßnagel[134] comes up with largely comparable results, although he regards the dividing lines described above as formalistic, because they do not take the actual effect of technical standards into account and assume a separation not found in the practice between political and legal effect on the one hand and value-free expertise in technical standardization on the other. The legislator would have to make essential substantive decisions himself, namely on the safety philosophy to be followed, the acceptable risk threshold, the acceptable upper limit for damage, and on the future development and use of environmentally and socially relevant technical systems. Such a 'pluralistic approach' would simply not be practicable given the 'numerous everyday decisions on the equipping of technical systems'. The large number of necessary detailed rules could only be made through the making of technical standards with the participation of the existing expertise and in social self-administration.

[134] Roßnagel 1993: 177-179.

3.3. Constitutional Requirements of References to Technical Rules

Marburger summarizes a meaningful and basic assumption in making references in specifications of legal norms in particularly fitting manner[135]:

> 'The reference in specifications of legal norms is based on the legislative consideration that the referred technical rules were made in an orderly procedure in expert bodies with the (representative) participation of interested circles and the public and that they were therefore presumably suitable for danger control. This valuation is without any internal justification if those preconditions mentioned are not present. The effect of this presumption can therefore be taken away by the proof that procedural provisions for the making of technical rules, to the extent that they were of substantial importance for the contents of the rules, were not complied with'.

Given the State renunciation of its regulatory power and the considerable actual effects of technical standards on the market positions of individual undertakings as well as on the protection of employees, consumers and the environment, Marburger[136] gives the following five minimal constitutional requirements for standardization procedures:

- Relevant expertise must be comprehensively represented on the standardization committees.
- All interests involved should have balanced representation in the procedures for arriving at standards.
- The public must have an opportunity to influence the contents of the standards produced.
- Technical standards must be subject to regular revision.
- The procedure must be laid down in binding fashion.

The greatest difficulties in meeting these legal requirements, which are also appropriate for European standardization procedure, lie mainly in securing the balanced involvement of all interests concerned. Regarding the action field of the DIN, Gusy[137] has noted one-sided representation of interests in various respects:

[135] Marburger 1991: 43-44 (translation, J.F.).
[136] Marburger 1979: 138-146.
[137] Gusy 1986.

- Private interests may take precedence over public interests which are not concretely enough defined and often not personally represented on the committees.

- The factor of honorary standardization work one-sidedly favours industrial suppliers.

- Consumers are under-represented and able to articulate their interests only with great difficulty.

- There is an overlapping of interests between industry and standardization that is hard to break down. The expertise of the applicants from industry cannot be outweighed.

Taking these difficulties of a balanced consideration of interests into account, the minimal constitutional requirements proposed by Marburger are partially put in more precise terms and supplemented[138]:

a) The orientation towards the common good should be expressly anchored for all standardization associations as the aim of the standards.

b) The working groups are to be put together in such a pluralistic manner that the newest state of scientific knowledge and experience is provided for, and conflicting interests neutralized; Denninger refers to the *'im Sinne der Gemeinwohlorientierung produktiven Prinzipien der Gegenmachtbildung, der Erkenntnisförderung durch Kontrastinformation und des Minderheitenschutzes'* (– in the sense of an orientation to the general welfare – productive principles of the building of countervailing power, of the promotion of knowledge through contrasting information, and of the protection of minorities)[139].

c) In order to ensure a pluralistic structure of the standardization committees and the consideration of all affected, even if not equally articulated interests, specific public interests – such as consumer, environmental, industrial and data protection – which are often plagued with organizational weaknesses, should be institutionally recognized, if necessary in the form of an attorney model, financially supported by the State. In light of the significantly differing personal, material and organizational starting conditions of the players, an approximation of the actual preconditions for using rights of participation through procedural and substantive measures is being demanded[140].

[138] Cf., Roßnagel 1993: 179-180.
[139] Denninger 1990: 172-173.
[140] Cf., Führ 1993: 100.

d) The transparency of the procedure and the outcome is not only to be ensured to all those in the standardization bodies, but rather to those potentially affected. To ensure this, the draft standards and the outcome of the standardization work would have to be easily accessible to all those interested and to be acquainted at reasonable prices[141]. The public which is interested in, but not institutionally included in the standardization process, is to be given an opportunity to put forward its position.

e) The adopted technical rules are to be submitted to periodic examinations in order to ensure the topical consideration of the newest technical developments and of possible new knowledge of risks.

3.4. Inadmissible Delegation of Public Tasks to Private Standardization?

A delegation of sovereign powers of the Community to private organizations is not provided for in the EEC Treaty. The European Court of Justice has permitted it within very narrow limits in two early decisions in relation to the EEC Treaty. Going from the jurisprudence of the ECJ in the two *Meroni* cases[142], the following conditions apply for the admissibility of the transfer of sovereign powers to subordinate authorities outside of the EC institutions[143]:

- The Commission may not delegate more extensive powers than it itself has.
- The delegation may only be in relation to the preparation or carrying through of decisions.
- The Commission may not delegate a latitude for judgement or discretion.
- The delegated competence must remain under the control and responsibility of the Commission.
- The 'institutional balance' between the EC institutions may not be distorted.

[141] There are considerable problems here arising from the means of financing standardization activity. In 1993 e.g. 68.0% of the income of the DIN, which came to an overall total of DM 160 million, came from publishing and other revenue, and thus predominantly from the sale of technical standards, while 16.1% came from contributions made by private industry and 15.9 % from public funds. Cf., DIN Annual Report 1992/93, 47.

[142] ECJ, Cases 9/56 and 10/56, Judgments of 13.6.1958, ECR [1958], 11 *et seq.*; 53 *et seq.* — Meroni.

[143] Cf., W. Hummer, Art. 162, No. 43; I.E. Schwartz 1983: Art. 235, Nos. 265-291; Hilf 1982: 316-321; Fallon 1989: 175-179.

This is demonstrated in particular in the case of the Low Voltage Directive, where the sliding reference to technical standards does not represent an inadmissible delegation of public tasks to private standardization bodies. The ECJ has not dealt explicitly with this question, but has not expressed any doubt as to the admissibility of the reference technique employed in the Low Voltage Directive[144]. The possible criticism has been brought out very succinctly by Röhling[145], which can be summarized as follows:

Sliding reference to technical standards in their current version is alleged to constitute inadmissible delegation of sovereign powers to non-sovereign organizations, since the tasks transferred go far beyond mere implementing powers. Community agencies are allowed practically no influence on the production of the technical standards and the balance between Community institutions is encroached upon. Reference to standards can allegedly not be justified even on the 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. 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).

These concerns, raised in relation to directives according to the new approach to technical harmonization and standards under partly modified conditions, do not however prove right finally[146]: products must satisfy those essential safety requirements laid down in the directives. Those technical specifications assigned to the European standardization bodies remain mere recommendations for manufacturers and importers despite their actual far-reaching binding effect; the European standardization organizations are not transferred any sovereign powers. Conformity with the harmonized standards only establishes the refutable presumption[147] of compliance with the essential safety requirements, which can in principle be satisfied in a different manner.

[144] ECJ, Case 123/76, Judgment of 14.7.1977, ECR [1977], 1499 — Commission vs. Italy; Case 815/79, Judgment of 2.12.1980, ECR [1980], 3583 — Cremonini, Vrankovich.

[145] Röhling 1972: 122-127.

[146] Taking a different view: Breulmann 1993: 199-238, who regards the practicized inclusion of private standardization associations in the process of legal harmonization in the Community as *de facto* a hidden delegation of rule-making powers.

[147] For a different view: Breulmann 1993: 151-175, who refers to a *'qualifiziert widerlegbare Tatbestandsbindung'* (qualified refutable fact binding).

The Member States can comply with their responsibility for the health and safety of users as well as other protective goals through the safeguard clause procedure where harmonized standards are lacking. The essential safety requirements in the directives are far more detailed and precise in comparison to the Low Voltage Directive and particularly to the explicitly legally defined safety requirements in the applicable Member State regulations[148]. Combined with the standardization mandates of the Commission, they represent clear goal requirements for the setting of harmonized standards by the European standardization organizations[149].

Roßnagel summarizes the demands of legal policy on associational control of technology as follows[150]:

> 'Democratic control of technology through the law is dependent on an additional control through associational standard-setting. Legal control of technology can however only request and accept such supportive work if it does not neglect its own controlling task and the associational standard-setting satisfies minimal legal requirements'.

The Community is doing far more justice to the necessity of making all essential decisions itself through the current implementation of the new approach to technical harmonization and standards than, for example, the German legislator, who is largely satisfied with requirements with a degree of precision such as 'generally recognized rules of technology'. The minimal legal requirements of associational standard-setting are however in the matters of transparency and balance of interests not fulfilled.

---

[148] The Low Voltage Directive contains a catalogue of 11 extraordinarily vague formulated safety goals, kept within half a page. The Directive relating to machinery, which has a comparable range of application, contains – before being supplemented – a 12-page detailed catalogue referring to very specific dangers, and which is coordinated with an extensive standardization programme of the CEN on safety of machines. The interpretative documents for the concretion of the essential requirements of the Directive relating to construction products, which are an essential basis for standardization mandates, total 163 pages.

[149] The essence of the above legal conception was formulated at an early stage by Starkowski 1973: 143-160. Grabitz 1980: 82-91 is in favour of a solution according to which directives lay down the binding procedural requirements in a general clause, make sliding references to non-binding technical standards aimed at filling it in, and impose the refutable presumption on Member States, that products conform to a directive when they satisfy the technical standards referred to.

[150] Roßnagel 1993: 169.

4. CONCLUSIONS

4.1. Procedural Framework Supervision of Associational Control of Technology

The Community is on the road to taking over the essential features of the cooperative relationships which have formed in Member States between the State, standardization associations and other economic interest associations. The Community has conceptually established that it now acts in a cooperative network with Member States and other Community players in the field of technological regulation as well as in other policy areas such as environmental protection[151] and industrial protection[152]. In granting harmonized standards greater relevance in its internal market policy, the Community has brought about an unforeseen revival of European standardization and a very fundamental shift from national to European standardization. It raises so to speak the 'ruling capacity'[153] of European standardization organizations. In technical safety law, the Community and the European standardization organizations are symbiotically dependent on each other along the lines of 'relief of the State through associations' and 'relief of associations through the State'[154].

The neo-cooperative arrangements of the Community in the area of technical standardization and certification slip away from the general forms of legal activity by the Community, namely in the form of directives, regulations and decisions. A direct legal behavioural control in relation to the autonomous associational actors who are not even confined to the area of the Community[155]

---

[151] Cf. especially, the fifth environmental action programme "Environment and Sustainable Development", COM (93) 23 final, vol. II of 3.4.1992, 29-31, 82-84 and the Commission Decision of 7.12.1993 on the setting-up of a general consultative forum on the environment, OJ L 328 of 29.12.93, 53-54.

[152] Cf., Commission Communication, General Framework for Action by the Commission of the European Communities in the Field of Safety, Hygiene and Health Protection at Work (1994 to 2000), COM (93) 560 final of 19.11.1993.

[153] Cf., Voelzkow, Hilbertz, Heinze 1987; Streeck, Schmitter 1985.

[154] Cf., Traxler 1986: 359; Traxler, Vobruba 1987: 13.

[155] This applies in two ways: Not only are standardization organizations of EC Member States members of CEN and CENELEC, but beyond this the international standardization by ISO and IEC overrides their standardization work, cf., Para. U.1.1. of the Joint Rules of CEN and CENELEC; cf. also, Nos. 44-49 of the Commission Communication on Standardization in the European Economy, OJ C 96 of 15.4.92, 2 *et seq.* — 25% of the current work programme of the CEN concerns direct recognition of international standards; only about 10% of European standards from the CENELEC are independent pieces of work, 72% are identical

is out of the question, rather only an influencing of the conditions of the frame (procedure, exchange of information, cooperation of personnel, financing) can be influenced; the Community must restrict itself to a procedural framework supervision[156]. The sovereign regulation of associational self-regulation forms the means of its intervention[157]. Besides aspects of effectivity with the aim of quicker technological integration in Europe, this involves the concrete provision of essential requirements for harmonized standards for the protection of public interests and organizational and procedural guarantees, in order to increase the transparency of standardization work, to hinder one-sided preferential treatment of interests and to mobilize the necessary social knowledge for an environmentally and socially compatible shaping of technology.

4.2. Some Steps to the Reform of European Standardization

The cooperation of the Community and European standardization organizations is, after the only very limited progress made by the Green Paper on European Standardization, in many ways in need of improvement with regard to an increase in plurality and transparency:

a) Direct forms of participation in European Standardization beyond consultative participation in standardization bodies should be developed for industrial protection, environmental protection, consumers and other general interests, since the danger exists that a mere representation could be 'filtered out' by the national delegations.

b) A direct procedure for objections against draft European standards should be introduced at the European level for the (specialist) public with interests involved, in addition to the objection procedures coordinated by national standardization organizations.

c) Harmonized standards should be examined during the procedure for setting the standards with regard to their conformity to the essential requirements. The Commission, which takes on the role of guarantor here, should rely on consultation with experts through bodies established for specific product groups and plants as well as with the European Environment Agency

---

standards adopted from IEC standards while 18% are based on them with common European alterations.

[156] On the changed meaning of the law in neocorporatist arrangements cf., Traxler, Vobruba 1987 and Teubner 1985.

[157] Cf. especially on this concept, Voelzkow 1993.

for environmental aspects and with the European Agency for Health and Safety at Workplace for industrial safety. European associations should also have a right to instigate an examination of the conformity of harmonized standards with the binding goals.

d) The transparency of European standardization is to be increased in all stages; this applies in particular to the drafting of standardization agendas by the European standardization organizations and the assignment of standardization mandates by the Commission.

e) Panels should be set up in the European standardization organizations according to the national examples for the preparation of interpretative documents on product-specific environmental protection and the coordination of aspects of industrial safety and environmental and consumer protection as well as their inclusion in individual standardization bodies.

f) The general principles for cooperation between the EC Commission and the European standardization bodies should be reassessed in light of accumulated experience and giving consideration to the discussion over the Green Paper on European Standardization. In particular, they should be adjusted to the requirements of transparency of standardization and the balanced representation of interests.

g) The transparency of European standardization could be increased considerably, if the proposed standards were published in a widely distributed and easily accessible 'standards journal' at the beginning of the public hearing. At the moment, it is extremely difficult and expensive for undertakings, individuals or interest groups which are not informed about certain proposals for standards as a result of their participation in the working groups of the national standardization institutions to get actual information about developments in European standardization work and to obtain the relevant documents in due course. This proposal is not without difficulties: the sale of technical standards in printed form is the most important source of financing for the standardization work. Connected with this proposal is the open question of the use of data banks or information networks for the dissemination of standards and proposed standards in the near future.

4.3. Extension of the New Approach to Other Political Spheres: Green Paper on the Environment related Standardization

The New Approach to Technical Harmonization and Standards has been gradually refined and systematized with the preparation of numerous product group-specific directives. It has moreover been completed by a conclusive system for certification. In doing so, it has proven that the so-called model-directive provides a guide for the particular directives, giving a basic orientation while allowing deviations and additions in order to do justice to the specific risks and requirements of the specific product categories.

The development of the New Approach to Technical Harmonization and Standards is closely tied to the dismantling of technical barriers to trade and the policy on the completion of a single market. Whether, and in which manner, the reference to harmonized standards can be used in other areas – such as environmental protection, occupational safety, quality control of foodstuffs, and energy policy – in setting up trans-European networks with the aim of a proper technical control needs a wide public debate, as occurred on the topic of the development of European standardization for a quicker technological integration in Europe. There are, for example, undoubtedly considerable differences between technical standards for the acceptability of goods for the market, on the one hand, and for the requirements on locally bound technical plants, on the other. The standardization at the research and development phase follows its own rules in research-intensive sectors and, in particular, in the area of system technologies[158]; it is characterized by reciprocity of standardization, research and development and is of great importance for the process of technical innovation in the area of key technologies. Which rank European standardization is to take in the areas of occupational safety is in need of clarification[159].

Under which modifications the New Approach to Technical Harmonization and Standards, which can unburden and accelerate the law making process of the European Community, can be transferred to the sector of the Common Environmental Policy is a question which needs a programmatic public debate, before it can be used on a more general basis in the sector of

[158] Cf., Commission Communication, High-Technology and Preliminary Standardization, COM (88) 314 final of 23.6.1988; Thiard, Pfau 1992; Eichener, Voelzkow 1993.

[159] Cf., the joint viewpoint of the Federal Minister for Labour and Social Affairs, of the supreme industrial safety authorities of the Länder, of the occupational health and safety agencies, of the social partners, and of the DIN on standardization in the area of the directives which are based on Article 118a of the EC Treaty, Bundesarbeitsblatt 1/1993, 37-39.

environment protection. This public discourse has to involve broad circles of experts and social groups, taking into consideration the new conceptual framework of the Fifth Environmental Action Programme. In many other sectors, the publication of a Green Paper by the Commission has proven an adequate means to mobilize a broad interested public and to stipulate a programmatic debate in a transparent manner. In order to avoid use-less confrontations, this debate should be prepared by the Commission with the support of the European standardization organizations and the European environmental groups.

In addition, the Commission should support research projects and seminars for the development of ecological balance sheets relating to specific products and production processes as well as for the preparation of technical product standards which integrate the environmental aspects of all phases of development, production, use and disposal. Further, it would be very useful to evaluate the application of the so-called Eco-Audit-Regulation[160] in firms and undertakings and to use the practical experiences for the environment-related standardization.

4.4. Framework Regulation on European Standardization

The legal requirements of the reference to harmonized standards ought to be written down in a formal legal act in order to clarify the current state of knowledge and experience. An amendment of the so-called model-directive is not sufficient for this purpose because the respective Council Resolution is addressed to the Community legislator only. Therefore, a Community Directive on standardization is needed, which elucidates the principles valid for the European Community as well as for the Member States. In principle, such a regulation could be realized on the occasion of the review of the Treaty on European Union. But to regulate such specific subjects at the level of the primary Community law would make it very difficult to respond to new needs or knowledge and to change these formally determined principles.

The following formulation is proposed:

'For the purpose of the concretion of those requirements of products, procedures and technical plants regulated in its legal acts, the Community can

[160] Council Regulation (EEC) No. 1836/93 of 29.6.1993 allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit scheme, OJ L 168 of 10.7.93, 1-18.

assign the making of technical specifications to the European standardization organizations under the following conditions:

- It must itself determine to a high level and as precisely as possible the essential requirements which products or technical plants must satisfy for the protection of safety and health, the environment, and other non-economic interests.

- The technical specifications must satisfy the essential requirements, may have no legally binding character whatsoever and must be regularly reviewed.

- The relevant expertise must be fully represented in the standardization committees.

- The interested circles, in particular the public offices, industry, users, consumers, trade unions, environmental protection associations, and a representative of the Commission, must be able to participate in the making of the technical specifications; the public is to be given the opportunity to express its opinion on the drafts.

- The draft standards and the outcome of the standardization work must be easily accessible to all those interested.'

The adjustment of the General Principles on the Cooperation between the Commission and the European Standardization Organizations should be negotiated on this basis.

As a follow-up to the so-called model-directive, an inter-institutional agreement or organic law is to lay down the more exact form of legal acts which refer to harmonized standards. The possible special requirements of the reference to harmonized standards in specific policy areas or with a view to certain goods to be protected are to be taken into account. In extending the regulatory technique of referring to standards, it must in particular be clarified in which manner the Commission may consult with special expert committees, in addition to consultations with the Standing Committee for Standards and Technical Rules, in preparing standardization mandates and in monitoring harmonized standards with regard to their conformity with the appropriate essential requirements.

***

REFERENCES

Anselmann, N. (1986): Die Rolle der Europäischen Normung bei der Schaffung des europäischen Binnenmarktes, Recht der Internationalen Wirtschaft 32, 936-941.

Anselmann, N. (1991a): Die Bezugnahme auf harmonisierte technische Regeln im Rahmen der Rechtsangleichung, in: P.-Ch. Müller-Graff (ed.), Technische Regeln im Binnenmarkt, Baden-Baden, 101-114.

Anselmann, N. (1991b): Technische Vorschriften und Normen in Europa. Harmonisierung und gegenseitige Anerkennung, Bonn.

Anselmann, N. (1993): EG-Richtlinien für Medizinprodukte, DIN-Mitteilungen 72, 689-692.

Arndt, G. (1979): Die dynamische Rechtsnormverweisung in verfassungsrechtlicher Sicht — BVerfGE 47, 285, Juristische Schulung 1979, 784-789.

Baragiola, P. (1991): ETSI — Offene Kommunikation, einheitliche Normen, XIII-Magazine, April 1991, 22-23.

Bericht über Arbeiten der Koordinierungsstelle Umweltschutz im DIN für den Zeitraum Januar 1992 bis Juni 1993, Bonn 1993.

Bestel, H. (1994): DIN — Innovationen für die Zukunft. Jahrespressekonferenz 1994, DIN-Mitteilungen 73, 424.

Bosserhoff, H.-W. (1980): Sechs Jahre Verbraucherrat, DIN-Mitteilungen 59, 670-671.

Bosserhoff, H.-W. (1987): Prioritätenprogramm für die Normung von Konsumgütern — verbrauchergerechte Normung, DIN-Mitteilungen 66, 530-534.

Bosserhoff, H.-W. (1992): Stand der Angleichung der technischen Normen und die Bedeutung für die Verbraucher, Verbraucherpolitische Hefte, No. 14 (July 1992), 131-153.

Breuer, R. (1989), Die internationale Orientierung von Umwelt- und Technikstandards im deutschen und europäischen Recht, Jahrbuch des Technik- und Umweltrechts, 43-116.

Breulmann, G. (1993): Normung und Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft, Berlin.

CEN (1992): CEN Consultation Document, Environmental standardization by CEN. A proposal for a general outline of activities, Brussels.

Denninger, E. (1990): Verfassungsrechtliche Anforderungen an die Normsetzung im Umwelt- und Technikrecht, Baden-Baden.

Dey, W. (1987): EG-Richtlinie über die Sicherheit von Maschinen, DIN-Mitteilungen 66, 233-235.

Dey, W. (1988): Neue Aktivitäten des CEN auf dem Gebiet "Maschinensicherheit", DIN-Mitteilungen 67, 696-705.

Dey, W. (1990): CEN-Normung zur Maschinensicherheit. Strategie, Arbeitsweise und Stand der Arbeiten, DIN-Mitteilungen 69, 666-674.

Dey, W. (1993): Ergebnisse des "Reprogramming" im CEN zur Maschinen-Sicherheit, DIN-Mitteilungen 72, 231-233.

Dey, W. (1994): CEN-Normung zur Maschinen-Sicherheit — auf gutem Weg — erfolgreich, DIN-Mitteilungen 73, 277-279.

Dey, W. / Sälzer, H.J. (1988): Sicherheit von Maschinen und Geräten (CEN-Arbeit), DIN-Mitteilungen 68, 174-176.

DIN (ed.) (1982): Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, vol. 17, Berlin, Köln.

Doktor, J. (1990): Sicherheitstechnische Normen für überwachungsbedürftige Anlagen in Europa nach 1992, Technische Überwachung 31, 349-351.

Eichener, V. / Heinze, R.G. / Voelzkow, H. (1990): Die Harmonisierung technischer Normen in der Europäischen Gemeinschaft: Probleme und Perspektiven, in: U. von Alemann / R.G. Heinze / B. Hombach (eds.), Die Kraft der Regionen. Nordrhein-Westfalen in Europa, Bonn, 618-633.

Eichener, V. / Heinze, R.G. / Voelzkow, H. (1993): Techniksteuerung im Spannungsfeld zwischen staatlicher Intervention und verbandlicher Selbstregulierung, in: R. Voigt (ed.), Abschied vom Staat — Rückkehr zum Staat?, Baden-Baden, 393-421.

Eichener, V. / Voelzkow, H. (1993): Entwicklungsbegleitende Normung: Integration von Forschung & Entwicklung, Normung und Technikfolgenabschätzung, DIN-Mitteilungen 72, 764-768.

Ernst, W. (1973): Rechtsgutachten zur Gestaltung des Verhältnisses der überbetrieblichen technischen Norm zur Rechtsordnung, Berlin.

Europäische Kommission (1994): Leitfaden für die Anwendung der nach dem Neuen Konzept und dem Gesamtkonzept verfaßten Gemeinschaftsrichtlinien zur technischen Harmonisierung, Luxemburg.

Falke, J. (1988): Normungspolitik der Europäischen Gemeinschaften zum Schutz von Verbrauchern und Arbeitnehmern, Jahrbuch zur Staats- und Verwaltungswissenschaft 3, 217-246.

Fallon, M. (1989): Setting up a Community Product Safety Policy. Institutional Aspects, in: Ch. Joerges (ed.), Product Liability and Product Safety in the European Community, European University Institute, Working Paper 89/404, 162-181.

Fangmann, H. (1991): Europa auf dem Weg zum offenen Markt für Telekommunikationsendgeräte, Europäische Zeitschrift für Wirtschaftsrecht 2, 585-588.

Feldhaus, G. (1994): Grundlagen des Umweltschutzes — Bericht über die Arbeit des NAGUS, DIN-Mitteilungen 73, 456-460.

Fritze, A. (1989/1990): EWG-Richtlinie "Maschinen", Kompaß. Zeitschrift für Sozialversicherung im Bergbau 1989, 1-3, 54-57; 1990, 287-293.

Fritze, A. (1990): EG-Richtlinie Persönliche Schutzausrüstungen, sicher ist sicher 1990, 126-132.

Führ, M. (1993): Technische Normen in demokratischer Gesellschaft. Zur Steuerung der Technikanwendung durch private Normen, Zeitschrift für Umweltrecht 4, 99-102.

Grabitz, E. (1980): Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin.

Grefen, K. (1991): Harmonisierung technischer Regeln im EG-Binnenmarkt: Beitrag der Kommission Reinhaltung der Luft im VDI und DIN, Staub. Reinhaltung der Luft 51, 199-205.

Großklaus, D. (1991): Normung im Bereich Gesundheit und Umwelt im europäischen Rahmen am Beispiel der Lebensmittel und Bedarfsgegenstände — aus der Sicht des Bundesgesundheitsamtes, DIN-Mitteilungen 70, 269-272.

Gusy, Ch. (1986): Wertungen und Interessen in der technischen Normung, Umwelt- und Planungsrecht 1986, 241-250.

Hartlieb, B. / Krieg, K.G. (1987): Europäische Normung ja — aber wie?, DIN-Mitteilungen 66, 125-130.

Hilf, M. (1982): Die Organisationsstruktur der Europäischen Gemeinschaften, Berlin.

Hummer, W., Kommentar zu den Artikeln 155 - 163, in: E. Gra-bitz / M. Hilf (eds.), Kommentar zur Europäischen Union, München.

Joerges, Ch. (1988): The New Approach to Technical Harmonization and the Interests of Consumers: Reflections on the Requirements and Difficulties of a Europeanization of Product Safety Policy, in: R. Bieber / R. Dehousse / J. Pinder / J. Weiler (eds.), 1992: One European Market? A Critical Analysis of the Commission's Internal Market Strategy, Baden-Baden, 175-225.

Joerges, Ch. / Falke, J. (1991): Die Normung von Konsumgütern in der Europäischen Gemeinschaft und der Richtlinien-Entwurf über die allgemeine Produktsicherheit, in: P.-Ch. Müller-Graff (ed.), Technische Regeln im Binnenmarkt, Baden-Baden, 159-202.

Joerges, Ch. / Falke, J. / Micklitz, H.-W. / Brüggemeier, G. (1988): Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft, Baden-Baden.

Karpen, U. (1970): Die Verweisung als Mittel der Gesetzgebungstechnik, Köln.

Karpen, U. (1976): Die Verweisungstechnik im System horizontaler und vertikaler Gewaltenteilung, in: J. Rödig (ed.), Studien zu einer Theorie der Gesetzgebung, Berlin, 221-243.

Kiehl, P. (1990): EG-Bauproduktenrichtlinie und ihre Auswirkungen auf die Normungsarbeit, DIN-Mitteilungen 69, 250-256.

Kypke, U. (1982): Technische Normung und Verbraucherinteresse. Strukturelle, konzeptionelle und steuerungspolitische Probleme technischer Regelwerke, Köln.

Lamb, I. (1991): Normung und Umweltschutz. Fachtagung der Koordinierungsstelle Umweltschutz im DIN, Informationsbrief Umweltrecht 2, 106-108.

Lehmann, K. / Graßmann, J. (1990): Überprüfung von produktbezogenen DIN-Normen auf Umweltrelevanz, Berlin, 76-78.

Leichsenring, Ch. (1987): Unfallverhütungsvorschriften und EG-Recht, sicher ist sicher 1987, 446-452.

Lübbe-Wolff, G. (1991): Verfassungsrechtliche Fragen der Normsetzung und Normkonkretisierung im Umweltrecht, Zeitschrift für Gesetzgebung 1991, 219-248.

Maier, L. (1994): Verbrauchervertretung in der europäischen Normung, DIN-Mitteilungen 73, 632-634.

Marburger, P. (1979): Die Regeln der Technik im Recht, Köln.

Marburger, P. (1991): Formen, Verfahren und Rechtsprobleme der Bezugnahme gesetzlicher Regelungen auf industrielle Normen und Standards, in: P.-Ch. Müller-Graff (ed.), Technische Regeln im Binnenmarkt, Baden-Baden, 27-55.

Marburger, P. / Gebhard, T. (1993): Gesellschaftliche Umweltnormierungen, in: A. Endres / P. Marburger (eds.), Umweltschutz durch gesellschaftliche Selbststeuerung. Gesellschaftliche Umweltnormierungen und Umweltgenossenschaften, Bonn, 1-48.

Micklitz, H.-W. (1989): Considerations Shaping Future Consumer Participation in European Product Safety Law, in: Ch. Joerges (ed.), Product Liability and Product Safety in the European Community, Working Paper No. 89/404 of the European University Institute, 182-203.

Molkenbuhr, G. (1991a): Gemeinschaftsrecht und Normenharmonisierung im Baurecht: Zur Umsetzung der EG-Bauproduktenrichtlinie (98/106/EWG), Münster.

Molkenbuhr, G. (1991b): Die EG-Bauproduktenrichtlinie. Ein Beitrag zur Harmonisierung baurechtlicher und technischer Normen, Deutsches Verwaltungsblatt 1991, 745-751.

Nicolas, F. / Repussard, J. (1994): Gemeinsame Normen für die Unternehmen, 2nd ed., Luxemburg.

Ossenbühl, F. (1967): Die verfassungsrechtliche Zulässigkeit der Verweisung als Mittel der Gesetzgebungstechnik, Deutsches Verwaltungsblatt 1967, 401-408.

Partikel, H. (1989): Europäische Arbeitsschutzpolitik — Risiko und Chance, Soziale Sicherheit 1989, 146-149.

Pelkmans, J. (1987): The New Approach to Technical Harmonization and Standardization, Journal of Common Market Studies 25, 249-269.

Pelkmans, J. / Vanhenkelen, M. (eds.) (1986): Coming to Grips with the Internal Market, Maastricht, 9-30.

Pickert, K. / Köpcke, R. (1992): Die Arbeit des Technikbüros des EGB, forumarbeit 4/1992, 41 *et seq.*

Produktnormung und Umweltschutz. Bericht der Koordinierungsstelle Umweltschutz im DIN für den Zeitraum Juli 1993 bis Dezember 1994, Bonn 1995.

Quander, P. (1989): Europäische Normen and Standards, in: F. Arnold (ed.), Handbuch der Telekommunikation, Köln, Para. 11.3.1.1., pp. 17-20.

Reich, N. (1987): Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften. Eine problemorientierte Einführung in das europäische Wirtschaftsrecht, Baden-Baden.

Reihlen, D. (1989): Auswirkungen des EG-Binnenmarktes auf die technische Regelsetzung, DIN-Mitteilungen 68, 449-457.

Reihlen, D. (1991): Ergebnisse der 43. ordentlichen Sitzung des Präsidiums des DIN, DIN-Mitteilungen 70, 1-9.

Reuter, A. (1990): Die neue Maschinenrichtlinie: Ein europäischer Binnenmarkt für Maschinen- und Anlagenbau, Betriebs-Berater 1990, 1213-1217.

Röhling, E. (1972): Überbetriebliche technische Normen als nicht-tarifäre Handelshemmnisse im Gemeinsamen Markt, Köln.

Roßnagel, A. (1993): Rechtspolitische Anforderungen an die verbandliche Techniksteuerung, in: H. Kubicek / P. Seeger (eds.), Perspektive Technikssteuerung. Interdisziplinäre Sichtweisen eines Schlüsselproblems entwikkelter Industriegesellschaften, Berlin, 169-180.

Rühl, J. (1994): Normung und gesetzliche Regelungen für den Umweltschutz, DIN-Mitteilungen 73, 153-156.

Sapir, M. (1992): Das Technikbüro des Europäischen Gewerkschaftsbundes, Die Mitbestimmung 38, 35-36.

Schatz, H. (1984): Verbraucherinteressen im politischen Entscheidungsprozeß, Frankfurt, New York 1984.

Schiffer, H.-W. (1991): Normung und Umweltschutz, DIN-Mitteilungen 70, 371-374.

Schwartz, I.E. (1983): Kommentar zu Art. 235 in: H. von der Groeben / H. von Boeckh / J. Thiesing / C.-D. Ehlermann (eds.), Kommentar zum EWG-Vertrag, 3d ed., Baden-Baden, 1157-1264.

Schwierz, M. (1986): Die Privatisierung des Staates am Beispiel der Verweisungen auf die Regelwerke privater Regelgeber im Technischen Sicherheitsrecht, Frankfurt.

Staats, J.-F. (1978): Zur Problematik bundesrechtlicher Verweisung auf Regelungen privatrechtlicher Verbände, Zeitschrift für Rechtspolitik 1978, 59-62.

Starkowski, R. (1973): Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin.

Streeck, W. / Schmitter, P.C. (1985): Gemeinschaft, Markt und Staat — und die Verbände? Der mögliche Beitrag von Interessenregierungen zur sozialen Ordnung, Journal für Sozialforschung 25, 133-157.

Teubner, G. (1985): Verrechtlichung — Begriffe, Merkmale, Grenzen, Auswege, in: F. Kübler (ed.), Verrechtlichung von Wirtschaft, Arbeit und sozialer Solidarität, Frankfurt, 334 *et seq.*

Thiard, A. / Pfau, W.F. (1992): Forschung & Entwicklung und Normung. Ein Leitfaden, Luxemburg.

Traxler, F. (1986): Interessenverbände der Unternehmer. Konstitutionsbedingungen und Steuerungskapazitäten, analysiert am Beispiel Österreichs, Frankfurt, New York.

Traxler, F. / Vobruba, G. (1987): Selbststeuerung als funktionales Äquivalent zum Recht? Zur Steuerungskapazität von neo-korporatistischen Arrangements und reflexivem Recht, Zeitschrift für Soziologie 16, 3-15.

Troge, A. (1991): Normung im Bereich Gesundheit und Umwelt im europäischen Rahmen am Beispiel des Umweltschutzes — aus der Sicht des Umweltbundesamtes, DIN-Mitteilungen 70, 283-284.

Veit, B. (1989): Die Rezeption technischer Regeln im Strafrecht und Ordnungswidrigkeitenrecht unter besonderer Berücksichtigung ihrer verfassungsrechtlichen Problematik, Düsseldorf.

Vieweg, K. (1991): Technische Normen im Binnenmarkt, in: P.-Ch. Müller-Graff (ed.), Technische Regeln im Binnenmarkt, Baden-Baden, 57-78.

Voelzkow, H. (1993): Staatliche Regulierung der verbandlichen Selbstregulierung — Schlüssel für eine gesellschaftliche Technikssteuerung, in: H. Kubicek / P. Seeger (eds.), Perspektive Technikssteuerung. Interdisziplinäre Sichtweisen eines Schlüsselproblems entwickelter Industriegesellschaften, Berlin, 105-128.

Voelzkow, H. / Eichener, V. (1992): Technikssteuerung durch Verbände. Institutionelles Arrangement und Interessenberücksichtigungsmuster bei der Harmonisierung technischer Normen in Europa, in: K. Grimmer / J. Häusler / St. Kuhlmann / G. Grimmer (eds.), Politische Technikssteuerung, Opladen, 267-287.

Voelzkow, H. / Hilbertz, J. / Heinze, R.G. (1987): "Regierung durch Verbände" — am Beispiel der umweltschutzbezogenen Technikssteuerung, Politische Vierteljahresschrift 28, 80-100.

Welsch, J. (1990): Soziale Technikgestaltung durch Demokratisierung technischer Normen. Einige Überlegungen aus gewerkschaftlicher Sicht, WSI-Mitteilungen 43, 650-660.

Wengel, J. (1992): Neuere Tendenzen im Europäischen Normungsgeschehen, Die Mitbestimmung 38, 32-34.

Werle, R. (1993): Politische Technikssteuerung durch europäische Standardisierung?, in: H. Kubicek / P. Seeger (eds.), Perspektive Technikssteuerung. Interdisziplinäre Sichtweisen eines Schlüsselproblems entwickelter Industriegesellschaften, Berlin, 129-142.

Winckler, R. / Cassassolles, J. / Verdiani, D. (1974): Kommentar zur Niederspannungs-Richtlinie der Europäischen Gemeinschaften vom 19. Februar 1973, Berlin.

Zachmann, K. (1988): Sicherheit von Maschinen — Werdegang einer Richtlinie, DIN-Mitteilungen 67, 538-540.

SELECTED DOCUMENTS

Council Directive of 19.2.1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, OJ L 77 of 26.3. 73, 29-33.

Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 *(Cassis de Dijon)*; OJ C 256 of 3.10.80,2-3.

Council Resolution of 7.5.1985 on a new approach to technical harmonization and standards, OJ C 136 of 4.6.85, 1-9.

Council Directive of 3.5.1988 on the approximation of the laws of the Member States relating to safety of toys, OJ L 187 of 16.6.88, 1-13.

Commission Communication, High-Technology and Preliminary Standardization, COM (88) 314 final of 23.6.1988.

Council Resolution of 4.11.1988 on the improvement of consumer involvement in standardization, OJ C 293 of 17.11.88, 1.

Council Directive of 21.12.1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products, OJ L 40 of 11.2.89, 12-26.

Council Directive of 14.6.1989 on the approximation of the laws of the Member States relating to machinery, OJ L 183 of 29.6.89, 9-32.

Commission Communication of 15.6.1989, A Global Approach to Certification and Testing. Quality Measures for Industrial Products, OJ C 267 of 19.10.89, 3-27.

Council Directive of 21.12.1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ L 399 of 30.12.89, 18-38.

Council Directive of 20.6.1990 on the approximation of the laws of the Member States relating to active implantable medicinal devices, OJ L 189 of 20.7.90, 17-35.

Commission Communication of 16.10.1990 on the Development of European Standardization — Action for Faster Technological Integration in Europe *(Green Paper)*, OJ C 20 of 28.1.91, 1-35.

Economic and Social Council, Opinion of 20.3.1991 on the Commission's Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, OJ C 120 of 6.5.91, 28-33.

Council Directive of 29.4.1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 128 of 23.5.91, 1-18.

European Parliament, Resolution of 11.7.1991 on European standardization, certification and testing, OJ C 240 of 16.9.91, 208-212.

Commission Communication, Fifth Environmental Action Programme 'Environment and Sustainable Development', COM (93) 23 final, vol. II of 3.4.1992.

Commission Communication, Standardization in the European Economy. Follow-up to the Commission Green Paper of October 1990, OJ C 96 of 15.4.92, 2-18.

Council Resolution of 18.6.1992 on the role of European standardization in the European economy, OJ C 173 of 9.7.92, 1-2.

Council Directive of 14.6.1993 on medicinal devices, OJ L 169 of 12.7.93, 1-43.

Council Regulation (EEC) No. 1836/93 of 29.6.1993 allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit scheme, OJ L 168 of 10.7.93, 1-18.

Council Decision of 22.7.1993 concerning the modules for the various phases of the conformity assessment procedure and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives, OJ L 220 of 30.8.93, 23-39.

Commission Communication, General Framework for Action by the Commission of the European Communities in the Field of Safety, Hygiene and Health Protection at Work (1994 to 2000), COM (93) 560 final of 19.11.1993.
Commission Decision of 7.12.1993 on the setting-up of a general consultative forum on the environment, OJ L 328 of 29.12. 93, 53-54.

Commission Communication to the Council, "Making the Most of the Internal Market": Strategic Programme, COM (93) 632 final of 22.12.93.

Communication of the Commission with regard to the interpretative documents of Council Directive 89/106/EEC, OJ L 62 of 28.2.94, 1-163.

***

EUI WORKING PAPERS

EUI Working Papers are published and distributed by the
European University Institute, Florence

Copies can be obtained free of charge
– depending on the availability of stocks – from:

The Publications Officer
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (FI)
Italy

Please use order form overleaf

Publications of the European University Institute

To

The Publications Officer
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (FI) – Italy
Telefax No: +39/55/4685 636
E-mail: publish@datacomm.iue.it

From

Name .....
Address.....
.....
.....
.....
.....

❒ Please send me a complete list of EUI Working Papers
❒ Please send me a complete list of EUI book publications
❒ Please send me the EUI brochure Academic Year 1996/97

Please send me the following EUI Working Paper(s):

No, Author .....
Title: .....
No, Author .....
Title: .....
No, Author .....
Title: .....
No, Author .....
Title: .....

Date .....

Signature .....

Working Papers of the Robert Schuman Centre

RSC No. 94/1
Fritz W. SCHARPF
Community and Autonomy Multilevel Policy-Making in the European Union *

RSC No. 94/2
Paul McALEAVEY
The Political Logic of the European Community Structural Funds Budget: Lobbying Efforts by Declining Industrial Regions

RSC No. 94/3
Toshihiro HORIUCHI
Japanese Public Policy for Cooperative Supply of Credit Guarantee to Small Firms - Its Evolution Since the Post War and Banks' Commitment

RSC No. 94/4
Thomas CHRISTIANSEN
European Integration Between Political Science and International Relations Theory: The End of Sovereignty *

RSC No. 94/5
Stefaan DE RYNCK
The Europeanization of Regional Development Policies in the Flemish Region

RSC No. 94/6
Enrique ALBEROLA ILA
Convergence Bands: A Proposal to Reform the EMS in the Transition to a Common Currency

RSC No. 94/7
Rosalyn HIGGINS
The EC and the New United Nations

RSC No. 94/8
Sidney TARROW
Social Movements in Europe: Movement Society or Europeanization of Conflict?

RSC No. 94/9
Vojin DIMITRIJEVIC
The 1974 Constitution as a Factor in the Collapse of Yugoslavia or as a Sign of Decaying Totalitarianism

RSC No. 94/10
Susan STRANGE
European Business in Japan: A Policy Crossroads?

RSC No. 94/11
Milica UVALIC
Privatization in Disintegrating East European States: The Case of Former Yugoslavia

RSC No. 94/12
Alberto CHILOSI
Property and Management Privatization in Eastern European Transition: Economic Consequences of Alternative Privatization Processes

RSC No. 94/13
Richard SINNOTT
Integration Theory, Subsidiarity and the Internationalisation of Issues: The Implications for Legitimacy *

RSC No. 94/14
Simon JOHNSON/Heidi KROLL
Complementarities, Managers and Mass Privatization Programs after Communism

RSC No. 94/15
Renzo DAVIDDI
Privatization in the Transition to a Market Economy

RSC No. 94/16
Alberto BACCINI
Industrial Organization and the Financing of Small Firms: The Case of MagneTek

RSC No. 94/17
Jonathan GOLUB
The Pivotal Role of British Sovereignty in EC Environmental Policy

RSC No. 94/18
Peter Viggo JAKOBSEN
Multilateralism Matters but How?
The Impact of Multilateralism on Great Power Policy Towards the Break-up of Yugoslavia

*out of print

RSC No. 94/19
Andrea BOSCO
A 'Federator' for Europe: Altiero Spinelli and the Constituent Role of the European Parliament

RSC No. 94/20
Johnny LAURSEN
Blueprints of Nordic Integration. Dynamics and Institutions in Nordic Cooperation, 1945-72

***

RSC No. 95/1
Giandomenico MAJONE
Mutual Trust, Credible Commitments and the Evolution of Rules for a Single European Market

RSC No. 95/2
Ute COLLIER
Electricity Privatisation and Environmental Policy in the UK: Some Lessons for the Rest of Europe

RSC No. 95/3
Giuliana GEMELLI
American Influence on European Management Education: The Role of the Ford Foundation

RSC No. 95/4
Renaud DEHOUSSE
Institutional Reform in the European Community: Are there Alternatives to the Majoritarian Avenue?

RSC No. 95/5
Vivien A. SCHMIDT
The New World Order, Incorporated: The Rise of Business and the Decline of the Nation-State

RSC No. 95/6
Liesbet HOOGHE
Subnational Mobilisation in the European Union

RSC No. 95/7
Gary MARKS/Liesbet HOOGHE/Kermit BLANK
European Integration and the State

RSC No. 95/8
Sonia LUCARELLI
The International Community and the Yugoslav Crisis: A Chronology of Events *

RSC No. 95/9
A Constitution for the European Union?
Proceedings of a Conference, 12-13 May 1994, Organized by the Robert Schuman Centre with the Patronage of the European Parliament

RSC No. 95/10
Martin RHODES
'Subversive Liberalism': Market Integration, Globalisation and the European Welfare State

RSC No. 95/11
Joseph H.H. WEILER/ Ulrich HALTERN/ Franz MAYER
European Democracy and its Critique - Five Uneasy Pieces

RSC No. 95/12
Richard ROSE/Christian HAERPFER
Democracy and Enlarging the European Union Eastward

RSC No. 95/13
Donatella DELLA PORTA
Social Movements and the State: Thoughts on the Policing of Protest

RSC No. 95/14
Patrick A. MC CARTHY/Aris ALEXOPOULOS
Theory Synthesis in IR - Problems & Possibilities

RSC No. 95/15
Denise R. OSBORN
Crime and the UK Economy

RSC No. 95/16
Jérôme HENRY/Jens WEIDMANN
The French-German Interest Rate Differential since German Unification: The Impact of the 1992-1993 EMS Crises

RSC No. 95/17
Giorgia GIOVANNETTI/Ramon MARIMON
A Monetary Union for a Heterogeneous Europe

RSC No. 95/18
Bernhard WINKLER
Towards a Strategic View on EMU - A Critical Survey

*out of print

RSC No. 95/19
Joseph H.H. WEILER
The State "über alles"
Demos, Telos and the German Maastricht Decision

RSC No. 95/20
Marc E. SMYRL
From Regional Policy Communities to European Networks: Inter-regional Divergence in the Implementation of EC Regional Policy in France

RSC No. 95/21
Claus-Dieter EHLERMANN
Increased Differentiation or Stronger Uniformity

RSC No. 95/22
Emile NOËL
La conférence intergouvernementale de 1996
Vers un nouvel ordre institutionnel

RSC No. 95/23
Jo SHAW
European Union Legal Studies in Crisis?
Towards a New Dynamic

RSC No. 95/24
Hervé BRIBOSIA
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on Belgium

RSC No. 95/25
Juliane KOKOTT
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on Germany

RSC No. 95/26
Monica CLAES/Bruno DE WITTE
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on the Netherlands

RSC No. 95/27
Karen ALTER
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Explaining National Court Acceptance of European Court Jurisprudence: A Critical Evaluation of Theories of Legal Integration

RSC No. 95/28
Jens PLÖTNER
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on France

RSC No. 95/29
P.P. CRAIG
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on the United Kingdom

RSC No. 95/30
Francesco P. RUGGERI LADERCHI
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on Italy

RSC No. 95/31
Henri ETIENNE
The European Court and National Courts - Doctrine and Jurisprudence: Legal Change in its Social Context
Report on Luxembourg

RSC No. 95/32
Philippe A. WEBER-PANARIELLO
The Integration of Matters of Justice and Home Affairs into Title VI of the Treaty on European Union: A Step Towards more Democracy?

RSC No. 95/33
Debra MATIER
Data, Information, Evidence and Rhetoric in the Environmental Policy Process:
The Case of Solid Waste Management

RSC No. 95/34
Michael J. ARTIS
Currency Substitution in European Financial Markets

RSC No. 95/35
Christopher TAYLOR
Exchange Rate Arrangements for a Multi-Speed Europe

RSC No. 95/36
Iver B. NEUMANN
Collective Identity Formation: Self and Other in International Relations

*out of print

RSC No. 95/37
Sonia LUCARELLI
The European Response to the Yugoslav Crisis: Story of a Two-Level Constraint

RSC No. 95/38
Alec STONE SWEET
Constitutional Dialogues in the European Community

RSC No. 95/39
Thomas GEHRING
Integrating Integration Theory: Neofunctionalism and International Regimes

RSC No. 95/40
David COBHAM
The UK's Search for a Monetary Policy: In and Out of the ERM

***

RSC No. 96/1
Ute COLLIER
Implementing a Climate Change Strategy in the European Union: Obstacles and Opportunities

RSC No. 96/2
Jonathan GOLUB
Sovereignty and Subsidiarity in EU Environmental Policy

RSC No. 96/3
Jonathan GOLUB
State Power and Institutional Influence in European Integration: Lessons from the Packaging Waste Directive

RSC No. 96/4
Renaud DEHOUSSSE
Intégration ou désintégration? Cinq thèses sur l'incidence de l'intégration européenne sur les structures étatiques

RSC No. 96/5
Jens RASMUSSEN
Integrating Scientific Expertise into Regulatory Decision-Making.
Risk Management Issues - Doing Things Safely with Words; Rules and Laws

RSC No. 96/6
Olivier GODARD
Integrating Scientific Expertise into Regulatory Decision-Making.
Social Decision-Making under Conditions of Scientific Controversy, Expertise and the Precautionary Principle

RSC No. 96/7
Robert HANKIN
Integrating Scientific Expertise into Regulatory Decision-Making.
The Cases of Food and Pharmaceuticals

RSC No. 96/8
Ernesto PREVIDI
Integrating Scientific Expertise into Regulatory Decision-Making.
L'organisation des responsabilités publiques et privées dans la régulation européenne des risques: un vide institutionnel entre les deux?

RSC No. 96/9
Josef FALKE
Integrating Scientific Expertise into Regulatory Decision-Making.
The Role of Non-governmental Standardization Organizations in the Regulation of Risks to Health and the Environment

*out of print