

2. Ausgabe / Number 2

Hanse Law Review (HanseLR)

ISSN 1863-5717



December / Dezember 2010

Jahrgang 6 / Volume 6

Special Issue/Sonderausgabe:

European Product Safety, Completion of the Internal Market and the New Approach to Technical Harmonisation and Standards – Reissued

Prof. Dr. Gert Brüggemeier, Prof. Dr. Josef Falke, Prof. Dr. Dr. h.c. Christian Joerges and Prof. Dr. Hans-W. Micklitz (Special Issue Editors / Herausgeber der Sonderausgabe)

Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz

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

Christian Joerges

Product Safety, Product Safety Policy and Product Safety Law

Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz

Examples of Product Safety Legislation

Josef Falke and Christian Joerges

The “Traditional” Law Approximation Policy Approaches to Removing Technical Barriers to Trade and Efforts at a “Horizontal” European Product Safety Policy

Josef Falke and Christian Joerges

The New Approach to Technical Harmonization and Standards, its Preparation through ECJ Case Law on Articles 30, 36 EEC and the Low-Voltage Directive, and the Clarification of its Operating Environment by the Single European Act

Christian Joerges and Hans-W. Micklitz

The Need to Supplement the New Approach to Technical Harmonization and Standards by a Coherent European Product Safety Policy

Christian Joerges and Hans-W. Micklitz

Completing the New Approach through a European Product Safety Policy

Hanse Law Review (HanseLR)

The E-Journal on European, International and Comparative Law

HANSE LAW REVIEW (HanseLR)

Editors in Chief:

Tobias Pinkel (Editorial Board), Rhea Psarros (Student Editor)

Editorial Board:

Franz Christian Ebert, Katharina Eisele, Maike Frommann,
Andreas Ritsch, Katharina Kühn, Soehnke Wagner

Student Editors:

Olga Herzenberg, Björn Hoops, Evelyn Krause, Lena Kröger,
Fabian Kuwert, Anne Hattenhauer, Jens Richter, Ricarda Rösch, Lea Schönfeld,
Max Schwartz, Sascia Siebs, Adeline Sozanski

<http://www.HanseLawReview.org>

Vol. 6 No. 2

Pages 107-406

24 December 2010

ISSN 1863-5717

Mail/Adresse: Hanse Law Review, Fachbereich Rechtswissenschaft, Gebäude GW 1
Universitätsallee, P.O. Box 33 04 40, 28334 Bremen

E-Mail: info@hanselawreview.org

Special Issue/Sonderausgabe

European Product Safety, Completion of the Internal Market and the New
Approach to Technical Harmonisation and Standards – Reissued

Europäische Produktsicherheit, Vollendung des Binnenmarktes und der neue
Ansatz zur technische Harmonisierung und Normung – Neudruck

Special Issue Editors/Herausgeber der Sonderausgabe**Gert Brüggemeier, Josef Falke, Christian Joerges and
Hans-W. Micklitz****Content/Inhalt**

Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz	
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards – Reissued	109
Abstract	107
Christian Joerges	
Product Safety, Product Safety Policy and Product Safety Law.....	117
Abstract	115
Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz	
Examples of Product Safety Legislation.....	137
Abstract	135
Josef Falke and Christian Joerges	
The “Traditional” Law Approximation Policy Approaches to Removing Technical Barriers to Trade and Efforts at a “Horizontal” European Product Safety Policy	239
Abstract	237
Josef Falke and Christian Joerges	
The New Approach to Technical Harmonization and Standards, its Preparation through ECJ Case Law on Articles 30, 36 EEC and the Low-Voltage Directive, and the Clarification of its Operating Environment by the Single European Act	289
Abstract	287
Christian Joerges and Hans-W. Micklitz	
The Need to Supplement the New Approach to Technical Harmonization and Standards by a Coherent European Product Safety Policy.....	351
Abstract	349
Christian Joerges and Hans-W. Micklitz	
Completing the New Approach through a European Product Safety Policy.....	383
Abstract	381

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

Gert Brüggemeier,^{} Josef Falke,^{**} Christian Joerges^{***} and
Hans-W. Micklitz^{****}*

Abstract Deutsch

Diese Einführung eröffnet die Sonderausgabe der Hanse Law Review mit einer frühen, aber keineswegs veralteten und bislang nur auf Deutsch zugänglichen Studie zum Verhältnis von Produktnormung und Produktsicherheit. Es handelt sich um die erste Untersuchung zu dem – damals – neuen Ansatz zur technischen Harmonisierung und Normung, in der dargelegt wurde, warum die Normungspolitik durch eine europäische Produktsicherheitspolitik ergänzt werden sollte und in welchen Formen dies geschehen kann. Die Analysen der Interdependenzen zwischen dem Abbau technischer Handelshemmnisse und der Entwicklung einer Produktsicherheitspolitik im Binnenmarkt sind auch heute noch von Bedeutung. Dem Kernanliegen hat die europäische Rechtspolitik mit der Verabschiedung der Richtlinie zur allgemeinen Produktsicherheit Rechnung getragen. Bestätigt hat sich dabei die grundsätzliche theoretische Einsicht, dass „Marktschaffung“ und „Marktregulierung“ zusammengehören. Die grundsätzliche Bedeutung dieser Maßnahme ist also auch darin zu sehen. Sie ist über Produktnormung und Produktsicherheitspolitik hinaus für alle Sektoren der Binnenmarktpolitik relevant.

^{*} Gert Brüggemeier, Professor (Emeritus) of Private Law, European Economic Law and Comparative Law at the University of Bremen.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{***} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

^{****} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

Abstract English

This article introduces its readers to the present special edition of the Hanse Law Review, which re-publishes a pioneering study on the interdependence between product standardisation and product safety. That study concerned the “new approach to technical harmonisation and standards”. Its main message is that the standardisation policy, which seeks to facilitate the free movement of goods, needs to be complemented by a Europe-wide product safety policy.

The study has so far been not been available in English. Its analyses and insights have paved the way for the adoption of the directive on general product safety. The theoretical arguments of the study are of exemplary importance. They concern the whole range of Europe’s internal market policies.

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

Gert Brüggemeier, Josef Falke,** Christian Joerges*** and
Hans-W. Micklitz*****

Preface and Acknowledgements

The present publication resulted from a study undertaken on behalf of the Commission of the European Communities (Directorate General XI) in the wake of the by now legendary “New approach to technical harmonisation and standards”.¹ Its original German version² was translated with the help of an additional Commission grant into English and French and then published as a series of Working Papers of the European University Institute, Florence.³ Since then very substantial changes have occurred, with the integration project in general and in the field under scrutiny here (1). And yet, all of these developments and changes notwithstanding, our study is not outdated but remains in many respects instructive (2). Last but not least, it left many traces in our later work (3).

1.

The most clearly visible effect for which our study has paved the – conceptual – ground is the Directive on general product safety. We had, most directly in Chapter V of our study⁴ pleaded for a public law complement to the European standardisation policy on the one hand and to the Directive on product liability of 1985⁵ on the other. To be sure and also

* Gert Brüggemeier, Professor (Emeritus) of Private Law, European Economic Law and Comparative Law at the University of Bremen.

** Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

*** Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

**** Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

¹ Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards, OJ C 136, 4.8.1985, 1 ff.

² Joerges, Christian, Josef Falke, Hans-W. Micklitz, Gert Brüggemeier, , *Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft*, Schriftenreihe des Zentrums für Europäische Rechtspolitik, Band 2, (Nomos, Baden-Baden, 1998).

³ Joerges, Christian, Josef Falke, Hans-W. Micklitz, Gert Brüggemeier, ‘European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards’, European University Institute Working Papers in Law, No. 1991/10-1991/14 (5 Volumes), San Domenico di Fiesole/FI 1991.

⁴ Vol. V in the WP Series: Christian Joerges, Hans-W. Micklitz, ‘The need to supplement the new approach to technical harmonisation and standards with a coherent European product safety policy’.

⁵ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, 29-33, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, OJ L 141, 4.6.1999, 20-21.

unsurprisingly, neither Directive 92/59⁶ on general product safety, as adopted in 1992 nor its amended version, Directive 2001/95⁷, realised all of our recommendations. It seems nevertheless remarkable that the Community legislature had recognised in principle that product safety needs to resort to a mix of policy instruments which allow for sensitive responses to public concerns. While the practical significance of the Directive we had helped to design can be questioned; the importance of the “new approach to technical harmonisation and standards on which we had commented extensively,⁸ can hardly be overestimated. It seems equally significant, that the revision of the New Approach, as undertaken in 2008,⁹ has in principle respected the need to accompany “market-making” by regulatory policies. The two regulations 764/2008¹⁰ and 765/2008¹¹ and the Decision 768/2008¹² established a general all-encompassing frame for the market surveillance of products and services which are not subject to more specific product related requirements as they are in place in particular for pharmaceuticals, pesticides and chemicals. The committee system to which we have resorted in our comments on the New Approach and our plea for a new regulatory instrument, has first been consolidated in Council Decision 87/373/EEC¹³ and is now, after the adoption of the Lisbon Treaty, envisaging quite dramatic changes.¹⁴ The EU rules on product liability as enshrined in Directive 85/374, remained untouched. Three major reports from the European Commission¹⁵ explored the need for reform and – at the end – found it to be superfluous.¹⁶ Some of these developments continue established patterns, while others are indicating shifts in regulatory strategies. Their future will depend on their potential to cope with the enormous challenges posed by the changing contexts to which they have to respond: the enlargement of the EU,

⁶ Council Directive 92/59/EEC of 29 June 1992 on general product safety, OJ L 228, 11.8.1992, 24-32.

⁷ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, 4-17.

⁸ See in particular Volume 4 of the WP series: Josef Falke, Christian Joerges, ‘The new approach to technical harmonisation and standards, its preparation through the ECJ case law on Articles 30, 36 EEC and the Low Voltage Directive, and the clarification of its operating environment by the Single European Act’ (chapter 4 of the present publication).

⁹ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. The Internal Market for Goods: a cornerstone of Europe’s competitiveness, COM(2007) 35 final, 14.2.2007.

¹⁰ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L 218, 13.8.2008, 21-29.

¹¹ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to marketing of products and repealing Regulation (EEC) No 339/934, OJ L 218, 13.8.2008, 30-47.

¹² Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, 82-128.

¹³ Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ L 197, 18.7.1987, 33-35, amended by Council Decision 1999/468/EC of 28 June 1999, OJ L 184, 17.7.1999, 23-26, amended by Council Decision 2006/512/EC of 17 July 2006, OJ L 200, 22.7.2006, 11-13.

¹⁴ Proposal for a Regulation of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, COM(2010) 83 final, 9.3.2010.

¹⁵ COM(95) 627 final, 13.12.1995, COM(2000) 893 final, 31.1.2001; COM(2006) 496 final, 14.9.2006. See further European Commission, Green Paper ‘Liability for defective products’, COM(99) 396 final, 28.7.1999.

¹⁶ In contrast to the Member States and the Council, see Council Resolution of 19 December 2002 on amendment of the liability for defective products Directive, OJ C 26, 4.2.2003, 2-3.

globalisation processes, the new trade patterns which are mainly induced by the growing economic power of China – it is estimated that the Union is importing 80% of its consumer products.

2.

While the implications of these new challenges are still unpredictable, it seems important to remain aware of the basic orientations and policy options of the establishment of the Internal Market. The most important decisions were taken and implemented in the 80s – and this is precisely the period which our study has examined in depth. We can indeed claim to have pioneered analyses of the interdependence of, and tensions between, the removal of “technical barriers to trade” on the one hand and the establishment of a European-wide product safety policy on the other. The Articles “Product Safety, Product Safety Policy and Product Safety Law” by *Christian Joerges*, “The ‘traditional’ law approximation policy approaches to removing technical barriers to trade and efforts at a ‘horizontal’ European product safety policy” by *Josef Falke* and *Christian Joerges*, “The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act”, by *Josef Falke* and *Christian Joerges*, and “The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy” by *Christian Joerges* and *Hans-W. Micklitz* of this volume describe, analyse and evaluate these moves and countermoves in detail: the debates on the relation between legislating on technical standards in directives and the generation of standards by private bodies, the legislature’s principled focus on laying down “essential safety requirements” and the delegation of their elaboration to non-governmental standardisation bodies; the institutional framework of this arrangements which was laid down in the Memorandum of Understanding between the European Commission and the European Standardisation Bodies, CEN and CENELEC.¹⁷ These arrangements were complemented by the comitology procedures which gained paradigmatic importance in the “political administration” of the internal market and were to pave the way for the Open Method of Co-ordination, the Lamfalussy procedure, and the recent Monti-Report.¹⁸ The legitimacy and the accountability of what was later presented and intensively discussed as “new modes of governance” was already at issue in the New Approach launched in 1985. Neither seem our analyses outdated nor do we see any reason to withdraw from our core argument: the establishment of market freedoms and the removal of barriers to trade does has to be accompanied by a genuine European product safety policy. Market integration needs to be socially and politically embedded. In hindsight we are becoming aware of the Polanyian touch in our argument which is today getting ever more important.¹⁹

¹⁷ This understanding was first established in 1984, and laid down in the General Guidelines for Cooperation between the European Commission and CEN and CENELEC, agreed on 13 November 1984, and published as CEN/ CENELEC Memorandum No 4, Part 1. See now General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association, OJ C 91, 16.4.2003, 7-11.

¹⁸ A new strategy for the single market at the service of Europe’s economy and society. Report to the President of the European Commission, available at http://ec.europa.eu/bepa/pdf/monti_report_final_10_05_2010_en.pdf.

¹⁹ Caporaso, James A. & Sydney Tarrow, ‘Polanyi in Brussels: European Institutions and the Embedding of Markets in Society’, [2009] 63 *International Organization* 593–620

The structure of the study seems still equally instructive. We have developed our argument in series of steps, starting with a discussion of the concept of product safety, comparative legal analyses, a reconstruction of the failures of Europe's traditional harmonisation policy, moving then to the "New Approach" and its interplay with both standardisation and the general duty to market only safe products, on the specific functions of product liability law and the need for effective post market control mechanisms. The core issues we have discussed – such as the concept of safety, the relation between technical and scientific knowledge on the one hand and the political assessments of safety concerns on the other, the tensions between market freedoms and social regulation protection – have remained topical. We would even suggest that the Europe's regulatory schemes in the field of financial services or internet services deserve to be revisited in the light of the experience gained in the regulation of product safety. It seems to us that product safety regulation is a case of exemplary importance for the future European integration process. Suffice it here to point again to the two regulations 764/2008 and 765/2008 and the Decision 768/2008, which generalize and develop further the regulatory philosophy enshrined in Directives 92/59 and 2001/95 on general product safety in that they establish a European-wide market surveillance mechanism.²⁰ The interrelation between statutory pre- and post market control on the one hand and liability in tort or via particular product liability rules on the other is gaining pace in the US and probably soon in Europe too.

To underline the exemplary importance of the concern for product safety in the establishment of Europe's internal market is not meant to downplay failures and difficulties. The legislative patterns and the web of regulatory instruments mirror the problematic of Europe's diversity. The Union did not manage to establish a European Product Safety Agency;²¹ there is no European forum for the discussion safety concerns and the co-ordination of the implementation of safety policies is far from perfect.

3.

One excuse for not making the English version of our study more easily accessible was the involvement of all of us in research issues which our study had helped to generate. When looking back at these activities we became aware of both the broadness of their scope *and* their inherent communalities.

- a) Gert Brüggemeier has dealt with the product liability section of the present study. He intensified his comparative research in the common law of torts and the civil laws of delict during the last decades; working on comparative liability law in general²², on personality rights²³ and on constitutionalisation of private law²⁴ especially. Recently he worked as a legal consultant to the legislative committee of the PR of China engaged in drafting an Act on the law of delict. So finally, although notoriously sceptical towards

²⁰ See notes 7-8 *supra*.

²¹ But there are agencies for certain categories of products: European Medicines Agency (EMA), European Food Safety Authority (EFSA), European Chemicals Agency (ECHA).

²² See, *inter alia*, his *Common Principles of Tort Law. A Pre-Statement of Law*, (British Institute of International and Comparative Law, London, 2004); *Haftungsrecht. Struktur, Prinzipien, Schutzbereich*, (Springer, Berlin, 2006).

²³ Gert Brüggemeier, Aurelia Colombi Ciacchi, Patrick O'Callaghan (eds.), *Personality Rights in European Tort Law*, (Cambridge University Press, Cambridge, 2010).

²⁴ Gert Brüggemeier, Giovanni Comandé, Aurelia Colombi-Ciacchi (eds.), *Fundamental Rights and Private Law in the European Union*, 2 vols., (Cambridge University Press, Cambridge, 2010).

European initiatives to unify the private law, he completed a model draft bill on civil liability law.²⁵

- b) Josef Falke coordinated on behalf of the European Commission and the EFTA Secretariat a comparative study on legal aspects of standardization in the Member States of the EC and the EFTA.²⁶ Further research activities were undertaken in the fields of comitology²⁷, international standards for the reduction of trade barriers and national concepts for health and safety policy,²⁸ standardization policy in the frame of the General Agreement on Trade in Services²⁹, a comparative analysis of institutions and procedures of risk assessment and risk management and revision of the New Approach on Technical Harmonization and Standards³⁰.
- c) Christian Joerges dedicated, first in a research project organised jointly with Josef Falke in Bremen, and then continued in Florence in collaboration with Ellen Vos, much energy to Europe's most mysterious institution, namely Comitology.³¹ This research lead with an inherent and irresistible logic to his research on Europe's turn to governance undertaken mostly at the EUI in Florence.³² Europeanization, however, can no longer be studied in isolation. The turn to the globalisation was hence unavoidable. That research is primarily undertaken in Bremen, gain in co-operation with Josef Falke – und still under way.³³

²⁵ See Brüggemeie, Gert, Zhu Yan, *Entwurf für ein chinesisches Haftungsgesetz – Text und Begründung: ein Beitrag zur internationalen Diskussion um die Reform des Haftungsrechts*, (Mohr Siebeck, Tübingen, 2009); *id.*, *Civil Liability Laws. Europe, China, Russia, and Brasil. Texts and Commentaries*, (Cambridge University Press, Cambridge, forthcoming 2010).

²⁶ Falke, Josef, Harm Schepel, *Legal Aspects of Standardisation in the Member States of the EC and EFTA, vol. I: Comparative Report*, (Publications Office of the EU, Luxembourg, 2000); *id.*, (eds), *Legal Aspects of Standardisation in the Member States of the EC and EFTA, vol. II: Country Reports*, (Publications Office of the EU, Luxembourg, 2000); Falke, Josef, *Rechtliche Aspekte der Normung in den EG-Mitgliedstaaten und der EFTA, Band 3: Deutschland*, (Publications Office of the EU, Luxembourg, 2000).

²⁷ Falke, Josef, 'Comitology and Other Committees: A Preliminary Assessment', in: R.H. Pedler, G.F. Schaefer (eds.), *Shaping European Law and Policy: The Role of Committees and Comitology in the Political Process*, (EIPA, Maastricht, 1996), 117-165; Falke, Josef, Gerd Winter, 'Management and Regulatory Committees in Executive Rule-making', in G. Winter (ed.), *Sources and Categories of European Union Law. A Comparative and Reform Perspective*, (Nomos, Baden-Baden, 1996), 645-675; *id.*, 'Comitology: From Small Councils to Complex Networks', in: M. Andenas, A. Türk (eds.), *Delegated Legislation and the Role of Committees in the EC*, (Kluwer, The Hague-London-Boston, 2000), 331-377.

²⁸ Falke, Josef, *Internationale Normen zum Abbau von Handelshemmnissen – Analyse der Abkommen und normungspolitischen Diskussion*, (Bericht 29 der Kommission Arbeitsschutz und Normung, Bonn 2001).

²⁹ Falke, Josef, 'Normung und Dienstleistungen. Anforderungen und Handlungsspielräume nach dem Allgemeinen Übereinkommen über den Handel mit Dienstleistungen (GATS)', ZERP-Diskussionspapier 1/2004.

³⁰ Falke, Josef, 'Management von Risiken technischer Produkte im Rahmen der Neuen Konzeption zur technischen Harmonisierung und Normung. Alte Prinzipien, empirische Erfahrungen und neue Orientierungen', in: A. Ciacchi, Ch. Godt, P. Rott, J. Smith (eds), *Liber amicorum Gert Brüggemeier*, (Nomos, Baden-Baden, 2009), 437-488.

³¹ Joerges, Christian, Josef Falke, *Das Ausschußwesen der Europäischen Union. Praxis der Risikoregulierung im Binnenmarkt und ihre rechtliche Verfassung*, (Nomos: Baden-Baden, 2000); Joerges, Christian, Ellen Vos, *EU Committees: Social Regulation, Law and Politics*, (Hart, Oxford-Portland, 1999; see previously, Joerges, Christian, Jürgen Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology', [1997] 3 *European Law Journal* 273-299.

³² See, in particular, Joerges, Christian, Yves Mény, J.H.H. Weiler, 'Mountain or Molehill? A Critical Appraisal of the Commission White Paper on Governance', *European University Institute-Robert Schumann Centre/ NYU School of Law-Jean Monnet Center* 2002, <http://www.eui.eu/RSCAS/Research/OnlineSymposia/Governance.shtml>; Joerges, Christian & Renaud Dehousse, *Good Governance in Europe's Integrated Market*. *Collected Courses of the Academy of European Law*, vol. XI/2, (Oxford University Press, Oxford, 2002).

³³ See Joerges, Christian, Inger-Johanne Sand, Gunther Teubner, *Transnational Governance and*

- d) Hans Micklitz focused in his post-1988 research first on post market control measures first in comparative perspectives,³⁴ then on the management of emergency procedures with particular emphasis on the multi-level structure of the EU.³⁵ In his habilitation thesis he dealt with product safety in the transnational economy.³⁶ Later research projects, concerned the liability for services³⁷ and product safety management in the Baltic Sea Alliance.³⁸

4.

We conclude quite confidently that our study has merits which militate in favour of its renewed publication. One additional aspect became apparent to us while we were looking back at our later work. We all continued to deal with problems we had identified in our common study. That impact is documented in the previous paragraphs. To a considerable degree, the dynamics of the field and our interest to follow its developments stood in the way of a book publication. The option of an online publication was simply not available in 1991. We are all the more grateful to the editors of the *Hanse Law Review* to provide us with that opportunity. We would like to express our gratitude to Ian F. Fraser who has shouldered the entire translation burden. The quality of his work deserves to become more widely visible and accessible.

Bremen and Florence, December 2010

Gert Brüggemeier, Josef Falke, Christian Joerges and Hans-W. Micklitz

Constitutionalism, (Hart, Oxford, 2004); Christian Joerges, Ernst-Ulrich Petersmann (eds.), *Constitutionalism, Multilevel Trade Governance and Social Regulation*, (Hart, Oxford: Hart, 2006), 2nd ed. Forthcoming 2010; Joerges, Christian, Josef Falke (eds.), *Karl Polanyi, Globalisation and the Potential of Law in Transnational Markets*, (Hart, Oxford, forthcoming 2010).

³⁴ Micklitz, Hans-W (ed.), *Post Market Control of Consumer Goods* (ZERP Schriftenreihe, Band 11), (Nomos, Baden-Baden, 1990):

³⁵ Micklitz, Hans-W, Thomas Roethe, Stephen Weatherill (eds.), *Federalism and Responsibility – A Study on Product Safety Law and Practice in the European Community*, Graham & Trotmann, London, 1994).

³⁶ Micklitz, Hans-W, *Internationales Produktsicherheitsrecht, Zur Begründung einer Rechtsverfassung für den Handel mit risikobehafteten Produkten* (ZERP Schriftenreihe, Band 21), (Nomos, Baden-Baden, 1996).

³⁷ Micklitz, Hans-W., *Liability of the Safety for Services* (VIEW Schriftenreihe, Band 21), (Nomos, Baden-Baden, 2006).

³⁸ Micklitz, Hans-W., Thomas. Roethe, *Produktsicherheit und Marktüberwachung im Ostseeraum – Rechtsrahmen und Vollzugspraxis* (VIEW Schriftenreihe, Band 26), (Nomos, Baden-Baden, 2008).

Product Safety, Product Safety Policy and Product Safety Law⁺

*Christian Joerges**

Abstract Deutsch

Mit der Etablierung der Produktsicherheitspolitik als eigenständiges Politikfeld in der Mitte des 20. Jahrhunderts haben sich verschiedene Instrumente zur Sicherstellung und Überwachung der Sicherheit von technischen Konsumgütern herausgebildet, die je spezifische Charakteristiken aufweisen. Der Autor untersucht diese Instrumente, deckt ihre Stärken und Schwächen auf und beleuchtet ihre Beziehungen zueinander. Zu diesem Zweck legt er zunächst sein Augenmerk auf das Erkennen der Risiken, die von technischen Konsumgütern ausgehen, wobei er dafür verschiedene Statistiken und Studien heranzieht. In einem zweiten Schritt wird analysiert, wie diese Daten aus verschiedenen Perspektiven bewertet werden können. Die Kriterien zur Evaluierung der Sicherheit eines Produktes sind niemals streitfrei; sie reagieren auf Anwendungskontexte, spiegeln aber theoretische Vorverständnisse, die sich in juristischen, politischen und ökonomischen Evaluationen niederschlagen und die Entwicklung der Instrumentarien der Produktsicherheitspolitik anleiten. Die Analyse der jeweiligen partikulären Funktionen, Einsatzgrenzen und Anwendungsproblemen erweist, dass die mannigfaltigen Maßnahmen der in der Praxis zur Anwendung kommenden Maßnahmen der Produktsicherheitspolitik unzureichend koordiniert bleiben.

⁺ This article has originally been published in 1991 as Chapter I, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 1, EUI Working Paper Law No. 91/10.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

Abstract English

Since the establishment of product safety as a new policy field in the middle of the twentieth century a variety of instruments for the ensuring and controlling of the safety of technical consumer products have been developed. The author analyses these instruments and their specific characteristics, describes their strengths and weaknesses and examines their mutual relationships. He departs from the identification of risks, which arise from technical consumer products, using for this purpose several available statistics and pertinent empirical studies. In a second step he analyses how these data are being evaluated from different viewpoints and hence can bias the assessment of the safety of a product. This dependence determines yardsticks of product safety policies and their implementation. The critical analyses of the particular functions, strengths and weaknesses of these instruments reveals, that the coordination of the instruments of product safety policies and their implemented has remained unsatisfactory.

Product Safety, Product Safety Policy and Product Safety Law⁺

*Christian Joerges**

Introduction

Questions of product safety alarm the public again and again. Information on the hazardousness of products used daily in household and leisure, short- and long-term environmental hazards, and risk associated with materials and technical faults at the workplace occupy the media, attract the attention of experts and provoke a search for the guilty and demands for remedial measures to be taken by the State.¹ In addition to concern about the hazards of large-scale technology, public attention is focused on dangers presented by medicines, foodstuffs and chemicals, whilst in comparison technical consumer products tend to offer less spectacular things to say.² The emphasis of socio-political and legal discussion is similarly distributed.³ Empirical research aimed at showing how attitudes towards hazards caused by technology change and at drafting appropriate recommendations for the policy treatment of such risks⁴ mainly covers large-scale technological projects. Legal science concentrates on the development of environmental law and new regulations, particularly on pharmaceutical products and also on chemicals. Against this background it is easy to forget that in the field of technical consumer products the results of large-scale and intensive accident research are available, that this research is indispensable in assisting companies to make decisions on the technical design of products and that regulations on the safety of technical consumer products have long since left behind them the naive notion of abstract safety standards which can be fulfilled completely. However, the key legal concepts expressing this realization sound more familiar, more small-scale and less ambitious. Product safety law is not concerned with threshold values, as in the case of law covering the environment, labour and foodstuffs or with “effectiveness” or “non-objection certificates” as in the case of pharmaceutical products, but with “generally accepted rules of the art” (“allgemein anerkannte Regeln der Technik”, § 3 of the Gerätesicherheitsgesetz) or with justified safety expectations which manufacturers have to comply with in accordance with the product liability Directive.

⁺ This article has originally been published in 1991 as Chapter I, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards – Vol. 1*, EUI Working Paper Law No. 91/10.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SFB597).

¹ See the colourful, though USA-related, examples given by *Feldman, L.P.*, *Consumer Protection. Problems and Prospects*, St. Paul/New York/Los Angeles/San Francisco 1980, 73 et seq.; *Lowrance, W.W.*, *Of Acceptable Risk. Science and the Determination of Safety*, Los Altos, Cal. 1976, 102 et seq.

² Though there are some counter-examples, the most prominent being *Nader, R.*, *Unsafe at Any Speed*, New York 1965.

³ Cf. for more details *Brügemeier, G./Falke, J./Holch-Treu, H./Joerges, Ch./Micklitz, H.-W.*, *Sicherheitsregulierung und EG-Integration*, Bremen ZERP-DP 3/84, 8 et seq.

⁴ Cf. *Paschen, H./Bechmann, G./Wingert B.*, *Funktionen und Leistungsfähigkeit des Technology Assessment im Rahmen der Technologiepolitik*, in: *Kruedener, J./Schubert, K. (Ed.)*, *Technikfolgen und sozialer Wandel, Zur Steuerbarkeit der Technik*, Köln 1981, 57 et seq.

There are objective reasons for these differences. The risks of nuclear power stations, the level of residual risk to be tolerated or the long-term effects of air pollution or food additives place different requirements on the identification and legal assessment of risks than do the dangers resulting from defective cots and playpens. Nevertheless, it would be illusory to imagine that the problems of technical consumer products are simple. The potential danger is considerable, and it can be just as difficult to assess the contribution of a construction feature towards accidents as it is to assess the health hazard of chemicals (see section 1 below). In connection with technical consumer products too we must ask which risks are unavoidable, which must be eliminated at all costs and which should be reduced through design requirements. The alignment of corresponding decisions to technical standards specifying general safety duties is equivalent to setting a threshold value establishing the extent of permissible risks in general terms (see section 2 below). And finally, a range of subtle and expensive instruments has also been developed for the purpose of regulating the safety of technical consumer products. The simple blanket clauses of safety laws in this area are entirely compatible with a regulatory practice which proceeds no less demandingly than is customary in the present-day regulation of health or environment hazards (see section 3 below).

1. The identification of risks

The potential danger of technical consumer products was for a long time underestimated or only rarely appreciated by the public. A change in attitude began to be noted in the fifties and sixties. As early as 1961 the United Kingdom passed a first product safety law (the Consumer Protection Act 1961),⁵ and in the Federal Republic of Germany the Act on Technical Work Materials (Gesetz über technische Arbeitsmittel) of 1968 (GtA) was replaced in 1979 by the Appliances Safety Act (Gerätesicherheitsgesetz) (GSG) which laid down a general safety obligation for technical consumer products;⁶ since 1983 France has had a general law on consumer safety (Loi No.83-660 relative à la sécurité des consommateurs)⁷. The sixties saw the development in the USA of a widespread social regulation movement which led to a large number of legislative measures.⁸ The establishing of the National Commission on Product Safety in 1968, one of the most popular successes of this movement, can be regarded as the birth of a modern product safety policy for technical consumer products.⁹

⁵ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 3.3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸ *Pertschuk, M.*, Revolt against Regulation. The Rise and Pause of the Consumer Movement, Berkeley/Los Angeles/London 1982, 5 et seq. and the summary in *Bollier, D./Claybrook, J.*, Freedom from Harm, Washington, D.C./New York 1986, 275 et seq.

⁹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 4.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; also OECD, Safety of Consumer Products. Policy and Legislation in OECD Member Countries, Paris 1980, 14 et seq.

1.1. Data

“Americans – twenty millions of them – are injured each year in the home as the result of incidents connected with consumer products. Of the total, 110,000 are permanently disabled, and 30,000 are killed. A significant number of them could have been spared if more attention had been paid to hazard reduction. The annual cost to the nation of product-related injuries may exceed \$5.5 billion”.¹⁰

This much-quoted passage from the final report of the National Commission on Product Safety on the potential hazards of technical consumer products refers to all accidents in which these products played “a role”. As a result, a number of States subsequently developed accident information systems aimed at systematically identifying the involvement of consumer products in accidents and the data¹¹ provided by these systems are as worrying as the National Commission on Product Safety’s figures.

In 1981 the Consumer Product Safety Commission reported that the use of consumer products had led to 33 million injuries and 28,000 deaths.¹² In Britain, where a start on preparing accident statistics was made in 1976 (England and Wales), the number of injuries requiring medical treatment is estimated at 3 million per year and the number of deaths at 7,000 per year.¹³ In the Netherlands, the 1985 annual report on the *Privé Ongevallen Registratie Systeem (PORS)* revealed that in 1984 there had been 633,000 accidents necessitating hospital treatment and 2,141 deaths.¹⁴ The European Commission estimates that in the Community as a whole there are more than 30,000 deaths and 40 million injuries each year, at an annual cost of over 30,000 million ECU.¹⁵

Shortly after publication of the National Commission on Product Safety’s final report, an alternative survey method was tried out in the form of a “Household Safety Study”¹⁶ financed by several American companies and government departments. In the first phase of the study 27,000 households were questioned about injuries and damage sustained during the past three months. In the second phase diary records of 22,000 households covering a similar period were evaluated. “Environment-linked” accidents were found to be the most

¹⁰ National Commission on Product Safety, Final Report Presented to the President and Congress, Washington, D.C. 1970, 1.

¹¹ Cf. OECD, Data Collection Systems Related to Injuries Involving Consumer Products. Report by the Committee on Consumer Policy, Paris 1978.

¹² Evidence of Commission Chairman S. Statler, given to the hearings before the Subcommittee on Health and Environment of the Committee on Energy and Commerce. House of Representatives, 98th Congress, First Session on H.R. 2271 and H.R. 2201, 5 and 12.3.1981, No. 97-4, Washington D.C. 1981, 321. For the bases of these estimates cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹³ Cf. Cmnd. 9302, The Safety of Goods, 1984, White Paper, para. 9, and details of the British system in *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 2.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁴ Cf. Stichting Consument en Veiligheid, Report of 1984 Data Home Accident Surveillance, Amsterdam 1985, 2 et seq., 10, 12, 46. The report “Veiligheid in de privésfeer” (Tweede Kamer, vergaderjaar 1983-84, 18.453), Nos. 1-2, 12, 17 et seq., estimates the dangers of accidents resulting from medical treatment at 2 to 2.6 million.

¹⁵ Cf. Section 6.2. of the report (COM (84) 735, section 6.2) on the model study attached to the Commission Proposal for a Council Decision on introducing a Community system of information on accidents in which consumer products are involved (7 January 1985); for further details see *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

¹⁶ Chicago 1972.

important category, with accidents in sport and play in second place; the user's own (mis-)behaviour was universally found to be a major factor in the cause of accidents. A similar method was adopted for a study of household and leisure accidents carried out in 1985 on behalf of the Government of the Federal Republic of Germany by the HUK (association of insurance companies).¹⁷

According to the findings of this study, 3 million home or leisure-time accidents requiring medical treatment or having an effect lasting for more than 14 days (and 100 million minor accidents) can be assumed for the Federal Republic of Germany,¹⁸ with 12,000 deaths per year. In order to be able to define the role of products more precisely, the study distinguishes between five accident categories. According to the study, only in the case of "handling" accidents, which account for 17% of accidents, are faulty appliances a potential cause; in practice they are responsible for still fewer, only 2% of all accidents. If cases of incorrect use are disregarded and a distinction made between old and new appliances, the figure falls still further. The conclusion is that "technical shortcomings on newly purchased machines, tools or other appliances are clearly an insignificant factor in the causes of household and leisure accidents".¹⁹

1.2. Recording problems

"Measuring" hazards is a science in itself. When developing accident information systems it is necessary to reflect on whether data should be collected from hospital accident units and/or doctors' surgeries, how a representative sample can be obtained, to what level of detail information on the nature of injuries, the victims and the circumstances of the accident can be collected, and which product categories it would be useful to distinguish²⁰. However, the data collected after clarification of all these questions still do not permit any definite conclusions on how dangerous products are. As well as the accident rate, the seriousness of injuries is also important. It is very difficult to grade and assess injuries. In the USA, the National Electronic Injury Surveillance System (NEISS) uses an Age-Adjusted Frequency-Severity Index for this purpose, taking into account not only the accident figures for individual product categories, but also the average nature of injuries, with an additional distinction by user age;²¹ as of late, accident-related economic costs are also calculated, using an Injury Cost Model.

The "measuring" of product hazards can be taken even further. It seems logical for critics of the NEISS to insist that intensity of product use be considered or to call for

¹⁷ *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985; cf. for more details *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁸ *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 4 et seq.

¹⁹ *Loc. cit.*, 190.

²⁰ Cf. OECD, Data Collection Systems Related to Injuries Involving Consumer Products. Report by the Committee on Consumer Policy, Paris 1978, 27 et seq. and the two preliminary studies published in the Netherlands on the extension of the PORS *Bruggers, J.H.A./Rogmans, W.H.J.*, Registratie van Ongevallen in de privésfeer, Veiligheids Instituut, Amsterdam 1982 and *Rogmans, W.H.J.*, Ernst en omvang van Ongevallen in den privéseer, Veiligheids Instituut, Amsterdam 1982.

²¹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 4.2.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> and by way of comparison the OECD report, Severity Weighting, 1979.

epidemiological studies which would provide more accurate statistical information on the extent to which specific population groups are affected, or for the US Product Safety Commission itself to test new procedures for gathering data on causes of accidents.²² But accident circumstances are extraordinarily complex.²³ They are influenced both by permanent and fortuitous background factors (physiological and psychological capabilities and environmental factors on the one hand, and personal factors such as illnesses and external circumstances on the other), and by unexpected events which distract the person's attention or disturb his concentration. Product quality, the effect of normal wear on the same, and sudden faults are no more than contributing factors to a complex process. Consequently, accident information systems can treat the data they collect on the involvement of products in accidents only as an impulse for more detailed follow-up studies of typical accident patterns or individual accident circumstances – the only way to obtain true information on the contribution of design features towards accidents. Such studies inevitably lead to a question of appraisal: as soon as statements on the hazardousness of products are no longer limited to statistical connections between product characteristics and accidents, in other words where the safety of products is to be judged, a distinction has to be drawn between the spheres of responsibility of manufacturers and users. We shall return to this subject presently.

The difficult measurement and classification problems encountered in developing and applying accident information systems cannot be evaded by alternative study methods either. The example of the HUK study and its conclusion brings this difficulty out. While the survey method used there does allow all accidents to be taken into account and distortions to the data resulting from concentrating on hospital accident units to be excluded, the involvement of hospitals has the advantage that a suitably trained external observer can record the relevant data immediately after an accident (particularly useful in the case of accidents involving children). A survey, by contrast, depends on the psychological skill of the interviewer and the ability of the interviewee to express himself and remember things accurately, which means that in some cases, particularly accidents to children, no reliable information can be obtained. The most important advantage of accident information systems over later surveys is however probably that they rule out one severe source of error, namely the victims' memory or forgetfulness.²⁴

But the HUK study not only aims to measure hazards, but at the same time pursues the ambitious goal of assessing the safety of products. For this purpose a very small number of "case studies" were carried out, with the cases selected from among the handling accidents. These studies, based on the interviews with the persons concerned, contain some very firm assessments (users chose "easy alternatives", acted "carelessly", "did not pay attention",

²² Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

²³ Cf. Netherlands report "Veiligheid in de privésfeer", (fn. 14 above), 21, and *Compes, P.C.*, Sicherheitsstrategie und -taktik in der Privatsphäre, Einführung in die Problematik, in: *Unfall-Risiken der Privatsphäre. Epidemiologie - Diagnose - Prävention*, VI. Internationales GfS-Sommer-Symposium, 3.-5. Juni 1985, Wuppertal 1986, 59 et seq. and *Gürtler, H.*, Standard-Unfallhergänge im Hausbereich. Bedingungsgefüge - Ablauf - Folgen, in: *Unfall-Risiken der Privatsphäre. Epidemiologie - Prävention*, VI. Internationales GfS-Sommer Symposium, 3.-5. Juni 1985, Wuppertal 1986, 83 et seq.

²⁴ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

“were thinking about television”, “were trying to carry too much luggage”, “selected an unsuitable position”, or “were distracted by children”).²⁵ Such assessments are no doubt unavoidable in evaluating product safety. But simply questioning accident victims is a very poor basis for making judgments. A pilot study by the US Consumer Product Safety Commission²⁶ shows that only 27% of accident victims surveyed were capable of answering the question whether their accident should be attributed to a product defect, to the age of the product, to its design, to their own errors, personal inadequacies or environmental factors.²⁷ It also stresses that the interaction between survey personnel and respondents influences the findings in ways that are hard to calculate, that there is a tendency on the part of accident victims to blame themselves, that it is, above all, unrealistic to expect reliable, appropriate statements on product defects, still less design faults, from users, and that therefore interviewers must be trained not only psychologically, but also technically. Clearly, therefore, a product hazard survey that is not only to measure the involvement of products in accidents but also to supply conclusions as to causes and responsibilities has to be a much more sophisticated matter than the HUK study has been.

2. Assessment of hazards

According to the well-known statement by W.W. Lowrance, “a thing is safe if its attendant risks are judged to be acceptable”.²⁸ The references to the limitations of accident information systems and the weaknesses of the HUK study will no doubt have demonstrated the importance of the distinction between identifying the hazards of products and assessing their safety. “Safety” is a normative concept and cannot be assessed by a generally applicable unequivocal formula. Safety assessment procedures must therefore be flexible, above all because the hazards to be assessed vary tremendously in nature and intensity.

2.1. “Proper use”, “foreseeable use”, “foreseeable misuse”, “unreasonable risk of injury”

In the legal policy debate on consumer product safety, the distinction between “proper” and “foreseeable use” or “misuse” plays a central role. The distinctions represent intuitively

²⁵ Pfundt, K. op. cit. (fn. 17), 1985, 99, 101, 105, 119. Such assessments can be found even in cases that have elsewhere led to governmental regulations. Thus, the section on lawnmowers states that the majority of accidents were caused by blades that were running or slowing down, but it states even earlier that the machine is dangerous not during mowing as such, but when stopping, starting or being cleaned (loc. cit., 136). It was precisely these characteristics that led in the US to the development of relevant safety standards (see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.3.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>).

²⁶ US Consumer Product Safety Commission, Division of Hazard and Injury Data Systems: Results of a Pilot Study to Collect Causal Data from Victims Treated in Hospital-Emergency-Rooms for Product-Related Injuries from April 15, 1985 through April 28, 1985, Washington, D.C. 1985.

²⁷ All the same, 10% of those questioned identified manufacturing or design faults as causes of accidents. This very high proportion by comparison with the findings of the HUK study is a further indication of the relevance of forgetfulness in the case of retrospective studies. In 11% of cases, product misuse was seen as the cause of an accident; 42% of these, though, concerned children under ten, whose “mistakes” were in part typical childish behaviour.

²⁸ *Lowrance, W.W.*, Of Acceptable Risk. Science and the Determination of Safety, Los Altos, Cal. 1976, 75; similarly cf. e.g. OECD, Product Safety. Risk Management and Cost-Benefit-Analysis, Paris 1983, 13.

plausible demarcations of the spheres of responsibility of manufacturers and users. Those who would like to see the responsibility of manufacturers limited to cases where products are put to their proper use plead for predictability and delimitation of liability, and at the same time appeal to the independence and judiciousness of users. Those who on the other hand wish to make manufacturers take account of foreseeable misuse are quickly accused of adopting paternalistic attitudes, and seem to assume that technical progress tends to place excessive demands on users. Between the two extremes of proper use and foreseeable misuse lies the category “foreseeable use”. This compromise formula allows the manufacturer to be made liable in cases where, for example, his subjective definition of the use of his products does not correspond to the “normal” use; on the other hand, the user's own responsibility in the case of a foreseeable but “unreasonable” use is established.

The legal discussions on these divisions have an important fundamental meaning, but their practical significance is limited. The abandoning of “proper” use as the basis for manufacturer's liability acknowledges that what safety law is about is social protection, which no manufacturer can determine unilaterally by laying down what “proper use” is, nor any consumer ignore in making his purchase decisions. In this context the abandoning of the criterion of proper use is fundamental, and there is general agreement on this.

However, § 3 (1) of the German GSG explicitly protects the user of technical consumer products only where they are put to their “proper use” and also refers to the “generally accepted rules of the art”. In explaining the phrase “proper use”, § 2 (5) of the GSG does, however, state that this is either the use specified by the manufacturer or the “normal” one for the product. These criteria may clash; accordingly, the reference to “normal use” means that the manufacturer no longer has the power to “define” the care to be expected from users of his product.²⁹ Even more importantly, especially in connection with safety matters, the relevant standards (DIN 820, Part 12, and DIN 31.000/VDE 1000) lay down more stringent requirements, specifying that “foreseeable misuse” must be taken into account. This amendment to § 3 (1) of the GSG on the assessment of safety aspects corresponds to the general trend in present-day safety legislation and product and manufacturers' liability law.³⁰

Whilst it is important to retain this basic consensus on safety policy, it is difficult on the other hand to deduce precise criteria for establishing the appropriate safety level from the alternatives to “proper use”. All norms are both capable of being interpreted and in need of interpretation. If, as required by DIN 820, Part 12 and DIN 31.000/VDE 1000, foreseeable misuse must be taken into account, a decision must be made on whether and to what extent this has to be done at the product design stage (“direct safety technique”) or whether other protective measures are needed (“indirect safety technique”), or whether safety information should be sufficient (“indicatory safety technique”).³¹ The concept of “foreseeable” use

²⁹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3.3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

³⁰ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> and on European Law *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

³¹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3.5. Online available at: <http://www.hanselawreview.org/pdf10/>

leaves similar room for interpretation. Whilst Article 1 of the French Consumer Safety Act of 21 July 1983³² refers to “conditions reasonably foreseeable by an expert” and the level of safety which can “legitimately” be expected, a decision is still required on the degree of anticipation to be required of the manufacturer and where the limits of legitimate consumer expectations lie. The fact that such decisions involve a difficult compromise between hazard avoidance, technical possibilities and economic constraints is well known from product liability law.³³

In the face of these problems the American Consumer Product Safety Act 1972 has contented itself, in § 1 (b)(2), with describing the aim of the legal regulations as protecting the consumer against an “unreasonable risk of injury”. It is evident from the background material, though not from the text of the Act itself, that a multiplicity of factors are to be balanced against each other: the likelihood of damage, its severity, the usefulness of products, the costs of antihazard measures, but also the obviousness of dangers, so that the question of the user’s own responsibility remains an essential and legitimate aspect.³⁴

As a result, terms such as “foreseeable use” and “foreseeable misuse” are certainly helpful in developing safety standards and in offering some guidance to courts and competent authorities.³⁵ At the same time, however, the need to adapt these terms shows that in order to be able to specify the appropriate safety level, a whole series of further aspects must be considered and assessed.

2.2 Hazard assessment, freedom of decision and cost-benefit analyses

The contrast between the “paternalistic” protection of the consumer against his own foreseeable incorrect behaviour on the one hand and insistence on the consumer’s own responsibility in the case of incorrect use of products is a permanent feature of the entire debate on the justification for and limits of product regulation by the State. The contrast between “paternalism” and “own responsibility” also takes the form of a dispute between political and moral judgement on the one hand and economic rationality concepts on the other. But not only have new terms been invented in these debates; relevant framework conditions for an appropriate decision on the level of safety have also been reconsidered.

[Vol6No02Art03.pdf](#).

³² Journal Officiel 115 No. 168, 2261; cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

³³ Cf. for details *Brüggemeier, G.*, *Deliktsrecht. Ein Hand- und Lehrbuch*, Baden-Baden 1986, para. 544 et seq.

³⁴ For details on the difficulties of interpreting the “unreasonable risk” test, see *Hoffmann, M.E.*, The Consumer Product Safety Commission: In Search of a Regulatory Pattern, *Columbia J. of Law and Social Problems* 12 (1976), 393, 401 et seq.; see also *LaMaccia, J.T.*, The Consumer Product Safety Act: Risk Classifications and Product Liability, *Indiana L. Rev.* 8 (1985), 846, 849 et seq.

³⁵ This debate is therefore fully documented; cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> for French law, *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.6.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> for British law and *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf> and *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.3. for European law. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

2.2.1. Political and moral hazard assessments

As soon as the safety level of technical consumer products is recognized as a normative decision problem, the question of the rationality of the procedures concerned has to be settled whilst at the same time the selection of a particular decision procedure also affects the criteria taken into account to arrive at a decision.³⁶ As long as the manufacturer does not have to comply with a specific safety level and consumers may define their own safety interests and are themselves responsible for observing the same, the safety level will remain a function of supply and demand decisions.

On the other hand, if the “accepted” state of the art is to be regarded as the binding minimum norm, the logical consequence is to make technical experts responsible for laying down these rules.³⁷ Finally, anyone who does not wish to leave safety decisions to market forces, but also does not wish to abide by the average level or the state of the art and sees the guaranteeing of safety as a political task will assign this task to either State authorities or independent agencies.

R. B. Lave has drafted a list of how such agencies can be used.³⁸ The elimination of hazards by strict bans can be called for, but as a rule such bans quickly turn out to be unenforceable. The best available technology can be demanded, but this norm too is usually controversial and particularly in the case of technical consumer products would be an illusion. Another possibility is to balance the health risks for a product against its uses, either ignoring or taking particular heed of economic factors; this means that in the first case the decision is based on safety criteria only, whilst in the second case all socially relevant factors will be considered. Even if in the latter case the decision framework remains discretionary, it is suitable for application in connection with consumer product safety regulation. The technical complexity and hazards of such products vary considerably. Some are essential despite inherent dangers, e.g. kitchen knives. Sometimes there can be a dispute about how necessary products are, as in the case of the banning of skateboards in Norway.³⁹ The ability to come to terms with hazards varies from one age group to another, as a result of which design safety demands also differ. Finally, the effects of safety requirements on production costs and selling prices do not just have an economic significance. They can put products beyond the means of specific population groups and thus have a discriminatory effect.

This large number of potentially relevant aspects does not exclude appropriate structuring of the decision process. This is illustrated by the OECD report on “Product Safety, Risk Management and Cost-Benefit Analysis”,⁴⁰ which distinguishes six groups of considerations: general aspects of the product concerned (in particular its distribution and its usefulness); technical characteristics (including a check on technically possible alternatives); analysis of hazards attributable to design or misuse respectively; analysis of hazards due to the organization of the production process rather than to design;

³⁶ Cf. in particular *Lave, L.B.*, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, D.C. 1981, 8 et seq.

³⁷ Consistently, DIN 31.000/VDE 1000 says that in case of doubt safety requirements take priority over economic considerations.

³⁸ *Lave, L.B.*, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, D.C. 1981, 8 et seq.

³⁹ Cf. OECD, *Product Safety. Risk Management and Cost-Benefit-Analysis*, Paris 1983, 34 et seq.

⁴⁰ *Loc. cit.*, 45-51; a more general and even more sophisticated list is provided by *Lowrance, W.W.*, *Of Acceptable Risk. Science and the Determination of Safety*, Los Altos, Cal. 1976, 86 et seq.

differentiation by age groups, recognizability of dangers, likelihood of misuse; increased costs resulting from safety requirements and anticipated economic effect of a reduction of hazards.

2.2.2. Economic rationality criteria

In view of the intangible nature of normative safety policy decisions, the search for “objective” decision-making criteria is certainly understandable. The current call, particularly in the USA, for safety policy to be brought into line with cost-benefit analyses is often combined with a promise of clear and rational decision-making criteria. Cost-benefit analyses are seen as an instrument of regulation. However, the criteria of such analyses are linked to a view of the safety problem derived specifically from the market economy, namely the conceptualization of the “optimal” safety level as an economically rational decision balancing the cost and benefit of safety. Microeconomically, this means that the usefulness of safety measures is to be measured in terms of willingness to pay for a reduction of hazards that entails costs. A cost-benefit analysis of safety measures cannot take account of individual safety decisions (readiness to accept costs), as the cost and benefit of such measures affect consumers as a whole (and not always to the same extent). Cost and benefit must each be summated, and the conceptualization of the safety problem as an economic problem then means that the total cost of a measure should not in any event exceed its total benefit.⁴¹

As far as the cost side is concerned, quantification can be based on the anticipated effect of a measure on the market price of the products concerned. Limitations on usability (e.g. time taken to open safety locks, etc.) and costs of implementing a regulation must be estimated, whilst on the other hand the medium- or long-term scale advantages which the introduction of a universally binding safety standard may bring must also be taken into account. It is still harder to quantify benefit. In addition to savings on medical costs and wage payments to sick workers, the suffering of potential victims must also be quantified; the American Consumer Product Safety Commission bases its findings on solatia awarded by American juries⁴², whereas the corresponding “benefit” in Europe would be considerably lower. The most familiar quantification problems concern deaths. One way is to use loss of income, but more widespread is recourse to wage differences between hazardous and less hazardous occupations, since an approach can be based on observable behaviour patterns on (labour) markets.⁴³

Taking a position in principle on the application of cost-benefit analysis to problems of safety regulation serves little purpose unless we go into the details of the different variants of this analysis method. However, a thorough cost-benefit analysis indisputably involves considerable expense, is often based on very unreliable estimates⁴⁴ and does not take

⁴¹ Out of the extensive literature available, cf. *Miller III, J.C./Yandle, B.* (eds.), *Benefit-Cost Analyses of Social Regulation*, Washington, D.C. 1979; a brief introduction can be found in OECD, *Product Safety. Risk Management and Cost-Benefit-Analysis*, Paris 1983, 63 et seq.

⁴² Non-authorized memorandum of the US Consumer Product Safety Commission of 25 February 1986 by P.H. Rubin, 3.

⁴³ A summary of the situation can be found in *Viscusi, W.K.*, *Risk by Choice. Regulating Health and Safety in the Workplace*, Cambridge, Mass./London 1983, 93 et seq.

⁴⁴ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 4.3.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> (lawnmowers) and 4.3.2 (formaldehyde) and the examples in OECD, *Product Safety. Risk*

account of possible distributive effects or the effects of regulations on competition; furthermore, criteria for calculating benefit in cash have to abstract from individual suffering, so that cost-benefit calculation requires willingness by the decision-maker to take an abstract approach.

3. Instruments of Safety Regulation

The spectrum of regulatory action is wide, and the possibilities include preventive approval regulations, performance standards, certification procedures, voluntary standards and safety symbols, warnings, safety campaigns, follow-up market controls (recalls and bans) and rules on liability. Employment of all these instruments is dependent on prior strategic and conceptual thinking. Product hazards can be reduced preventively by product bans, compulsory safety regulations or standards and certification requirements, as well as by information campaigns and, especially at work, by training measures. Liability rules, follow-up market control measures and safety-conscious purchasing advice also have an indirect effect on the safety level of products. However, in practice the decision on which of these possibilities to apply is very much subject to objective constraints. The most obvious of these is a direct result of the area concerned: the number and diversity of technical consumer products, technical progress and the different behaviour patterns and protective interests of users make positive regulation of all safety aspects of consumer products impracticable. Accordingly, if only for pragmatic reasons, it is advisable to assess the efficiency and performance limitations of the market mechanism before introducing any regulatory measures.

3.1. Self-regulation by the market and market-complementary regulation

Markets too are regulatory mechanisms. Their particular characteristic is that they do not specify the “regulatory outcome”, but rely on the supply-and-demand discovery process. It can be shown that under certain circumstances markets bring about an optimum allocation of resources. This applies to the price-performance relationship in general and therefore also to the safety level of products. Here too it is a matter of weighing up benefit and cost in order to decide which safety precautions are economically viable and which hazards should be tolerated. However, the market process brings optimum results only under certain model conditions which in practice are difficult to guarantee, particularly as far as the level of safety is concerned.⁴⁵ This is particularly true of the rationality of consumers’ safety decision.⁴⁶ Only a “fully” informed decision would be economically rational. This condition is sometimes followed strictly, sometimes less so. It will certainly not be fulfilled, in fact it cannot be fulfilled, as long as the stage reached by medical research does not permit conclusions on health hazards. On the other hand this condition is not sufficient in cases where the user of a product endangers not only himself, but others as well. “Normal” cases are more difficult to assess. The hazards are recognizable, but the user does not bother to obtain the information, for reasons of economy or convenience. Attention is drawn to

Management and Cost-Benefit-Analysis, Paris 1983, 79 et seq.

⁴⁵ Cf. Oi, 1973; *Streit, M.E.*, Reassessing Consumer Safety Regulation, in: Giersch, H. (ed.), *New Opportunities for Entrepreneurship*, Tübingen 1984, 190 et seq.

⁴⁶ This is even conceded by *Viscusi, W.K.*, *Regulating Consumer Product Safety*, Washington D.C./London 1984, 5 et seq.

hazards, but the information cannot be processed; hazards are seen but ignored, since “bad things always happen to the other guy”.⁴⁷ In addition, suppliers can put such cases of “information failure” to strategic use. In any event we should not expect product advertising to draw attention to hazards, and we must not automatically assume that a high level of safety is always beneficial to the supplier.⁴⁸

3.1.1. Information policy measures

If under certain circumstances markets produce an optimum level of safety, the logical consequence is to react to safety problems primarily by means of regulative strategies aiming to guarantee the functional conditions of the market process. The policy of informing the consumer then has priority, especially as the individual consumer then has the freedom to make the best decision to suit his purposes. The actual organization of such measures is in fact difficult and their effectiveness often questionable.⁴⁹ In order to “fully” compensate for information deficits, information should be supplied to the consumer in such a way that he can recognize and take notice of it. Simplification may help where receptiveness is limited, but information must also be expressed in a suitably explicit manner in order to overcome tendencies to ignore it. However, as shown by the example of the warning on swimming pool slides required by the Consumer Product Safety Commission,⁵⁰ these objectives may conflict; for instance, information in restrained form may be ineffective from the safety point of view, whilst effective information may have a dubious effect from the point of view of competition.

Such conflicts can also occur in the case of broader information policy measures. Safety symbols can under certain circumstances be awarded or product tests designed in such a way as to provide simple and reliable safety information without unfairly distorting the competition process on the supply side. However, the safety effect of such measures is dependent on a large number of peripheral conditions.⁵¹ Finally, whilst general information campaigns in principle reach all persons potentially concerned, they are a regulatory instrument with a tendency to go beyond the framework of an information policy aiming to optimize market processes.⁵²

3.1.2. Product liability

A manufacturer’s strict liability for defective products constitutes, from the viewpoint of economic analysis of liability law, a form of compulsory insurance of consumers against particular hazards involved in the use of products; the customer’s freedom to choose “uninsured”, but cheaper, products and to rely on his own care in using the product is thus

⁴⁷ Calabresi, G., *The Costs of Accident*, New Haven/London 1970, 56.

⁴⁸ Cf. Akerlof, G.A., *Market for Lemons: Quality and the Market Mechanism*, *Quarterly J. of Economics* 84 (1970), 488 et seq.

⁴⁹ For the up-to-date situation cf. Dedler, K./Gottschalk, J./Grunert, K.G./Heiderich, M./Hoffmann, A.L./Scherhorn, G., *Das Informationsdefizit der Verbraucher*, Frankfurt/New York 1984.

⁵⁰ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 4.3.2.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁵¹ Cf. Silberer, G./Raffée, H., *Warentest und Konsument*, Frankfurt/New York 1984.

⁵² Cf. Mayer, L.N./Nicosia, F.M., *Consumer Information: Sources, Audiences, and Social Effect*, in: Katz, R.N. (ed.), *Protecting the Consumer Interest*, Cambridge, Mass. 1976, 41 et seq.

lost.⁵³ However, the obligation on the manufacturer to take responsibility is only an incentive to reduce product hazards. It remains up to the manufacturer what steps he takes in response: design changes, liability insurance, waiting and seeing. This indirect mode of operation of liability law, which exploits the market mechanism, explains why product liability is often interpreted as a “pro-market” alternative to direct government regulation of product safety, and recommended as such.

The actual effects of product liability on the level of safety of consumer products depend on the details of liability, the treatment of development hazards, the requirements in respect of proving a connection between product defects and damage, the level of penalties and consequences of co-responsibility, etc. Moreover, only an analysis of these detailed regulations can show how far product liability in fact relies on the logic of the market process, and how far it additionally switches risks according to criteria of social acceptability. There are also other various factors which, independently of the more detailed legal aspects of liability, restrict its regulatory effects.⁵⁴ First of all it is highly doubtful whether penalties under liability law are or ever can be so formulated as to produce the required safety policy effects. At any rate the “signals” of product liability law are rather too irrational; for example, in the case of injuries to children a death can be “cheaper” than a serious injury. Secondly, the reactions of firms to claims for damages depend on contingent circumstances: the competition situation on relevant markets, the internal organization structures and financial strength of the firm concerned, and its willingness not to simply ignore the possibility of future penalties in favour of sure short-term advantages. A third cause is the insurability of the liability risk. Insurance premiums are obviously not specifically matched to risk. It seems possible to make distinctions only between branches or product groups, as adapting premiums to product-specific risk factors in all cases would not be compatible with the philosophy of insurance protection, nor in any case with insurance practice.⁵⁵ A fourth weakness of manufacturers’ liability stems from the extreme selectivity of the private prosecution system. The law covering manufacturers’ liability can neither guarantee that injured parties will take upon themselves the trouble and financial risk of a private prosecution, nor can or should it exclude out-of-court settlements.⁵⁶

3.2. Product standards

The weaknesses of information policy and product liability law mean that in principle the justification for preventive safety regulations is undisputed. It is also undisputed that the technical complexity of product regulations and of continually adapting them to technical progress is beyond the means of general parliamentary legislation procedures, meaning that the task of introducing specific regulations has to be delegated. In this connection there are ideally two alternatives: the introduction of legally binding safety regulations by specialized public agencies, or the introduction of self-administered safety norms by the

⁵³ Cf. on economic analysis of product liability, *Adams, M.*, *Ökonomische Analyse der Gefährdungs- und Verschuldenshaftung*, Heidelberg 1985, 17 et seq.

⁵⁴ Cf. *Pierce, R.J.*, *Encouraging Safety: The Tort Limits of Tort Law and Government Regulation*, *Vanderbilt L. Rev.* 33 (1980), 1281 et seq., *Sugarman, S.D.*, *Doing Away with Tort Law*, *California L. Rev.* 73 (1985), 558 et seq.; *Eads, G./Reuter, P.*, *Designing Safe Products. Corporate Responses to Product Liability Law and Regulation*, Santa Monica, Cal. 1983.

⁵⁵ See also *Schäfer, H.-B./Ott, C.*, *Lehrbuch der ökonomischen Analyse des Zivilrechts*, Berlin 1986.

⁵⁶ *Ramsay, J.D.C.*, *Rationales for Intervention in the Consumer Marketplace*. Office of Fair Trading, London 1984.

industry concerned. However, in practice these ideal alternatives are not encountered; product regulation is dominated by hybrid systems with a tendency towards “corporatism”.

3.2.1. Mandatory product standards

As the assurance of safety is one of the duties of the State, it would appear logical to make State authorities responsible for drafting product regulations. This is the path followed by modern product safety laws. The UK Consumer Protection Act 1961 delegated the issuing of safety regulations to the executive authorities, giving Parliament only the right to participate in the process, and the right of subsequent annulment.⁵⁷ In the USA the Consumer Product Safety Act, in its original version of 1972, went even further. It set up, in the form of the Consumer Product Safety Commission, a State agency (though protected from the direct control of the House of Representatives or the Administration), which was allowed to fix its own priorities and draft its own regulations.⁵⁸ The practical and organizational problems of such an allocation of responsibilities match the complexity of a comprehensive normative assessment of hazards.⁵⁹ For such an assessment it is first of all necessary to “measure” risks, i.e. to develop an information system for the identification of product hazards. A second precondition is that the authority concerned should be competent, from the technical and scientific point of view, to assess design characteristics of technical consumer products, to identify any risks and develop technically feasible requirements aimed at reducing the risk. A third precondition is that it should be competent, from the economic and sociological viewpoints, to assess the social consequences, implications for competition policy, costs and benefits of a regulation. Authorities invested with only legal competence to pass product regulations are not in a position, or if so only to a limited extent, to carry out a comprehensive assessment of risks.

Technical safety legislation has nowhere made adequate provision for the assessment of risks, whether in organizational or in technical terms. In the UK, the CPA 1961 was based on State adoption of standards drafted by the competent institutions and did not seek to set up independent administration for the implementation of safety regulations; these shortcomings were only partly counterbalanced by later measures.⁶⁰ In the USA, the CPSC was set up taking into account the preconditions for drafting product regulations. However, there too the available resources meant that from the outset only selective action was possible; above all, the legal and technical fields of responsibility of the CPSC were subsequently reduced to such an extent that the Commission’s role was limited to merely supervising standards drafted by the standards institutions, in sharp contrast to original intention.⁶¹

⁵⁷ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 2.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁵⁸ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 4.1.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁵⁹ See 2.2.1 above.

⁶⁰ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 2.2. and 2.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶¹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 4.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

3.2.2. Technical norms

The normative aspect of safety assessment does not become any simpler when responsibility for drafting product standards is transferred to private organizations, and the practical and organizational advantages of reducing the burden on the legislative process in this way are offset by an endangering of the normative quality of safety regulations. In the past the impulse for the “voluntary” introduction of product standards came from the development of industrial mass production, as the need for technical standardization became essential so that it would be possible to interchange and combine production elements.⁶² This function of private standardization is still valid, but has become more and more caught up in the whirlpool of society’s increasing demands that “technical” solutions take account of safety and environmental aspects.⁶³ The basis for criticism is as simple as it is obvious:⁶⁴ as long as the industries concerned are themselves responsible for standards, genuine consideration of safety and environmental aspects cannot be expected. The justification of such reservations about self-regulation as opposed to State regulation is in principle generally acknowledged. It is therefore also generally accepted that such a transfer of decision-making functions must be compensated for by laying down special requirements for the drafting of standards, which in particular must guarantee a “balanced” representation of all interests concerned in the standardization process and the consideration of “social” requirements, among them safety.⁶⁵ Finally, it is recognized that the State should remain in a position to set safety priorities and that standards should not become legally binding until they have been through an additional checking procedure.

The actual role played by “private” norms within the framework of genuine governmental product regulation on the one hand and the influence of the State on private standardization on the other moderate the contrasts between basically governmental and private standardization. However, for the time being the forms of interaction between State and society vary considerably. In the Federal Republic of Germany,⁶⁶ the United Kingdom⁶⁷ and now at European Community level,⁶⁸ the measure of influence of the State is restricted by conventions, or by mutually agreed “general principles”. However, the formal rights of participation of social groups differ, and the degree to which standardization results are

⁶² Cf. *Marburger*, P., *Die Regeln der Technik im Recht*, Köln/Berlin/-Bonn/München 1979, 181 et seq.; *Kypke*, U., *Gesellschaftliche Orientierung der überbetrieblichen technischen Normung unter besonderer Berücksichtigung verbraucherpolitischer Ziele*, Diss. Duisburg 1983, Ch. III; *Hamilton*, R.W., *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health*, *Texas L. Rev.* 56 (1978), 1329, 1331 et seq., 1368 et seq.

⁶³ Cf. *Schuchardt*, W., *Außertechnische Zielsetzungen und Wertbezüge in der Entwicklung des deutschen technischen Regelwerks*, *Technikgeschichte* 46 (1979), 227, 236 et seq.

⁶⁴ Cf. summary given by *Hamilton*, R.W., *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health*, *Texas L. Rev.* 56 (1978), 1329, 1379 et seq.

⁶⁵ Cf. *Marburger*, *Rechtliche Bedeutung*, 1982, 138 et seq.

⁶⁶ Cf. *Brüggemeier*, G./*Falke*, J./*Joerges*, C./*Micklitz*, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 3.4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶⁷ Cf. *Brüggemeier*, G./*Falke*, J./*Joerges*, C./*Micklitz*, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 2.6.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶⁸ Cf. *Falke*, J./*Joerges*, C., *The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act*, *Hanse Law Review (HanseLR)* 2010, 289, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

subjected to subsequent checks also does not seem to be uniform. In France the administration's possibilities for exercising direct influence seem to be more distinct.⁶⁹ In the USA the role of the CPSC in drafting voluntary standards has been defined in detailed regulations and its powers to introduce compulsory regulations remained significant for the inclusion of safety aspects in "voluntary standards".⁷⁰ Consequently, the only principle to become generally accepted is that technical safety regulations should be developed by private standards institutions drawing on the technical expertise of the industries concerned ("it is expensive to reinvent the wheel"⁷¹). There is, however, no consensus on the regulative mechanisms to guarantee acceptance of private standardization from the point of view of safety policy.

3.3 Follow-up market controls (Recalls and bans)

All product safety policy instruments aimed at the preventive control of design hazards of technical consumer products have a selective effect. State regulations can cover only a fraction of risks potentially requiring regulation; private standards institutes too must lay down priorities and cannot enforce the implementation of their norms, which are not legally binding. When all is said and done, the primary function of product liability is to compensate for any damage, and its influence on the level of safety is indirect and incomplete. However, preventive safety measures are not only inevitably selective, but also imperfect. The complexity of accidents means that particularly in the development of new products it is impossible in advance to recognize all hazards precisely. The selectiveness of preventive safety measures and the uncertainty of hazard forecasts are already two reasons to suggest that monitoring products in use and powers of subsequent intervention are essential. However, follow-up market controls also have a redistributive function. If the marketing of dangerous products is banned, traders suffer economic losses; if the products are already in the hands of final consumers, the repair or exchange of the products or the payment of compensation involves additional costs. The development of effective instruments of follow-up market control is, in the context of these functions, a difficult task from the legal point of view. However, above all because of the costs involved, the loss of image which the companies concerned may suffer and the potential effects on product liability procedures, follow-up market control comes up against considerable legal resistance.

In 1981 the OECD proposed solutions to the problems of follow-up market control based on the recall provisions of section 15 of the CPSA 1972.⁷² The OECD report divides the procedure into three stages:⁷³ (1) The essential first step is the systematic recording of information on product hazards. The main information sources are accident information

⁶⁹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> for more on this.

⁷⁰ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷¹ *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, *Texas L. Rev.* 56 (1978), 1329, 1447.

⁷² OECD, Recall Procedures, 1981; for US law cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷³ Cf. in particular OECD, Recall Procedures, 1981, 14 et seq., 31 et seq.

systems and reports from supervisory or certification authorities, followed by reports from manufacturers and importers, and complaints from consumers and consumer organizations. (2) When the dangers have been identified suitable remedies must be taken. First of all the consumers concerned must be warned about the hazards, then positive action must be taken to eliminate hazards and provide compensation for any damage. Measures must be adapted to the individual case; repairs may be sufficient, but in some cases products will have to be exchanged or destroyed and damages paid. (3) For the collection of information, assessment of hazards, and the preparation and monitoring of remedial measures it is necessary to set up a central authority which is in a position to carry out follow-up market control and must therefore be invested with the required legal powers.

No Community Member State has yet fulfilled these requirements. German law provides for marketing bans (§ 5, GSG), but a recall obligation exists only in conjunction with manufacturers' liability.⁷⁴ English law provides for "prohibition orders" and "prohibition notices" which the Secretary of State can invoke in the case of "imminent hazards" (see § 3 (1) a - c of the Consumer Safety Act 1978); in practice, however, these instruments are not applied and it is not intended to develop them into a recall procedure.⁷⁵ In France the Consumer Safety Law of 21 July 1983 is a potentially far-reaching instrument providing for recalls through the State machinery, but as yet it has hardly been tried out.⁷⁶

In the face of such reticence and resistance in the Member States, it should be noted at this point that the Community's current efforts to complete the internal market will be bound to have consequences for the development of follow-up market controls. The principle that products with European certificates of conformity manufactured according to foreign standards or tested by foreign institutes should be allowed to move freely in all Member States will encounter safety-motivated reservations which may also be linked to protectionist interests. We will return to the resulting need for action at a later stage.⁷⁷

⁷⁴ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, and *Brüggemeier, G.*, *Deliktsrecht. Ein Hand- und Lehrbuch*, Baden-Baden 1986, para. 563 et seq.

⁷⁵ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.3.3. and 2.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁶ Article 3 of *Loi No. 83-660 (fn. 32)* and *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.5.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁷ *Falke, J./Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>; *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3. and 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>; *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 251, 3.2. and 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>; *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

4. Recapitulation

Product safety represents a scarcely consolidated policy area, where information measures, liability rules, self-regulatory mechanisms and legal intervention exist side by side. Each of these instruments fulfils specific functions and therefore uses different regulative mechanisms. However, at the same time each instrument leads its own legal life; as yet there is no coherent product safety policy to coordinate these instruments, take account of the effectiveness of each, harmonize safety standards and control the development of legal instruments with the overall aim of reducing product hazards. As far as the approximation of laws in the European Community is concerned, this situation results in both problems and opportunities. The difficulties stem from the fact that the approximation of laws in a specific field involves inter-State coordination of heterogeneous legal instruments, and therefore may result in changes which lead to gaps in protection, in turn causing difficulties in reaching agreement or even resistance to the implementation of Community law. On the other hand, as shown by the example of environment law, it is precisely in new policy areas that willingness to change and learn is likely to be encountered -provided that integration policy provides the incentives and constraints that are needed to bring about innovation.

Examples of Product Safety Legislation⁺

Gert Brüggemeier,^{*} Josef Falke,^{**} Christian Joerges^{***} and
Hans-W. Micklitz^{****}

Abstract Deutsch

Auf Schritt und Tritt treffen die Bemühungen um die Verwirklichung des gemeinsamen Marktes auf Handelshemmnisse, die aus einer Vielfalt von Sicherheitsvorschriften in den Mitgliedstaaten resultieren. Eine Beseitigung dieser nicht-tarifären Handelshemmnisse durch deregulative Strategien kommt nicht ernsthaft in Betracht. Einschlägige rechtsvergleichende Untersuchungen nationaler Gesetzgebung, die deren regulativen Philosophien einbeziehen und die Problematik ihrer praktischen Umsetzung einbeziehen würden, sind bislang nicht verfügbar. Die folgenden Analysen befassen sich mit den Spezifika der Regelungsansätze des französischen, englischen und deutschen Rechts. Die USA sind einbezogen, weil der amerikanische *Consumer Product Safety Act* als das avancierteste, wenn auch umstrittene Beispiel einer zeitgemäßen Produktsicherheitspolitik gilt und überdies dessen Implementation durch eine unabhängige Agentur in der Gemeinschaft breite Aufmerksamkeit findet.

⁺ This article has originally been published in 1991 as Chapter II, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards – Vol. 2 and 3*, EUI Working Paper Law No. 91/11 and 91/12.

^{*} Gert Brüggemeier, Professor (Emeritus) of Private Law, European Economic Law and Comparative Law at the University of Bremen.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{***} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

^{****} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

Abstract English

In their efforts to establish a common European market the Community institutions became aware of wide range of non-tariff barriers to trade which stem from national product safety legislation. “Deregulation” is no realistic option in that field in view of the strength of public concerns with product safety. In order to prepare the grounds for Community action comparative research seems indispensable. Comparative analyses which would include the regulatory philosophies of pertinent legislation and the methods of its implementation are so far simply unavailable. The four studies on France, Britain, Germany and the United States in this chapter have to fill a gap. They identify the specifics of these systems and extend their analyses to the role of standard setting and certification. The United States are included because their Consumer Product Safety Act and its implementation through a regulatory agency provide a particularly sophisticated, albeit controversial, example which the Community needs to be aware of when designing its own policies.

Examples of Product Safety Legislation⁺

Gert Brüggemeier,^{} Josef Falke,^{**} Christian Joerges^{***} and
Hans-W. Micklitz^{****}*

Introductory Remark

Up-to-date comparative accounts of product safety law in force in Community Member States are unavailable. This is no coincidence. Technical safety law, to the extent that it deals with technical consumer goods, has been largely ignored by academic legal science, and therefore still less noticed in comparative law. Moreover, product safety law specifically is much more strongly bound up than, say, general civil law with technical and organizational administrative structures that must be known in order to understand its regulatory functions, but are hard for the foreign observer to gain access to. The description below will therefore have to proceed selectively, and will be confined to the law of France, Britain and the Federal Republic. Restriction to these States is problematic because it means overlooking innovative developments in smaller Member States and the situation in new ones. But the choice of France, Britain and the FRG is in line with the economic importance of these States and their general influence in the Community. US law is also taken into account, since important stimuli to the further development of product safety law came from the American Consumer Product Safety Act.

1. Product safety law in France

French product safety law is hard to fit into a market-oriented approach¹. The French analytical framework, conceived from a State or administration viewpoint, of prevention/repression/reparation, cuts straight across a German market-oriented category frame of market-related rules, setting of standards and follow-up market controls². Given the emerging Europeanization of safety policy, it is important to grasp what convergence exists and seek to bring it into a European, self-contained product safety policy.

⁺ This article has originally been published in 1991 as Chapter II, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 2 and 3, EUI Working Paper Law No. 91/11 and 91/12.

^{*} Gert Brüggemeier, Professor (Emeritus) of Private Law, European Economic Law and Comparative Law at the University of Bremen.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{***} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SFB597).

^{****} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

¹ Since France can be regarded as a market economy in the German sense only conditionally; see *Behrens, P./Korb-Schikaneder, F.*, *Europäisches Wettbewerbsrecht vor französischen Gerichten*, *RabelsZ* 1984, 457 et seq.

² This classical approach can be found in precisely the same way in the consumer policy debate; see *Calais-Auloy, J.*, *Proposition pour un Nouveau Droit de la Consommation. Rapport de la Commission de la Refonte de Droit de la Consommation au Secrétaire d’Etat auprès du Ministre de l’Economie des Finances et du Budget chargé du Budget et de la Consommation*, Paris 1985, 77 et seq.

1.1. French perspectives on product safety law

An approach to the field can be secured from a schematic overview of French safety and standards policy. A historical outline of the development of both policies will be attempted. An evaluation of the process might seem to be a bold venture, but the Europeanization of product safety has to start from a definition of the state of Member States' product safety policy. A more technical matter is the explanation of the French categorical framework of prevention/repression/ reparation, but this is a necessary prerequisite for an understanding of the specifically French way of perceiving and understanding product safety policy.

1.1.1. Schematic overview of French product safety and standards policy

The diagrams below make no claim to completeness, but do aim to outline the tendencies operating in both policy areas. This cannot be done without considerable simplification. As starting point has been taken the state of legal development at the turn of the century. This is simply because relevant laws were enacted in France shortly thereafter. The thread of development is then picked up again for pragmatic reasons after the Second World War, with special consideration going to the wave of reforms in the 1970s, which then led to a phase of regression. Since there has not been a coherent product safety policy in France so far, at least not including technical standards, development in both policy areas must initially be described separately. This leads to a time shift, since standards policy as it were leaps over the reform phase of the 70s, and does not take on importance in France until economic crises, unemployment and the wave of deregulation began to determine day-to-day politics. For the conceptual framework, the classical French system of prevention/repression/reparation³ has been adopted. A transfer of this conceptual approach into standards policy makes it possible to compare regulatory instruments in each policy area with each other and thereby show that there is no overlap.

“Prevention” includes the following measures: information, standard setting both private and governmental, follow-up market control (administratively ordered recall), prohibition orders and the work of the French Consumer Safety Commission.

“Repression” concerns primarily penal sanctions, but also covers imposition of compensatory payments and accompanying measures of sanction (bans or recalls ordered by judges, confiscation, destruction, closures etc.).

“Reparation” deals with the French version of manufacturer liability.

The reasons for the French conceptual structure lie in the one-sidedly administrative perspective on product safety as whole. The viewpoint has already undergone some change through inclusion of reparation as an instrument of safety policy, first incisively practised by the Commission de la Refonte.⁴ The liberalization policy pursued for some ten years now in France ought to lead to a blurring of the outlines of the categories, since the private economy, the consumer and the courts will gain ground in safety regulation. However, at present the whole political, legal policy and legal theory debate on standardization and product safety in France continues to follow traditional lines.

³ This distinction is based essentially on the work of the Commission de la Refonte (fn. 2 above) and the description of product safety law by *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, *Dalloz* 1984, 13 et seq., 19 et seq., which is so far the sole comprehensive overall description of the law.

⁴ See *Calais-Auloy, J.*, Proposition pour un Nouveau Droit de la Consommation, Rapport de la Commission de la Refonte de Droit de la Consommation au Secrétaire d'Etat auprès du Ministre de l'Economie des Finances et du Budget chargé du Budget et de la Consommation, Paris 1985.

1.1.2. Product safety and standardization side by side

The conceptual framework of French product safety policy has (from the consumer's viewpoint too and especially) led to a very narrow understanding of product safety, which has no room for a number of relevant cross-connections. Thus, there is no systematic incorporation of standardization into product safety policy. This is still more true of certification, which is hardly discussed at all. Though manufacturer liability is included in safety policy, it is treated only as leading to individual compensation for damages, not as an instrument for controlling product safety. Finally, there is no discussion of the relationship between manufacturer liability and technical standard setting. The research approach pursued here, of bringing product safety and technical standards into relation with each other, meets in France partly with rejection and partly with misunderstanding. It is rejected because the administration continues to be seen as the best guarantor of product safety; it is misunderstood because the connecting lines are not seen, due to the absence of intermeshing between product safety and standards; indeed perhaps they do not even exist. The last point is true at any rate for the sphere of manufacturer liability, which seems not to refer to technical standardization at all.

Regulation of product safety is a task for government in France.⁵ Standards are set by order. The administration's responsibility for product safety has remained unshaken even by the reform attempts of the 80s. The setting up of a Consumer Safety Commission⁶ was fitted seamlessly into an administrative product safety policy, for all that was done was to shift tasks from the administration, without limiting ultimate administration responsibility and control at all. Looking closely at the distribution of roles among the three powers, the thing to stress from a French viewpoint as a decisive change in law on consumer safety in 1983 was the cautious inclusion of the courts in product safety policy.⁷ Still existing legislative and executive mistrust of inclusion of the judiciary can be seen from the fact that though Art.1 is conceived as a general clause, it is not directed explicitly at the courts. Accordingly, until the significance of Art. 1 has become clear, more importance should attach to the courts' power, newly introduced in 1983, to issue a banning order or withdraw products from the market by emergency procedure on application - and not just the relevant secretary of state or consumer minister, or certain administration officials.⁸ The 1978 law still saw product safety policy entirely administratively, and was explicitly aimed at excluding the courts from prevention.⁹

Standardization is in France a task for government.¹⁰ AFNOR has been incorporated into the governmental organization of standardization, with the task of drawing up technical standards, which however has to be supervised and checked by the Commissioner for Standardization as representative of the State. AFNOR has discretion only insofar as it is allowed by the French administration. The essentially governmental and administrative organization of standardization also meant that the reforms of the 1980s changed nothing. Nevertheless, the reform is bringing shifts that might in the long term lead to a change in the division of tasks between government and the economy. The keywords are privatization

⁵ For details see 1.4 below.

⁶ See 1.3 below.

⁷ *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, *Dalloz* 1984, 13 et seq., 19 et seq.

⁸ See point 1.4.1 below.

⁹ *Calais-Auloy, J.*, *Droit de la Consommation*, Paris 1980, 113 et seq.

¹⁰ See point 1.7 below.

and politicization of standardization. Privatization comes in since the reform made the administration yield some competences to the privately organized standards body AFNOR; politicization because creation of the Supreme Council for standardization makes the guidelines for standardization policy into a topic of public debate. The parallel with the standardization agreement reached in 1975 between DIN and the Federal Government suggests itself.¹¹ No intermeshing of the reform attempts in product safety law and in standardization, which were pushed forward in parallel, they took place, at least openly. With some exaggeration, one might say that product safety was discussed without standardization, and standardization without product safety. Para. 3 of the GSG (reference to standards) constitutes, from the German viewpoint, the bridge between the two policy areas. C. Germon and P. Marano¹² proposed the “German solution” in their report to the French Ministry for Industry. No discussion of the advantages and drawbacks of the German approach took place. However, there were some hints at it. The rearrangement of French standardization was aimed primarily at strengthening the French economy’s competitiveness; expansion of consumer protection and the setting up of a supreme council for standardization were to enhance acceptance of French standards in public awareness. Though the German GSG and German consumer trust in standards were taken by C. Germon and P. Marano as a shining example, the French plainly went their own way towards increasing the national competitiveness. Comparison of the reform proposals with the law shows that the French government ultimately shrank from copying the German method of reference.

1.2. The “safety philosophy” of the 1983 law

While Art. 1 of the French law on product safety¹³ does lay down a general obligation on the manufacturer to bring only safe products to the market, reference to the “generally recognized rules of the art” (allgemein anerkannten Regeln der Technik) is lacking:

Les produits et les services doivent, dans des conditions normales d'utilisation ou dans d'autres conditions raisonnablement prévisibles par le professionnel présenter la sécurité à laquelle on peut légitimement s'attendre et ne pas porter atteinte à la santé des personnes.

The constitutive elements of this general clause are (1) the “autres conditions prévisibles par le professionnel” and (2) “la sécurité à laquelle on peut légitimement s’attendre”. It is sometimes disputed that these are indeed two constitutive elements, since the “safety one may legitimately expect” also covers admissible use. This is not so.¹⁴ The “other reasonably foreseeable conditions” describe the safety requirements on manufacture of the product. The addressee is the manufacturer. The “safety one may legitimately expect”, on the other hand, defines the consumer’s justified expectations of safety. Though the viewpoints can theoretically be separated, in practice they nevertheless stick very closely together. For the

¹¹ Cf. 3.4.2 below.

¹² Germon, C./Marano, P., La normalisation clé d'un nouvel essor, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982.

¹³ Loi no. 83-660 du 21 juillet 1983 relative à la sécurité des consommateurs et modifiant diverses dispositions de la loi du 1er août 1905, German translation in PHI 1984, 71 et seq.

¹⁴ Schmidt-Salzer, J., Kommentar EG-Richtlinie Produkthaftung, Bd. 1: Deutschland, Heidelberg 1986, Art. 6, para. 13 et seq., 116 et seq., 138 et seq.

actual safety level must include requirements on the manufacturer and the consumer's expectations.

1.2.1. The general clause in Art. 1

The important innovation in the 1983 law was the general duty of safety imposed on the manufacturer. France was thus drawing the consequences of the almost complete failure of the 1978 framework regulations.¹⁵

Only two orders were issued between 1978 and 1983. Accordingly, administrative regulation of the classical type could be regarded as having failed. The cumbersome decision-making process within the administration must have given the stimulus for setting up a separate consumer safety commission, which would have some autonomy at least in the areas of information gathering, assessment and processing. In 1985 the Commission had a budget of 2.4 million francs at its disposal, 500,000 francs of which is supposed to be for carrying out research. The secretariat consists of four people, including a secretary.

Through the general clause, the Commission can itself consider almost any question; it is not dependent on special authorization by any order or provision. Just this was the weakness of the 1978 law.¹⁶ Administrative cumbersomeness again no doubt helped in having the courts brought back in to the process of State standard setting. Even these changes, however, do not alter the main thrust of product safety regulation. As before, the chief addressee is the administration, which alone can give the safety obligation legal bindingness, by specifying the general clause by enacting orders, or by a ministerial decree.¹⁷

Since the French legislator has rejected adoption of the method of reference to standards, the question remains open as to how the safety standards can be made specific. Technical standards can be adduced as aids to interpretation, but their observance does not offer the French manufacturer any protection against action under Art. 1.¹⁸ In practice, the manufacturer's main fear must be of the activities of the Consumer Safety Commission, which has explicitly stated that the safety requirements of Art. 1 may well lie higher than those of the technical standards drawn up by AFNOR.¹⁹

1.2.2. Determination of safety levels

The shift in French safety philosophy emerges clearly from the change in wording from the 1978 safety law's "conditions normales d'utilisation" to the 1983 "autres conditions raisonnablement prévisibles par le professionnel (qui doivent présenter) la sécurité à laquelle on peut légitimement s'attendre". The 1983 safety law for the first time separated the distinct standpoints of consumer and manufacturer, and at the same time heightened the

¹⁵ Loi no. 78-23 du 10 janvier 1978 sur la protection et l'information des consommateurs de produits et de services. The decisive passage of Art. 1 goes "dans des conditions normales d'utilisation". On the Act, see *Calais-Auloy, J.*, *Droit de la Consommation*, Paris 1980, 113 et seq.

¹⁶ *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, *Dalloz* 1984, 13 et seq., 19 et seq., 14 et seq.

¹⁷ More details in 1.4 below.

¹⁸ *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, *Dalloz* 1984, 13 et seq., 19 et seq., 17, para. 13.

¹⁹ Commission de la Sécurité des Consommateurs, 1er Rapport au Président de la République et au Parlement, 1985 (cited below as Commission, 1985), 15; Commission de la Sécurité des Consommateurs, 2ème rapport au Président de la République et au Parlement, 1986 (cited below as Commission, 1986), 13.

requirements on the manufacturer. The criterion is not proper use, but reasonably foreseeable use; this is what the manufacturer has to take as guide in design and production. Not many problems are presented by the consumer's position. The definition states clearly that it is not the individual viewpoint that should be decisive, but the position of the average consumer.²⁰

Far greater difficulties of interpretation are presented by the intensification of the safety obligations on manufacturers.²¹ The elementary political significance of the change in safety policy becomes clear from the stormy parliamentary debate. Admittedly, the preliminary draft had focused on "condition anormale d'utilisation" (improper use), thus considerably contributing to raising the temperature. Efforts then concentrated on clarifying what was to be understood by "autres conditions raisonnablement prévisibles par le professionnel". The French debate becomes comprehensible only if it is borne in mind that consumer organizations were pressing for adoption of "improper use". The move away from "condition anormale d'utilisation" made two things clear: (1) improper use resulting from culpable conduct by the consumer was not to be covered by the general clause; (2) on the other hand, foreseeable collective error was to be covered. The parliamentary debate centred on the "condition anormale" alone. By contrast, there was wide unanimity about obliging manufacturers to take account not only of foreseeable conduct but also specifically of foreseeable misuse. But even the French formulation of the general clause is of no further help when it comes to distinguishing collective foreseeable misuse from misuse that is unforeseeable because it is improper. The distinction will be left up to the judge, who will have to decide how far the marketing of a faulty product is criminal, or else to be compensated for by payment. This presupposes that in the specific case an order has been issued that makes the general clause specific.

It is hard to give any meaningful summary. Experience with the new product safety law of 1983 is very limited, so that the important fact that remains is that in the European Communities it is only in France that there is a "safety philosophy" that explicitly includes foreseeable "misuse".

1.3. Information policy and the Commission for Consumer Safety

A State policy on safety information has existed in France only since 1983. The 1978 law,²² even though its title includes "information to consumers", provided no measures to meet the consumer's specific safety requirements. It was only with the 1983 law²³ and its creation of the Consumer Safety Commission that there was an instrument aimed essentially at improving information.

1.3.1. Information from regulatory bodies

The Commission has the task of gathering, analysing and (within limits) informing the public of necessary data on product safety.²⁴ To make it possible to set up a database,

²⁰ Pizzio, J.-P., La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq., 15.

²¹ On all this see Pizzio, J.-P., La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq., 15-17.

²² Op. cit., 14 et seq.

²³ See above, fn. 13.

²⁴ Pizzio, J.-P., La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq., 19 et seq. and the two annual reports of the Consumer Safety Commission (fn. 19 above).

almost all authorities and institutions that might be concerned with safety problems connected with the use of consumer goods are obliged to inform the Consumer Safety Commission.²⁵ Theoretically, therefore, all authorities nationwide would be obliged to notify the Consumer Safety Commission of all damage, accidents, and suspicions that might have to do with the manufacture or use of an unsafe consumer item. The courts are included in the obligation of notification. In practice, this is a compromise in the dispute about setting up a national accident surveillance system. Just as with other European Community Member States, France too in the early 80s gave out contracts for research into the feasibility of a national accident surveillance system to combat accidents and unsafe products.²⁶ The arguments adduced against setting up a national accident surveillance system more or less coincide with the German stance against a Community one.²⁷ In fact, the Community directive on setting up an accident surveillance system has overtaken developments in France.²⁸ The Consumer Safety Commission has since its creation been doing the necessary preliminary work to permit a nationwide accident surveillance system. To date, four hospitals have declared their willingness to cooperate. How far the notification obligation on French supervisory authorities is suitable for setting up a wider, or different, data picture is still an open question. At any rate, the French courts have been *de facto* refusing cooperation.²⁹ The Commission's 1985-6 annual report allows no conclusion as to whether the authorities in fact furnish the Commission with information, or whether information that does come in is technically useful.

The Consumer Safety Commission is further responsible for sifting incoming data, determining significant points and selecting those to analyse further. Here it may draw on the help of the French laboratories. Its small staff makes it hard for the Commission to develop activities of its own to any noteworthy extent. It is largely reduced to using factual and issue analyses from third parties, or to trusting to their quality. Cooperation has intensified in the second year of the Commission's existence.³⁰

Data evaluation finds its formal conclusion in the production of reports or parliamentary position papers. These are later published in the activities reports for each calendar year. The Commission is aiming at publication in the French Official Journal.³¹

1.3.2. Consumer information

The Consumer Safety Commission can also approach the public itself.³² Though it is forbidden from sending reports or opinions to the press itself, it does have the possibility of

²⁵ Art. 14 (2) of the 1983 Act (fn. 13 above).

²⁶ *Accidents Domestiques*, 1981; cf. esp. the ministerial position on this report: *Ronze, B.*, (Inspecteur Général des Finances). Note sur un recensement éventuel des données relatives aux accidents de la consommation, 2.7.1981, Paris 1981.

²⁷ See esp. *Ronze, B.*, (Inspecteur Général des Finances). Note sur un recensement éventuel des données relatives aux accidents de la consommation, 2.7.1981, Paris 1981, in his "Resumée et Conclusions".

²⁸ See the Council decision of 22 April 1986 concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products, OJ L 109, 26 April 1986, 23; for details on this see *Falke, J./ Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

²⁹ For a criticism see Commission, 1985, 13.

³⁰ Thus Commission, 1986, 12-14.

³¹ See Commission, 1986, 16 et seq.

³² On this cf. Commission, 1985, 15.

publishing a summary. This has in fact been done, to date without objection. This means that the Commission has opened up a way of bringing safety problems in handling consumer goods to the attention of consumers. The Commission is at present considering how it can reach consumers still better. A quarterly publication of its findings, a safety bulletin as it were, might serve this end. For direct contact with the consumer, however, much greater importance attaches to whether the videotext system TELETEL, widespread in France (1.8 million users) can be successfully used to disseminate information. A pilot study has furnished conclusions about the prospects by the end of 1987³³.

1.4. Preventive regulation of product safety³⁴

In the whole conception of product safety law, the administrative regulation of product safety stands at the centre of interest. For it is only if the general clause can be made specific in further administrative measures that it can – quite apart from the range of tasks of the Consumer Safety Commission – develop legal effect for the commercial circles involved. The distinction between normal procedure and emergency procedure is central to an understanding of the French safety law.

1.4.1. The normal procedure for product regulation

For removing unsafe products from the market, the law³⁵ provides for a still relatively cumbersome procedure, justified on grounds of finality and of possible heavy damages for the industries concerned. In formal terms, the procedure can be split into two sections. The first phase takes place before the Consumer Safety Commission, which is called on by either the minister, a consumer organization, the industry, the trade or individuals to take up a problem. The Commission may also take up a matter itself. Once the affair has got going, the Commission sets experts from laboratories and other scientific institutions to work evaluating the product. At the same time firms involved are heard.³⁶ They can present their position and may make proposals for removing the hazard by changes to the product. The Commission has wide discretion as to how it acts during such negotiations. Only if it is convinced that the product continues not to offer the safety required by Art.1 does it furnish a recommendation as to how the ministries should respond to the hazard from the product. The *second phase* then takes place within the administration. The ministry or ministries are in no way bound by the Commission's suggestions. Their importance will depend ultimately on whether the relevant ministries tend to follow the recommendations, or to incorporate them into measures to be taken. According to the text of the law, two categories are available:

- firstly, general measures, laid down by way of regulation. These are ones that concern a range of products or of services. These regulations require agreement among several ministries as to whether there is in fact a need to adopt a regulation;
- secondly, specific measures, which may be laid down by ministerial order. Only a named product or service may be the object of these. Agreement among ministries is necessary.

³³ Thus Commission, 1986, 5.

³⁴ The following account is based on the final report of the Commission de la Refonte (fn. 2 above) and the explanations by Pizzio, *J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq.

³⁵ Art. 2 of the 1983 Act (fn. 13 above).

³⁶ As stressed by Commission, 1985, 5.

By contrast, there are no differences as to the means available to the ministries to ban the risk. The 1983 law considerably expanded the arsenal available for combatting hazards by comparison with the 1978 law³⁷.

1.4.2. The emergency procedure for product regulation

However, the normal procedure is much too clumsy when a danger that has arisen has to be responded to quickly. Accordingly, the law provides for the possibility of emergency measures, to be adopted without involving the Consumer Safety Commission. At the same time, though, they are provisional in nature. The only requirement for initiating the emergency procedure is the existence of an actual situation of risk. This need not be grave; it is the imminence of the damage that creates the urgency, not the severity. Accordingly, a non-immediate risk situation justifies commencement only of the normal procedure, even if it is severe. With a view to increasing the range of possibilities of intervention, the law³⁸ provides for various types of emergency measure, which coexist:

- the minister, or secretary of state, responsible for consumer protection may adopt a provision, without involving the Consumer Safety Commission. This kind of measure is valid for at most one year: long enough for decision-taking within the normal procedure as to whether a definitive regulation should replace the provisional one;
- a judge too can issue a injunction order for recall of a product. He takes his decision on application from a consumer organization or a ministry. The provisions on entitlement to take action derive from the *Loi Royer*.³⁹ The injunction order may not have a duration of more than six months. The normal procedure has then to be used to decide whether the measure is to be maintained or suspended. Firms are no longer allowed, as hitherto, to market the products again after this period has expired. If penal proceedings are embarked on, the examining judge or the criminal court is competent. The judge can take only specific measures relating to a particular product;
- various administration officials specifically mentioned in the law⁴⁰ may seize products and even have them destroyed. Such measures are to lead to the commencement of court proceedings, with involvement of the public prosecutor within 24 hours. A prerequisite is that the urgency of the measure be beyond all doubt. In cases of mere suspicion, the officials can only block the product for 14 days pending results of scientific and technical tests. Whatever the outcome of the measure, a copy of the record of proceedings is to be sent to the Consumer Safety Commission.

It is still quite unclear whether the emergency procedure will make headway.

1.5. Post market controls

Any description of French safety law has to go thoroughly into the administration's role in follow-up market controls. Neglecting the whole repressive control machinery would give a completely distorted picture of French product safety law, since this is the area where

³⁷ On this see 1.5.2 below.

³⁸ Art. 3 of the 1983 Act (fn. 13 above).

³⁹ *Calais-Auloy, J.*, *Droit de la Consommation*, Paris 1980, 205 et seq.

⁴⁰ Art. 4 of the 1983 Act (fn. 13 above).

control is centred.⁴¹ The repressive powers will first be described (1.5.1.), and then a special description of recall given (1.5.2.).

1.5.1. Repressive product regulation

Scarcely anywhere else in French safety law does the fragmentary nature of its provisions emerge more clearly. This concerns in part the substantive legal requirements for action by way of post market control. There is nothing in the 1983 law that makes marketing unsafe products a criminal offence.⁴² Were that so, the control authorities could engage in post market controls without their powers first having to be specified by ordinance or by ministerial decree. In the absence of any ordinance laying down specific penal sanctions for manufacturing and distributing particular products or groups of products, the only grounds for intervention have to be based Art. 1 of the 1905 law in its 1978 version. Since that date, the scope of Art. 1 has included acts of deception in connection with use of the thing sold.⁴³ Thus, for instance, sale of a hazardous product can be punished if the risks ought to have been brought to the buyer's attention. The 1983 act's fragmentariness in regulation is still more striking when it comes to who has the post market control. The law creates no administrative infrastructure, no special safety authority with hundreds of inspectors, but merely extends the area of action of the "Direction Générale de la Consommation et de la Répression des Fraudes" (DCRF).⁴⁴ Admittedly, the 1905 law⁴⁵ also extended that body's powers of intervention; in part specifically to controls on products, but in part more generally, i.e. to the whole area of application of the 1905 law. This mixing makes it hard to understand the control machinery, and not only for outsiders.

The first step in control is the search for and establishment of breaches of the law. The relevant provisions of the 1983 law on the one hand strengthen existing intervention powers of DCRF officials, and on the other create new control instruments. A full picture cannot be given; we shall confine the description to an outline of the chief powers.⁴⁶

The officials have a right to enter firms' premises at any time of day or night. This access right is now extended to rooms not used exclusively for business purposes but also private ones. Should the businessman concerned refuse access, officials may inspect the premises only if the public prosecutor gives them permission. More recently, the officials have also been given the right to inspect production documents. Without prior court permission, they can seize dangerous products or remove them.

If breach of the law has been found, a broad range of sanctions is available. The prerequisite is either that a decree provides for punishment for the manufacture or marketing of an unsafe product, or that the intervention requirements of Art. 1 of the 1905 act are present. Sanctions available under the 1983 act centre round a range of measures besides punishment that can be ordered at the time of sentencing. This requires the issue of a decree in normal procedure or else a ministerial order in emergency procedure. Three

⁴¹ On this see the account by *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq.

⁴² Significantly, the Commission de la Refonte (fn. 2 above, 82) calls for precisely this penal general clause.

⁴³ *Calais-Auloy, J.*, Droit de la Consommation, Paris 1980, 128.

⁴⁴ *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq., 19 et seq.

⁴⁵ Loi du 1er août 1905 sur les fraudes et falsifications en matière de produits ou de services.

⁴⁶ This account is based on *Pizzio, J.-P.*, La loi du 21 juillet 1983 sur la sécurité des consommateurs, Dalloz 1984, 13 et seq., 19 et seq., 19 et seq.

types can be distinguished: the court may order publication of the decision or require specific information of the public; it may order recall or destruction of the product at issue; it may confiscate illegally acquired gains.

In addition to the new provisions on measures accompanying punishment, mention should also be made of the codification of longstanding case law of the Higher Criminal Court, according to which the manufacturer of a product infringes Art.1 of the 1905 Act if he brings a product to market without first checking that it complies with safety and health provisions in force. The Higher Criminal Court had seen criminal responsibility of the manufacturer as established when, against the express tenor of Art. 1, he could be accused merely of gross negligence⁴⁷. The regulations take over the case law, but do not extend it to mere traders. That does not mean, however, that traders can escape their responsibility. French case law⁴⁸ has long recognized that traders can be made responsible under the provisions of Art. 1 of the 1905 Act if they have neglected specific duties on traders (unsuitable storage, inadequate conservation, inadequate labelling). Indeed, a trader has even been condemned for breach of Art.1 of the 1905 Act because he had distributed goods whose nonconformity with the legal provisions was clear.

The closeness in content to comparable efforts at differentiation in German case law on product liability is evident. But while in the FRG breach of duty by manufacturer or trader as a rule leads to entitlement to compensation for damage, France relies more intensively on administrative solution of the problem. The parallel is interesting above all from the viewpoint of allocation of the burden of proof. German civil case law takes it that infringement of safety provisions in force (or non-compliance with technical standards) is a *prima facie* indication of the defectiveness of a product and therefore also of fault. But *prima facie* rules of this kind are not enough to justify *criminal* condemnation of the manufacturer. In principle, the administration has to show that the manufacturer had not carried out the necessary checks. This seemingly clear burden of proof is however brought into question by Art. 7 of the 1983 Act. Art. 7 takes it that a manufacturer who has not observed officially prescribed checks on verification of compliance with the law has, unless the contrary is shown, infringed Art. 1 of the 1983 Act. But there is a difference between Art.1 of the 1983 Act and Art. 1 of the 1905 Act insofar as the 1983 Act lacks a criminal-law general description of an offence, allowing condemnation merely because a product does not comply with the requirements of the general clause. Nevertheless one may envisage types of case in which the presumption under Art. 7 of the 1983 Act leads to condemnation under Art. 1 of the 1905 Act.⁴⁹

1.5.2. Product recalls

The 1983 Act for the first time provides the possibility of compelling the recall of a product. This requires either the issuing of a regulation or in urgent cases a ministerial order.

Article 2 says: "These *regulations* may likewise specify that products be removed from the market or recalled for modification, that the purchase price be reimbursed in whole or in part or products be exchanged, and that consumer information obligations be laid down."

⁴⁷ Calais-Auloy, J., *Droit de la Consommation*, Paris 1980, 129, and references from the case law.

⁴⁸ On this Pizzio, J.-P., *La loi du 21 juillet 1983 sur la sécurité des consommateurs*, Dalloz 1984, 13 et seq., 19 et seq., 25, para. 47.

⁴⁹ Op. cit.

Article 6 says: "They (the Ministers responsible for consumer protection or the departmental Minister concerned) may also order the publication of warnings and precautionary measures for use, as well as recalls for exchange, repair or full or partial reimbursement of the purchase price."

To avoid misunderstandings, it should be clear that the Courts too can order recalls on the basis of Article 1 of the 1983 Act, without being empowered by a regulation or ministerial order. To date no use has been made of the regulatory powers of Article 2.

Conversely, it would be wrong to conclude on the basis of the formal absence of regulations that product recalls with involvement of governmental bodies do not take place in France. For practice up to October 1984, O. Dellenbach⁵⁰ has presented a case study that draws a strict distinction according to whether the safety threshold appearing in

technical standards was demonstrably set too low, or whether a safety standard existed at all. In the first group of cases, Dellenbach has analysed in more detail three cases that caused much furore in France in the second half of the 70s: (1) Crash helmets that were subject to material fatigue; (2) fan heaters that easily caused fires; (3) electrically unsafe automatic egg boilers. For all the differences in detail, the three cases took an almost identical course. The unsafeness of the products was discovered on carrying out product tests. Attempts by consumer organizations to negotiate an agreement with the manufacturers on possible recall and its terms failed. The consumer organizations then went before the public, at the same time informing the competent authorities. Under public pressure, the French administration saw itself compelled to put pressure on the firms to secure recall of the products.

The picture is less clear cut in areas where the technical standards contain no safety requirements: carrycots and child-proof seals on cleaning products. Again it were consumer organizations that discovered the problem. The campaign for child-proof seals gained additional weight through the involvement of the anti-poisons centres.⁵¹ The campaign against unsafe carrycots led after six years to the establishment of a technical standard, which was however declared non-binding and did not cover other similar dangerous products. French consumer organizations had asked

for the passing of a relevant regulation, on the basis of the Act of 10 January 1978 (the predecessor of the 1983 Act). The fight for childproof cleaning product containers ultimately led to adoption of a regulation on the basis of the Council Directive of 18 September 1979 on the harmonization of legal and administrative provisions for the classification, packaging and labelling of dangerous substances (Art.15(2)).⁵² Far more interesting than the course of proceedings in this group of cases is an international comparison of delays in making a regulation. In Britain a safety standard for carrycots has been in existence since 1965, and childproof seals have been compulsory in the US since 1970.⁵³

⁵⁰ For an account of the issues, see *Dellenbach, O.*, *Les Normes de Sécurité*, Mémoire Droit de la Consommation soutenue en Octobre 1984, Université de Montpellier, Directeur de Mémoire: J. Calais-Auloy, Montpellier 1984, 32-44.

⁵¹ *Activité des Centres Anti-Poisons*, 1982.

⁵² OJ L 259, 15 October 1979, 10.

⁵³ On issues connected with this regulation see *Viscusi, W.K.*, *Consumer Behaviour and the Safety Effects of Product Safety Regulation*, *J. of Law and Economics* 28 (1985), 527 et seq., 537 et seq.; see also, 4.6. below.

1.6. Liability⁵⁴

Following the development of contractual guarantee liability and of liability in tort virtually irrespective of fault between 1962 and 1972,⁵⁵ French case law in the next ten years went on to make a considerable contribution towards bringing the two types of liability closer together.⁵⁶ While the rule of non-cumulation (of claims based on contract and tort) continues to apply, the case law has nevertheless *de facto* developed a unitary concept of fault for both law of tort and law of contract. This unitary concept of fault is based in law of contract on liability of the professional vendor, or else through direct liability of the manufacturer, while in law of tort it leads to liability irrespective of fault as the outcome, at any rate where the injured party was demonstrably supplied with a faulty product.⁵⁷ The injured party to the contract has the burden of proving that the defect had arisen before supply. This allocation of the burden of proof may lead to problems, particularly in supply chains where it can no longer be determined where the defect arose. Liability in tort presupposes, as in German law, that the injured party can show the defectiveness of the product.

A second important approximation of law of contract to law of tort lies in the development of groups of cases comparable to those in German law. This is true at least for defects in design, manufacture and instructions. Development defects can consistently be covered only by contractual liability in France. Conversely, as far as can be discovered no duty in law of tort to monitor products (post market or post sale duties) seems to exist.

The approximation of the two types of liability has been considerably strengthened by adoption of the product liability directive.⁵⁸ The typically French problem of two types of liability according to whether the contractual partner or an uninvolved third party is the injured party was eliminated at the preparatory stage of the Community directive in favour of a unitary type of liability for injured contracting parties or an uninvolved third party. Though national law on contractual liability continues to exist, the classical distinction loses significance in practice.

An admittedly cursory survey of the French case law suggests the conclusion that consumer disputes play a great part, but that the cases of injury were in the main ones involving specifically French peculiarities. Thus, in France a need continued to exist into the 70s for many households to store propane gas containers, since no central gas supply was provided (and is to some extent still not). Containers exploding during transport, on consignment or in use have much concerned the French courts and made their contribution to the

⁵⁴ The following account is based essentially on *Viney, G.*, *La responsabilité de fabricants et distributeurs*, *Economica* 1975; *Ghestin, J.*, *Conformité et Garanties dans la Vente*, Paris 1983 and *Lamy Commercial, Concurrence-Distribution-Consommation*, Paris, 1985, 1286 et seq., para. 4678 et seq.; a description from a German viewpoint is given by *Weber, K.-H./Rohs, U.*, *Produzentenhaftung im französischen Recht*, *PHI* 1984, 36 et seq.

⁵⁵ See *Ghestin, J.*, *Conformité et Garanties dans la Vente*, Paris 1983, 244 et seq. (esp. 251 et seq.), who follows the stages in the case law on the development of guarantee liability irrespective of fault. There is no key decision like the German *Hühnerpest* judgment (BGHZ 51, 90 et seq.) in the law of contract. The case is different in law of tort. Here the decisive judgment that altered the burden of proof in favour of the consumer was *Cour de Cassation Civile*, 21 March 1962, *Bull. Civ. I*, 155. Other decisions in this connection are in *Viney, G.*, *La responsabilité de fabricants et distributeurs*, *Economica* 1975, 76, note 19.

⁵⁶ Much information can be found in *Lamy Commercial* (fn. 54 above), 1286 et seq., para. 4678 et seq. A description of the legal position from a German viewpoint is offered by *Weber/Rohs*, 1984.

⁵⁷ References in *Lamy Commercial* (fn. 54 above), 1288, para. 4683.

⁵⁸ *Ghestin*, speech at the Conference "Sécurité et Défense des Intérêts Economiques des Consommateurs. Droit National et Communautaire", 17-18 April 1986 in Dijon.

development of manufacturer liability in tort. A second specifically French variant in the development of manufacturer liability is the great importance of liability cases connected with the production, supply and use of agricultural products. Characteristically, French case law has transferred strict contractual liability to agriculture, without any beating about the bush.⁵⁹ Correspondingly, the French bill to implement the product liability directive is likely to include agricultural products.⁶⁰

France is ahead of all Member States in almost fully unifying the concept of defect in the area of prevention and repair. Art. 1 of the 1983 Act and Art. 6 of the Product Liability Directive, in the French version, are by no means co-incidentally very similar, and in part identical in tenor. In the negotiations on the Product Liability Directive, France managed largely to push through its conception of defect.⁶¹

1.7. Technical standardization and product safety⁶²

The basic structure of French standardization, with its peculiar interweaving of government and the economy, was created by the Vichy Government in 1941.⁶³ It gives the French Government great influence on standardization that goes beyond a single company. This influence has effects first of all on the organization of standardization. This is largely integrated with the national administration, if not organizationally then at least functionally. The Commissioner for standardization exercises the office of Government Commissioner in AFNOR. AFNOR and the Bureaux de Normalisation (trade associations for standardization) are part of the Service Public, i.e. they are comparable with firms under controlled administration. AFNOR's statutes are laid down by the State, which also determines and appoints its decision-making bodies. A special statute provides for financing of AFNOR through a parafiscal levy. Another peculiarity is the possibility of giving technical standards gradations of legal effect. The range goes from quasi-binding for the administration to universal bindingness including the economy.

1.7.1. Privatization trends

A multiplicity of ministerial decrees and orders over the decades has not shaken the basic division of tasks. The decree of 26 January 1984⁶⁴ on the status of standardization also keeps the basic structure. At the same time, one may note a shift in competencies within the

⁵⁹ Lamy Commercial (fn. 54 above), 1289, para. 4687 b).

⁶⁰ Directive on liability for defective products of 25 July 1985, OJ L 210, 7 August 1985, 29; more in *Falke, J./Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>. An official French bill converting the Directive is not yet available.

⁶¹ This is due fairly largely to Ghestin himself, who was involved in the government decision-making process in France and likewise belonged to the Commission de la Refonte which had worked out the 1983 Safety Act; see also *Ghestin* (fn. 58 above).

⁶² A fundamental account in German is *Lukes, R.*, Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG- und EFTA-Staaten, Köln/Bonn/München 1979, 5 et seq.; the description is based on his account. Much information on the history is also in *Rasera, M.*, L'A.F.N.O.R. et la liaison administration-industries, *Semaine Juridique, Cahier de Droit de l'Entreprise C I* 1980, 28 et seq., 28 et seq.

⁶³ The relevant acts, decrees and orders are reprinted in *German, C./Marano, P.*, La normalisation clé d'un nouvel essor, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982, 109 et seq.

⁶⁴ Décret no. 84-74 du 26 janvier 1984 fixant le statut de la normalisation, reprinted in *Enjeux* No. 44, 2/1984 52 et seq., and in German in *DIN-Mitt.* 63 (1984), 255 et seq.

fixed framework from the State towards AFNOR, i.e. the private standardization organization. This development was actually already introduced with the 1941 Decree. Until last year France had pursued the intention of organizing standardization governmentally.⁶⁵ Accordingly, AFNOR had no standardization powers. It had only to encourage the drawing up of standards, verify the proposals from the standardization associations and propose them for recognition by the Comité Supérieur de Normalisation. The 1941 Decree clearly cut back administrative *standardization* activity. This continues to be possible formally, but the emphasis in governmental activity has since been on the supervision exercised by the Minister for Trade and Industry or the Minister for Agriculture over all technical standardization above company level. In practice, this control is exercised by a high official in the Ministry of Trade and Industry, the Commissaire à la Normalisation (Commissioner for standardization). The Standardization Commission is at the top of the French administrative hierarchy. Only five people work in it: the Commissioner himself, a deputy and three clerks. This small staff contradicts glaringly with the broad tasks assigned to the Commissioner by the 1941 Decree. He is not only to lay down general guidelines for drawing up standards, supervise the application of standards and decide on applications to depart from them, and supervise the work of the French standardization agencies, but also – at any rate theoretically – to verify the content of each individual standard. In this he was supported at the time by the Comité Consultatif, which was absorbed the Comité Supérieur de Normalisation. The wide range of tasks led to manifold difficulties, which the Commissioner sought in 1964 to eliminate by abandoning practically all technical control.⁶⁶ But the Commissioner was unable to perform the other control tasks either. In practice what emerges as its most important task was organizing communication between ministers interested in standardization and AFNOR or the Branch Standardization Committees. The relationship between the Commissioner for Standardization and AFNOR as newly regulated in the 1984 Decree takes account of developments over the last 20 years. Registration of technical standards had de facto been transferred to AFNOR before 1984, and it also decides on homologation.⁶⁷ All that remains of the former wide powers of the Commissioner for Standardization is the duty of supervision and a right to veto. The Commissioner has also given up its arbitration role in standardization committees, which had often given ground for criticism.⁶⁸

1.7.2. Democratization tendencies

The stepwise privatization of standardization – from governmental standardization pre-1941 to comprehensive supervision and control over privately organized standardization to recognition of privately organized standardization subject to an ultimate governmental veto – has run in parallel with a process of democratization of the guidelines of standardization policy.⁶⁹ The term democratization is justified in so far as the circles of participation in

⁶⁵ *Rasera, M.*, L'A.F.N.O.R. et la liaison administration-industries, Semaine Juridique, Cahier de Droit de l'Entreprise C I 1980, 28 et seq.

⁶⁶ On this *Lukes, R.*, Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG- und EFTA-Staaten, Köln/Bonn/München 1979, 22.

⁶⁷ See 1.7.4 (1) below.

⁶⁸ *German, C./Marano, P.*, La normalisation clé d'un nouvel essor, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982., 69 et seq.; Annex 2, "Rapport du groupe de travail - Normalisation et sécurité des travailleurs".

⁶⁹ This process was introduced by *German, C./Marano, P.*, La normalisation clé d'un nouvel essor, rapport au Ministre

policy formation have been steadily enlarged. While in the Comité Supérieur de Normalisation the State had dominated policy formulation, the economy was already given a place in the consultative activity of the Comité Consultatif. Creation of the Standardization Supervisory Board⁷⁰ completed the opening to consumers and trade unions, which now have a sit and a say in a body with an important part to play politically. “The Standardization Supervisory Board shall propose to the Minister for Industry, taking account of national and international economic requirements, of the major national programmes and of the special needs of both sides of industry as expressed in the economic plan, the general orientation for standardization work”.⁷¹ Though without powers of decision, the Standardization Board is to provide assistance in setting French standardization policy guidelines. In other words, the French State is covering its retreat from standardization by strengthening participation by consumer organizations and trade unions. Democratization of policy formation cannot therefore simply be equated with greater orientation of standardization policy to the needs of consumer organizations and unions.

1.7.3. AFNOR

The stepwise shift of standardization work from the State towards AFNOR has considerably affected its range of action and tasks.⁷² Today, centralization and coordination of all French standardization activity is incumbent on AFNOR. It passes instructions from the Ministers competent for standardization or the Commissioner for standardization to the Bureaux de Normalisation and verifies their implementation. It is responsible for supporting technical standardization committees in working out draft standards, and for homologation procedure.

In practice, standardization work lies largely in the hands of AFNOR itself. The industrial standardization associations are often not financially in a position to set up their own technical standardization committees and maintain them. AFNOR has to provide assistance, set up a technical standardization committee in the technical sector concerned and support it with staff and above all resources. Yet AFNOR is not entirely autonomous here, since the setting up of a technical standardization committee requires ministerial authorization.

1.7.4. Categories of standardization

The shift in powers from Government to AFNOR appears particularly clearly in the various categories of standardization, only two of which are however important for our purposes: approved and registered standards.⁷³

de la Recherche et de l'Industrie, Paris 1982.. On the “new” French standardization policy, however, see also *Marano, P.*, L'avenir de la normalisation: une mission élargie des moyens accrus, *Enjeux* No. 31, 12/(1982), 40 et seq; *Marano, P.*, Quelle normalisation pour de nouveaux enjeux, *Enjeux* No. 31, 12/1982, 42 et seq. Deux grands principes animent la réforme: concertation et décentralisation, entretien avec Laurent Fabius, *Ministre de l'industrie et de la recherche*, *Enjeux* No. 44, 2/1984, 48 et seq. (in which the political objectives are very clearly expressed). From a German viewpoint, Schulz, 1983, and the German translation of the address by Laurent Fabius at the first meeting of the Supreme Council on Standardization, *DIN-Mitt.* 63 (1984), 610 et seq.

⁷⁰ See fn. 64 above.

⁷¹ From Art. 1 of the German translation of the Decree (fn. 64 above).

⁷² AFNOR statutes were also amended accordingly. The version adopted by the General Assembly on 7 December 1983 is reprinted in *Enjeux* No. 44, 2/1984, 55 et seq.

⁷³ The account in *Lukes, R.*, Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG-

- (1) *Approved standards* have existed since 1941. These are standards given official recognition by the State. Approval takes place through ministerial decree, and is published in the “Journal Officiel”. The 1941 Act does not define in any more detail what the verification criteria in the approval procedure are. Simplifying heavily, one might say that the Commissioner for Standardization has to verify standards brought before him to see if they are against the “public interest”. This category of standard is the most important, both in number and in the importance of the individual standards. However, the numbers are steadily declining in relative terms. While in 1968 70% of all official French standards were still given approval, this percentage had fallen to 54% by 1972.⁷⁴ Observance of Government-recognized norms was made compulsory for all national procurements by the 1941 Decree. However, this obligation was not much applied in practice. Accordingly, the competent Minister, following detailed consultations between the various ministers, the Commissioner for Standardization and AFNOR, issued an administrative order⁷⁵ whereby the bindingness of standards for government contracts in principle remained; but the principle was not to be applied rigidly, but flexibly in accordance with the needs of the Administration and of the generality. Pragmatic count was thus being taken of the actual facts.

The 1941 Act also allows approved standards to be declared universally binding. Branches of the economy involved are then obliged to take the binding technical standards into account. The 1941 Act however fails to clarify the conditions on which this declaration of universal bindingness can be made. With the restructuration of standardization, the decision on approval of technical standards was transferred to AFNOR. AFNOR has to check a proposed standard to see whether it is in line with the general interest and does not offer grounds for objections that might prevent its adoption (as a government-approved norm). Approval as a norm is declared by AFNOR’s Administrative Board, after the proposed standard has passed the verification and control procedures. The Commissioner for standardization can however oppose AFNOR’s decision on approval of a draft standard. Decree No. 84/74 of 26 January 1984⁷⁶ contains no provision for the case where the Commissioner for standardization makes use of his veto right. In particular, no procedure for taking up the conflicting interests is provided for.

At the same time, the Decree of 26 January 1984 once again confirms the bindingness of approved standards on public procurements by the State, public bodies or state-subsidized firms. As far as that goes, then, nothing has changed from the previous legal position. What is unusual, though, is the way the French Government seeks to stress this intention.

Against customary usage, the Prime Minister had a circular to this effect published on 26 January 1984.⁷⁷ Its contents largely coincide with the 1971 compromise sketched out above. The circular nevertheless demonstrates how little attempts to increase the importance of the approved standards have borne fruit in practice.

und EFTA-Staaten, Köln/Bonn/München 1979, 23-25, continuous to be pertinent.

⁷⁴ Figures in *Lukes, R.*, *Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG- und EFTA-Staaten*, Köln/Bonn/München 1979, 24.

⁷⁵ Circulaire du 15 janvier 1971 relative à une recommandation de la section technique de la commission centrale des marchés publics concernant les spécifications techniques dans les marchés.

⁷⁶ J. O., Février 1984, N. C. 1127.

⁷⁷ Circulaire du 26 janvier 1984 portant sur la référence aux normes dans les marchés publics et dans la réglementation, J. O., février 1984, N. C. 1127, reprinted in German in *DIN-Mitt.* 63 (1984), 257 et seq.

As before, approved standards can be declared universally binding. But the conditions under which a declaration of universality can be made are now specified. Article 12 of the 1984 Decree says:

Where for reasons of public order, public safety, protection of the life and health of people and animals or safeguarding of vegetation, protection of national cultural treasures of artistic, historical or archeological value or for compelling reasons connected with the effectiveness of tax inspection, the propriety of business procedures and the protection of the consumer the need arises, application of a confirmed (approved) standard may by decree be declared mandatory, subject to the special exceptions provided for under the conditions of Art.18 (admissibility of possible departures).

This clarification was a response from the French Government to frequent criticism by the European Court of Justice and the Commission of the EC of the general provisions allowing standards to be declared universally binding.⁷⁸ The links with European law will be gone into further below.

- (2) *Registered standards* were introduced in 1966.⁷⁹ They have since enjoyed a steady increase in popularity. This is shown *inter alia* by the fact that by 1972 33% of all French standards were already in this category, whereas in 1968 the figure had been only 18%. This popularity is closely connected with the simpler procedure for bringing out a registered standard. This category of standard is favoured above all in areas of rapid technical change. Registered standards have not to date been the object of governmental regulation. A change has taken place in practice, since registration initially took place through the Commissioner for Standardization but has gradually passed into the hands of AFNOR. Registration is not bound up with any verification of contents. It takes place when the technical standards committees consider the standardization procedure to be complete and wish to make their results available to the economy. There is a link with approved standards to the extent that registered standards often constitute a preliminary stage towards Government-recognized standards.

1.8. Certification and product safety

No special certification procedure for verifying safety standards, nor offering an external indication of them by a special safety mark exist in France. The proposal by C. Germon and P. Marano⁸⁰ to introduce a special safety mark, on the model of the German regulations, was rejected, for unknown reasons. Accordingly, safety can be an object of certification only along with other characteristics of the product. Types of this comprehensive certification are the mark of conformity (Norme Française) and the qualification certificates (Certificat de Qualification).

⁷⁸ On the background to the problem see Lukes, 1979, 28. The European reference is discussed under 1.9.1 (3).

⁷⁹ Lukes, R., *Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG- und EFTA-Staaten*, Köln/Bonn/München 1979, 25.

⁸⁰ German, C./Marano, P., *La normalisation clé d'un nouvel essor*, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982, 52.

1.8.1. NF mark of conformity

The conditions for awarding the French mark of conformity, NF, are regulated by a decree of 1942.⁸¹ To that extent, certification is an integral part of the overall reorganization of standardization in 1941-3. The mark of conformity can in principle be issued for any product but is in practice important mainly for household appliances. The mark testifies that the product bearing it has met the standards drawn up by AFNOR or the standardization associations and subsequently given approval. It is incumbent on AFNOR to check whether the product in fact meets the standard. Considered this way, the NF conformity mark provides objective information. However, this information is often misunderstood by the consumer. Consumers believe that the conformity mark indicates a particularly high quality of product, whereas in fact the standard merely lays down a kind of minimum.⁸² This problem is quite well known and arises in other countries too. The safety of a product can theoretically be checked by the legally prescribed procedure where the underlying norm regulates important elementary characteristics of the product. This is exactly what happened with the technical standard on durability of crash helmets, since the French Government has by decree obliged all crash helmet manufacturers to put their product through certification procedure. This is, however, a unique exception.⁸³

Criminal penalties can be derived from Art. 1 of the 1905 Act, if the manufacturer uses the NF conformity mark without authorization. The civil-law position is less unambiguous.⁸⁴ The purchaser can, referring to the absence of conformity, terminate the contract and perhaps even claim compensation for damages. But the purchaser may also by Art. 1382 of the *Code Civile* claim damages from the Certification Office itself, if it has omitted to exercise its control powers. Such a claim for damages is a purely hypothetical case, as even AFNOR is not in a position to set up an all-embracing control network to guarantee disclosure of infringements. Moreover, at any rate in the event of unauthorized use of the conformity mark NF, it would have to be clarified how far Art. 6 of the 1942 Decree ruling out such liability by the Certification Office still applies.

1.8.2. Certificates of qualification

The conditions for issuing certificates of qualification are regulated in the 1978 Act,⁸⁵ the predecessor of the 1983 Safety Act. The relevant passages have not been abrogated by the new Act. The motivation for the legal regulation of the issuing of certificates of qualification was the growing enthusiasm of industrial associations to pump up sales of their products by creating a quality mark for their association and regulating the certification procedure internally. Familiar examples are "Coton Flor" or "Qualité France". A problem, and not only from the consumer viewpoint, was that neither minimum

⁸¹ Reprinted in *German, C./Marano, P.*, La normalisation clé d'un nouvel essor, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982, 124 et seq.; described in *Lukes, R.*, Überbetriebliche technische Normung in den Rechtsordnungen ausgewählter EWG- und EFTA-Staaten, Köln/Bonn/München 1979, 50 et seq.

⁸² *Calais-Auloy, J.*, Droit de la Consommation, Paris 1980, 94, para. 65.

⁸³ For an account of the issues see *Dellenbach, O.*, Les Normes de Sécurité, Mémoire Droit de la Consommation soutenue en Octobre 1984, Université de Montpellier, Directeur de Mémoire: J. Calais-Auloy, Montpellier 1984.

⁸⁴ On the possible legal consequences see *Calais-Auloy, J.*, Droit de la Consommation, Paris 1980, 95 et seq., fn. 13.

⁸⁵ On this see *Calais-Auloy, J.*, Droit de la Consommation, Paris 1980, 95 (para. 9); *Repussard, J.*, La certification en France, Enjeux No. 43, (1/1984), 51 and *Bonhomme, M.-H.*, L'Information certifiée, une des plus anciennes Revendications des Consommateurs, Enjeux No. 43, 1/1984, 62 et seq; and comprehensively *Schroeder, C.*, La qualification des produits, Thèse, Paris 1984.

requirement existed for awarding the certificates, nor quality requirements. The French Government commissioned a study in 1976⁸⁶ that came to the conclusion that it was urgently necessary to a properly functioning market for the confusion to be cleared up.

The object of the 1978 legal regulations was to allow certificates of qualification only where they gave the consumer *objective* and *comprehensible* information on the characteristics of the product. This was to be secured partly by allowing certifications henceforth only by Government-recognized bodies. The competent Ministry, the Ministry for Industry, must during approval procedure verify the institution's impartiality, and that there are guarantees in objective (technical) and personnel terms that the certification procedure can be properly carried out. By early 1984 18 institutions had been accepted, foremost among them AFNOR. This seemed to have put a stop to the current practice of self-certification of products to promote sales. But only seemed, since self-certified products have to date not disappeared from the French market.

In order to meet the self-set goal of providing the consumer with objective information, the legislator would through the certification procedure have to set minimum requirements for "quality". The difficulties of such an endeavour are obvious. The French legislator has dodged the issue by speaking merely of certain characteristics (*certaines caractéristiques*). Apparently the French legislator wanted to avoid going into the definition of quality. Industry associations and consumer organizations were given the task of specifying through negotiations what the "certain characteristics" might mean in specific cases. These negotiations are given formal shape in an Advisory Commission to the Ministry for Industry. It is not hard to see the opposing positions of the parties to the negotiations. The consumer side sees the chances of objective information as maximized if quality is standardized. Standardization must on this view cover the functional and utility characteristics of the product. Industry rejects the idea that quality can be standardized. Standardization would allegedly eliminate differences between products and threaten the mechanism of competition. The debate closely resembles the discussions in the Federal Republic of Germany on the meaning and purpose of comparative product information on quality.⁸⁷ The German legislator too declined to define quality and handed over the task to both sides of the market. This road seems in both countries to have ended in a blind alley. Neither has arrived at any noteworthy amount of comparative quality information. Theoretically, the French model could also be applied to the issuing of safety certificates. But this aim would be obstructed by the one-sided sales-oriented regulation of certificates of qualification. The safety of a product can be used only to a limited extent to boost sales.

1.9. The 1983 Act in the light of European Community Law

The object of the analysis is to bring the French viewpoint into the debate on European safety law. The sole basis for a treatment of the French position to date is the study by J.-P. Pizzio.⁸⁸ His whole portrayal is adapted to the French way of looking at things, to the extent that European Community law too is considered and analysed from the viewpoint of

⁸⁶ *Repussard, J.*, La certification en France, Enjeux No. 43, (1/1984), 51, refers to this in his account, though without mentioning the exact title.

⁸⁷ On this see *Micklitz, H.-W.*, Three Instances of Negotiation Procedures in the Federal Republic of Germany, JCP 1984, 211 et seq. (deutsch: Verhandlungsmodelle im Verbraucherschutz, MD VZ-NRW 1984, 67 et seq.).

⁸⁸ *Pizzio, J.-P.*, La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986.

whether administrative means of sanction are available to implement product safety. European Community policy was always to allow Member States much leeway in their implementation of the substantive law. The report keeps to this premise.⁸⁹ Community intervention with French administration arouses considerable mistrust. The inclusion of the Single European Act in the description gives Pizzio a chance to go into the relationship between internal market policy and product safety policy in more detail. Since by contrast with environment protection and labour protection, consumer protection was not included in the treaties as a policy objective, product safety must be taken to be subordinated to the goal of creating free movement of goods.⁹⁰

The analysis of the relationship between the Product Safety Act and European Community Law is done in two stages. The 1983 Act is first checked for its interaction with free movement of goods, and then specifically for the effects of the new approach on French safety policy, and on the 1983 Act itself.

1.9.1. The 1983 Act and free movement of goods

- (1) *Scope of the 1983 Act*: Article 8 is aimed at regulating cases of conflict between Community law and the 1983 Act. The wording seems to make it clear that the 1983 Act is no longer applicable where the products concerned are already covered by a Community directive. An interpretation *au pied de la lettre* would have the consequence of excluding only regulation by *Statute*, while the French government would be free to regulate product safety by decree even in the event of conflict. This rather jesuitical version is however immediately abandoned, and for all forms of regulation the substantive focus is whether the products have already been the object of a Community provision. It follows that in cases of total harmonization France retains competence of its own only in the emergency case provided for in the 1983 Act. But even here Community law can retain primacy over French national safety law as long as the harmonization measure includes a special safeguard clause explicitly covering such emergency measures.⁹¹
- (2) *The duty to notify regulatory measures under the 1983 Act*: If these are measures to be taken as part of a normal procedure, then the objective scope of the Directive of 28 March 1983⁹² covers a comprehensive obligation of notification including now agricultural products, foodstuffs, medicaments and cosmetics.⁹³ To date (1986) the duty of notification has become relevant on two occasions, when the French legislator embarked on specifying the general clause in the 1983 Act by issuing special decrees.⁹⁴ In the first case Pizzio notes a delay of nearly two and half months, but the proposed decree has not yet come into force in France. The second case is more interesting, above

⁸⁹ Op. cit., 9 et seq.

⁹⁰ Op. cit., 15.

⁹¹ Op. cit., 19 et seq.

⁹² OJ L 109, 26 April 1983, 8. For details on this see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁹³ OJ L 81, 26 March 1988, 75.

⁹⁴ *Pizzio, J.-P.*, La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986, 31 et seq.; and basically *Lecrenier, S.*, Les Articles 30 et suivants CEE et les Procédures de Contrôle prévues par la Directive 83/189/CEE, RMC 1985, 6 et seq.

all because it involves the first decree issued on the basis of the 1983 Act.⁹⁵ It forbids the manufacturer, sale and importation of erasers that look like foodstuffs. The Community has since, in response to various national measures banning imitations of edible products, adopted a directive on products of misleading appearance liable to endanger consumer health or safety, which covers all types of products.⁹⁶

The notification obligation becomes more problematic in the case of an emergency measure.⁹⁷ Certainly, the Information Directive provides for an abbreviated procedure, but localized bans, withdrawals from sale and the like are not covered by the obligation of notification. Since however in France the “Commissaires de la République” have wide-ranging competences regionally, there is a loophole here for measures regulating safety that might escape Community notice.

Another question is the extent to which regional measures on product regulation are (or must be) notified to the Community on the rapid information system.⁹⁸

Pizzio⁹⁹ regards the notification procedure as extremely effective, since experience to date in France shows, he says, that the Commission's consultation procedures offer adequate possibilities for making national safety regulations compatible with Community Law.

- (3) *Compatibility of the 1983 Act with Articles 30 and 36 of the EEC Treaty*: “Measures having equivalent effect” within the meaning of Art. 30 EEC also include technical standards drawn up by AFNOR. A specifically French possibility of conflict results from the possibility of declaring standards legally binding by decree. The taking of this step led in 1983 to the bringing of an action for breach of treaty, because of the legal bindingness of a technical standard on the manufacturing of refrigerators.¹⁰⁰ Following the Commission's intervention, France changed the scope and coverage of the standard but kept its legal bindingness.¹⁰¹ But France feels very sure of its chances of justifying national health and safety provisions through Art. 36 EEC or the Cassis de Dijon Case Law on Art. 30 EEC.

1.9.2. The 1983 Act and the new approach to technical harmonization and standards

In his commentary on the new approach to technical harmonization and standards, J.-P. Pizzio¹⁰² points to a number of noteworthy problems which are however only partly dealt with in the report:

- The essential requirements should be defined in such a way as to be capable of leading to sanctions (behind this there is again the specifically French - administrative - approach to safety policy).

⁹⁵ Of 18 février 1986, published in J. O., 28 février 1986.

⁹⁶ OJ L, 11 July 1987, 49.

⁹⁷ Pizzio, J.-P., La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986, 32.

⁹⁸ Council decision of 2 March 1984 introducing a Community system for rapid exchange of information on hazards in using consumer products, OJ L 70, 13 March 1984, 16 et seq.

⁹⁹ Pizzio, J.-P., La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986, 33 et seq.

¹⁰⁰ Written Question N° 835/2, OJ C 93, 7 April 1984, 1.

¹⁰¹ See J. O., Novembre 1984, N. C. 10307; and in general Pizzio, J.-P., La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986, 38.

¹⁰² Op. cit., 52 et seq.

- Member States should be banned from subjecting technical products to prior approval procedures.
- Should consumer protection necessitate the inclusion to any large extent of technical specifications in the fundamental requirements, recourse to the new approach would, he says, not be appropriate. Deciphered, this means that Pizzio doubts the effectiveness of reference to standards in this very area of the safety and health of persons.
- The problem of certification could be solved on the example of the Franco-German bilateral model; i.e. mutual recognition of certification institutes and their certificates, and also mutual recognition of safety marks (though one would have first to be created in France).

In very general terms, the new approach is claimed to have effects on the relationship between product safety and technical standards. Member States would have to adopt a policy of deregulation in the area of product safety. Accordingly, *de jure* or *de facto* binding technical standards would in the long term have to be broken down and adapted to the requirements of the common market. This would require the building up of trust in technical standardization as a guarantee of product safety, but also, at the level of the Common Market, compel recognition of the equality in principle of safety levels, even where solutions differ.

At the end of the report, Pizzio¹⁰³ asks the decisive question: What happens when the Community has adopted a directive defining the safety requirements in principle but a Member State nevertheless wants to take national measures that go beyond the defined goal? The problem already arises with the Directive on simple pressure vessels,¹⁰⁴ which in departure from Art. 1 of the 1983 Act is based on a safety concept that does not include foreseeable misuse. By a circuitous route through a treatment of the *Cremonini v. Vrankovich* ruling¹⁰⁵ of the European Court of Justice, Pizzio¹⁰⁶ arrives at the following conclusions:

- The primacy of Community law makes it compulsory to allow even products that would not comply with Art. 1 of the General Clause of the 1983 Act to circulate freely. (Though Pizzio does not say this explicitly, the differing safety concepts in the Community Directive on simple pressure vessels (usage in accordance with instructions) and in the 1983 Safety Act would not be an obstacle to the capacity of their circulation).
- Recourse to Art. 36 would be open to Member States only where the basic requirements had not been fully defined.
- It would follow that where the Community had adopted particular directives on the basis of the model Directive, a Member State would be able to pursue a national safety policy only in the context of the safeguard clause procedure.

¹⁰³ Op. cit., 65.

¹⁰⁴ OJ L 220, 8 August 1987, 48.

¹⁰⁵ ECJ [1980] 3583, case 815/79, judgment of 2 December 1980. For details on the low-voltage Directive, see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹⁰⁶ *Pizzio, J.-P.*, La loi du 21 juillet 1983 et le droit communautaire. Rapport de recherche rédigé par Mlle. Foucher sous la direction de J.-P. Pizzio, Dijon 1986, 68 et seq.

1.10. The bilateral agreement between the Federal Republic of Germany and France on the removal of technical barriers to trade¹⁰⁷

In July 1983 Chancellor Kohl and French Prime Minister Mauroy agreed the following measures on a reciprocity basis¹⁰⁸:

- mutual recognition of safety standards of equal value from the technical viewpoint;
- improvement of relations between applicants and test centres;
- mutual recognition of test centres.

The negotiations for converting the agreement into national law on each side were handed over to a Franco-German working party. The object of the following account is not so much to give a detailed analysis of the bilateral agreement as to attempt to estimate the effect and function of the bilateral agreement for a European safety policy.

1.10.1. Background to the bilateral agreement

Immediately after enactment of the German Machine Protection Act (*Maschinenschutzgesetz*), various Member States were already active in Brussels to ensure that the Act would not have any negative effects on free movement of goods.¹⁰⁹ The Federal Government agreed at the time to incorporate foreign standards, especially those of Community Member States, in a separate list accompanying the Machine Protection Act (today the Appliance Safety Act (*Gerätesicherheitsgesetz*)). AFNOR then drew up a sixty-page list of a 1,000 French standards on technical devices, which was submitted to the German authorities. On the German side, however, the view was taken that it was impossible to take the French standards into account. The requirement for the incorporation of a note on the standards in the annex to the Act was to be compliance with the following three conditions:

- a) the French standards would have to be available in German translation.
- b) the French standards would have to contain specifications on the safety of persons.
- c) the French standards would have to be individually verified by an expert committee.

In fact, the Federal Government did not then meet its clear formal agreement.

From around the mid 70s, German technical standards and thus also the Appliance Safety Act came increasingly under fire from French critics.¹¹⁰ There were reports of difficulties

¹⁰⁷ On this see *Laurent, J.*, Bilaterale Abmachungen im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus französischer Sicht, DIN-Mitt. 63 (1984), 117 et seq; *Winckler, R.*, Bilaterale Abmachungen im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus der Sicht der deutschen Industrie, DIN-Mitt. 63 (1984), 120 et seq; *Strecker*, 1984; joint declaration by AFNOR and DIN on standardization, DIN-Mitt. 63 (1984), 194 et seq.; *Becker, U.*, Fortschritte durch Vertrauen, BArbBl. 2/1985 et seq.; *Winckler, R.*, Rechtsvorschriften für Anlagen, Geräte und Stoffe - Bestandsaufnahme und kritische Würdigung. Materialien und Geräte unter besonderer Berücksichtigung des Gerätesicherheitsgesetzes, der 2. DurchführungsVO zum EnWG und der Niederspannungsrichtlinie, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 26 et seq., *Beauvais, E. v.*, Diskussionsbeitrag, in: *Recht und Technik, Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im französischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 76 f.

¹⁰⁸ Thus *Becker, U.*, Fortschritte durch Vertrauen, BArbBl. 2/1985 et seq., 37.

¹⁰⁹ *Strecker, A.*, Bilaterale Abmachung im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus der Sicht des Bundesministeriums für Wirtschaft (BMWi), DIN-Mitt. 63 (1984), 123-124, 123.

¹¹⁰ *Laurent, J.*, Bilaterale Abmachungen im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus französischer Sicht, DIN-Mitt. 63 (1984), 117 et seq., 117,

for French industry in exhibiting their goods at trade fairs in the Federal Republic. In themselves these obstacles to trade would hardly have been sufficient to make the technical standards into an object of high-level politics. But the issue acquired greater importance when in the late 70s and early 80s the French made a connection between their growing current account deficit and the technical standards. In fact, on Commission's statistics, German consignments to France more or less exactly doubled between 1977 and 1982, thus rising by 100%, while in the opposite direction the rate of increase was only around 75%.¹¹¹ We need not here go into whether there is indeed a connection between the balance of payments deficit and German standards as potential technical obstacles to trade. In any case, the French succeeded in bringing in the European Community in the person of DG III Director-General Braun, who in a lecture to a German audience more or less adopted the French version as his own by calling the Germans the secret sinners in the setting up of non-tariff barriers to trade. Encouraged by the press, the equation 40,000 German standards = 40,000 technical obstacles to trade began to circulate.

On the other side, the Germans referred to a practice of French authorities begun some time in the early 1980s of adopting decrees that *de facto* made the import of German products into France impossible.¹¹² These decrees for particular individual groups of products were always built up on the same pattern: (1) the product had to meet a French standard and (2) this had to be documented by a test certificate and a NF-mark. The majority of decrees concerned safety requirements for wood-working machines.¹¹³

The mutual reproaches led in 1983 to the surprising outcome of a bilateral agreement. Apparently, following the controversially pursued public debate, pressure to negotiate was so great on both sides that action had to follow. The exchange of ideas and information between the authorities and the relevant institutions intensified. One product of the intensified relationships was the colloquium organized in Strasbourg in June 1984 by the Franco-German society for science and technology on cooperation between German and French testing and standardization institutions.¹¹⁴ In it, competent experts, significantly, discussed the areas that the Community had mentioned in the preliminary work on the model directive as deserving priority in harmonization: construction, measuring equipment, materials testing and welding techniques.

But the bilateral agreement did not meet purely with acceptance. The joint declaration by AFNOR and DIN makes reservations about the need for a bilateral level of standardization clear.¹¹⁵ Bilateral agreements might, from the viewpoint of the standardization institutions, serve a transitional function only as an interim solution for relevant problem areas, while in principle standardization at European or international level was to be aimed at. It is hard to say how far the commencement of an action for breach of the Treaty against the French decrees on admission of woodworking machines was directly or indirectly induced by the bilateral agreements.¹¹⁶ It is in any case conceivable that through its action the Community

¹¹¹ Winckler, R., Bilaterale Abmachungen im Zusammenhang mit der Anerkennung Deutscher und Französische Normen - Darstellung aus der Sicht der deutschen Industrie, DIN-Mitt. 63 (1984), 120 et seq., 120.

¹¹² Strecker, A., Bilaterale Abmachung im Zusammenhang mit der Anerkennung Deutscher und Französische Normen - Darstellung aus der Sicht des Bundesministeriums für Wirtschaft (BMWi), DIN-Mitt. 63 (1984), 123-124, 123.

¹¹³ On this see Becker, U., Fortschritte durch Vertrauen, BArbBl. 2/1985 et seq., 34 and Table I.

¹¹⁴ AFAST, 1984.

¹¹⁵ Joint declaration by DIN and AFNOR (fn. 104 above).

¹¹⁶ ECJ [1986] 419, case 188/84, judgment of 28 January 1986 - woodworking machines. On this judgment see also Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case

wished to pull the rug from under the bilateral agreements between France and the Federal Republic. One indication in this direction is the almost complete identity in the thrust of the German and European criticisms of French administrative practice. For in the action for breach of treaty, the European Community attacks precisely those market admission regulations on woodworking machines that had been the basis for the German attacks on the French Government.¹¹⁷ On the other hand, the Commission's bill of complaint was not submitted to the ECJ until July 1984, by which time the bilateral agreement had long been concluded.

1.10.2. Results

Following the end of the political talks, AFNOR in an initial phase checked at the highest level 281 DIN standards in 19 branches of industry (excluding electrical engineering) to compare them with the 295 corresponding French standards.¹¹⁸ This list was the starting point for initial activities by the competent authorities in both countries to begin being serious about facilitating circulation of goods. The conference organized by the Franco-German Society for Science and Technology supplies further illumination as to the chances and difficulties for the bilateral agreement. In relation to the three objects of the agreement mentioned at the beginning the following provisional balance sheet can be drawn up:

- (1) The chances for mutual recognition of standards differ considerably from one branch of industry to another. The Strasbourg conference brought out highly differentiated findings in the branches discussed there. The situation in the construction industry is so different in both countries that necessary research work would first of all have to be done in order to be able to define political goals. By contrast, the situation as regards measuring instruments is relatively clear. While there are considerable formal differences, in substance the two systems largely overlap. Harmonization seems possible if the political will to break down the formal distinctions is present. The situation is different again in the area of welding techniques and material testing. Here the need for removal of existing obstacles to trade seems to be very great, but the objective meets with not only political but also technical difficulties. Experts are agreed in their assessment when it comes to electrical engineering. Here the international network of technical standards and testings centres is so widely developed that a bilateral agreement could at most have negative effects.

The nature of the bilateral agreement has since become clear. It is certainly not concerned with facilitating trade in consumer goods. To that extent, there is only a very indirect connection with the topic being discussed here. However, the bilateral agreement is interesting for the way it uses techniques to make the legal systems compatible with the various foreign standards.

The BMA has, according to information from the French Ministry for Foreign Trade and Industrial Development, published an initial list C on the general administrative

law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.2.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹¹⁷ It is sufficient to compare the decrees attacked by the Commission in case 188/84 (fn. 116 above) with the survey in *Becker, U.*, *Fortschritte durch Vertrauen*, *BArbBl.* 2/1985 et seq., 35.

¹¹⁸ *Laurent, J.*, *Bilaterale Abmachungen im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus französischer Sicht*, *DIN-Mitt.* 63 (1984), 117 et seq., 118.

provisions of the Appliances Safety Act, of 118 French standards.¹¹⁹ The list is based on an assessment that the French standards listed therein are in principle equivalent to the German standards contained in list A. The authorities should intervene only where there is reason to doubt whether the French standards correspond to the safety level prevailing in the FRG.¹²⁰

French law requires different solutions, since it does not have the device of the derogating clause as in the Appliances Safety Act. Since manufacturers are obliged to comply with a norm specified by a decree (Arrêté), German standards can be incorporated into the system only if this obligation is met through them too. This presupposes abstract verification of the equivalence of German standards before including them in the decree. The French Ministry for Industry has in this way incorporated 9 DIN standards important in the eyes of the German Federal Ministry for the Economy into its system of binding technical standards, thereby giving them the same legal bindingness as the corresponding French standards.¹²¹

- (2) To improve the relationships between applicant and test centre particularly in the case of small and medium-sized enterprises, both governments have decided to explain the bases of the test centres' activity and the relationship between test centre and applicant. In the meantime, circulars to the test centres in accordance with the Appliance Safety Act and general guidelines for applying the conformity tests in accordance with the French decree on standards have been published.¹²² Both publications explain the administrative, technical and financial aspects of the national conformity tests.
- (3) Before mutual recognition of test centres, though, there is still a long way to go politically. Although there is agreement that certificates or test marks probably cause greater technical obstacles to trade than do different technical standards, the bilateral agreement has so far shown hardly any effect. Nevertheless, inclusion of the LNE (Laboratoire Nationale d'Essais) in the list of test centres under the Appliance Safety Act has made a start. Information on the procedure aimed at is provided by the Joint Declaration by AFNOR and DIN.¹²³

In the area of certification with the NF mark and the DIN test and inspection mark, AFNOR and DIN will collaborate by in principle carrying out tests of products and inspections of methods of manufacture in the country of origin and by systematically aiming at mutual recognition of these tests and inspections in the context of and in implementation of the regulations drawn up for the purpose by CENCER.

This passage makes it clear that a strict distinction has to be drawn between full mutual recognition of test results *and* conveyance of certifying power to a foreign office. The furthest-reaching goal is full mutual recognition of test results, but at present efforts are being concentrated on conveying certification powers. This would mean, to give one example, that German testing institutions would be entitled to test French products to see whether they meet the requirements of the NF conformity procedures. Conversely, the Federal Republic has declared its willingness to grant French test centres empowerment to

¹¹⁹ BArbBl. 11/1984, 52 et seq. Cf. *Becker, U.*, Fortschritte durch Vertrauen, BArbBl. 2/1985 et seq., 37.

¹²⁰ Op. cit., 37.

¹²¹ Op. cit., 37.

¹²² Op. cit., 38. The German paper was published in BArbBl. 11/1984, 52. Cf. also 3.3.4. below.

¹²³ Joint declaration by DIN and AFNOR, DIN-Mitt. 63 (1984), 194 et seq.

confer the German safety mark GS, if full mutuality is guaranteed “with the maintenance of the usual reservations”.¹²⁴

1.10.3. Effect and function of the bilateral agreement on the creation of a Community safety policy

The opposite poles of the analysis are an accusation of protectionism and a possible pioneering role. Protectionist tendencies might be pointed to in the bilateral agreement because in the European Community a Franco-German axis is build up that might have disadvantageous effects on integration in the common market. While list C under the general implementing regulations for the Appliances Safety Act is at least theoretically open also for the inclusion of norms of other European Community Member States, in France explicit inclusion of foreign standards in the decree is necessary in order to guarantee the possibility for the goods to be traded in France. This comparative cumbersomeness of the French administration has readily been treated as an argument for the flexibility of the German system of reference to standards. This would, however, be to overlook that an administrative act is necessary for the incorporation in the list too. To that extent, the accusation of protectionism applies both to France and to the Federal Republic. The tendency to a Franco-German alliance within the Community is strengthened still further if the fact is included that in the standardization the French are concerned above all with information technology.¹²⁵ Finally, the cautious attitude of both DIN and AFNOR should be pointed out, since both continue to maintain the objective of international standardization and regard bilateral agreements as at best a transitional possibility, tending as they do to impede international trade in goods.

Yet there are positive things about the bilateral agreement too. Mutual recognition of standards in special Franco-German committees is objectively nothing other than political harmonization as also aimed at in the context of the Standing Committee under the model directive. Franco-German preliminary work, as done for instance at the Strasbourg colloquium in 1984, might thus accelerate procedure in the Standing Committee. Possibly even more important, however, is the attempt to be serious about mutual recognition of test centres. The model directive did not cover this issue¹²⁶ and the standardization organizations themselves have got scarcely anywhere with it outside the area of electrical engineering. A bilateral solution to this extremely important question might be able to act as a model for European regulations on mutual recognition. In very general terms, the bilateral agreement seems in relevant technical and political circles to have aroused considerable response and not only in the Federal Republic and France.

¹²⁴ *Strecker, A.*, Bilaterale Abmachung im Zusammenhang mit der Anerkennung Deutscher und Französischer Normen - Darstellung aus der Sicht des Bundesministeriums für Wirtschaft (BMWi), DIN-Mitt. 63 (1984), 123-124, 124.

¹²⁵ On this see *German, C./Marano, P.*, La normalisation clé d'un nouvel essor, rapport au Ministre de la Recherche et de l'Industrie, Paris 1982, throughout.

¹²⁶ See *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

2. Consumer Product Safety Law in Britain⁺

2.1. Introduction

In the world's oldest industrial country too, consumer product safety law has followed the path of development typical of most developed societies. It follows the tradition of governmental technical control starting in the 19th century, and develops relatively late out of technical (plant/factory) safety law and safety-at-work law. Accordingly, it concentrates firstly on protection of life and limb. Its instruments are administrative control and criminal sanctions. Moreover, safety law for consumer products is, more than technical safety law and safety-at-work law, *market regulation*. That places it under stronger requirements as to economic efficiency and public policy legitimation. In Britain too, this ambivalence marks the structure of existing consumer product safety law and the current debate on prospects for extending it.

2.2. The Consumer Protection Act 1961

2.2.1. Pre-history

Technical safety law in England and Wales stands unchanged within the tradition of the heroic age of the 19th-century factory acts. This command and control model of government regulation of safety as a rule consists in a broad definition of goals by the legislator. To achieve the goal, an administrative structure is set up. The top of the administrative body largely autonomously determines measures to be taken in order to secure the legal objective. Implementation and verification is incumbent on an inspectorate on the spot. Accordingly, there is relatively wide freedom of action. Informal conflict settlement and cooperation are clearly to the fore. Recourse to the criminal courts constitutes the ultimate – rarely used – legal means of sanction against safety infringements. While the Health and Safety at Work Act 1964 – the first comprehensive regulation of British safety-at-work law – still largely follows this regulatory model (with a separate administrative structure), consumer product safety law took a different road from the outset.¹²⁷

Till the end of the 1950's, there were legal regulations only for individual cases of particular consumer products [Fabrics (Misdescription) Act 1913; Heating Appliances (Fireguards) Act 1952; Oil Burners (Standards) Act 1960].¹²⁸ In 1959 the Committee on Consumer Protection was set up and in 1960 submitted an interim report, followed by a comprehensive final report in 1962.¹²⁹ The main impetus for this initiative came from the “consumer sovereignty fallacy”, which could not longer be overlooked. The Committee's proposal aimed at institutionalizing consumer power in the form of a governmental Consumer Council made up of independent persons.¹³⁰ Its main tasks were to be: gathering information; verifying the existence of a need for political action; influencing the public to

⁺ The account is confined to England and Wales.

¹²⁷ On the development of consumer protection law in Britain in general, see *Borrie, G.*, *The Development of Consumer Law and Policy - Bold Spirits and Timorous Souls*, London 1984.

¹²⁸ The latter two were repealed by the Consumer Protection Act 1961 and replaced by safety regulations under the CPA: the Heating Appliances (Fireguards) Regulations 1973 and the Oil Heaters (Safety) Regulations 1977.

¹²⁹ Final Report of the Committee on Consumer Protection, 1962.

¹³⁰ *Op. cit.*, 278 et seq.

take specific consumer-protection policy measures. Fifteen years later, the 1976 Green Paper on consumer safety again advocated the setting up of a Consumer Committee;¹³¹ 21 years later a consumer protection committee of this type was set up in France.¹³² In Britain, by contrast, legislation took a different course. In 1961 – before the Committee on consumer protection had finished its work but in implementation of some of the recommendations from its interim report – a safety law covering all consumer products was enacted for the first time: the Consumer Protection Act (CPA).

2.2.2. The content of the CPA 1961

The Consumer Protection Act (CPA) 1961, slightly amended in 1971 and 1977, is a mere *framework law*. It does not itself contain any substantive regulations of relevance to safety. Essentially, it covers three points:

- Section 1 implements the main recommendations of the 1960 Interim Report of the Committee on Consumer Protection:¹³³ the executive (the competent Secretary of State) is empowered to enact binding safety requirements for particular types of product where this appears advisable. The safety requirements relate to two things: 1) requirements on composition, content, planning, design, manufacture and packaging of products, to avoid danger to life and limb; 2) requirements on instructions and warnings to potential purchasers.
- Section 2 contains the *general obligation* on every professional seller of the product in question at all stages of trade to observe the safety requirements formulated in the Safety Regulations. This duty of observance does not apply to *inter alia* private sellers (Section 2 (3) (a) CPA) or exporters (Section 2 (3) (b) CPA).
- Section 3 regulates the sanctions for infringing the Safety Regulations. Infringements of the duty of observance pursuant to Section 2 are subject to criminal proceedings (Section 3 (2) CPA). In the event of damage, *any* person damaged by the unsafe product can raise criminal compensation claims against the seller (offence of breach of statutory duty - Section 3 (1) CPA). General common-law entitlements to compensation remain untouched (tort and contract).¹³⁴

2.2.3. Assessment

All in all the CPA 1961 keeps to the approach of individual case regulation in safety law. All that happens is that competence to regulate the individual cases is shifted from the legislature to the executive. For enactment of safety regulations, the CPA makes no formal approval by either House of Parliament necessary. Usually, though, the Joint Committee on Statutory Instruments, a joint committee of both Houses of Parliament, is involved. Section 1 (5) lays a duty on the Secretary of State to consult “such persons or bodies of persons as appear to him requisite” before issuing a regulation. A safety regulation can be suspended at any time by decision of either House of Parliament (“negative resolution procedure” – Section 1 (6) CPA). The CPA 1961 is innovative in its consumer protection policy effect in two ways: by extending the power of legal regulation to *all consumer*

¹³¹ Consumer Safety. A Consultative Document, Cmnd. 6398, London HMSO, 28.

¹³² Cf. 1.3 above.

¹³³ Interim Report of the Committee on Consumer Protection, Cmnd. 1011, London HMSO 1960.

¹³⁴ Cf. 2.7 below.

products and by making safety regulation *dynamic* through delegating power to issue safety regulations to the executive without involvement of Parliament. One weakness is implementation. No separate hierarchical administrative structure was set up to apply the CPA. Verification of observance of safety requirements was instead left to the local authorities, the trading standards officers of the local Weights and Measures Authorities. These are entitled – but not obliged – to carry out inspections within the area of application of safety regulations, and to take random samples of goods for further investigation. They are not given any further powers. In particular, the local implementing bodies cannot issue any prohibition orders. Over and above formal sanction, the CPA trusts to voluntary observance of the safety regulations and to the market-complementary method of consumer information or sensitization. Altogether, between 1961 and 1978, eighteen safety regulations on the basis of the CPA were issued.¹³⁵ There do not however seem to be any indications as to how many sellers had proceedings brought against them in that period for breach of safety regulations.

2.3. The Consumer Safety Act 1978

2.3.1. Background

A further stocktaking of consumer product safety law in Britain came fifteen years after enactment of the CPA, in the 1976 Government Green Paper on “Consumer Safety”.¹³⁶ This summarized the then prospects for a British consumer product safety law, which in the later White Papers of 1982, 1984 and 1985 were merely taken up again in part and given

¹³⁵ Regulations made under the Consumer Protection Act 1961, Section 1, now in force.

<i>Subject</i>	<i>Statutory Instrument No.</i>
The Stands for Carry Cots (Safety) Regulations 1966	SI 1610
The Nightdresses (Safety) Regulations 1967	SI 839
The Toys (Safety) Regulations 1974	SI 1367
The Electrical Appliances (Colour Code) Regulations 1969	SI 310
The Electrical Appliances (Colour Code) Regulations 1970	SI 811
The Electrical Appliances (Colour Code) Regulations 1977	SI 931
The Electric Blankets (Safety) Regulations 1971	SI 1961
The Cooking Utensils (Safety) Regulations 1972	SI 1957
The Heating Appliances (Fireguards) (amended by Regulations 1973 1977/167)	SI 2106
The Pencils and Graphic Instruments (Safety) Regulations 1974	SI 226
The Glazed Ceramic Ware (Safety) Regulations 1975	SI 1241
The Electrical Equipment (Safety) Regulations 1975 and 1976	SI 1366 and 1208
The Vitreous Enamel-Ware (Safety) Regulations 1976	SI 454
The Children’s Clothing (Hood Cords) Regulations 1976	SI 2
The Oil Heaters (Safety) Regulations 1977	SI 167
The Babies’ Dummies (Safety) Regulations 1978	SI 836
The Cosmetic Products (amended by Regulations 1978 (also S2(2) ECA 72) 1984/1260; to be revoked in 1988)	SI 1354
The Perambulators and Pushchairs (Safety) Regulations 1978	SI 1372
The Oil Lamps (Safety) Regulations 1979	SI 1125
The Cosmetic Products (Amendment) (revoked by Regulations 1983 (also S2(2) ECA 72) 1984/1260))	SI 1477

¹³⁶ Consumer Safety (loc. cit, fn. 131).

new emphases. Four main points are picked out as shortcomings of consumer protection policy.¹³⁷

- Lack of regular systematic *information* on product-related accidents and of in-depth studies on the exact involvement in accidents of such products, or on cumulative causes of accidents; lack of international exchange of information.
- Lack of *BSI standards* for consumer products, and difficulties in developing and/or updating them;
- *Cumbersomeness* and *procedural restrictions* of safety regulations, in particular the absence of any possibility outside the regulations to respond to new hazards and issue banning orders or have products recalled;
- Weaknesses in implementing safety regulations.

Among the proposals for improving consumer protection we shall here deal only with the set of technical standards. In order to secure a wider range of specific technical standards, the Government contemplates the following possibilities:¹³⁸

- Introduction of special safety standards;
- Setting of time limits for developing new technical standards; in this context adoption of the offeror procedure practised by the US CPSC is recommended;¹³⁹
- Generalized formulation of safety requirements in safety regulations, even if no British Standard is available, so that manufacturers themselves can develop appropriate technical solutions;
- A shift to the method of non-binding reference to technical standards in safety regulations;
- Development of conformity marks;
- Encouraging economic associations to develop self-regulatory codes of conduct in the area of consumer safety law too, as already usual in competition law under encouragement from the Office of Fair Trading (since 1973).

2.3.2. The content of the CSA 1978

An initial partial response to the criticism and proposals in the 1976 Green Paper was the Consumer Safety Act 1978.¹⁴⁰ The characteristic of this Act, still authoritative today, is flexibilization on the sanctions side. The rigid two-dimensionality of overall empowerment by statute and regulation of individual cases by the executive is abandoned. Besides the safety regulation, three other instruments are added to the executive's range of safety law measures; the prohibition order, the prohibition notice and the notice to warn. The only one important in practice is the prohibition order, which supplements safety regulations by acting as a time-limited emergency measure.

The CSA contains essentially five points:

- (1) Section 1 lays down "the law" of safety regulations. The objects of the regulations are firstly - here made explicit for the first time - the *safety* of consumer products,¹⁴¹ and

¹³⁷ Loc cit., 11 et seq.

¹³⁸ Loc cit., 16 et seq.

¹³⁹ Cf. 4.3.1. below.

¹⁴⁰ On the information aspect cf. 2.8 below.

We shall not here go into the technical legal difficulties arising from continued co-existence of the CPA with its regulations and the CSA.

¹⁴¹ The concept "safe" is defined in Section 9 (4) CSA: "Safe means such as to prevent or adequately to reduce any

secondly the furnishing of consumers with appropriate *information* (Section 1 (1) CSA). The way these goals are to be met through the regulations is set out in detail in Section 1 (2). A notable feature, as a further reflection of the proposals in the 1976 Green Paper, is the prominent place given to technical standards. Technical standards as a substantive reference point for safety regulations appear in four of the nine points. In the context of measures to inform and warn the consumer, marks are also explicitly mentioned.

The procedure for enacting safety regulations is, by comparison with the CPA, made formal. Competence remains with the executive (Secretary of State). However, the duty of consultation is extended. The Secretary of State is now obliged to consult organizations that represent interests affected by the regulation (Section 1 (4) CSA). One example of what this means is that in connection with the Novelty (Safety) Regulations 1980, 66 people and/or organizations were consulted. Additionally, safety regulations must now be approved by both Houses of Parliament (Section 7 (7) – “affirmative resolution procedure”).¹⁴² Both mean considerable complication and prolonging of the procedure for issuing safety regulations.

- (2) Section 3 regulates the new instruments of action. The cumbersomeness of the safety regulation procedure is evidently to be compensated here by opening up additional possibilities of rapid regulatory intervention.

Prohibition orders (Section 3 (1) (a) CSA) are orders that prohibit the sale of a particular group of products.¹⁴³ The Secretary of State has in principle to announce the issue of a prohibition order 20 days in advance, secure opinions and check those received. This “preliminary procedure” may be dispensed with only in urgent cases (“emergency procedure”). The prerequisites for an “urgent case” are not specified in any more detail. Prohibition orders expire by law after 12 months. Additionally, they may at any time be waived by decision of either House of Parliament (Section 7 (6) CSA).

Prohibition notices (Section 3 (1) (b) CSA) are issued to a particular person. The procedure for issuing prohibition notices is regulated in Schedule 1 Part II CSA - in too much detail and out of all proportion to their practical relevance. Intensive exchange of information between the trader/importer affected and the Secretary of State is provided for. This seems to amount to legal regulation of the prevailing practice at the implementation stage of informal settlement of disputes.

Notices to warn (Section 3 (1) (c) CSA) are instructions to suppliers to provide information or warnings on particular hazards of products supplied by them¹⁴⁴.

- (3) *Contraventions* of prohibition orders, prohibition notices or notices to warn issued by the Secretary of State are criminally (Section 2 CSA) and civilly (Section 6 CSA – offence of breach of statutory duty) actionable.
- (4) For the first time, a comprehensive *information right* of the Secretary of State is also given legal embodiment. He may secure information, call for documents and ask to see them, etc. Breaches of this duty on suppliers constitute an offence.
- (5) Section 5, taken together with Schedule 1 Part III, regulates in detail the powers of the implementing agencies. These are – as under the CPA – confined to the right to enter

risk of death and any risk of personal injury from the goods in question or from circumstances in which the goods might be used or kept, ...”

¹⁴² For details on procedure, see *Weatherill, S./Woodroffe, G.F.*, Consumer Safety in the United Kingdom. Report for the European Communities, Contract No. 85-B 6673-11-005-11-C, 93 et seq.

¹⁴³ Details of the procedure are regulated in Schedule 1 Part I CSA.

¹⁴⁴ The procedure is regulated in Schedule 1 Part III CSA.

business premises, see documents, take samples of products for further investigation, and where necessary secure assistance from authorized agencies to enter business premises by force and, in compliance with prescribed procedures, forcibly open receptacles.

2.3.3. Assessment

The thinking of the CSA 1978 is characterized by the division of labour between safety regulations and prohibition orders. Prohibition orders are a response to new types of product hazard. During their 12 months duration, experience accumulated can be used to decide whether there is justification for extending the provisional measure into a safety regulation. Of the eight prohibition orders issued under the CSA between 1978 and 1983, six have been converted into safety regulations. Prohibition notices and notices to warn have not so far played any role in practice.

Statements on the effectiveness of the CSA in guaranteeing the safety of consumer goods can only be tentative. As against the eighteen safety regulations made under the CPA between 1961 and 1978, fourteen were made under the CSA between 1978 and 1985.¹⁴⁵ As regards formal punishments for contravention of safety regulations and prohibition orders, the government's first five-year report (pursuant to Section 8 (2) CSA) to Parliament on practice with the CSA (and CPA), of 1983, gives the following figures¹⁴⁶:

Table 1: Contraventions of safety regulations

<i>Period</i>	<i>Number of persons convicted</i>	<i>Number of breaches of the law</i>
1.11.78 - 31.3.79	54	59
1.4.79 - 31.3.80	98	142
1.4.80 - 31.3.81	109	158
1.4.81 - 31.3.82	185	439

¹⁴⁵ Regulations made under the Consumer Safety Act 1978, Section 1

<i>Subject</i>	<i>Statutory Instrument No.</i>
The Dangerous Substances and Preparations (Safety) Regulations (amended by 1980 (also S2 (2) ECA 72) 1985/127)	SI 136
The Upholstered Furniture 1980 (Safety) (amended by Regulations 1983/519)	SI 725
The Novelties 1980 (Safety) (amended by Regulations 1985/128)	SI 958
The Filament Lamps for Vehicles (Safety) Regulations 1982	SI 444
The Upholstered Furniture (Safety) (Amendment) Regulations 1983	SI 519
The Pedal Bicycles (Safety) Regulations 1984	SI 145
The Pedal Bicycles (Safety) (Amendment) Regulations 1984	SI 1057
The Motor Vehicles Tyres (Safety) Regulations 1984	SI 1233
The Cosmetic Products (Safety) Regulations 1984 (also ECA 72 & CPA 61)	SI 1260
The Gas Catalytic Heaters (Safety) Regulations 1984	SI 1802
The Food Imitations (Safety) 1985 (amended by Regulations 1985/1191)	SI 99
The Dangerous Substances and Preparations (Safety) (Amendment) Regulations 1985	SI 127
The Novelties (Safety) (Amendment) Regulations 1985	SI 128
The Food Imitations (Safety) Amendment Regulations 1985	SI 1191

¹⁴⁶ According to *Weatherill, S./Woodroffe, G.F.*, Consumer Safety in the United Kingdom. Report for the European Communities, Contract No. 85-B 6673-11-005-11-C, 122.

1.4.82 - 31.3.83	256	665
------------------	-----	-----

Much greater importance, however, attaches to “soft implementation”, to cooperation between the on-the-spot implementing agencies, the trading standard officers, and the manufacturers and traders concerned.

Summarizing, one may say that there is consumer product safety law in Britain only to the extent that safety regulations and/or prohibition orders have been issued under the CPA and CSA. Local implementing agencies can act only on the basis of these provisions for individual cases. Their powers are limited to the disclosure of breaches. They have no powers to prohibit further sale of unsafe goods, far less order recalls of products that cause damage. The CPA and CSA continue the traditional dual strategy of British safety law unchanged: (1) voluntary compliance with safety regulations following informal warnings from the authorities, and (2) where necessary, penal sanctions. The only additional possibility is an official Government warning through the media against buying particular products.

2.4. Present prospects for development

2.4.1. Legal reform projects

Six years after enactment of the CSA, the 1984 Government White Paper “The Safety of Goods”¹⁴⁷ brought a new stock-taking of British consumer good safety law. Moving on from the fundamental Green Paper of 1976, it singles out the following two main weaknesses of the CSA.

As regards *implementation*, the possibilities offered of pursuing the most effective and cheapest road to consumer protection, namely preventing unsafe products coming to market at all, are too slight. Obligatory safety checks or safety marks as legal prerequisites for sale are rejected, with explicit reference to problems in connection with Community law (technical barriers to trade). Instead, more lasting preventive effects are expected from higher criminal penalties (higher fines), and extension of powers for local implementing agencies to make preventive checks is recommended. Moreover, local authorities have no way of preventing further illegal sale of goods or of withdrawing from the market goods clearly out of line with safety regulations or prohibition orders. Above all, institutional provisions are required in order to catch unsafe imports (specially from non-EEC countries) at the frontiers.

It should be noticed in passing that these suggestions led to an amendment to the CPA and CSA, the Consumer Safety (Amendment) bill, which was enacted in August 1986. As regards the problem of checks on imported goods, obviously felt to be urgent, the customs and excise authorities are given the right to impound imported products for 48 hours for investigation by the competent local implementing bodies. They have also to inform the competent bodies of any suspicions they may have.

The range of instruments available to local implementing bodies is extended by the introduction of the *suspension notice*. This allows the competent authorities, on justified suspicion of infringement of a safety regulation or prohibition order, to issue sales bans valid for 6 months. Finally, for the first time (!), the possibility is opened up of withdrawing

¹⁴⁷ Cmnd. 9302, London HMSO, July 1984.

unsafe products from the market. On application from a local authority, a court may order the destruction or confiscation of incriminated goods. Recall procedure is still not provided for.

The decisive step towards making British consumer good safety law effective is however seen as a change in the underlying conception: replacement of individual case regulation through safety regulations and prohibition orders by generalization of the safety law approach. The introduction of a *general safety duty*, already present in the Health and Safety at Work Act (Section 6 HSWA) and favoured in the 1976 Green Paper, is once again advocated. This duty would require all manufacturers and traders (importers, wholesalers, retailers, etc.) to bring only safe goods to market in Britain. It would allow the implementing agencies, without having to pass through safety regulations or prohibition orders, to proceed directly against any trader because of any consumer product whatever, provided it be *unsafe*. While the CSA 1978 was still endeavouring to give an exhaustive definition of the concept of safety (Section 9 (4))¹⁴⁸, the 1984 White Paper completely abandons any such legal semantics of safety. The safety of consumer goods is defined by referring to “sound and modern standards of safety”. The 1984 White Paper is thus bringing into safety law on consumer products what had already been achieved in 1974 by the HSWA but was only adumbrated by the CSA 1978: the step to delegalization, or to “legislation by reference to standards” (J. Fraser). “Sound standards” are in the first place British Standards,¹⁴⁹ but also European and international standards that have been recognized as such. Observance of relevant standards would indicate “due diligence”, and rule out criminal responsibility.¹⁵⁰

The 1984 White Paper’s approach – possibly not uninfluenced by similar considerations at European level – very strongly links interests in the international competitiveness of the British economy¹⁵¹ and in safety and consumer protection policies. Once this link is set up, experience shows that the latter have the worse of it. The consequences of this kind of “reference to standards” approach for consumer product safety policy are obvious, even though they have not yet been drawn and do not even seem realizable at all: development of genuine (consumer product) safety standards and/or effective consumer involvement in the standardization process.

The 1985 White Paper “Lifting the Burden”¹⁵² again expresses the Government’s intentions in legal policy: to move towards a general safety duty and wind down single-case regulation. This consumer protection policy approach is now even more closely tied in with an overall deregulation programme intended to eliminate needless regulatory burdens and costs for the British economy.

¹⁴⁸ Cf. fn. 141.

¹⁴⁹ In November 1982 a memorandum of understanding between Government and BSI was signed, recognizing the BSI as the national standardization body and aimed at speeding up production of technical standards. It is reprinted in the White Paper “Standards, Quality and International Competitiveness”, 1982, Annex A.

¹⁵⁰ For details see 2.7 below.

¹⁵¹ Cf. esp. the White Paper, “Standards, Quality and International Competitiveness”, London HMSO 1982.

¹⁵² Cmnd. 9571, London HMSO, July 1985, based on an interministerial study on administrative and legislative obstacles for small firms in Britain: “Burdens on Business”, London HMSO, March 1985.

2.4.2. Consumer Protection Act 1987

In November 1986 the British Government published the draft of a Consumer Protection Bill,¹⁵³ which was passed by Parliament in summer 1987. The Consumer Protection Act 1987 (CPA) contains three substantive sections:

(1) Incorporation of the Community Product Liability Directive into British law; (2) revision of the CSA 1978 by introducing a general safety requirement and (3) a regulation on deceptive price indications. In this context only the second part, on consumer protection or consumer product safety (consumer safety) is of interest. This part came into force in autumn 1987. It thus brings both aims – generalization of consumer product safety requirements and policy of reference to technical standards – into legislative practice. In future, the supreme principle in British consumer protection law will be not to bring any goods to the market that “fail to comply with the general safety requirement”. Consumer goods within the meaning of the Act are products intended for private use and consumption. Separately regulated areas like cars, medicines, tobacco, etc. are excepted.

The general safety requirement is not met if consumer goods “are not reasonably safe having regard to all circumstances” (Section 10 (2) CPA). Among such circumstances are mentioned: (1) characteristics of goods that would constitute a defect within the meaning of the Community Product Liability Directive; (2) technical (safety) standards; (3) the technical possibility of producing a product more safely, if this is in reasonable relation to the costs incurred, etc.

The new Act does not apply to secondhand goods; to goods not intended for the British market; or to retailers to whom the lack of safety was not apparent. Moreover, it is always a sufficient defence to show that the product meets the requirements of a safety regulation or a tested technical (safety) standard. The *regulatory* instruments of the CSA 1978, as last augmented by the 1986 Amendment, are unchanged. In particular, the general safety duty does not correspond to any general recall powers for the competent Government offices. There is only the limited possibility of issuing a suspension notice on the basis of an existing safety regulation or prohibition order.

As far as penalties go, a distinction has to be drawn: breach of the general safety duty is merely an offence punishable by fine or imprisonment. There is *no* civil sanction. This is kept for the new product liability law,¹⁵⁴ as a conversion of the Community Product Liability Directive. Contraventions of specific governmental regulatory measures, in particular safety regulations, retain their traditional twofold character as crimes and as the tords of breach of statutory duty.

2.5. Accident information systems

The consumer protection policy debate in Britain takes on a special quality because the relevant legal policy work was set on an empirically based scientific foundation. Since the mid-70s, the UK had been developing the most comprehensive accident information system of the times alongside NEISS in the US, namely the Home Accident Surveillance System (HASS). Following a preliminary stage in 1976, there has since 1977 existed in England and Wales a system for collecting data on accidents at home and in the garden. Twenty hospitals with 24-hour accident and emergency services are incorporated into the system as

¹⁵³ Reprinted in PHI 1987, 18-26. The Consumer Protection Act 1978 is published by HMSO, London 1987.

¹⁵⁴ Which came into force on March 1988, as Part I of the Consumer Protection Act 1987.

information sources. In an alternating pattern, ten hospitals at a time supply data on non-fatal accidents requiring medical treatment in hospital. Fatal accidents are surveyed and assessed by the Office of Population Censuses and Surveys (OPCS). According to the last available HASS report, from 1986 and based on 1985 figures,¹⁵⁵ every year in Great Britain, i.e. England, Scotland and Wales,¹⁵⁶ 5005 people die in home accidents; 3.1 million people are sufficiently seriously injured as to require medical treatment. Home accidents constitute 40% of all fatal accidents in Great Britain (as against 42% road accident deaths), and at 34% are by far the biggest proportion of accident victims treated in hospitals. The number of fatal home accidents in the narrower HASS survey area, England and Wales, has been very stable at around 4800 since 1980.

The hospital figures collected by HASS on non-fatal accidents are systematically assessed and published every year. In particular, the annual report contains product-related data on accident frequency. Additionally, the Safety Research Section of the Department of Trade and Industry does in-depth studies, or has them done, to determine where there is need for political action in the form of a safety regulation.

The Community experimental model accident survey system of 1981 was largely inspired by this British example. Its present successor, the demonstration project of 22 April 1986, is however patterned more closely on the Dutch model (PORS), under test since 1980. It goes beyond HASS in three respects: (1) non-restriction to house and garden, but inclusion of leisure and sport activities; (2) inclusion of fatal accidents too; (3) diversification of information sources to more than just hospital casualty services. In Britain, HASS is at present being extended on the model of the Community demonstration project; specifically, a Home Accident and Death Database (HADD) is being added, into which sport and leisure accidents are subsequently to be integrated. The pilot stage began in November 1986 with one initial hospital. Inclusion of Scotland and Northern Ireland, i.e. the extension of the accident information systems (HASS/HADD) to Great Britain and to the United Kingdom as a whole, is still to be awaited.

2.6. Technical standardization

2.6.1. British Standards Institution

The central institution for standardization in Britain today is the British Standards Institution. The BSI is similar in history and structure to the DIN. It started in 1901 as the Engineering Standards Committee, founded by engineering associations. The first technical standard was on rolled steel sections for rails. In 1918 it became the British Engineering Standards Association. A Royal Charter of 1928 gave it legal capacity. The present name was adopted in 1931. The tasks of the BSI, as formulated in Royal Charters of 1928, 1931 and 1981, consist primarily in developing technical standards and in certification of products.

Today the BSI is headed by a board responsible for general standardization policy. Below the board are six Councils in specific areas: building, chemistry and health, engineering, electricity, technology and computing. There is also a Quality Assurance Council, responsible for product certification, tests and inspection. The latter recently (1984) developed into the National Accreditation Council for certification bodies. Its tasks are to

¹⁵⁵ Home Accidents, 1986.

¹⁵⁶ Figures for Scotland are supplied to HASS by the Scottish General Register Office.

monitor and authorize for product certification and quality assessment other certification bodies than the BSI. Practical standardization work is done by some 300 technical committees.¹⁵⁷ In these, some 28,000 experts, primarily from interested business circles, work on a voluntary basis. The BSI has more than 1074 permanent employees.

Besides the technical committees, the Consumer Standards Advisory Committee is of importance from the viewpoint of consumer goods safety. Some 70-80 representatives of consumer associations work on it. The Consumer Committee developed out of the Women's Advisory Committee introduced in 1951. Its task is to ensure involvement of consumer interests in the standardization process. The Consumer Committee is at present represented on 230 technical committees. Since consensus or unanimity by Committee members is a precondition for adoption of a technical standard by the BSI, opposition by a consumer representative can block a standard.

At present there are 10,124 British Standards. 8,900 standards are being worked on (more than half of them international standards). The BSI budget at present amounts, according to the 1985-6 Annual Report, to 26 million pounds. This sum derives mainly from contributions from the 18,000 members, from the sale of standards specifications and from government contributions (4.5 million pounds).

2.6.2. Methods of "reference to standards"

British Standards are, like DIN standards, mere recommendations. They have no legal standing.¹⁵⁸ This has changed since the "reference to standards" policy pushed by the British Government in worker and consumer protection law since the late 70's. This policy is in turn determined by the great political value attaching to British Standards for the international competitiveness of the British economy in the last decade, especially following UK entry to the EEC in 1973. Among political expressions of this situation are the (already cited) 1976 Green Paper on consumer safety, the GATT Agreement on Technical Barriers to Trade, to which Britain acceded in early 1980, the 1982 Memorandum of Understanding between Government and BSI, and particularly the 1982 White Paper "Standards, Quality and International Competitiveness".

Ignoring for the moment the possibility of using British Standards for contractual description of performance, something done above all by the State when placing orders, there are four ways of particular importance for giving technical standards legal relevance:¹⁵⁹

- A formerly widespread reference method (figuratively speaking) is to incorporate a British Standard, in modified form or sometimes verbatim, into a safety regulation. An example of this is the Oil Heaters Regulations of 1961/1966. By contrast with reference proper, here it is the regulation itself - even though (partly) incorporating a British Standard - that independently, and exhaustively, regulates the technical requirements.
- *Strict reference.* With this reference method, so far the major one in Britain, the provision (as a rule a safety regulation) refers for safety standard, test procedure, etc. directly to a British Standard, indicating the BS number and date. Compliance with this technical standard is then a legal obligation. In German terminology, this is a case of rigid/static

¹⁵⁷ The data refer to the BSI's Annual Report for 1985-6.

¹⁵⁸ Every British Standard contains the following clause: "Compliance with a British Standard does not of itself confer immunity from legal obligation".

¹⁵⁹ Cf. also BS O: A Standard for Standards, Part 1: 1981, clause 9.

legal reference. Any change to the technical standard necessitates adaptation of the safety regulation. Examples of this are the Heating Appliances (Fireguards) Regulations (1973) and the Nightdresses (Safety) Regulations 1967.

- *Undated reference.* In this case the safety regulation refers to one or more specific standards by simply mentioning the BS number, but compliance with the norm is not made binding. The manufacturer/importer then has alternative possibilities of meeting the safety requirements. This reference is made on a “deemed to satisfy” basis.
- *General reference.* The legal provisions may however also describe the safety requirements in general, or abstractly contain a general safety obligation.¹⁶⁰ The manufacturer/importer/trader is free to choose the way he wishes to meet the requirements. One acceptable way will be to comply with the relevant British Standard, or equivalent technical standards, if they exist. More recently, the Ministry has gone over to providing so-called *administrative guidance*. Here there is a clear statement of which technical norms satisfy the safety requirement concerned. This reference is made on the so-called “approved” basis. Practical examples are the Electrical Equipment (Safety) Regulations 1975, the Building Regulations and the area covered by the HSWA. By contrast with administrative provisions under § 11 of the German GSG, administrative guidance has no formal legal standing.

This model (“approved” basis) ought also to be applicable now that a general safety duty has been statutorily introduced into consumer product law. Specific safety requirements will now be defined by “sound and modern practice” or “sound and modern standards of safety”. What this in turn means would have to be specified in approval schemes, which would no doubt be worked out under BSI direction with broad involvement of governmental and consumer representatives. Technical standards passing this test of certification or approval would then be published in a list, comparable to that for administrative guidance.

Though they have no legal significance, informal recommendations of technical standards by local implementing agencies continue to be of great importance in practice.

The two methods of non-binding legal reference to technical standards (“undated and general reference”) seem to be becoming steadily more common in Britain. In particular, the 1982 Government White Paper “Standards, Quality and International Competitiveness” is decidedly in favour of this regulatory approach (“statute plus BSI”). The parallels with the “new approach” to harmonization of technical standards at Community level are unmistakable. The introduction of a general safety duty in consumer product safety law, announced in the 1984 and 1985 White Papers and brought about through the Consumer Protection Act 1987, is thus merely a consistent development of this legal area, in respect of both industrial policy and consumer protection policy.

2.6.3. Product Certification

Certification is an area that has been intensively discussed and dealt with in Britain, partly also from trade policy standpoints. In 1982, certification procedure was available for between 200 and 300 types of product. In the main, BSI kitemarks are issued. Product certification is handled by the BSI through the Certification and Assessment Department.

¹⁶⁰ E.g. Section 6 (1) (a) HSWA 1974, which, borrowing from § 3 (I) GSG, postulates a general duty “to ensure, so far as is reasonably practicable, that the article is so designed and constructed as to be safe and without risks to health when properly used”.

Besides this, there are other recognized certification institutions in particular areas: among them are the British Electrotechnical Approvals Board (BEAB) for electrical products and the British Board of Agrément (BBA) in the area of building and construction. In Britain, three marks of conformity or quality are usual:

- *BS number*. Mere use of the BS number has the weakest force. It contains merely a statement, not checked by anyone else, by the user or manufacturer that the product has been manufactured in accordance with the relevant British Standard.
- *Kitemark*. This conformity mark has existed since 1903. Authorization to use the kitemark is given by the BSI following checking at the manufacturing plant to ensure that the requirements are met. At the end of 1986 there were 1,365 kitemarks. The BSI Inspectorate carries out continual checks to ensure that the provisions are still being complied with.
- *Safety mark*. Since to date there are (as yet) no specific safety standards and a British Standard is not necessarily oriented towards coverage of all possible relevant safety requirements, in 1974 a safety mark was introduced. Firms may use it on products that have met special safety requirements when tested by the BSI. Eventually, however, in practice the safety mark has so far not caught up with the kitemark. As against the 1,365 kitemarks at the end of 1986, there were only 37 safety marks.

A fairly important procedure in Britain is that of *quality assessment*. This centres not around an individual product, but on whether a manufacturing or service firm in general meets the requirements of BS 5750,¹⁶¹ the BSI's basic quality standard. Firms that meet the requirements – at present there are 1,402 of them – are registered by the BSI. This registration also seems to be of interest to the firms concerned from a marketing viewpoint.

2.7. Liability

Traditionally in safety law in Britain, the main non-administrative response to contraventions of safety regulations is criminal sanction.¹⁶² The CSA lays down penalties of up to three months imprisonment and fines of up to 1000 pounds (Section 2 (4)). However, the conditions under which the accused may put forward the defence of due diligence are in each case regulated in detail.¹⁶³ While the HSWA 1974 explicitly excludes civil sanctions, they are explicitly permitted by the CPA 1961 and the CSA 1978. The Consumer Protection Act 1987 once again provides only criminal sanctions for breaches of the general safety requirement (Section 10 (1) CPA). As to liability, in consumer product safety law in England and Wales there were three possible grounds of claim, of which however we shall describe only the first two in more detail, given their more direct relevance: breach of statutory duty, negligence (“product liability in tort”) and contract.

¹⁶¹ BS 5750 has since been adopted internationally as ISO 9000.

¹⁶² With the general political trend towards deregulation in Britain too, the interministerial study “Burdens on Business” (op. cit., fn. 152), p. 62, has recently for the first time unreservedly recommended restriction to civil law and to insurance solutions. But even outside the narrower area of consumer product safety law, increasing decriminalization of economic regulation is being called for. Cf. *Tench, D.*, *Towards a Middle System of Law*, London 1981; *Breaking the Rules: The Problem of Crime and Contraventions. A Report by Justice*, London 1980.

¹⁶³ Section 2 (6) CSA; Section 12 Consumer Safety (Amendment) Bill.

2.7.1. Breach of statutory duty

The most interesting from the liability point of view, even though to date it has no practical importance¹⁶⁴ in consumer product safety law, is the offence of breach of statutory duty. This institution is controversial in the English legal literature on liability. Dias/Markesinis, for instance, say that it lies “between” liability on grounds of negligence and strict liability.¹⁶⁵ Firstly, Section 6 (1) CSA clearly states that breaches of obligations under safety regulations, prohibition orders or prohibition notices constitute a civil offence of breach of statutory duty. It seems also to be undisputed that this is strict liability, since the criminal-law defence of due diligence is ruled out. Liability is based on merely marketing an unsafe or damage-causing consumer product. However clear this differentiation may seem at first sight, the demarcation becomes unclear when one comes to consider the cases of primary interest here, where the manufacturer/trader has complied with a technical standard referred to (in particular a British Standard). No problems arise with the case where a safety regulation bindingly prescribes compliance with a particular standard (Section 1 (2) (b) CSA). Here compliance with a technical standard that ultimately proves technically inadequate (for instance, because it is out of date) excludes breach of statutory duty as a ground of liability. More interesting, since it will no doubt be of greater importance in future, is *non-mandatory* reference to technical standards, for instance pursuant to Section 1 (2) (c) CSA.

For civil liability on grounds of breach of statutory duty, it must here suffice for the plaintiff to show that there has been a breach of the relevant safety regulation, in other words, an unsafe product has been brought to market. Since action for breach of statutory duty does not require negligence, the defence that a relevant British Standard has been complied with is not admissible. The main defence open in breach of statutory duty cases is to show that the person suffering the damage is (largely) co-responsible. Compensation for damage is limited to personal injuries. Exclusion of liability or limitation of liability is null and void.¹⁶⁶

Whether the courts will maintain this line of interpretation in the sense of “strict liability” in consumer product safety law in England and Wales is at present completely uncertain. Firstly, there have not so far been any relevant decisions. Secondly, with the Consumer Protection Act 1987, British legislation has in part taken a different course. Breach of the general safety requirement now introduced has been specified solely as the elements of an offence. The liability aspect has been left for British product liability law, which has to implement the Community product liability Directive. By contrast with the National Consumer Council’s expectations expressed in 1984,¹⁶⁷ the offence of breach of statutory duty does thus *not* extend to the general safety duty. Breach of statutory duty remains confined to the safety regulations and comparable governmental regulatory acts. Most recently, in this area, there has been a noticeable general trend by courts in England and Wales to look at the political objectives lying behind individual-case statutory regulations

¹⁶⁴ According to information from the legal expert of the Department of Trade and Industry’s Consumer Safety Unit, no action for compensation on the basis of breach of statutory duties can be traced. See also the DTI’s document of November 1985, “Implementation of EC Directive on Product Liability”, § 42.

¹⁶⁵ *Dias, R.W.M./Markesinis, B.S.*, Tort Law, Oxford 1984, 156. Cf. also in general *Stanton, K.H.*, Breach of Statutory Duty in Tort, London 1986.

¹⁶⁶ Section 3 (1A) CSA, introduced by the Unfair Trade Act 1977.

¹⁶⁷ The Safety of Goods (loc. cit., fn 22), 7-10.

in order to specify the content and extent of the statutory duty and the circumstances that mean breach of it.¹⁶⁸ Since it has however become clear since the 1980s that in the view of both Government and Parliament “sound and modern standards of safety” ought to define the scope of the duty, it cannot be ruled out that if standards “approved” by the BSI¹⁶⁹ are observed, liability for breach of statutory duty will not arise.

2.7.2. Negligence (manufacturer liability)

Liability under the common-law offence of negligence takes us outside the narrower context of consumer protection law. Entitlement may here arise – subject to any special provisions of accident insurance or labour law – for anyone harmed by a product: a worker in a production process; a businessman in connection with goods he uses in his trade; the final private consumer. Liability for damage lies primarily with the manufacturer of a product, who also has to answer for negligence by his employees, on the principles of vicarious liability.

Offence-based manufacturer liability on grounds of negligence¹⁷⁰ developed relatively late in English common law. Whereas in the US and in Germany the foundations had been laid by similar decisions at the highest judicial level at around the same time, 1915-1916¹⁷¹, this did not come about in England until 1932. The landmark decision *in re M’Alister* (or *Donoghue*) v. *Stevenson*¹⁷² for the first time assumed positive duties of care between persons outside contractual relationships, which could be breached merely by being negligent (“not using reasonable care”). Subsequently, negligence liability by manufacturers of defective products was consolidated. The general duty of care was differentiated into manufacturing duties (“production defects”), design duties (“design defects”) and duties of instruction (“marketing defects”). Procedurally too it may now be taken as a basis in England and Wales – comparable in this respect with the FRG – that it is in principle sufficient for the injured party to show that interests protected under the law of tort have been injured during proper use of the product in question. By the *res ipsa loquitur* rule, the manufacturer’s negligence is (refutably) presumed.

As regards the evidentiary position of technical standards, it is in principle to be taken as a basis in English law too that conformity with a standard or departure from one is not synonymous with conduct in accordance with or contrary to one’s duty. Non-compliance with a British Standard engenders a strong presumption of negligence. Observance of relevant technical standards to which non-binding reference has been made places the onus on the plaintiff to provide positive proof of the manufacturer’s negligence. In cases of strict reference, compliance with the technical standard concerned should suffice to rule out negligence.

At least since *Walton v. British Leyland UK Ltd.* (1978) a duty to monitor a product and respond accordingly seemed to have been recognized. This is the counterpart in law of tort to the regulatory “notice to warn”. In the *Walton v. British Leyland* case, the car manufacturer was condemned to make compensation for damages, on grounds of tortious breach of a duty of recall. English law has also developed duties of care and transaction

¹⁶⁸ *Dias, R.W.M./Markesinis, B.S.*, Tort Law, Oxford 1984, 158.

¹⁶⁹ Cf. 2.6.2 above.

¹⁷⁰ Cf. esp. *Hepple, B.A./Matthews, M.H.*, Tort, Cases and Materials, 3rd ed., London 1985, 258 et seq.

¹⁷¹ RGZ 87,1 - Brunnensalz (1915); *Mac Pherson v. Buick Motor Comp.*, 217 N.Y. 382, 111 N.E. 1050 (1916).

¹⁷² A. C. 562 (1932).

under law of tort for the marketing stages. The road to “strict liability”, taken in the law of most US States since 1963,¹⁷³ has not been completed by English law of tort any more than by German manufacturer liability law.

2.7.3. The present legal policy situation (1987)

Starting with the forthcoming implementation of the Community product liability Directive in British law and the British Government’s undertaking as regards legal policy to introduce a general safety duty into consumer protection law, in 1987 several options opened up for developing product liability law: (1) Introduction of a general safety duty into the Consumer Safety Act; raising criminal penalties; removal of the offence of breach of statutory duty from the CSA, with revised provision for it in a special act on product liability; (2) Introduction of a general safety duty into the CSA, with retention of (possibly raised) criminal and civil sanctions; implementation of the Community Directive in a separate product liability act.

The Consumer Protection Act 1987 largely implemented the second option. Accordingly, British product liability law will, as far as consumer goods are concerned, in future be based on three principles:

- Modified strict liability under the Product Liability Act (implementing the Community Directive);
- Breach of statutory duty in so far as safety regulations or comparable measures have laid down specific duties as to conduct;
- General liability in common law, specifically under law of tort (negligence).

Infringement of the newly introduced general safety requirement remains irrelevant for purposes of civil law. Criminal sanctions only are provided.

2.8. Information

As regards information on product hazards, two addressees should in principle be distinguished: (1) the regulatory authority and (2) potential purchasers of the unsafe product.

2.8.1. Information of regulatory bodies

As regards information to governmental agencies on damage-causing products, the 1976 Green Paper referred to the following sources:¹⁷⁴

- individual Government departments;
- complaints about product defects from MPs and the public;
- local authorities;
- consumer associations and the Royal Society for the Prevention of Accidents;
- the national and international press and specialist journals;
- the BSI;
- the Office of Population Censuses and Surveys (OPCS).

¹⁷³ Greenman v. Yuba Power Products Inc., 59 Cal. 2d 57, 377 P. 2d 897.

¹⁷⁴ Cmnd. 6398, 1976, page 2.

By far the greatest importance at present, though, attaches to the HASS/HADD accident information system as regards reporting on non-fatal accidents in England and Wales. HASS and HADD are described above.

2.8.2. Information to purchasers of products

Purchaser information outside the market traditionally plays a major role in Britain. Three elements in particular should be stressed: comparative tests of goods, conformity marks and consumer education.

As in other countries reported on, *comparative tests of goods* have long been customary in Britain too. A prominent part in this connection is played by the Consumer Association Ltd. This is a private-law non-profit-making organization founded in 1957, financed exclusively from membership dues. Membership at present amounts to some 700,000. The Consumer Association carries out comparative tests on all types of consumer goods and relevant services. Test results are published in the magazine "Which?", directly available only to members. Since, however, test results are also reported on television and in the press and the magazine is available in public libraries, the Consumer Association and "Which?"¹⁷⁵ have an importance in general for consumer education that cannot be much less than the German Stiftung Warentest and its magazine "test".

In addition to general "brand names" (including various types of marks used by various firms or businesses), conformity marks or trade marks are of importance as conveyors of information to purchasers. Certification trade marks, above all the BSI kitemarks, are regulated in general in the Trade Marks Act 1938 (S 37). Authorized use of the conformity mark testifies to compliance with particular quality or safety requirements.

One peculiar feature of the British situation is the importance attached to consumer protection, here primarily in connection with safety in the home, through *consumer education*, even in school. The Royal Society for the Prevention of Accidents (ROSPA), maintained from public funds, is the main vehicle of the endeavour to get safety questions brought into syllabuses. The government's Press and Information Office supplies schools with film material for the purpose. Television stations broadcast corresponding "safety messages" in pauses between programmes.

3. Product safety policy in the Federal Republic of Germany

The description of product safety policy in the Federal Republic of Germany will concentrate mainly on the Appliances Safety Act and its implementation in practice (3.3) and on technical standardization of relevance to safety (3.4). A final section deals with liability for technical consumer products that cause damage (3.5). The account is introduced by notes on home and leisure accident research (3.1) and a discussion on some general questions on the German system of reference to technical standards (3.2).

3.1. Research into home and leisure accidents

While industrial accidents in particular have for years been fairly completely covered by the occupational accident insurance associations, as have road accidents and accidents in

¹⁷⁵ The "Shopper's Guide", published by the DTI and originally a possible competitor for "Which?", is of no significance today.

schools and nurseries,¹⁷⁶ the Federal Republic lacks comparable statistics for the area of home and leisure. The Federal Government did not take part¹⁷⁷ in the Community pilot experiment relating to a Community system of information on accidents involving products outside the spheres of occupational activities and road traffic,¹⁷⁸ and was also reluctant about the demonstration project decided on in April 1986 with a view to introducing a Community system of information on accidents involving consumer products.¹⁷⁹ It based itself above all on a study carried out by the Association of Liability Insurers, Accident Insurers, Automobile insurers and Legal Costs Insurers, a registered society (HUK-Verband e.V.) on home and leisure accidents in the Federal Republic;¹⁸⁰ till then findings on home and leisure accidents were available only for selected groups of people and types of accidents.¹⁸¹

The HUK study treats as a home or leisure accident an occurrence in which a person doing something not having to do with either a road traffic, occupation or school suffers an injury requiring medical treatment or leading to impairment for at least several days. An initial survey asked 89,393 representatively sampled households¹⁸² whether one or several household members had suffered a home or leisure accident in the last 12 months. The figures collected are not stated, though the projection based on them is. This estimates home and leisure accidents with personal injuries requiring medical treatment or at least leading to longish impairment at some 3 million for the Federal Republic; 15% of those injured will require in-patient treatment. The number of trivial home and leisure accidents is estimated at over 100 million per year.¹⁸³ It is further stated that in 1982 fatal accidents numbered approximately 11,000 in road traffic, some 2,500 at work or school, and some 12,000 at home or in leisure time. More than 3/4 of the last group of victims are over 64.¹⁸⁴ In methodological evaluation of the study, the extremely high forgetfulness curve should be noted. For the period within a month of the survey, 5.3 times as many accidents are mentioned as in the period within 12 months of the survey; for accidents with in-patient treatment, there was still a forgetfulness factor of 2.1 for the same period.¹⁸⁵ This rules out comparison of the HUK study with accident survey systems that collect figures directly from accident stations immediately after the accident, and also arouses doubt as to the reliability of the detailed accounts of the circumstances of accidents. Doubts about the

¹⁷⁶ Cf. the Federal Government reports on the state of accident prevention and the accident situation in the Federal Republic of Germany (Accident Prevention Report) the latest being the Accident Prevention Report 1985, BT-Drs. 10/6690, 5 December 1986.

¹⁷⁷ On the ground that project was too costly and that it was intending to promote surveys carried out at regular intervals. See answer to written question No. 2194/84, OJ C 203, 12 August 1985, 3.

¹⁷⁸ Cf. Council decision 81/623/EEC of 23 July 1981, OJ L 229, 13 August 1981, 1 et seq.

¹⁷⁹ OJ L 109, 26 April 1986, 23 et seq.

¹⁸⁰ *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985. Cf. *Mertens, A.*, Heim- und Freizeitunfälle: Aufklärung intensivieren, BArbBl. 5/(1986), 32 et seq., 321 et seq.; *idem*, 1986, 246 et seq. On the methodology of accident analysis, see also *Pfundt, K.*, Zur Methodik einer Risiko-Analyse im Bereich von Heim und Freizeit, in: Unfall-Risiken der Privatsphäre. Epidemiologie - Diagnose - Prävention. VI. Internationales GfS-Sommer-Symposium, 3.-5.6. 1985, Wuppertal 1986, 99 et seq.

¹⁸¹ The findings are briefly summarized in *Pfundt*, 1985, 205-211. Cf. also *Compes*, 1986; *Kern*, 1986; *Henter/Milarch/Hermanns*, 1978; specifically on do-it-yourself accidents, *Tittes*, 1986.

¹⁸² Not including foreigners and people living in institutions.

¹⁸³ *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 9.

¹⁸⁴ *Op. cit.*, 10-14.

¹⁸⁵ *Op. cit.*, 4.

study's methodological grip arise also from the facts that not a single accident resulting in death was covered and that the proportion of accidents involving children was only 15%, whereas for instance in the Netherlands study it was 30%.¹⁸⁶

A second phase of survey asked for further details on the course and consequences of accidents, in telephone interviews on a total of 3,064 accidents.¹⁸⁷ The breakdown by individual category of accident is as follows:¹⁸⁸

Accidents in sport and games	44%
Accidents in locomotion	24%
Accidents in manipulation	17%
Accidents involving motion on the spot	8%
Passive accidents	8%

Manipulation accidents are 12% with a machine and 32% with a tool. These two categories together make up 8% of all accidents surveyed; because of the relatively slight consequences of the accidents and the resulting higher forgetfulness rate, the proportion is probably to be estimated higher in reality.¹⁸⁹

The case studies did not from the outset provide any category for covering design-related causes of accidents, but made only the following behaviour-based assignments:¹⁹⁰

Infringement of elementary safety rules	2%
Failure to observe a fairly obvious safety rule.....	15%
Everyday situation that "went wrong"	72%
Accident to child because of clumsiness, with adult unable to intervene....	10%

Altogether, the HUK study summarizes to the effect that technical inadequacies in newly purchased machines, tools or appliances seem to play no part in the causation of home and leisure accidents. The Appliances Safety Act was supposed to have ensured that hardly any inadequate, dangerous to handle machines were still being sold. 99% of home and leisure accidents are seen as being the consequences of more or less serious mistaken actions.¹⁹¹

In his politically ambitious account and assessment of the study, Mertens comes to the conclusion that accidents with appliances and machines as yet undamaged by wear and tear that have been used properly and safely accounted for much less than 0.5% of all home and leisure accidents.¹⁹² The conclusion he claims to be obvious, that the major part of appliance and machine accidents are due to improper or unsafe use or to damage through wear and tear, can derive support only from the "case studies"¹⁹³ on the handling accidents, which are full of very tendentious assessments, and also presupposes that wear and tear and mistaken actions are negligible when it comes to setting technical standards. The Stiftung Warentest comes to a quite different estimate. It believes that many accidents today classed as user caused could very quickly come to be seen as appliance caused if the necessary

¹⁸⁶ Report of 1984 Data Home Accident Surveillance System, Amsterdam 1985, 18.

¹⁸⁷ By way of comparison, the Dutch accident survey system in 1984 covered some 70,000 cases.

¹⁸⁸ For details see *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 23-57.

¹⁸⁹ *Op. cit.*, 40-44.

¹⁹⁰ Calculated from *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 163-165, 184. On the methodological problems of allocation see *loc. cit.*, 203-208.

¹⁹¹ *Loc. cit.*, 190.

¹⁹² *Mertens, A.*, Heim- und Freizeitunfälle: Aufklärung intensivieren, BArbBl. 5/(1986), 32 et seq. 34.

¹⁹³ *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 96-188.

creativity were applied to thinking how foreseeable misuse could be avoided by suitable technical arrangements.¹⁹⁴

We do not wish here to go any further into the fact that in 1984 24% of appliances tested by trade inspection offices in any case proved defective¹⁹⁵ nor into the serious, widespread shortcomings in systematic market control by the North Rheni-Westshfalia Central Office for safety technique that have come to light.¹⁹⁶ One observation of Mertens that remains convincing is that data collection on accidents must be made much more detailed if it is to be of use for technical standardization. What he deduces from this, however, is not the need for intensive directed studies, for instance on handling accidents with appliances and tools, but instead the basic principle of “hazard analysis that has stood the test of decades” which he says makes it possible to prevent accidents beforehand by applying technical safety principles to removing danger spots and sources of risk. According to him, the Community should instead of focusing its accident prevention work on appliance and machine accidents that have already happened “concentrate more on intensifying supranational work on technical safety regulations and standards”.¹⁹⁷

3.2. The reference technique in general

A characteristic of German product safety law, as of German safety law in general, is the “interplay between governmental legal standards and private technical standards drawn up by technical and scientific associations, in a complex multilayered system of standards”.¹⁹⁸ The object of technical safety law is on the one hand to protect life, health, property and the environment against damage from technical products and installations, and on the other to provide legal guarantees in connection with economic activities bound up with certain technical risks. To this end, statutes and legal ordinances lay down binding safety objectives, vaguely defined using such formulae as “generally recognized rules of art”, “state of the art” or “state of science and technology”. These indefinite legal concepts are amplified by references to technical rules or standards drawn up by public-law committees of experts or by private standardization associations. Manufacturers or users of potentially dangerous technical products or installations are not legally bound by the technical rules or standards, but may choose other solutions if at least the same level of safety is achieved (deviation clause). This is intended to take account of the rapid development of modern technology and avoid hampering progress and producing rapid outdateding.

¹⁹⁴ Loose, P., Sicherheitstechnische Prüfung von Gebrauchsgütern durch die Stiftung Warentest, in: Unfall-Risiken der Privatsphäre. Epidemiologie - Diagnose - Prävention, VI. Internationales GfS-Sommer-Symposium, 3.-5.6.1985, Wuppertal 1986, 361 et seq., 366.

¹⁹⁵ For details here see the survey in 3.3.5. below.

¹⁹⁶ For details see the 1984 Annual Report of the Trade Supervisory Office of Land Nordrhein-Westfalen, 49-59; Fischer, R., Systematische Marktkontrollen durch die Zentralstelle für Sicherheitstechnik. Ein Beitrag zur Abwehr sicherheitswidriger Produkte, MD VZ-NRW 2-1984, 48 et seq.

¹⁹⁷ Mertens, A., Heim- und Freizeitunfälle: Aufklärung intensivieren, BArbBl. 5/(1986), 32 et seq.

¹⁹⁸ Marburger, 1979, 111. A typical example is the resolution of the Committee for Technology of 2 December 1966 (published in VDI Information No. 14, April 1967), which says: “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 technical and scientific bodies in voluntary self-regulation”.

The choice among the expressions “generally recognized rules of art”, “state of the art” and “state of science and technology” determines the lag in adapting legal requirements to technical or scientific advance.¹⁹⁹ The legally indefinite expression “generally recognized rules of art” focuses on the prevailing view among technical practitioners, on what is generally regarded as tried and tested in professional practice. This criterion thus always lays behind further technical advance. 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. If this cannot (yet) be achieved technically, permission may not be issued, since the limit to the requirement is not set by what is currently technically achievable. Detailed technical rules have been displaced from the context of governmental law-making to the allegedly more flexible level of non-governmental regulation, so as to permit quicker adaptation to technical progress but above all to allow for representative collaboration by “interested circles” in industry and the economy, science, technical monitoring organizations and other interested and expert groups in society. P. Marburger speaks of the structural principles of flexibility and cooperation.²⁰⁰ R. Wolf calls the standardization logic of technical regulation a “self-regulatory mechanism in the shadow of regulative policy”.²⁰¹ Before dealing with the specific form of private technical standardization and its controlled adoption by government in the area of safety of technical consumer goods in detail, we shall briefly summarize the German debate on the legal admissibility of reference to technical rules,²⁰² since the legal admissibility of the new approach to technical harmonization and standards raises similar questions.

¹⁹⁹ Fundamental to the reference trial is the so-called Kalkar decision of the German Constitutional Court of 8 August 1978, BVerfGE 49, 80 (135 et seq.); see Breuer, 1976, 67 et seq. From the burgeoning literature, see Marburger, 1979, 145-176; *Rittstieg, A.*, Die Konkretisierung technischer Standards im Anlagenrecht, Köln/Berlin/Bonn/München 1982, 21-43; *Wolf, R.*, Der Stand der Technik. Geschichte, Strukturelemente und Funktion der Verrechtlichung technischer Risiken am Beispiel des Immissionsschutzes, Opladen 1986, 277-295.

²⁰⁰ *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979., 117-120.

²⁰¹ *Wolf, R.*, Der Stand der Technik. Geschichte, Strukturelemente und Funktion der Verrechtlichung technischer Risiken am Beispiel des Immissionsschutzes, Opladen 1986, 153-159. The effect of unburdening the State was already stressed by *Gasde, F.*, Das Gesetz über technische Arbeitsmittel (GtA) als Modell einer liberalen Regelung, wie sich der Staat unter Verweisung auf Technische Regelwerke entlasten kann, in: Technische Regelwerke - ein Beitrag zur Staatsentlastung, Schriften des Gemeinschaftsausschusses der Technik, Nr. 4, Düsseldorf 1972, 16-17.

²⁰² See *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979., 117-120; *idem*, Die gleitende Verweisung aus der Sicht der Wissenschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde Bd. 17, Berlin/Köln 1982, 27 et seq.; *idem*, Marburger, P., Rechtliche Bedeutung sicherheitstechnischer Normen, in: Risiko - Schnittstelle zwischen Recht und Technik, VDE-Studienreihe 2, Berlin/Offenbach 1982, 119 et seq., 129-135; *Schwierz, M.*, Die Privatisierung des Staates am Beispiel der Verweisungen auf die Regelwerke privater Regelgeber im Technischen Sicherheitsrecht, Frankfurt/Bern/New York 1986, 63-99; *Ossenbühl, F.*, Die verfassungsrechtliche Zulässigkeit der Verweisung als Mittel der Gesetzgebungstechnik, DVBl. 1967, 401 et seq.; *Karpen, U.*, Die Verweisung als Mittel der Gesetzgebungstechnik, Köln 1970; *idem*, Die Verweisungstechnik im System horizontaler und vertikaler Gewaltenteilung, in: Rödig, J. (Ed.), Studien zu einer Theorie der Gesetzgebung, Berlin/Heidelberg/New York 1976, 221 et seq.; *Arndt, G.*, Die dynamische Rechtsnormverweisung in verfassungsrechtlicher Sicht - BVerfGE 47, 285, JuS 1979, 784 et seq.; *Brügger, W.*, Rechtsprobleme der Verweisung im Hinblick auf Publikation, Demokratie und Rechtsstaat, Verwaltungs Archiv 78 (1987), 1 et seq., 41-44; *Buckenberger, H.-U.*, Gleitende Verweisung aus der Sicht der Wirtschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 52 et seq. *Schnapauß, K.-D.*, Gleitende Verweisung aus der Sicht der

There is no dispute as to the admissibility of *rigid reference*²⁰³ in which a law or regulation refers to a quite specific version of a technical rule. Here the legislator can verify the content of the technical standard, and the content of the standard referred to cannot be altered without assent by the legislator. Rigid reference to technical standards is nothing other than a drafting abbreviation in the text of the statute. It does not transfer any legislative powers to non-legitimated non-governmental bodies, and it complies with the constitutional principle of certainty of law. The amplitude of the reference makes the content of the technical rule referred to binding not only on the administration but also on the citizen.

Since rigid reference bindingly prescribes a particular technical solution, it is a suitable method for linking legal standards with technical rules only where one or several technical standards can be referred to, where technical development has already reached some sort of end-point and major innovations are unlikely, or will remain irrelevant as far as the object of legal protection is concerned. By comparison with statutory regulation of individual technical questions, rigid reference means unburdening the legislative bodies and the statutory text of detailed technical questions, allowing more flexible adaptation to technical advance, since it is not the text of the statute or regulation that has to be reworked, but only a formal correction to the reference that is required.

The admissibility of *sliding or dynamic reference*, where reference is made to one or more technical standards in their most current form, was for long disputed.²⁰⁴ P. Marburger names four legislative functions of sliding reference:²⁰⁵

- To free the legislator or regulator of a regulatory task for which they usually lack the necessary technical understanding²⁰⁶ (unburdening the legislator);

Verwaltung, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 40 et seq; *Staats, J.-F.*, Zur Problematik bundesrechtlicher Verweisung auf Regeln privatrechtlicher Verbände, ZRP 1978, 59 et seq.; *Strecker, A.*, Rechtsfragen bei der Verknüpfung von Rechtsnormen mit technischen Normen, in: Technische Normung und Recht, DIN-Normungskunde, Bd. 14, Berlin/Köln 1979, 43 et seq.; *Vogel, H.J.*, Technische Normung im Spannungsfeld zwischen Rechtsordnung und technischem Fortschritt, DIN-Mitt. 58 (1979), 451 et seq.; *Ernst, W.*, Rechtsgutachten zur Gestaltung des Verhältnisses der überbetrieblichen technischen Norm zur Rechtsordnung, Berlin/Frankfurt 1973, 27-41. Finally, see also Arbeitsschutzsystem, Bd. 1, 1980, 299-308.

²⁰³ On rigid reference, see *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979, 387-389; *Hunscha, A.*, Die starre Verweisung aus der Sicht der Wissenschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 75 et seq; *Meyer*, Die starre Verweisung aus der Sicht der Wirtschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde Bd. 17, Berlin/Köln 1982, 88-89; *Strecker, A.*, Starre Verweisung auf Normen in Rechtsetzung und Verwaltung, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 79 et seq.

²⁰⁴ On sliding or dynamic reference, see *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979., 390-407; *Schwierz, M.*, Die Privatisierung des Staates am Beispiel der Verweisungen auf die Regelwerke privater Regelgeber im Technischen Sicherheitsrecht, Frankfurt/Bern/New York 1986, 57-99; *Marburger, P.*, Die gleitende Verweisung aus der Sicht der Wissenschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde Bd. 17, Berlin/Köln 1982, 27 et seq; *Buckenberger, H.-U.*, Gleitende Verweisung aus der Sicht der Wirtschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 52 et seq; *Schnapauß, K.-D.*, Gleitende Verweisung aus der Sicht der Verwaltung, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde, Bd. 17, Berlin/Köln 1982, 40 et seq.

²⁰⁵ *Marburger, P.*, Die gleitende Verweisung aus der Sicht der Wissenschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde Bd. 17, Berlin/Köln 1982, 27 et seq., 29 et seq.; *idem*, 379-383.

²⁰⁶ More clearly, it may be said that in the area of technology the State has a structural information deficit vis-à-vis the industry that does the research development work (cf. *Marburger, P.*, Die Regeln der Technik im Recht,

- to keep the text of the statute or ordinance free of complicated and often very voluminous detailed technical provisions (unburdening the law);
- to allow rapid adaptation of the content of the law to technical advance, by shifting the technical details of safety regulation out of the formal legislative procedure (flexibility);
- to allow involvement of expert circles in law-making (cooperation).

The involvement of “expert” circles *may* be a guarantee that technically practicable and also adequate safety solutions will be adopted if it can be made certain that the competent experts are in fact represented on the relevant standards committees. Involvement of those concerned in establishing technical standards ought to increase willingness to comply with the standards. This ought not, however, to be bought at the price of adopting objectively unsuitable regulations because of one-sided representation of interests – and “expert” circles are always also “interested” circles. The interests concerned must be represented truly comprehensively, including suppliers, consumers and representatives of the public interest.²⁰⁷ The procedure of private technical regulation, and specifically the way it is actually done and not what it said on paper, decides whether sliding reference will lead to adoption of apposite regulations in the public interest or decisions in the particular interest of manufacturers.²⁰⁸

Large constitutional objections have been raised against the admissibility of sliding reference to technical rules.²⁰⁹ It has been seen as disguised transference of law-making power to private persons, as infringement of the democracy principle, of the constitutionality principle, specifically of the precept of certainty and clarity of law, of the requirement for proper publication of laws and of the principle of separation of powers.

These objections are upheld against the admissibility of *sliding reference in supplementation of standards*, making reference *directly* and bindingly to technical standards in their successively current forms²¹⁰. With this form of reference, in which the technical regulations referred to become binding law in their current version for both citizen and administration, the legislator or regulator refrains from determining the content of the law, or leaving it to private standardization bodies. What this comes down to is a blanket law, a law whose content can be altered at the whim of the private regulator.

*Sliding reference in specifications of norms*²¹¹ occurs always in connection with an indefinite term in the legal text, which it serves to specify. The law may, for instance, prescribe compliance with the “recognized rules of art”; as a rider or in connection with this, it may then be stated that particular technical standards count as such recognized rules

Köln/Berlin/-Bonn/München 1979, 381 et seq.).

²⁰⁷ Cf. *Marburger, P.*, Die gleitende Verweisung aus der Sicht der Wissenschaft, in: Verweisung auf technische Normen in Rechtsvorschriften, DIN-Normungskunde Bd. 17, Berlin/Köln 1982, 27 et seq., 30.

²⁰⁸ For details on the procedure for drawing up DIN standards see 3.4.3 below.

²⁰⁹ See *Ossenbühl, F.*, Die verfassungsrechtliche Zulässigkeit der Verweisung als Mittel der Gesetzgebungstechnik, DVBl. 1967, 401 et seq; *Karpen, U.*, Die Verweisung als Mittel der Gesetzgebungstechnik, Köln 1970, 131 et seq.; *idem*, Die Verweisungstechnik im System horizontaler und vertikaler Gewaltenteilung, in: Rödiger, J. (Ed.), Studien zu einer Theorie der Gesetzgebung, Berlin/Heidelberg/New York 1976, 221 et seq., 232 et seq.; *Arndt, G.*, Die dynamische Rechtsnormverweisung in verfassungsrechtlicher Sicht - BVerfGE 47, 285, JuS 1979, 784 et seq.

²¹⁰ On this see *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979, 390-395, *idem*, Gleitende Verweisung, 1982, 31-34.

²¹¹ On this see *Marburger, P.*, Die Regeln der Technik im Recht, Köln/Berlin/-Bonn/München 1979, 395-407; *idem*, Gleitende Verweisung, 1982, 34-37. *Schwierz, M.*, Die Privatisierung des Staates am Beispiel der Verweisungen auf die Regelwerke privater Regelgeber im Technischen Sicherheitsrecht, Frankfurt/Bern/New York 1986, 61 et seq. speaks about “dynamic references that prescribe a general safety criterion”.

of art. What is legally binding on the manufacturer of a product or the operator of an installation is only compliance with the statutory safety standard, which thus conclusively determines the duties as to conduct. Often machinery is developed for controlled response to relevant technical rules. Thus, the Federal Ministry for Labour and Social Affairs verifies DIN standards of relevance to safety before including them in list A of the General Administrative Regulation under the Appliances Safety Act.²¹² The new approach to technical harmonization and standards likewise creates, through administration of the list of standards, a possibility of checking the harmonized standards and the declared national equivalent ones for their compliance with the underlying safety requirements.²¹³ This *additional* reference to specific technical rules is intended on the one hand to give addressees of the norm an indication of how to comply with the legal safety requirements, and on the other to oblige the competent authorities to accept appliances or installations that meet the technical standards listed. Firms are free to choose solutions departing from the technical rules if at least the same level of safety is attained. If they keep to the listed technical standards, there is a (refutable) presumption that the statutory safety duty has been met. Whether a technical regulation referred to in fact meets the statutory safety standard is subject to judicial verification. The competent administrative authorities remain free to act against a product manufactured or installation operated in accordance with the standards, where there is a concrete risk. Observance of technical standards acts merely as an indicator of compliance with the statutory safety obligation.

3.3. The Appliances Safety Act and its application in practice

The German law on technical appliances (the Gerätesicherheitsgesetz - Appliances Safety Act (GSG))²¹⁴ is regarded as a model for the Low-Voltage Directive, and along with it as providing the pattern for the new approach to technical harmonization and standards. The GSG, an offshoot of labour protection law, has developed into one of the most important German laws for preventive protection of consumers against defective products, and at the same time forms a link between governmental product safety policy and safety-related technical standardization. In presenting the GSG, therefore, one has therefore always immediately to include technical standardization of relevance to safety.

²¹² For details see 3.3.4 below.

²¹³ For more on this see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²¹⁴ Of 24 June 1968 (BGBl. I, p. 717), last amended on 18 February 1986 (BGBl. I, p. 265). In general on the GSG see *Schmatz/Nöthlich*, *Gerätesicherheitsgesetz. Kommentar und Textsammlung, Sonderausgabe aus dem Handbuch „Sicherheitstechnik“*, hrsg. von Schmatz/Nöthlich; *Jeiter, W.*, *Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel)*, München 1980; *Meyer, T.R.*, *Gerätesicherheitsgesetz*, Berlin 1979; *Peine, F.-J.*, *Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar*, Köln/Berlin/Bonn/München 1986; *Zimmermann*, *Gerätesicherheitsgesetz*; *Lindemeyer, B.*, *Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen*, in: *Brendl, E.*, *Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis*, Gruppe 11, 167 et seq.; *Diekershoff, K.H.*, *Gerätesicherheitsgesetz*, in: *Handbuch zur Humanisierung der Arbeit*, Bd. 1, Bremerhaven 1985, 607 et seq.; *Marburger, P.*, *Die Regeln der Technik im Recht*, Köln/Berlin/-Bonn/München 1979, 71-78.

3.3.1. Lines of development

The 1929 Industrial Safety Bill already included the basic idea of guaranteeing safety for workers through quality requirements on appliances; the competent authorities themselves were to determine the requirements on machines needed to protect workers' life and health. In the same year, the ILO adopted a recommendation on responsibility for protective devices on mechanically driven machines. In 1963 it extended its earlier recommendation and decided on Convention No. 119 on machine protection, with the supplementary recommendation No. 118. This was the basis for the Machine Safety Bill,²¹⁵ which took the following guidelines:

- All technical appliances should be covered, whether for use in factory, office, home or leisure;
- Safety requirements on appliances should not be detailed in regulations, but emerge from safety rules developed by experts;
- In principle manufacturers or importers should be responsible for the perfect safety of products.

This meant that three decisive steps had been taken: manufacturer responsibility was to aim at *preventive hazard elimination* through safety-minded development, design and manufacture of technical appliances. Till then, only the employer had been under an obligation, as part of a labour-law duty of care in accordance with the industrial safety and accident prevention regulations, to make only safe appliances and machines available to the employees in his premises. Still more than the businessman, the non-commercial final consumer is with advancing technical content no longer in the position to verify the technical safety of appliances. Accordingly, the idea developed in the industrial safety context of preventive hazard protection is consistently extended to *all technical utility goods*, including those for home and leisure use.²¹⁶ With the rapid development of technology and the range of goods on offer, the focus is placed not on administrative quality requirements but on the *generally recognized rules of art*, to which special provisions and regulations are a guide. The supervisory authorities confine themselves to spot checks and to intervention in hazardous situations.

With effect from January 1980²¹⁷ the law on technical work materials that had come into force in November 1968 with the brief title "Machinenschutzgesetz (Machine Safety Act)" was amended, both to give it the new brief title "Gerätesicherheitsgesetz (Appliances Safety Act)", appropriate to the broad scope, and to include inspection of installations, provide

²¹⁵ On the historical background to the development see *Lukes, R., Vom Arbeitnehmerschutz zum Verbraucherschutz - Überlegungen zum Maschinenschutzgesetz*, RdA 1969, 220 et seq., 220 et seq.; *Eberstein, H.H., Technische Regeln und ihre rechtliche Bedeutung*, BB 1969, 1291 et seq., 1292 et seq.; *Diekershoff, K.H., Gerätesicherheitsgesetz*, in: *Handbuch zur Humanisierung der Arbeit*, Bd. 1, Bremerhaven 1985, 607 et seq., 609-611; *Jeiter, W., Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel)*, München 1980, 1-4; *Peine, F.-J., Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz)*, Kommentar, Köln/Berlin/Bonn/München 1986, Einführung, para. 5-15. Cf. also the explanatory statement to the draft Act on technical work materials, BT-Drs. FAO/834, 5.

²¹⁶ The title of Lukes' 1969 article is significant (*Lukes, R., Vom Arbeitnehmerschutz zum Verbraucherschutz - Überlegungen zum Maschinenschutzgesetz*, RdA 1969, 220 et seq.).

²¹⁷ Gesetz zur Änderung des Gesetzes über technische Arbeitsmittel und der Gewerbeordnung, 13 August 1979 (BGBl. I, p. 1432).

legal guarantees for the safety mark “GS = geprüfte Sicherheit (Tested Safety)” introduced by the Federal Minister of Labour, and extend the scope, to some extent, to dealers.²¹⁸

3.3.2. Scope

The GSG is addressed to manufacturers and importers in so far as they market or display technical work materials by way of trade or independently in the context of a business undertaking (§ 1 (1) GSG). Although the Länder,²¹⁹ the consumer associations and the Trade Supervisory Offices²²⁰ had advocated bringing dealers fully under the GSG, they were covered only exceptionally,²²¹ on the grounds that retailers were not in a position to make technical safety assessments of products and that there were sufficient possibilities of fighting the danger at source. § 1 (3) GSG explicitly states that the employer’s responsibility under the industrial safety and accident prevention regulations remains unaffected. In this connection, particular importance attaches to § 5 of the Accident Prevention Regulations, “General Provisions” (VBG 1), which obliges the businessman to require suppliers to furnish only those technical work materials that are in line with the Accident Prevention Regulations and the generally accepted rules of art in safety technique and industrial medicine.

The GSG applies to all technical work materials for which there are no specific regulations. Accordingly, it does not apply to vehicles in so far as they are subject to road traffic regulations, nor to technical work materials which by nuclear safety provisions are subject to special requirements, or which are used exclusively by the Army, the Technisches Hilfswerk, the border guards or the police, nor where other provisions aimed at hazard prevention pursuant to § 3 GSG regulate the marketing or display of technical work materials (§ 1 (2) GSG). Accordingly, for instance, toys are governed by the Foodstuffs and Consumer Goods Act in respect of any toxic properties, and by the GSG in respect of mechanical risks.

Technical work materials are, according to § 2 (1) GSG, ready-for-use equipment such as tools, working equipment, working machinery, powered machinery, lifting and conveying devices which can be used for their purpose without the addition of other parts. This work equipment is by § 2 (2) GSG placed on the same footing as protective equipment, lighting, heating, cooling, ventilating or air-conditioning equipment, household appliances, sports and do-it-yourself appliances and toys.²²² Appliances intended exclusively for export may be displayed on Federal territory even though they do not meet the requirements of the GSG, provided that it is clearly indicated that they are intended only for export out with the territory of Federal Germany.²²³

²¹⁸ On the latter see the Joint Declaration by Trade and Industry Federations on the application of the Appliances Safety Act of 25 April 1978, printed in *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 7-9.

²¹⁹ Cf. the explanatory statement by Bayern on the amendment to the GtA proposed in July 1977, BR-Drs. 133/77, 3 et seq.

²²⁰ See *Wilke*, 12 Jahre Gesetz über technische Arbeitsmittel, in: BAU (Ed.), Sicherheit '80. Heim - Freizeit - Schule, Dortmund 1980, 48 et seq., 67 et seq.

²²¹ For more see 3.3.7 below.

²²² This provision once again demonstrates the GSG’s origin in industrial safety and its extension into the home and leisure area.

²²³ Decision of 24 February 1976 by the Federal Administrative Court, GewA 1976, 172.

3.3.3. General safety obligation - § 3 (1) GSG

The core of the GSG is the general safety duty under § 3 (1) GSG:

A manufacturer or importer of technical work materials may market or display these only if they are, according to the generally recognized rules of art and the industrial safety and accident prevention provisions, of such a nature that users or third parties are when properly using them protected against dangers of all kinds to life or health as far as the nature of that proper use permits. Generally accepted rules of art and the industrial safety and accident prevention provisions may be departed from where equal safety is guaranteed in another manner.

Users and third parties are thus to be protected against dangers of all kind to life and health. By way of guaranteeing comprehensive hazard protection, § 2 (4) of the General Administrative Provisions on the GSG (AVV-GSG)²²⁴ explicitly states that this concerns not only classical technical aspects of safety such as protection against moving parts or pieces thrown off, stability or protection against touching current-carrying parts,²²⁵ but also such hazards as those resulting from noise, air pollution, heat emission or other effects of use. Taking ergonomic approaches into account, this means all effects on people of the work materials.²²⁶

However comprehensively the object of protection may be defined, the other elements of the general safety duty on manufacturers and importers are defined restrictively.

3.3.3.1. Proper use

The GSG protects the user only in so far as he uses appliances “properly”. § 2 (5) GSG contains a legal definition, naming two circumstances from which proper use emerges: (1) a subjective characteristic, namely the manufacturer's or importer's indications (particularly those contained in publicity) on ways of using the technical work materials; (2) an objective characteristic, namely the usual use deducible from the design and construction of the technical work materials.

The manufacturer's or importer's indications as to application may contradict the usual use deducible from design and construction. In such cases of conflict, it is always, according to the Münster Administrative Appeals Tribunal,²²⁷ always the usual use deducible from design and construction that applies. The appliance must take account of users' habits. The manufacturer cannot escape his responsibility through instructions for use that go against the uses predictable from the appliance's design. The objective criterion of usual use is not subordinate to subjective criteria of indications from the manufacturer, but in cases of conflict overrides them, since otherwise the manufacturer could through indications of use avoid necessary safety measures. Since the decision cited has as far as can be seen remained isolated, it cannot be assumed that the dispute as to interpretation of proper use is over. Laborious justifications continue to be adduced to try to play down the equal-value objective criterion of para. 2 (5)(2) GSG and give priority in case of conflict to the manufacturer's instructions for use²²⁸.

²²⁴ 27 October 1970, Bundesanzeiger No. 205, 3 November 1970, amended by AVV, 11 June 1979, Bundesanzeiger No. 108, 13 June 1979.

²²⁵ On this cf. DIN 31000/VDE 1000.

²²⁶ See Zimmermann, N., Das Gerätesicherheitsgesetz, in: Brendl, E., Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Bd. III, Gruppe 11, S. 123 et seq., 131 et seq.

²²⁷ Judgment of 26 October 1978 by OVG Münster - XIII A 881/76, reprinted in Meyer, 1979, 257 et seq.

²²⁸ See Schmatz, H./Nöthlich, M., Gerätesicherungsgesetz, Kommentar und Textsammlung, Sonderausgabe aus dem

The standards underlying safety-related standardization work, DIN 820, part 12 and DIN 31000/VDE 1000, in part go beyond para. 2 (5) GSG. Thus, DIN 820, part 12 says that:

Technical safety requirements should be specified in such a way that (when the product is properly used) it is unlikely that people, animals or things will be endangered. Ergonomic considerations should apply. Foreseeable mistakes should be taken into account.²²⁹

This provision has wide-ranging importance, since DIN 820, in all its parts, is binding for the standardization work of all specialized standard committees of the DIN²³⁰. At any rate it provides consumer representatives on standardization committees with arguments for basing the establishment of safety standards not the manufacturers postulated application of an appliance but on usual habits, including mistaken ones, of particular, not specially trained, groups of users.

DIN 31000/VDE 1000 takes the following conceptual specification for proper use:

*Proper use within the meaning of this standard is the use for which the technical product is suitable according the manufacturer's indications including those in publicity. In cases of doubt, it is a use that would be taken as usual from the design, construction and function of the technical product. Proper use also includes compliance with operating and maintenance conditions stated and the taking of foreseeable misuse into account.*²³¹

DIN 3100/VDE 1000 starts from the basic idea that using technology brings hazards resulting in part from the technical products themselves, in part from the way people handle technical products.²³² Even hazards caused by foreseeable misuse should be combated by design measures, primarily those of direct safety technology, supported by those of indirect safety technology. In practical standardization work, the three-stage method for safety design,²³³ among the engineers that more or less monopolize standardization work is likely to drive the consumer policy debate on proper, usual or likely wrong use into the background

3.3.3.2. Generally recognized rules of art and the industrial safety and accident prevention provisions

§ 3 (1), the key provision of the GSG, refers in its definition of the safety criterion to the “generally accepted rules of art” and to the industrial safety and accident prevention provisions. With sliding reference to technical rules no lesser criterion can be set up; the requirements clearly lag behind advancing technological development. Accordingly, when a technical rule is generally recognized, it is the experts that have to apply the rules of safety technology that are authoritative. They must primarily be convinced that the rules of art are in line with the safety requirements to be placed on the technical work material. This technical safety solution need not be the one prevailing in practice, but must have been adequately tested in practice and have proved itself under operating conditions.²³⁴ Even

Handbuch Sicherheitstechnik, Berlin, Kennz. 1125, 11: The objective criterion was allegedly chosen only to make up for the manufacturer’s or importer’s shortage of data or to supplement inadequate data from the manufacturer or importer; *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 42 et seq.: In the case of divergent instructions for normal use, what the manufacturer states must decide, since the manufacturer may have new information.

²²⁹ DIN 820, Part 12, (3.9.1).

²³⁰ Cf. § 3 of the agreement between the Federal Republic of Germany and DIN of 5 June 1975.

²³¹ DIN 31000/VDE 1000, (3.3).

²³² DIN 31000/VDE 1000, (2.1).

²³³ For details see 3.3.5 below.

²³⁴ See the official explanatory statement on § 3 (1) GSG, BT-Drs. V/834, 7. See also *Schmatz, H./Nöthlichs, M.*

where the technical standards referred to follow higher requirements, and are for instance based on the “state of the art”, this does not tighten the general safety duty under § 3 (1) GSG, since it is only compliance with generally accepted rules of art that is made binding legally.

Whether DIN standards ought to come up to the “state of the art” or merely reflect “generally accepted rules of art” is not entirely clear in DIN’s own mind. On the one hand, DIN 820, Part 1, which lays down the basic principles for standardization work, says that standards have to *take account* of the current state of science and technology and of economic circumstances.²³⁵ In referring to the state of science and technology, DIN did not wish to anticipate the severest criterion in the conceptual triad of the Federal Constitutional Court’s Kalkar Decision.²³⁶ Along with the state of science and technology, economic circumstances are also to be “taken into account” at the same time. DIN 820, Part 4, states that a standard must be reworked if it is no longer in line with the state of the art.²³⁷ The guidelines for standardization committees give the working groups the task of ensuring that standards are in line with the findings of science and the state of technology.²³⁸ The principles for applying DIN standards state rather soothingly that while the rules for establishing DIN standards call for the state of the arts to be taken into, this call is, it is only because of the steady advance of technology, extremely hard to meet.²³⁹ Finally, the indications to users of DIN standards indicate as an objective that DIN standards ought to be introduced as “accepted rules of art”.

The clear impression one derives is that the formulations (of engineers) in the various DIN regulations are completely decoupled from the conceptual considerations of lawyers on technical safety law.

The industrial safety and accident prevention regulations²⁴⁰ are not binding solely in so far as they reflect the generally recognized state of safety technology. They are binding not because of consensus by authoritative experts, but because of the autonomous legislative power given by Government to the agencies of legal accident insurance, or from their character as legal ordinances. Many industrial safety provisions are based on the enabling provisions of §§ 120e, 139a GewO (industrial code); others on the Chemicals Act, the Nuclear Act, the Explosive Act or the Federal Mining Act. Among important Federal industrial safety provisions are:

- Verordnung über Acetylenanlagen und Calciumcarbidlager, 27.2.1980 (BGBl. I, S. 220) (Ordinance on Acetylene Plants and Calcium Carbide Stores), with a number of technical

Gerätesicherungsgesetz, Kommentar und Textsammlung, Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 6-9; *Diekershoff, K.H.*, Gerätesicherheitsgesetz, in: Handbuch zur Humanisierung der Arbeit, Bd. 1, Bremerhaven 1985, 607 et seq., 615; *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung, Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 176; *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 24-29.

²³⁵ DIN 820, Part 1, (5.7).

²³⁶ Decision of Federal Constitutional Court of 8 August 1978, BVerfGE 49, 80 (135 et seq.).

DIN 820, Part 1, dates from February 1974.

²³⁷ DIN 820, Part 4, (4).

²³⁸ Guides for DIN standard committees, August 1982 version, point 10 (8) (g).

²³⁹ Principles for applying DIN standards, point II.3.

²⁴⁰ For details see the list of industrial safety provisions in the Accident Prevention Report 1985, BT-Drs. 10/6690, 5 December 1986.

rules for Acetylene Plants and Calcium Carbide Stores, drawn up by the German Acetylene Committee;

- Verordnung über Arbeitsstätten, 20.3.1975 (BGBI. I, S. 729) (Workplaces Ordinance), with around 30 directives on workplaces;
- Verordnung über die Aufzugsanlagen, 27.2.1980 (BGBI. I, S.205) (Ordinance on Lift Installations), with a number of technical rules for lifts drawn up by the German Committee for Lifts;
- Verordnung für Anlagen zur Lagerung, Abfüllung und Beförderung brennbarer Flüssigkeiten zu Lande, 27.2.1980 (BGBI. I, S.273) (Ordinance for Installations for Storing, Bottling or Transporting Combustible Fluids by Land), with some 40 technical rules for combustible liquids, drawn up by the German Committee for combustible liquids;
- Verordnung über Dampfkesselanlagen, 27.2.1980 (BGBI. I, S.173) (Steam Boilers Ordinance), with some 65 technical rules for steam boilers, drawn up by the German Steam Boilers Committee;
- Verordnung über Druckbehälter, Druckgasbehälter und Füllanlagen, 27.2.1980 (BGBI. I, S.184) (Ordinance on Pressure Vessels, Pressurized Gas Containers and Filling Plants), with some 35 technical rules for pressure vessels, drawn up by the Technical Committee on Pressure Vessels under the Central Office for accident prevention and industrial medicine of the Association of Mutual Indemnity Associations, and 90 technical rules on pressurized gases drawn up by the German Pressure Vessels Committee;
- Verordnung über Gashochdruckleitungen, 17.12.1974 (BGBI. I, S.3591) (Ordinance on High Pressure Gas Lines), with 40 technical rules on high pressure gas lines, drawn up by the Committee on High Pressure Gas Lines;
- Verordnung über gefährliche Stoffe, 26.8.1986 (BGBI. I, S.1470) (Ordinance on Hazardous Substances), with more than 50 technical rules for hazardous substances, drawn up by the former Committee for Hazardous Working Materials and by the Committee for Hazardous Materials.

By § 708 (1) RVO, the Mutually Indemnity Associations are autonomously entitled to enact accident prevention provisions binding on their members, employers and employees. They are worked out in technical committees that include experts from the mutually indemnity associations and also representatives of the Factory Inspectorate, of producers and users of technical work material, of the trade unions and of employers, and are adopted by the Assembly of Representatives, which has a parity-based composition. Before they can enter into force, they require approval by the Federal Minister for Labour. Quick response to new technical development is out of the question, since this procedure for issuing rules takes 5 or 6 years.²⁴¹

The accident prevention regulations in general contain detailed indications only on rules of conduct for employees and the wearing of protective equipment.²⁴² Indications on safety design for machines and work equipment are by contrast formulated only very generally, in turn often referring to the “generally recognized state of the art”. Accordingly, the hope of using the industrial safety and accident prevention regulations to bring safety requirements

²⁴¹ *Andresen, K.*, Arbeitsschutz - wie es die Natur des Betriebs gestattet, in: *Kaiske, R.* (Ed.), *Gesundheit am Arbeitsplatz*, Reinbek 1976, 123 et seq., 130. Cf. the issue dates of the accident prevention regulations given in list B accompanying the AVV-GSG.

²⁴² A survey of rules and regulations of the Mutual Indemnity Associations can be found in *Baum*, 1986.

more in line with the present state of technology or science²⁴³ is illusory. Finally, in 1982 the DIN and the mutual indemnity associations concluded an agreement whereby the latter would in principle formulate safety objectives abstractly, not going into technical details, and the DIN would specify those objectives – apart from instruction for actions – in DIN standards.²⁴⁴ This means that in the medium term in the area of accident prevention too there will not be any technical regulatory material not involving DIN standards.

3.3.3.3. Deviation Clause

The deviation clause²⁴⁵ of § 3 (1) (2) GSG is intended to make progress in safety technology possible and also to allow the manufacturer to depart from the generally accepted rules of art as long as the safety technology solution he chooses is at least equivalent. This provision for departure becomes relevant where a technical rule contains not only general objects of protection, but detailed technical model rules. In such a case the technical safety objective which is to be attained in some other way has first to be derived from them.²⁴⁶

The deviation clause is of particular importance for foreign manufacturers and importers. In general, they too have under the GSG to observe the “recognized rules of art” on the territory of The Federal Republic.²⁴⁷ If the foreign rule of art is not identical with the domestic one but nevertheless provides the same level of safety, the product may not be objected to.²⁴⁸ If the same safety level is attained, the deviation clause thus allows foreign manufacturers to continue large production runs without losing the German market for

²⁴³ Thus *Diekershoff, K.H.*, Gerätesicherheitsgesetz, in: Handbuch zur Humanisierung der Arbeit, Bd. 1, Bremerhaven 1985, 607 et seq., 617.

²⁴⁴ Agreement between DIN and the Federation of Industrial Mutual Indemnity Associations, the Hauptverband der gewerblichen Berufsgenossenschaften e. V./Bundesverband der Unfallversicherungsträger der öffentlichen Hand e. V., DIN-Mitt. 62 (1983), 92-94. This also regulates in detail the involvement of legal accident insurance agencies in standardization work. On this agreement see *Buss, P.*, Zusammenarbeit der gewerblichen Berufsgenossenschaften mit dem DIN, DIN-Mitt. 63 (1984), 295 et seq.; *Jansen, M.*, Unfallverhütungsvorschriften und Normen. Erfahrungen aus der Zusammenarbeit, DIN-Mitt. 65 (1986), 157 et seq.; *Müller, G.*, Berufsgenossenschaften und DIN, DIN-Mitt. 65 (1986), 150 et seq.

²⁴⁵ In general on the Deviation Clause in § 3 (1) (2) GSG, see *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 18-21; *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 49-51; *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 190-194; *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 85-90.

²⁴⁶ See *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 19 et seq.; *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 50; *Peine, 1986*, § 3, para. 90.

²⁴⁷ See *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 15 et seq.; *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 175.

²⁴⁸ See *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 20; *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 191.

safety reasons.²⁴⁹ It thus leads to the same outcome as the case law on Art. 30 et seq. EEC. For goods from Community countries, it follows from Art. 30 EEC that they are freely marketable in all Member States if they have been marketed legally in the country of origin, unless the importing country can refer to objects of protection under Art. 36 EEC or to binding requirements in the sense of the Cassis judgment.²⁵⁰ If the same level of safety is maintained, any appeal to Art. 36 EEC in order to protect against dangers to life or health is ruled out. The bilateral agreements on mutual recognition of German and French standards²⁵¹ make it easier to use the GSG deviation clause, since list C in the general administrative regulations for the GSG gives the French standards that are, until proof of the contrary, to be taken as equivalent in safety level to the German standards. At the same time, the bilateral agreement is an indication that neither using the GSG deviation clause nor following ECJ Case Law on Art. 30 et seq. EEC are enough to avoid obstacles to trade between Member States.

The deviation clause applies in favour of manufacturers and importers even in respect of accident prevention regulations. Here distortions of competition may arise because an employer as user of work materials does not have a similar entitlement to deviate where the same safety is guaranteed.²⁵² As far as capital goods are concerned, a remedy could be found here if the various mutual indemnity associations declared a willingness to allow for corresponding departures in the accident prevention regulations.²⁵³ The problem will lose practical importance as the accident prevention regulations come to specify only general objects of protection but not the technical details for meeting them.²⁵⁴

It is controversial whether a manufacturer or importer who appeals to the deviation clause has to show that the same safety has been achieved in another way²⁵⁵, or whether the authority wishing to intervene must establish that the other technical safety solution is not

²⁴⁹ See *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 79.

²⁵⁰ See *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²⁵¹ See 1.10. above and 3.3.4. below.

²⁵² See *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq.

²⁵³ The Federation of Industrial Mutual Indemnity Associations has so far opposed this; cf. *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 192. Whether this position is compatible with Art. 30 et seq. EEC remains questionable even after the ECJ judgment of 28 January 1986 in Case 188/84, ECR [1986] 419-woodworking machines (see also the discussion in *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.2.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>). This judgment explicitly confirms Member States' right to decide on the equivalence of different safety conceptions, though not by simply giving blanket preference to the totality of their own accident prevention regulations.

²⁵⁴ On this trend, cf. the DIN agreement with the Mutual Indemnity Associations, DIN-Mitt. 62 (1983), 92-94 and *Schmatz, H./Nöhlich, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 17.

²⁵⁵ Thus *Schmatz, H./Nöhlich, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1135, 20 et seq. See also *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 87 et seq.

equivalent.²⁵⁶ Products are certainly freely marketable in principle without prior permission, even where the manufacturer takes advantage of the deviation clause. However, where the authorities intervene in the presence of a specific hazard, there is more to say for the idea of obliging a manufacturer or importer who departs from the regulation position to provide facts or proof of equal safety.

The obligation to comply with generally accepted rules of art and the industrial safety and accident prevention regulations does not apply to manufacturers or importers where the technical work materials have according to written statements by the proposed user being manufactured to order (§3 (2) GSG).²⁵⁷

3.3.4. Incorporation of standards in the lists

In Annexes A, B and C to the General Administrative Regulations on the GSG, the Federal Minister for Labour and Social Affairs indicates the rules of art compliance with which leads to a presumption that work material is in line with the underlying rules of art. Through continual supplementation and corrective adjustment (at present twice yearly), the latest results of standardization work and technical practice in the area of accident prevention are taken into account. In October 1987 the individual lists included a total of 1,708 safety rules,²⁵⁸ which break down as follows:

<i>List A (domestic technical standards)</i>	
DIN standards or VDE definitions	1,277
DVGW standards	3
VDI rules	25
<i>List B (accident prevention regulations, etc.)</i>	
Accident prevention regulations (UVV)	85
Implementing instructions on the UVV	64
Directives, safety rules and leaflets from the mutual indemnity associations	115
Ordinances, administrative regulations, technical rules and directives for installations monitored under § 24 GewO	21
<i>List C (foreign technical standards)</i>	
Standards of the French Standardization Organization AFNOR	118

This breakdown brings out the overwhelming importance of DIN standards or VDE definitions, which account for some 3/4 of the safety rules indicated. Table 2 gives an overview of the numerical development of regulations under the GSG. Since 1970, the number of safety rules included in the lists has more than quintupled. The lists are subject

²⁵⁶ Thus *Lindemeyer, B.*, Die Anforderungen des § 3 Gerätesicherheitsgesetzes an die Beschaffenheit technischer Arbeitsmittel. Probleme seiner rechtlichen Handhabung in der Praxis und Abwehr nicht sachgerechter Anforderungen, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Gruppe 11, 167 et seq., 192-194 and *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 51. See also § 2 (1) (2) AVV-GSG.

²⁵⁷ For more on this see *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 91-100.

²⁵⁸ See the first supplement to the list in the AVV-GSG, BArbBl. 9/1986, 63 et seq., which amended and supplemented the new version of the lists dating from January 1986 (BArbBl. 1/1986, 22 et seq.), and list A and B of the AVV-GSG, BArbBl. 11/1987, 47 et seq.

to continuing review. For instance, the September 1986 update deleted 112 technical rules and included 169 new ones.

In November 1984 list C was opened. On the basis of the bilateral agreement between France and the Federal Republic,²⁵⁹ it contains standards from the French Standardization Organization AFNOR, notified by the Ministry for Foreign Trade and Industrial Development, on which the competent authorities in the Länder, the Committee on technical work materials and interested circles have been heard.

Table 2: Development of regulation work under the Appliances Safety Act and number of recognized test centres²⁶⁰

<i>Year</i>	<i>Number of standards in list A and B</i>	<i>Number of standards in list C</i>	<i>Number of recognized test centres</i>
1970	287	-	-
1971	529	-	2
1973	623	-	21
1975	679	-	49
1977	823	-	62
1979	925	-	69
1981	983	-	69
1983	1210	-	76
1984	1210	118	76
1986	1565	118	78

If a manufacturer or importer refers to a standard in list C, the Trade Supervisory Office only then – unless safety is evidently guaranteed in another way, pursuant to the deviation clause in § 3 (1) (2) GSG – asks for this standard to be submitted in German. If the work materials prove to comply with the French standard, equal safety counts as guaranteed.²⁶¹

The Federal Minister of Labour is as a rule involved in the issuing of implementing regulations on the accident prevention regulations and in bringing out technical safety rules and leaflets of the accident insurance agencies; indeed, accident prevention regulations require his approval. In general, accordingly, no additional technical testing is necessary for inclusion of these regulations in list B.²⁶²

²⁵⁹ For details on this see 1.10. below.

²⁶⁰ Compiled from the 1985 Annual Report of the Federal Institute for Industrial Safety, p. 23, and the first supplement to lists A, B and C of the General Administrative Regulations under the Act on Technical Work Materials, September 1986, Bundesarbeitsblatt 9 (1986, 63-70).

²⁶¹ Cf. the BMA Circular of 3 October 1984 to competent Länder authorities, BArbBl. 11/1984, 52.

²⁶² Cf. *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1304, 67.

3.3.5. Principles of safety standardization

In establishing the technical norms for inclusion in list A, the Appliances Safety Division of the Federal Institute for Industrial Safety²⁶³ and the DIN Committee on Safety Technology work closely together.

The Commission on Safety Technology was set up in 1965 in connection with the preliminary work on the Act on Technical Work Materials, on the initiative of and with financial support from the Federal Minister of Labour.²⁶⁴ Its tasks are above all to encourage safety standardization work in the specialized DIN standardization committees, coordinate safety standardization in DIN, select suitable DIN standards for inclusion in the lists and propose them to the Federal Minister of Labour, and, acting on suggestions from the Federal Institute for Industrial Safety and the Trade Supervisory Offices, test whether standards with safety provisions are still in line with the current state of the art.²⁶⁵ It coordinates involvement of safety experts from the Factory Inspectorate and the Federal Institute for Industrial Safety in the specialized standardization committees, and in 1975 submitted a proposal, never discussed in detail, far less applied, to set up an accident information system covering also the home and leisure sectors.²⁶⁶ It includes representatives of Federal Ministries and of the Länder labour authorities, of the Federal Institute for Industrial Safety, of the legal accident insurance agencies, of the trade unions, of employer associations, of the Federal Association of German Industry, of standards workers and of science.

The Federal Institute for Industrial Safety delivers opinions on draft standards with safety relevance as part of the regular procedure for establishing standards, and tests the standards proposed by the Safety Technology Committee for inclusion in list A. In a kind of written soundings-taking procedure, it then gives expert circles interested a chance to comment on proposed changes or additions, though without going as far as a new round of discussion on the standards.²⁶⁷ In order to secure the broadest possible consensus of all expert circles and to cover all reservations and all findings, umbrella associations in industry, trade and handicrafts, and the unions, standardization workers, the DIN Safety Technology Committee, the Länder labour authorities and the members of the Committee on technical work materials are brought in.²⁶⁸

At this stage, immediately before publication of the lists, the number of objections still being raised is very small. This is due above all to the fact that test criteria are laid down in detail for all standardization work in DIN 31000/VDE 1000, “general guidelines for safety design of technical products”²⁶⁹ and DIN 820, Part 12 “standardization work, standards with technical safety provisions, design”²⁷⁰.

²⁶³ To which preliminary work on publishing the lists was transferred after 1974; Unfallverhütungsbericht 1976, BT-Drs. VII/4668, 71.

²⁶⁴ Till then the German Standards Committee, the predecessor of DIN, had neglected safety standardization. Cf. the letter from the President of the German Standards Committee to the chairmen and executive secretaries of the specialized standards committees of 18 February 1966.

²⁶⁵ For details on the tasks of the Safety Technology Commission see *Lehmann, K.*, *Kommission Sicherheitstechnik im DNA, Arbeitsschutz 1972*, 311 et seq.

²⁶⁶ Cf. *Lehmann, K.*, *Sicherheitsnormung - Auftrag vom Maschinenschutzgesetz, Arbeitsschutz 1975*, 330 f.

²⁶⁷ It is not intended that those whose objections against draft standards have failed in the regular standard-setting procedure should be offered a review body.

²⁶⁸ Cf. *Mertens, A.*, *Das Gesetz über technische Arbeitsmittel und die Normen, Vorschriften und Regeln, DIN-Mitt. 53 (1974)*, 327 et seq., 331.

²⁶⁹ On this see *Zimmermann, N.*, *Normen mit sicherheitstechnischer Festlegung, Arbeitsschutz 1977*, 347 et seq;

DIN 820, Part 12, published in May 1977, which brings together experience to date in the DIN Safety Technology Committee, the Federal Institute for Industrial Safety and the Federal Ministry of Labour, provides the structural criteria that safety standards must meet for inclusion in list A of the general administrative regulations under the GSG: safety requirements must be laid down concretely and unambiguously, and compliance must be fully and unambiguously testable. Requirements must be specified so exactly that test results are reproducible.

More important than these formal structural criteria are the substantive requirements that DIN 31000/VDE 1000 lays down for the safety design of technical products. The eventual standard of March 1979 had been preceded as long ago as December 1971 by a preliminary standard based on preliminary work under the auspices of the Federal Ministry of Labour.²⁷¹ It was to act as the basis for the specification of safety standards or VDE definitions²⁷² and allow initial assessment of technical products as regard safety, in so far as valid, specific and complete standards for this were not or not yet available.²⁷³ Its provisions are to be specified in standards for individual types of technical product or in VDE definitions for individual types of electrical equipment, and supplemented by indications as to relevant tests.²⁷⁴

The safety design of technical work materials is seen in the first place as a design task for engineers. In safety design the preferred solution should meet the safety objective in technically rational fashion as well as being economically the best, and *in case of doubt* safety requirements take priority over economic considerations.²⁷⁵ The following three-stage method applies: technical products should be so designed that no hazards are present (direct safety technology). If this is not or not fully possible, special safety devices that come into play automatically should be used (indirect safety technology). Only in third place come indications of the conditions under which hazardous use is possible (safety through instructions). The technique of safety through instructions is to be used in combination with direct and indirect safety technology even where hazards with products can be prevented only by particular actions on the part of the user.²⁷⁶ This restriction can amount to excluding foreseeable misuse from design safety technology and allocating it to the technique of safety through instructions.

To supplement and extend the general guidelines of DIN 31000/VDE 1000, technical safety provisions for particular areas that overlap specialities or safety objectives should be summarized in basic standards (infrastructure).²⁷⁷ Finally, in order to allow the DIN standards to have full product-specific effect, groups of products or individual products should be covered in standards for special fields or standards for components.²⁷⁸

idem, Sicherheitsnormen für technische Arbeitsmittel. Das neue Gerätesicherheitsgesetz und seine Durchführungsverordnungen, DIN-Mitt. 60 (1981), 102 et seq.

²⁷⁰ On this see *Zimmermann, N.*, DIN 31000/VDE 1000 - Wichtige Orientierung, BArBl. 6/1979, 44 et seq.

²⁷¹ On the preliminary work see *Ludwig, N.*, Sicherheitsgerechtes Gestalten technischer Erzeugnisse, DIN-Mitt. 49 (1970), 424; *Sälzer, H.J.*, Arbeitsausschuß Sicherheitstechnische Grundsätze (ASG) im DNA, Arbeitsschutz 1972, 313 et seq.

²⁷² DIN 31000/VDE 1000 (2.3).

²⁷³ DIN 31000/VDE 1000 (2.4). Some of the banning orders published are based, in the absence of specific product standards, directly on infringement of DIN 31000/VDE 1000.

²⁷⁴ DIN 31000/VDE 1000, (2.5).

²⁷⁵ DIN 31000/VDE 1000, (4.1).

²⁷⁶ Notes on DIN 31000/VDE 1000.

²⁷⁷ List A of the AVV-GSG at present contains 26 standards with general safety conditions.

²⁷⁸ See the notes to DIN 31000/VDE 1000 and *Zimmermann, N.*, DIN 31000/VDE 1000 - Wichtige Orientierung,

3.3.6. The safety mark “GS = geprüfte Sicherheit” (tested safety)

The GSG does not have an obligation to test technical work materials, but offers manufacturers and importers the possibility of securing confirmation from a recognized test centre, after a design test, that their appliances meet the provisions of § 3 (1) GSG or of a legal ordinance adopted pursuant to §§ 4 or 8a. If the result is positive they secure the right to use the safety mark “GS = geprüfte Sicherheit”, uniform for all types of appliance and accompanied by an identification of the test centre (§ 3 (4) GSG).²⁷⁹ It was introduced by the Federal Minister for Labour in 1977, after the Association for a Safety Mark had spent seven years failing to agree on one. It is intended to enable the consumer, in a simple, easily remembered way, to choose safer products, and as well as serving the marketing interests of manufacturers, it is also a way of lessening the burden on supervisory authorities, who should refrain from testing appliances bearing the mark²⁸⁰ unless there are grounds to suspect its illegal use.

The Federal Minister for Labour and Social Affairs, after consulting the Committee on technical work materials and with agreement from the Upper House of the German Parliament, determines by legal ordinance the testing centres competent for the design test. These must be suitable in staff and equipment for the task, economically independent and able to offer guarantees of reliable testing. The list of test centres also lays down the fields for which a test centre is recognized. At present there are 78 recognized centres,²⁸¹ among them 10 technical control boards, the Bavarian Provincial Institution for Trade, the Association of German Electrical Engineers, the German Vehicle Testing Association and three mail-order firms,²⁸² each with an intensive range of competences, plus 27 specialized committees of the mutual indemnity associations, three DIN standards committees, the Federal Institute for Materials Testing and 32 other test centres with very specific areas of competence.²⁸³ In the context of the bilateral agreement between France and the Federal Republic, the Laboratoire Nationale D’Essais was also recognized as a test centre in December 1985. Recognition is preceded by verification by the Federal Institute for Industrial Safety, relating *inter alia* to staffing and equipment and including a demonstration from among the range of areas of coverage applied for.²⁸⁴

BArBl. 6/1979, 44 et seq., 1979, 45 et seq.

²⁷⁹ On the GS mark see *Albertz, R.*, Sicherheitsgeprüfte Geräte - Wert des GS-Zeichens, s.i.s. 1985, 262 et seq.; *Schwarze, D.*, GS-geprüfte Geräte - Entlastung der Fachkraft für Arbeitssicherheit?, *Sicherheitsingenieur* 11/1983, 26 et seq.; *Zimmermann, N.*, Das Sicherheitszeichen Geprüfte Sicherheit, *Sicherheitsingenieur* 6/84, 14 et seq.; *idem*, Gerätesicherheit - Neuordnung der Aufgabenbereiche aller GS-Prüfstellen, *Amtl. Mitteilungen der Bundesanstalt für Arbeitsschutz* 1/1987, 10-11, 142a-144; *idem*, Gerätesicherheit - Neuordnung der Aufgabenbereiche aller GS-Prüfstellen, *Amtl. Mitteilungen der Bundesanstalt für Arbeitsschutz* 1/1987, 10-11; *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 54-58; *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 3, para. 112-144; *Kalwa, W.*, GS - Geprüfte Sicherheit: Seit 10 Jahren erfolgreich, *BArBl.* 11/1987, 11 et seq.

²⁸⁰ § 6 (1) AVV-GSG. In 1983, 8% of the defective technical work materials reported on in the “standard defect notifications” from the Trade Supervisory Offices bore a test mark from a recognized test centre; cf. the 1984 annual report of the Federal Institute for Industrial Safety, 1984, 21.

²⁸¹ For the development over time, see Table 2 above.

²⁸² These offered the chance of linking the proven work of the incoming merchandise checks with safety tests for the GS mark, at the same time achieving rapid spread of the GS mark to a broad range of goods.

²⁸³ See the list of test centres in the AVV-GSG, in the version in the October 1986 communication (*BArBl.* 10/1986, 50 et seq.).

²⁸⁴ For details, and on the test reports, see *Zimmermann, N.*, Gerätesicherheit - Neuordnung der Aufgabenbereiche aller GS-Prüfstellen, *Amtl. Mitteilungen der Bundesanstalt für Arbeitsschutz* 1/1987, 10-11142b-142d.

In order to arrive at uniformity of testing practice, test centres must undertake to participate in the information clearing houses for test centres in their field attached to the Committee for Technical Work Materials, and comply with agreements arrived at there. Apart from individual test contracts, the test centres have the following tasks. Should they find that technical work material for which they have given authorization to use the safety mark has been supplied defectively, they have to cause the manufacturer or importer to provide a remedy. If the faults are not removed, or unsafe appliances continue to be marketed, the Trade Supervisory Offices are to be informed. They have to note accidents arising in using appliances tested by them and see to the removal of faulty goods still found. They have to transfer their experience from testing work into standardization and regulatory work.²⁸⁵ If an applicant for a test refers to a French standard contained in list C, the test centre has to apply the French standard where the technical work material is not in line with the relevant German standards and equal safety is not obviously guaranteed.²⁸⁶

The GS mark has been widely used for many technical consumer goods. The total number of types of appliance or machine with valid GS marks amounted by 31 December 1985 to 85,000.²⁸⁷ Applicants for the GS mark have the chance to ask for the criteria related to their appliance so as to be able to take the safety requirements in force more reliably into account even at the design stage of technical work materials. Since in the case of many technical consumer products there is competition between various test centres, one cannot ignore the danger that differing test criteria might be applied and that manufacturers and importers might choose test centres likely to give them more favourable test results than others. The only remedy is extension of the information network among test centres, and the checks on test centres by the Federal Institute for Industrial Safety, which started in 1984.

In safety checks carried out by the Stiftung Warentest, appliances bearing the GS mark continually display serious safety shortcomings.²⁸⁸ The reasons adduced are that particular identifiable test centres interpret the regulations in force less strictly than would be

²⁸⁵ See the criteria, guidelines and instructions for test centres under § 3 (4) GSG, BArbBl, 11/1984, 50 et seq.

²⁸⁶ See the BMA Circular of 3 October 1984 to test centres, BArbBl, 11/1984, 52.

²⁸⁷ Unfallverhütungsbericht 1985, BT-Drs. 10/6690, 5 December 1986, 33.

²⁸⁸ *Loose, P.*, Sicherheitstechnische Prüfung von Gebrauchsgütern durch die Stiftung Warentest, in: Unfall-Risiken der Privatsphäre. Epidemiologie - Diagnose - Prävention, VI. Internationales GfS-Sommer-Symposium, 3.-5.6.1985, Wuppertal 1986, 361 et seq., 364 et seq.; see also „Normen sorgen für dicke Luft. Warentester legen zu Recht manchmal schärfere Maßstäbe an“, FR, 1 April 1987, p. 5. The Federal High Court recently explicitly decided that the Stiftung Warentest could apply more stringent criteria in safety testing than those in the technical standards: BGH, NJW 1987, 2222 et seq. Cf. *Vieweg, K.*, Verbraucherschutz durch technische Normen und vergleichende Warentests, NJW 1987, 2726-2727 and *Budde, E.*, Rechtsprechung und DIN-Normen, DIN-Mitt. 66 (1987), 317 et seq. In the standard-setting procedure, no consensus had been secured as to the necessary safety arrangements for electric compost choppers. The Stiftung Warentest, other consumer representatives and the Federal Institute for Industrial Safety had tried in vain to get their ideas on adequate safety included, but had to succumb to the supplier side in the opposition procedure. The Federal Minister for Labour has since recommended test centres that had already issued approval for the GS mark on compost choppers meeting the DIN standard to withdraw that approval. The Stiftung Warentest, which overlaps in personnel with the standardization associations, particularly with DIN, – it is represented on the five-member DIN Consumer Council and on some 100 standards committees and other DIN and VDE working bodies, and the Director of DIN is Chairman of the Administrative Board of Stiftung Warentest – only rarely goes beyond the requirements of technical standards in its testing practice. There are scarcely any testing programmes not based on technical standards, at any rate as far as safety testing goes. If an appliance does not meet the safety requirements, it is automatically graded “defective”. The manufacturers’ side understandably supports tighter ties to technical standards for the Stiftung Warentest. According to the “guidelines for industrial experts in the Stiftung Warentest” drawn up by the Federal Association of German Industry, the Stiftung Warentest should not grade a feature of a product poorer than “satisfactory” if it meets the requirements corresponding to the state of the art.

necessary, that products are altered after securing the mark, and that the safety regulations applied are inadequate.

3.3.7. Monitoring by the Trade Supervisory Offices; banning orders

The competent supervisory bodies for monitoring the Appliances Safety Act are the National Trade Supervisory Offices, 71 in number. The trade supervisory offices have a very wide range of tasks, with responsibilities for protection against nuisances, social industrial safety and, in the area of technical industrial safety, for workplaces, monitored installations, dangerous work substances, explosive materials, radiation protection, organization of industrial safety in factories and, of course, for technical work materials.²⁸⁹

An extensive empirical study in 1979 showed that they devoted only a fraction of their working time, some 2.2%, to application of the Appliances Safety Act.²⁹⁰ The trade supervisory offices are not obliged to make systematic checks on all technical work materials or all manufacturers or importers. Since 180,000 types of technical work materials come newly on to the market each year,²⁹¹ this would be far beyond their resources. From considerations of effectiveness, the principle applied is that of directed monitoring activities. They have to check technical work materials where a competent authority for industrial safety or legal accident insurance agency, officer of policy or other authorities, user of technical work materials or centre dealing with hazards protection under the GSG (Stiftung Warentest, works councils, test centres) has submitted a report on a defective technical work material or on an accident in using a technical work material.²⁹²

Because of time overloads on trade supervisory officers and on the Federal Institute for Industrial Safety a unique possibility is being unused here. This would be the building up of an accident information system which, though it could not lay any claim to representativity, would specifically pick out the cases where defective technical appliances had caused accidents or led to serious hazards. It is hard to understand why no resources have yet been found in order, for instance, to make systematic evaluations of defect reports passed on to the Länder in which manufacturers or importers of products whose safety has been impugned have their headquarters.²⁹³

Since the primary objective of the GSG consists in preventive hazard protection, the idea suggests itself of having trade supervisory offices at fairs and exhibitions of more than local importance²⁹⁴ test work materials on offer there, with economical use of staff.²⁹⁵ In 1984, 54% of all inspection in connection with the GSG took place at fairs and exhibitions. An advantage is that at fairs, where the latest technical work materials are displayed in large numbers and many types, a whole product range can be covered in each case, without having to trace manufacturing plants and importers scattered over the whole national territory, and also that testing can often be done before mass production begins. A

²⁸⁹ An illustrative picture of their wide range of tasks is presented by the annual reports of the Trade Supervisory Offices of the Länder.

²⁹⁰ Arbeitsschutzsystem. Untersuchung in der Bundesrepublik Deutschland, Dortmund 1980/515.

²⁹¹ Cf. *Haberland, N.*, Gerätesicherheitsgesetz - Vollzug in einem Bundesland, s.i.s. 1984, 366 et seq., 366.

²⁹² § 5 (2) GSG and § 1 AVV-GSG.

²⁹³ Not counting the figures for Baden-Württemberg, in 1984 alone there were 1,734 of them with several defects each.

²⁹⁴ Often in so-called Fairs Committees, along with technical supervisory officials of the accident insurance agencies.

²⁹⁵ Explicitly regulated in the Circular Order from the Minister for Labour, Health and Social Affairs of Land North Rhine-Westphalia on the implementation of the GSG of 26 July 1982, Ministerialblatt, p. 1473.

disadvantage is that in general testing is possible only through visual inspection, so that only defects that strike the eye can be covered, but no more detailed tests can be done, which would often require the dismantling or even destruction of the technical work appliance.²⁹⁶

Ad hoc market checks on particular types of technical work materials suggested by accident reports or safety tests as being particularly accident-prone are done by the Central Office for safety technology, radiation protection and nuclear technology of Land North Rhine-Westphalia. In view of the shocking accident situations in the private sphere, it concentrates mainly on types of appliances intended for use in the home, do-it-yourself, play and sport.²⁹⁷ The findings secured are, if not yet incorporated in technical safety standards, then used in standardization work.²⁹⁸

Should the trade supervisory offices discover defects implying danger to life or health of users or third parties given proper use, the severest sanction open to it, where other measures prove inadequate, is the banning order,²⁹⁹ preventing the technical work material from being marketed or displayed (§ 5 (1) (2) GSG). Whether an office has recourse to a banning order is in its own discretion, in accordance with its duty. Only in two particularly serious cases does § 5 (2) GSG lay down a duty to test, namely where a competent authority for industrial safety or a legal accident insurance agency has notified it that a technical work material has a defect in quality that endangers the life or health of users or third parties given proper use, or where during use of the technical work material an accident has occurred and there is good reason to believe that the accident can be attributed to a defect in the quality of the technical work material. If the law's objective, preventive accident protection, is not to be frustrated then the authority must act, if only to avoid public liability claims, since any other decision would mean acquiescing in a severe accident.³⁰⁰

The order to be issued to the manufacturer or importer, and only under very restrictive conditions to an exhibitor or trader,³⁰¹ must be accompanied by reasons, and the defects must be specified in detail. To ensure that banning orders are issued only in justified cases, the Trade Supervisory Office must before deciding, unless the danger of delay or the defect in the nature of the work materials is obvious, consult one of the agencies of legal accident insurance whose members use technical work materials of the same type (§ 6 (1) GSG). Should an accident have occurred because of the defect ascertained and other accidents are to be feared, immediate execution of the banning order should be directed (§ 7 (3) AVV-GSG). A copy of the banning order is to be sent to the Committee on Technical Work Materials (§ 6 (2) GSG).

²⁹⁶ Cf. *Wilke*, 12 Jahre Gesetz über technische Arbeitsmittel, in: BAU (Ed.), Sicherheit '80. Heim – Freizeit – Schule Dortmund 1980, 48 et seq., 52-54.

²⁹⁷ Cf. the progress report by *Fischer, R.*, Systematische Marktkontrollen durch die Zentralstelle für Sicherheitstechnik. Ein Beitrag zur Abwehr sicherheitswidriger Produkte, MD VZ-NRW 2-1984, 48 et seq., and the annual reports of the Trade Inspectorate of Land North Rhine-Westphalia 1982, 45-71; 1983, 47-55; 1984, 48-59.

²⁹⁸ Cf. the list of DIN Standards Committees and Committees of the German Electrical Engineering Commission on which Trade Supervisory Offices collaborated: Annual Report of the Industrial Inspectorate of Land North Rhine-Westphalia 1984, 263-266.

²⁹⁹ On banning orders see *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 5 para. 25-119; *Falke, J.*, Untersuchungsverfügungen über sicherheitstechnisch mangelhafte Geräte, VuR 1987, 3 et seq.

³⁰⁰ For details on this see *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986, § 5, para. 31-42.

³⁰¹ On banning orders against a trader or exhibitor see the statements in fn. 307-312 below.

Even though they are explicitly mentioned in the GSG as the sole means of sanction, banning orders constitute the last resort, to be used only in severe cases, where no remedy can be secured by more moderate measures. Less invasive measures are, for instance, cautions about defects ascertained and advice about eliminating them or an order to remove defects ascertained within a certain time and thereafter to sell only defect-free appliances.³⁰² They can be considered only where the manufacturer or importer is prepared to remedy the defects ascertained. Willingness to do so is higher before starting actual marketing. Cases have been reported where importers have after ascertainment of severe safety defects seen their negotiating position with the manufacturer as strengthened by a banning order. Since banning orders are based on Federal law they apply in principle in the whole of Federal territory, even if issued by Länder authorities.³⁰³

The *synopsis* below gives the picture of trade supervisory offices' test work under the GSG in 1984, not including systematic market spot checks carried out. It was already stressed that more than half the inspections take place at fairs and exhibitions. 57% of the 46,600 technical work materials tested are used primarily in industry, agriculture and administration, and some 29% are foreign manufactures. Of appliances tested, a total of 24% proved defective, 20% of the domestic ones and 34% of foreign products. The systematic market checks, not covered here mostly give considerably higher rates of defect.³⁰⁴ Appliances with defects on average have two of them. 42% of defects can be remedied by re-equipping, 40% by design measures, and 15.6% result from faulty instructions for use. However, 2.3% of defects are so serious that appliances are unusable, requiring redesign *ab novo*.

Synopsis: Tests by Trade Supervisory Offices under the Appliances Safety Act in 1984³⁰⁵

	<i>Number</i>	<i>%</i>
<i>Number of inspections</i>		
Total	13,799	100.0
at fairs and exhibitions	7,465	54.1
<i>Technical work materials tested</i>		
Total	46,566	100.0
mainly used in industry, agriculture, administration	26,521	57.0
mainly used in home, leisure, school, kindergarten	20,045	43.0
manufactured in Germany	33,185	71.3
manufactured abroad	13,381	28.7
<i>Technical work materials with safety defects</i>		
Total	11,195	100.0
domestic products	6,609	59.0

³⁰² See *Schmatz, H./Nöthlich, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung, Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1155, 6-8; *Jeiter, W.*, Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 73 et seq.; *Peine, F.-J.*, Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz), Kommentar, Köln/Berlin/Bonn/München 1986 § 5, para. 16-24.

³⁰³ BVerfGE 11, 1 (6).

³⁰⁴ Thus, BMX children's bicycles had a defect rate of 89%, and a particular kind of heating stove 90% (cf. Fischer, 1984); in 1976-8 65% of technical medical appliances (cf. *Wilke*, 12 Jahre Gesetz über technische Arbeitsmittel, in: BAU (Ed.), Sicherheit '80. Heim - Freizeit - Schule, Dortmund 1980, 48 et seq., 63) and 54% of fork-lift trucks (see Annual Report of the Industrial Inspectorate of Land North Rhine-Westphalia 1984, 57 et seq.) were defective from safety viewpoints.

³⁰⁵ Compiled from the annual reports of the trade supervisory offices in individual Länder for 1984.

foreign products	4,586	41.0
<i>Number of types of defect</i>		
Total	20,009	100.0
eliminable by re-equipping	8,407	42.0
eliminable by design measures	8,005	40.0
unusable - redesign necessary	466	2.3
defects in instructions for use	3,131	15.6
<i>Letters sent out following inspection</i>	1,433	
<i>Banning orders</i>	49	
<i>Court procedures</i>	4	

Banning orders were issued in only 49 cases. This small number is only in part because most defects could be more or less easily removed by re-equipping, design measures or changes to instructions for use. It is also due, apart from strict application of the proportionality principle, to the self-image of the trade supervisory offices, who see themselves more as advisers than as supervisory authorities.³⁰⁶

Table 3 shows the numerical trend in test inspections by trade supervisory offices and in banning orders from 1969 to 1984. The number of inspections grew steadily until 1974, reaching a plateau of around 14,000 thereafter. The number of banning orders grew from 1969 to 1975 to a unique peak figure of 377 then fell between 1976 and 1981, apart from the high value for 1979, to a figure between 150 and 190, and in 1984, at 49, was only just above the initial year, 1972. This means a critical point is being reached if trade supervisory offices still wish, in their search for less drastic solutions, to be able to use threats of banning orders credibly.

Banning orders against traders are possible only on tighter conditions.³⁰⁷ Exhibitors at fairs can be banned from displaying work materials with safety defects only if the manufacturer or importer cannot be traced (§ 5 (1) (2) GSG). Otherwise, banning orders to traders presuppose under § 5 (3) GSG that the manufacturer or importer has previously been banned from marketing the technical product, that the trader knows this banning provision, for which it is sufficient for the authority so to inform him, and that the trader has the possibility of returning the defective of technical work material³⁰⁸ but refuses to avail himself of this right of return. In view of this “protective barrier” of restrictive conditions on action, it is hardly surprising that the power to issue bans to the trade, so urgently called for by the trade supervisory offices,³⁰⁹ plays no part³¹⁰ in practice. It is scarcely possible for

³⁰⁶ 47% of Trade Supervisory officials see themselves more as advisers, 16% more as supervisors; cf. Arbeitsschutzsystem, Bd. 2, 1980, 587-590.

³⁰⁷ Cf. Schmatz, H./Nöthlich, M. Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1155, 15-27; Jeiter, W., Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 74-79; Peine, 1986, § 5, para. 108-119.

³⁰⁸ This condition reflects the legislators expectation that the Joint Declaration of industry and trade federations of 15 April 1978 (reprinted in Jeiter, W., Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 7-9) will give the trader a contractual right of return where a banning order has been issued against the manufacturer or importer. Cf. the letter from the German Congress of Industry and Trade of 23 August 1979 to Chambers of Industry and Trade (printed in Jeiter, W., Das neue Gerätesicherheitsgesetz (Gesetz über technische Arbeitsmittel), München 1980, 76-78).

³⁰⁹ Cf. Wilke, 12 Jahre Gesetz über technische Arbeitsmittel, in: BAU (Ed.), Sicherheit '80. Heim - Freizeit - Schule, Dortmund 1980, 48 et seq., 67 et seq.

³¹⁰ Of 353 banned types of appliances between 1982 and 1984 not a single one was through a trader, and in 1981 only

trade supervisory offices to forbid marketing of defective products that are already in the trade.³¹¹

Table 3: Numerical trend in test inspections by the trade supervisory offices and in banning orders³¹²

<i>Year</i>	<i>Number of Inspections</i>	<i>Number of Banning orders</i>
1969-1971	15,145	19
1972	5,275	40
1973	9,616	92
1974	9,529	211
1975	9,818	377
1976	10,614	183
1977	12,113	190
1978	13,017	178
1979	14,700	314
1980	14,902	147
1981	13,780	152
1982	14,290	98
1983	13,618	108
1984	13,799	49

Banning orders are published in the monthly newsletter on the GSG distributed by the Federal Institute for Industrial Safety in 500 copies for internal use by trade supervisory offices only.³¹³ Since 1981 the Federal Institute for Industrial Safety has been publishing non-appealable banning orders or those for immediate execution. This is intended to warn owners of defective appliances and, where technical work materials are still in trade, to bring dangers to the attention of traders and potential purchasers. By September 1986, 53 banning orders had been published.³¹⁴ One may however doubt whether publication in the Federal Labour Gazette some time after enactment of the banning order can bring about the widely effective information that is necessary. A broadly conceived concerted information campaign by trade supervisory offices, the Federal Institute for Industrial Safety, the mutual indemnity associations and the retail trade has so far been waged only in the case of

44 out of 240.

³¹¹ Cf. *Haberland, N.*, Gerätesicherheitsgesetz - Vollzug in einem Bundesland, s.i.s. 1984, 366 et seq., 369.

³¹² Compiled from *Meyer, T.R.*, Gerätesicherheitsgesetz, Berlin 1979, 38; *Diekershoff, K.H.*, Gerätesicherheitsgesetz, in: Handbuch zur Humanisierung der Arbeit, Bd. 1, Bremerhaven 1985, 607 et seq., 623 et seq.; annual reports of trade supervisory offices of individual Länder for 1982 to 1984.

³¹³ This information service prints all current information of significance for unitary application of the GSG; it has developed into an information clearing house among trade supervisory offices.

³¹⁴ Cf. BArbBl. 10/1981, 84 et seq.; 12/1981, 113 et seq.; 1/1983, 85 et seq.; 11/1984, 62 et seq. 4/1985, 94 et seq.; 9/1985, 82 et seq.; 12/1985, 110 et seq.; 9/1986, 97 et seq. These banning orders are regularly preceded by the following text: "The primary object of publication is to support recall actions or similar measures by the manufacturer or importer, and where appropriate also the trader. Above all, those in possession of items already supplied should be warned, and instructed not to use them or, in some cases, at least to take special measures." The average time between issue of a banning order and its publication in the Federal Labour Gazette was by September 1985 11 months (my calculation).

compressed-gas springs in revolving chairs, which are liable to break,³¹⁵ with successful effects since some 40% of the hazardous revolving chairs were reequipped. Since 1984 non-appealable banning orders or those for immediate execution have been publicized under the European Commission's system for information exchange on product hazards.³¹⁶

3.3.8. Limits of applicability; removal from storage

Despite its general approach, in no way specific to particular products, the GSG did not prove flexible enough to be able without additional measures to serve as the act for converting Community directive in the area of safety of technical work materials. This is evident particularly from the conversion of the Low-Voltage Directive³¹⁷ into German law. Because of the far-ranging correspondence between the content and concept of the GSG and the Low-Voltage Directive, the Federal Government took the view that no special legislative procedure would be required to convert the directive into national law. It was only once the Commission, which could not share this view, threatened to go before the ECJ that the Federal Government met the Commission's wish through the first ordinance under the Act on technical work materials³¹⁸ and the amendment to the general administrative regulations to the GSG,³¹⁹ thereby converting the Low-Voltage Directive "formally in every respect". The extent to which the first ordinance amended or extended the GSG is evident from the criticism, raised by the Commission:³²⁰

- It was not clear how far the existing state of safety technology in the Community within the meaning of the directive was identical with the general accepted rules of art within the meaning of the GSG;
- the GSG applied only to protecting people, not to the safety of domestic animals and the preservation of material values, as the directive laid down;
- the safety objectives listed in Annex I to the Directive in order to specify the general clause were not contained in the GSG;
- the general clause in the GSG referred to industrial safety and accident prevention provisions which possibly contained other requirements than the Directive's.

Despite the correspondences and similarities between the GSG pattern and the new approach to technical harmonization and standards, the GSG will not be enough to convert directives that follow the new approach, if only because of the difference in objects of protection, the modes of demonstrating conformity and above all the stating of relatively detailed basic safety requirements instead of referring to the generally accepted state of the

³¹⁵ Cf. the Annual Report for 1983 of the Federal Institution for Industrial Safety, 19 et seq.; and the Annual Report for 1983 of the Trade Inspectorate of Land North Rhine-Westphalia, 52-55.

³¹⁶ On the legal remedies open to purchasers of products whose manufacturers have been banned from continuing to distribute them, see *Falke, J.*, Untersagungsverfügungen über sicherheitstechnisch mangelhafte Geräte, VuR 1987, 3 et seq., 7-9.

³¹⁷ For details on the Low-Voltage Directive, see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³¹⁸ 11 June 1979 (BGBl. I, p. 629).

³¹⁹ § 3 (3) and § 6 (4) of the AVV-GSG were added.

³²⁰ Cf. *Zimmermann, N.*, Das Gerätesicherheitsgesetz, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Bd. III, Gruppe 11, S. 123 et seq., 147 et seq. The table presenting the differences between the GSG and the First Ordinance to the GSG (loc. cit., 157-161) brings out the untenability of the Federal Government's original position.

art. Reference to the generally accepted state of the art cannot come into consideration for the Community Directive if only because the Commission, following Article 100 a (3) in the Single European Act, must in its proposals for legal harmonization measures under Article 100 a in the areas of health, safety, environment protection and consumer protection take a very high level of protection as a basis.³²¹ Adoption of individual directives under the new approach ought thus in the medium term to lead to supplementation of the GSG by a whole fringe of ordinances for specific groups of products. The alternative would be to adopt a parallel act to the GSG, converting all the details of the new approach into national law. But even then it would presumably be necessary to convert each of the product/specific basic safety requirements, relatively detailed by comparison with the German tradition of product safety law,³²² separates into German law in each case – after all it is ultimately vague that determine the level of protection.³²³ The second ordinance under the GSG³²⁴ converts Directive 79/663/EEC,³²⁵ which forbids the marketing and use of decorative items containing dangerous liquids. Like the first ordinance under the GSG, it is based on § 4 (1) GSG, which empowers the Federal Minister for Labour and Social Affairs in fulfilment of obligations under bilateral agreements or binding Community decisions to determine by legal ordinance that technical work materials may be marketed only where particular requirements are met or when, following a design test, they have been generally accepted, or when they have passed a conformity test. Other Community directives likewise applying to technical work materials within the scope of the GSG have not led to further ordinances under the GSG because they concern monitored installations and were converted into German law as ordinances pursuant to § 24 of the German industrial code. These ordinances for monitored installations³²⁶ are industrial safety regulations within the meaning of § 3 (1) GSG.³²⁷

³²¹ On this cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 4.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³²² It is clear that the basic safety requirements are not merely described conceptually in a comprehensive general clause, but laid down in detail specifically for a product. But even after presentation of the first draft directives, it remains questionable how detailed the basic safety requirements are. Among controversial points are e.g. three sentences in Annex II, section B.III in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (OJ C 136, 4 June 1985, 1 et seq.), first introduced in this form in the final version. They run: “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. The degree of detail of the wording will depend on the subject matter.” These sentences both express the reservations of many Member States regarding far-reaching delegation of safety regulation to standardization bodies, and can be regarded as a retreat from the new approach even before its realization. Cf. the answer to written question No. 119/86, OJ C 19, 26 January 1987, 4 et seq.

³²³ Cf. also the verbatim inclusion of the essential safety requirements of the Low-Voltage Directive in § 2 of the First Ordinance under the GSG.

³²⁴ Of 26 November 1980 (BGBl. I, p. 2195).

³²⁵ Directive 79/663/EEC of 24 July 1979, OJ L 197, 3 August 1979, 37.

³²⁶ These are ordinances on steam boiler installations, pressure vessels, pressurized gas containers and filling plants, lift installations, electrical installations in premises where there is an explosion hazard, acetylene and calcium carbide installations and installations for storing, filling and transporting combustible liquids on land.

³²⁷ On the above cf. *Zimmermann, N.*, Das Gerätesicherheitsgesetz, in: *Brendl, E.*, Produkt- und Produzentenhaftung. Handbuch für die betriebliche Praxis, Bd. III, Gruppe 11, S. 123 et seq., 162-164.

Following a series of sensational accidents and the disclosure of widespread severe safety defects,³²⁸ § 8 a GSG created the conditions for adopting special requirements for licensing and operating medical technical appliances. This was done through the Medical Appliances Ordinance,³²⁹ which introduced special obligations on instructions and marks, a licensed design system for important types of appliances, the inclusion of all suppliers under the regulations and above all obligations on operators to carry out functional tests before commencing operation, employ only qualified staff, notify defects or malfunctions arising, regularly carry out safety checks and keep data sheets on the appliances. The comparison with technical medical appliances, now outside the scope of the GSG, and with the Medical Appliances Ordinance brings out the GSG's liberal underlying concept particularly clearly. Like the new approach, it rules out safety rules for the *operation* of hazardous installations or appliances.

4. The US Consumer Product Safety Act and its implementation by the Consumer Product Safety Commission

Adoption of the Consumer Product Safety Act (CPSA) by the 92nd Congress in 1972 was a success for the consumer movement and its legislative impact in the US. The CPSA and its implementation through the Consumer Product Safety Commission (CPSC) set up in 1973 are, however, important even outside the United States. The NY Act and its regulatory machinery has served as a model or at least a stimulus in all countries where product safety law has been further developed.³³⁰ Moreover, the many amendments to the CPSA and the difficulties in applying it have been taken as an illustration of the inadvisability of increased government influence on product safety.³³¹

Political controversies within the United States over the CPSA make an analysis aimed at deriving general conclusions for product safety law from experience with the new Act even more difficult. Whether the regulatory approach has "proved" itself, what supervisory machinery has been "successful" and what has "failed", what regulatory strategies ought therefore to be taken over at national and/or European level – all these points would be much easier to judge if implementation of the CPSA had taken a more peaceful course. But irregularities and constant amendments seem to be a typical feature of product safety policy

³²⁸ Between 1976 and 1978, 65% of medical electrical appliances tested showed numbers of severe safety defects, in part hazardous to life; cf. *Wilke*, 12 Jahre Gesetz über technische Arbeitsmittel, in: BAU (Ed.), *Sicherheit '80*. Heim - Freizeit - Schule, Dortmund 1980, 48 et seq., 63 et seq. In 1985 safety checks by the Bavarian Technical Control Board even showed a defect rate of 85%; cf. FR for 27 August 85, p. 18.

³²⁹ Ordinance on the safety of technical medical appliances (Medical Appliances Ordinance) of 14 January 1985 (BGBl. I, p. 93). On this cf. *Nöthlich*, M., *Sicherheitsvorschriften für medizinisch-technische Geräte*. Kommentar, Berlin 1985; *Zimmermann*, N., *Das Gerätesicherheitsgesetz*, in: *Brendl*, E., *Produkt- und Produzentenhaftung*. Handbuch für die betriebliche Praxis, Bd. III, Gruppe 11, S. 123 et seq., 164-166; *idem*, *Sicherheitsnormen für medizinisch-technische Geräte - die Vorschriften der neuen Medizingeräteverordnung*, DIN-Mitt. 64 (1985), 337 et seq.; *Hahn*, B., *Die neue Verordnung über die Sicherheit medizinisch-technischer Geräte*, NJW 1986, 752 et seq.; *Held*, H., *Medizingeräteverordnung - Sicherheit verbessert*, BArBl. 3/1985, 15 et seq.; *Theobald*, R., *Medizingeräteverordnung soll helfen, medizinisch-technische Geräte und deren Anwendung sicherer zu machen*, DIN-Mitt. 65 (1986), 252 et seq.; *Hartl*, M., *Die neue Medizingeräteverordnung*, VersR 1986, 1050 et seq.

³³⁰ This influence can clearly be seen in the relevant OECD reports: *Data Collection Systems 1978*; *Severity Weighting of Data on Accidents*, Paris 1979; *Safety of Consumer Products*, 1980; *Recall Procedures*, Paris 1981; *Product Safety*, 1983.

³³¹ For the most fully worked-out criticism, see *Viscusi*, W.K., *Regulating Consumer Product Safety*, Washington D.C./London 1984.

and product safety law, and description and interpretation have to get along with them. These considerations are taken account of in the description below by presenting the CPSA not only in its current version but also in its original one (4.1.) and by always referring when presenting the most important regulatory instruments to the changed conditions the CPSA has to operate in (4.2.-4.5.).

4.1. The original version of the CPSA and amendments to it

The CPSA's adoption in 1972 was the conclusion to years of preliminary work. The most important preparatory step was the setting up of the National Commission on Product Safety,³³² proposed in 1967 by Senator Warren Magnuson, initiator of many consumer policy legislative acts. The fact that Senator Magnuson was not aiming directly at enactment of a general product safety act but leaving the development of suitable proposals to an independent commission did much to help make his initiative successful.³³³ The Commission, appointed by President Johnson in 1968, was able to carry out its preliminary work and hearings unmolested by the otherwise customary pressures. In 1970 the Commission presented its voluminous final report.³³⁴ The report not only submitted the findings of broad-based surveys – on product hazards, accident information systems, voluntary product standards, consumer education, the state of product safety law, the relationship between Federal law and State law, product safety policy in other countries – but also contained proposals for general product safety legislation, the core of which was to be the setting up of a new independent agency.³³⁵

4.1.1. The CPSA 1972³³⁶

Two years after the National Commission on Product Safety's final report came out, the CPSA was passed by both Houses of Congress. On all major points, the Act followed the ideas of the preparatory Commission. This is all the more remarkable because the law, in both overall conception and regulatory machinery, broke new ground in many respects:

- This applies firstly to the CPSC itself. There have long been independent commissions in the area of so-called economic regulation (the Securities and Exchange Commission, the Interstate Commerce Commission, the Federal Trade Commission),³³⁷ but transfer of

³³² Act of Nov. 20, 1967, Joint Resolution 33, Pub. L. No. 90-146, 81 Stat. 466 (1976).

³³³ See the brief and informative description of this strategy in *Perschuk, M.*, *Revolt against Regulation. The Rise and Pause of the Consumer Movement*, Berkeley/Los Angeles/London 1982, 41 et seq.; detailed descriptions in e.g. the note on the Consumer Product Safety Commission, 1975, 1079 et seq.; *Schwartz, T.M.*, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq.

³³⁴ National Commission on Product Safety. *Final Report Presented to the President and Congress*, Washington, D.C. 1970.

³³⁵ Only one of the six commissioners, H.L. Ray, dissociated himself from the Commission's proposals (*loc.cit.*, 120 et seq.). He saw them as lacking more precise identification and consideration of incentives that could encourage industry itself to raise safety levels, and further recommended cooperation with private standardization organizations. These counsels have since been listened to. On the first point, see also the self-critical remarks by Commissioner M. *Perschuk, M.*, *Revolt against Regulation. The Rise and Pause of the Consumer Movement*, Berkeley/Los Angeles/London 1982, 141 et seq., and on the amendment to the provisions on binding standard setting, 4.1.2.1. below.

³³⁶ Pub. L. No. 92-573, 86 Stat. 1207 (1972).

³³⁷ See the descriptions in *Müller, J./Vogelsang, J.*, *Staatliche Regulierung*, Baden-Baden 1979, and *Weber, R.H.*, *Wirtschaftsregulierung in wettbewerbspolitischen Ausnahmehereichen*, Baden-Baden 1986, 174 et seq.

protection of consumer safety interests to an independent agency was an innovation.³³⁸ In the case of the CPSC, independence was respected towards not only private interests but also governmental ones. The five Commission Members are each appointed for seven years; budget appropriations need not be approved by the Office of Management and Budget (OMB), but simply by Congress directly.³³⁹

- It is also true of the broad range of tasks of the CPSC. The CPSA covers all consumer goods, except where other agencies are involved in monitoring safety hazards as part of their competence.³⁴⁰ Additionally, the CPSC was handed the administration of existing specific acts.³⁴¹ The Commission thus has a kind of general catch-all competence that always applies wherever there are no more specific regulations that take priority. But even where such priority regulations affect particularly important goods (particularly automobiles and medicaments), the scope remains significant. The jurisdiction of the CPSC is reckoned to apply to 15,000 consumer products;³⁴² the often cited estimate by the National Commission on Product Safety that some 36 million consumer product accidents occur yearly³⁴³ relates to these products not covered by special regulations.
- A further innovation was the attempt at making safety regulation “scientific”. § 5 CPSA provides for systematic collection and analysis of accident data, and gives the Commission tasks and powers in the area of research.³⁴⁴
- Another breakthrough is the introduction of a broad palette of regulatory machinery, ranging from information policy measures through standard setting and provisions for bans up to an elaborated recall system.³⁴⁵ This gamut of measures greatly encouraged the international debate on product safety policy³⁴⁶ and may be regarded as exhaustive: there is probably no safety policy measure which was not at least adumbrated, and then also tried out, through the CPSA.

The CPSA’s overall conception can be reduced to the two not necessarily mutually compatible strategies of making product safety policy “scientific” and “democratic”: product safety was declared a public goal, and entrusted to a relatively independent government agency that was to set its priorities, seek effective methods and in short pursue a “rational” policy; at the same time, however, the new institution was to differ from traditional bureaucracies, to take up safety policy submissions from the general public and to promote participation by societal groups.

4.1.2. Amendments

The original consensus expressed in the National Commission on Product Safety’s 1970 Report which had made enactment of the CPSA possible did not last. The controversies

³³⁸ See *Scalia, A./Goodman, F.*, Procedure of the Consumer Product Safety Act, University of California at Los Angeles L. Rev. 20 (1973), 899 et seq. Creation of the CPSC completed the network of newly created agencies in the area of social regulation: the National Highway Traffic Safety Administration had been founded in 1966, the Occupational Safety and Health in Administration in 1970 and the Environmental Protection Agency in 1970.

³³⁹ See §§ 4, 32 CPSA.

³⁴⁰ See §§ 3 (a) and 31 (a) CPSA.

³⁴¹ Federal Hazardous Substances Act 1960, Flammable Fabrics Act 1953, Poison Prevention Packaging Act 1070, Refrigerator Safety Act 1956 and Cigarette Safety Act 1984.

³⁴² Figures from Dr. G.C. Nichols, CPSC (International Affairs Division).

³⁴³ Op. cit. (fn. 334), 1.

³⁴⁴ See also section 27 (a) CPSA.

³⁴⁵ Specifically, see sections 7 (standards), 8 (product bans), 12 (seizures), 14 (certification), 15 (recalls).

³⁴⁶ See only the OECD Report “Safety of Consumer Products”, 1980.

over the legal justification for a government product safety policy and its appropriate means, largely kept latent during the preparatory phase of the Act, broke out later and have not settled down even yet.

Among the most striking successes of CPSA critics are the swingeing budget cuts the Commission had to take in the 1980s. The first budget, for 1974 and still based solely on recommendations from the Food and Drug Administration, amounted to some 30 million dollars.³⁴⁷ When the Commission then asked for its own appropriations for 1975 and 1976, it managed to secure increases to some 37 and 42 million dollars respectively from Congress.³⁴⁸ Until 1981 the budget kept to this figure in nominal terms, and was then cut in 1982 to 33 million dollars.³⁴⁹ It is still at this level today.³⁵⁰ Staffing reflects this development. The Commission began in 1973 with 579 workers, reached a peak of 914 in 1977,³⁵¹ and then gradually shrank back to the starting point. In all this it should be borne in mind that the dollar has lost some 50% of its value by comparison with 1974³⁵² and that therefore a return in nominal terms to the 1974 budget means *de facto* halving it.³⁵³ What suffered most from all these cuts were the technical and scientific sections of CPSC and its “field offices”, whose tasks lay particularly in the area of follow-up market control. Their numbers were cut from 13 to 5.³⁵⁴

4.1.2.1. Binding standards and product bans

The most important amendments to the CPSA concerned regulations on the issue of product standards. Authoritative prescription of binding safety standards was, according to the National Commission on Product Safety’s recommendations and the concepts behind the Act’s procedures, to be the most important instrument of the new product safety policy.³⁵⁵ Standards could according to section 7 (a) (1) and (2) CPSA 1972 refer to performance, composition, contents, design and construction, finish or packaging; however, in so far as not merely informative standards were concerned, the Commission was as far as possible to confine itself to performance standards. To develop standards, a procedure had been introduced that was supposed to offer consumer associations in particular chances of influence: the so-called offeror procedure. This made standard setting open to tender, and the Commission had the possibility of financially supporting its development by the selected offeror (section 7 (d) (2)).³⁵⁶

³⁴⁷ In constant dollars, this would be equivalent to a 1985 figure of some 70 million dollars.

³⁴⁸ Figures in *Cornell, N.W./Noll, R.G./Weingast, B.*, Safety Regulation, in: Owen, H./Schultze, ch.L. (eds.), Setting National Priorities. The Next Ten Years, Washington, D.C. 1976, 457 et seq., 478.

³⁴⁹ See table in *Viscusi, W.K.*, Regulating Consumer Product Safety, Washington D.C./London 1984, 40.

³⁵⁰ 35 million dollars in 1984; 36 million dollars in 1985, approx. 35 million dollars in 1986 and 1987 (figures from CPSC Authorization Act 1985, 99th Congress, 1st Session, Report, 99-60 Calendar No. 138, 7 and from Statler, 1984, 93).

³⁵¹ See *Viscusi, W.K.*, Regulating Consumer Product Safety, Washington D.C./London 1984, 40.

³⁵² See the figures accompanying the Consumer Product Safety Amendment Act of 1983, 98th Congress, 1st Session, Report 98-114, 9 et seq.

³⁵³ See the CPSC’s figures in the Hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce. House of Representatives, 98th Congress, 1st Session on H.R. 2367, 6/7 April 1983, Serial No. 98-29, Washington, D.C. 1983, 413.

³⁵⁴ See Consumer Product Safety Amendment Act of 1983, op. cit. (fn. 352), 9 et seq.

³⁵⁵ See references in *Klayman, E.*, Standard Setting under the Consumer Product Safety Amendments of 1981 - A Shift in Regulatory Philosophy, *George Washington L. Rev.* 1982, 96 et seq., 99 et seq.

³⁵⁶ See the detailed description in the note, The Consumer Product Safety Commission, 1975, 1121 et seq.; on the petition procedure, see also 4.3.1. below.

These provisions have undergone far-reaching amendment. In 1978, the CPSC was first of all given the possibility of refraining from the offeror procedure;³⁵⁷ in 1981 the procedure was then completely abolished.³⁵⁸ At the same time Congress fundamentally changed its originally critical attitude to binding standards: the Commission was henceforth to aim exclusively at performance standards and duties of information, but no longer to prescribe the “design” of a product (section 7 (a)). Still more important: “the Commission shall rely upon voluntary consumer product safety standards ... whenever such voluntary standard would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards” (cf. also section 9 (b) (2) (B)).

Additionally, the Commission was mandated to draw up a “final regulatory analysis”, setting out in detail the costs and benefits of the regulation it had in mind and the alternatives it had considered (cf. section 9 (c) (1) and (4), (f) (2) (A) and (B)). Also in 1981, the CPSC’s quasi-legislatory independence was considerably cut back. By the newly introduced section 36, Congress can now veto a product safety rule desired by the Commission.³⁵⁹

The amendments to section 9 CPSA did not affect only the issuing of binding standards. They also concerned regulations on the banning of products. Such bans could be promulgated under section 8 CPSA 1972, where products presented a disproportionate risk of injury, and this hazard could not be eliminated by a standard. Since Section 8 (2) requires a product ban to be promulgated “in accordance with section 9”, before a ban is ordered the possibility of “voluntary” standards must now be looked into, and above all an exact cost-benefit analysis produced.³⁶⁰

4.1.2.2. Right of petition and public information

Among the regulatory innovations of the CPSA 1972 was the power for interested persons and organizations to call on the Commission to develop or change a product regulation, and even in some cases to compel it through the courts to take action (section 10 CPSA 1972). This possibility of influence was abolished in 1981. All that now apply are the general (more restrictive) provisions of the Administrative Procedure Act.³⁶¹ The practical significance of this revocation seems however, in the light of a silent transformation in function of the right of petition through the 70s, to be slight.³⁶²

Considerable effects were however produced by corrections to the CPSC’s information policy, first through the courts and then confirmed in legislation. The relevant provision of section 6 CPSA distinguishes between information concerning business secrets (section 6 (a)) and other information on product hazards (section 6 (b)). The first category of information was already according to section 6 (a) CPSA 1972, to be treated confidentially. Other information was, however, pursuant to section 6 (b) CPSA 1972, to be passed on. In

³⁵⁷ Act of November 10, 1978, Pub. L. No. 95-631, §3 (a), 92 Stat. 3742, 3743.

³⁵⁸ Pub. L. No. 97-35, § 1203, 95 Stat. 703, 704-13 (1981); details in *Klayman, E.*, Standard Setting under the Consumer Product Safety Amendments of 1981 - A Shift in Regulatory Philosophy, *George Washington L. Rev.* 1982, 96 et seq., 100 et seq.

³⁵⁹ On the constitutional prerequisites for using the veto right, see the indications in *Claybrook, J.*, *Retreat from Safety*, New York 1984, 69.

³⁶⁰ For more details see 4.3.2 below.

³⁶¹ 5 U.S.C. § 553 (e) (1976).

³⁶² See *Schwartz, T.M.*, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq., 45 et seq., 55 et seq. and 4.3.1. below.

so far as this made particular manufacturers identifiable, they had to be given a chance to state their position, and the Commission was bound to control the accuracy of information as far as possible, and verify the fairness of any publication. A liberal information policy is in any case in line with the general objectives of the CPSA (section 5 (a) (1)), as with those of the Freedom of Information Act 1972,³⁶³ which in principle obliges the American authorities to comply with a request for information where not explicitly prevented by specific laws.

The CPSC thus had to face the difficulty of bringing these rights in principle to information into harmony with the restrictions contained in section 6 (b) CPSA. It used the expedient of differentiating between the mere (passive) passing on information that had come to it and unofficial (active) information: it was only in the latter case that it regarded verification as necessary before passing it on. This practice was initially partly approved and partly rejected by the courts,³⁶⁴ but then definitively overthrown by a Supreme Court decision.³⁶⁵ Following this, in 1981 section 6 CPSA was entirely recast. Since then, a manufacturer can, pursuant to section 6 (a) (3), designate any information concerning him as confidential, and have recourse to the courts against its being made public, should the Commission find this designation unjustified (section 6 (a) (6)). Even where business secrets are not involved, the Commission is bound to inform manufacturers before passing on any information, secure their opinion and verify the accuracy of all indications (section 6 (b) (1)); here too the manufacturer can, in case of dispute, call for a decision by the courts (section 6 (b) (4)). The Commission's possibilities of action through information policy have been severely restricted through these new requirements.³⁶⁶ A legislative initiative³⁶⁷ introduced by Senator H.A. Waxman in 1983 to change this position again failed.³⁶⁸

4.1.3. The regulatory "philosophy" of the CPSA in 1972 and the American deregulation movement

The legislative and statutory history of the CPSA forms part of the whole context of the rise of the consumer protection movement in the US during the 1960s, and the subsequent "revolt against regulation",³⁶⁹ which became official with President Reagan's assumption of office. This debate is so multilayered and at the same time so bound up with American traditions and conditions that it would be neither possible nor advisable to present it even in outline. However, in order to understand and assess the CPSA and its present significance, some indications as to the concrete repercussions of those developments on the CPSC's conceptual approach are called for. These were partly encouraged by the general political "climate", partly mediated through the influence of individual politicians, partly brought about through the legislative interventions described. However, even a description reduced

³⁶³ 5 U.S.C. § 552 (1976 and Supp. II 1978).

³⁶⁴ Cf. on the one hand *Pierce Stevens Chemical Corp. v. CPSC*, 585 F.2d 1382 (2d Cir. 1978), and on the other hand *GTE Sylvania, Inc. v. CPSC*, 598 F.2d 790 (3d Cir.), cert. granted, 100 S.Ct. 479 (1979); and exhaustively the comment on *The Consumer Product Safety Act, 1980*, 1180 et seq.

³⁶⁵ *CPSC v. GTE Sylvania Inc.*, 447 U.S. 102 (1980).

³⁶⁶ See submissions by S.D. Dornfield from the Society of Professional Journalists, jurist A.F. Popper and Commissioner St. M. Statler to the 1983 Congressional hearings (op. cit., fn. 553), 80 et seq., 90 et seq., 368 et seq.

³⁶⁷ Reprinted op. cit., 3 et seq.

³⁶⁸ Calendar No. 138, 99th Congress, 1st Session, Report 99-60 of 16 May 1985.

³⁶⁹ The title the book: *Perschuk, M.*, *Revolt against Regulation. The Rise and Pause of the Consumer Movement*, Berkeley/Los Angeles/London 1982.

in this way to the Commission's conceptual approaches has admittedly to risk crass simplification. By American standards, the CPSC is a very small agency, but it is not a monolithic block. Changes to its policies do not take place abruptly and uniformly, but in laborious, conflictual processes. With these reservations, three stages in the CPSC's history may be distinguished:

- The start-up phase, 1973-8: “[Chairman] Simpson and his staff have attempted to design their organization from the beginning so that its goal is clear and its method of standard setting minimizes arbitrariness. This is what political scientists have always asked heads of new agencies to do. Now, one has. It will be interesting to see what difference it makes”. These sentences end one of the first reports on the CPSC.³⁷⁰ Its generously optimistic verdict must have been founded above all on the endeavour to make product safety policy “scientific”, and therefore in particular upon the efforts of the newly established commission to arrive, on the basis of its data surveys, at rational debate and determination of priorities.³⁷¹ These initial hopes were later disappointed.³⁷² The Commission did not succeed in developing and effectively applying a convincing program. It took four years before three product regulations could be adopted (on swimming pool slides, matchbooks and plate glass).³⁷³ Information policy instruments and recall possibilities were not fully used. Not just industry but consumer associations too gave vent to severe criticisms.³⁷⁴ In the 1977 congressional hearings, J.E. Moss, himself a major proponent of enactment of the CPSA, confirmed the general misgivings very clearly.³⁷⁵
- The Commission's public image improved following the 1978 appointment of Susan King as its new chairman.³⁷⁶ The Commission then trimmed down its overambitious standardization programme, opened up an important new field of activity with its “chronical hazards program”³⁷⁷ and arrived at considered use of its regulatory instruments -mainly making the recall provisions of § 15 (b) CPSA effective.³⁷⁸
- Not least because of its successes during the consolidation phase following 1978, the CPSC managed to survive the deregulation wave following President Reagan's assumption of office. Moves by the OMB under D. Stockman to take away the Commission's independence and integrate it into the Department of Trade were unsuccessful. However, the Commission had to accept the cuts to its budget described

³⁷⁰ *Kelman, St.*, Regulation by the Numbers. A Report on the Consumer Product Safety Commission, Public Interest 36 (1974), 82 et seq., 102.

³⁷¹ For more details see 4.2. below.

³⁷² Symptomatic critical assessments can be found by the mid 70s in *Cornell, N.W./Noll, R.G./Weingast, B.*, Safety Regulation, in: *Owen, H./Schultze, ch.L.* (eds.), Setting National Priorities. The Next Ten Years, Washington, D.C. 1976, 457 et seq and *Hoffmann, M.E.*, The Consumer Product Safety Commission: In Search of a Regulatory Pattern, *Columbia J. of Law and Social Problems* 12 (1976), 393 et seq; see also *Feldman, L.P.*, Consumer Protection. Problems and Prospects, St. Paul/New York/Los Angeles/San Francisco 1980, 58 et seq., 60 et seq.

³⁷³ For more details see 4.3. below.

³⁷⁴ See *Bollier, D./Claybrook, J.*, Freedom from Harm, Washington, D.C./New York 1986, 171 et seq.; much evidence also in the hearings cited in fn. 375.

³⁷⁵ Hearings before the Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 95th Congress, 1st Session, No. 95-52, Washington, D.C. 1977, 1 et seq.

³⁷⁶ In 1977, during the brief transitional period from S.J. Byington's chairmanship, the Commission had already announced a change in its policy priorities (see 42 F.R. 53953, 4 October 1977).

³⁷⁷ For the programme and the opinion-forming process within the Commission see *Merrill*, 1981, 1264 et seq., 1297 et seq.

³⁷⁸ For details see 4.5. below.

above as well as the legislative amendments between 1981 and 1983 and interventions in personnel policy³⁷⁹. All these corrections were, and still are, marked by a clearer orientation of the Commission towards criteria of economic efficiency and (self-) control of its activities through cost-benefit analyses. A memorandum drawn up by P.H. Rubin, Associate Executive Director of the Division for Economic Analysis,³⁸⁰ documents this trend. The memorandum points to budget restrictions on the Commission, and recommends cost-benefit analysis as a way of using scarce resources better.³⁸¹ But its ambitions go further: all regulatory machinery should be verified on criteria of cost-benefit analysis, and the assessment of safety hazards implicit in individual consumer decisions should be recognized as the ultimately binding rationality criterion of safety policy.³⁸²

4.2. The accident information system and the CPSC's policy priorities

Any product safety policy, whatever regulatory philosophy it may follow, is bound to set priorities. This need becomes all the more urgent, the more comprehensive is its scope and the room for manoeuvre of the safety policy agency. The collection of data on accidents and accident risks is an obvious preparatory step towards a rational priority policy.³⁸³

The CPSC has various simple and more ambitious information sources available. It collects newspaper cuttings; it accepts consumer complaints through a free telephone service ("hotline");³⁸⁴ section 15 (b) CPSA obliges manufacturers and traders to notify the Commission of product hazards;³⁸⁵ also noteworthy in this connection is information from the Commission's "Field Services"; and a cooperation agreement was concluded with the association of American Trial Lawyers, which systematically gathers information on product liability actions.³⁸⁶

However, all these sources are of secondary importance. More important is the systematic evaluation of death certificates, along with reports from the "Poison Control Centers" and especially the data from the "National Electronic Injury Surveillance System (NEISS)".

4.2.1. The National Electronic Injury Surveillance System

A system for collecting accident data (the "Hospital Emergency Room Injury Reporting System") had already been developed in 1969 by National Commission on Product Safety Executive Director William V. White, and was extended in 1970 by the Food and Drug

³⁷⁹ See *Bollier, D./Claybrook, J.*, *Freedom from Harm*, Washington, D.C./New York 1986, 173.

³⁸⁰ P.H. Rubin, *Cost-Benefit Analysis*, 26 February 1986 (internal memorandum of the CPS).

³⁸¹ *Op. cit.*, 6.

³⁸² *Op. cit.*, 8 et seq., 3 et seq.

³⁸³ For the Community, see the Council decision of 22 April 1986 "concerning a demonstration project with a view to introducing a Community system of information on accidents involving consumer products", O.J. No.L 109, 26 April 1986, 23.

³⁸⁴ See 16 CFR 1003.

³⁸⁵ According to the CPSC's 1982 Annual Report (5), in 1981 30,000 death certificates were still being assessed. The 1984 Annual Report (II, 4) points out that this programme had to be considerably cut.

³⁸⁶ For the beginning of the cooperation, see *Statler, St.M.*, *CPCS: Only a Beginning*, Trial 1980, 77 et seq., 80 et seq.; *Johnson, L.L.*, *Cost-Benefit Analysis and Voluntary Safety Standards for Consumer Products*, Santa Monica, Cal. 1982, 63 et seq.

Administration. The Commission was able to draw on this preliminary work when it began, immediately after it had been set up, building up its own accident information system.³⁸⁷ The specific feature of this system is its orientation towards current accident data. These data are gathered in selected (originally 119, reduced to 74 in 1979 and 64 after 1984) hospital emergency service. Specially trained workers in these stations allocate accidents associated with the use of products to 19 general and some 900 more specific categories of product, grade their severity (on a scale of originally 8, now 7 grades) and the nature of the injury (by allocating it to one of 250 categories of injury), and the age and sex of those involved. These data are put in daily to the CPSC's computers. In a Consumer Product Hazard Index, the frequency and severity of hazards associated with a product are determined, and additionally evaluated on an Age-Adjusted Frequency-Severity Index. Today the NEISS still supplies data on some 200,000 accidents per year. However, it allows only retrospective conclusions as to the involvement of products in causing accidents and/or the (co-)responsibility of product users. Accordingly, the NEISS data have always been treated as only a starting point for in-depth studies. Only these follow-up studies can and should determine typical accident patterns and where appropriate the dangers arising from a particular product.³⁸⁸

4.2.2. Criticisms of the NEISS

The suitability of the NEISS as a source of data for determining priorities for action was never out of dispute. Objections concern partly technical, in principle correctible, factors regarding the reliability of the data collection and the differentiation of product categories, partly decisions hard to alter, such as the concentration on accident emergency services,³⁸⁹ but partly also the suitability in principle of the data themselves. Collection of accident figures is alleged to be demonstrative of the hazardousness of a product only if it can be related to the relevant intensity of use;³⁹⁰ the scaling of the intensity of injury according to a hazard index is said to be arbitrary;³⁹¹ and the precision of accident evaluation is said to

³⁸⁷ On this see *Kelman, St.*, Regulation by the Numbers. A Report on the Consumer Product Safety Commission, Public Interest 36 (1974), 82 et seq., 92 et seq.; *Hoffmann, M.E.*, The Consumer Product Safety Commission: In Search of a Regulatory Pattern, Columbia J. of Law and Social Problems 12 (1976), 393 et seq., 397 et seq. and the Commission document "The National Electronic Injury Surveillance System: A Description of Its Role in the U.S. Consumer Product Safety Commission", April 1986.

³⁸⁸ For more details see *Kelman, St.*, Regulation by the Numbers. A Report on the Consumer Product Safety Commission, Public Interest 36 (1974), 82 et seq., 94 et seq. According to the Commission's 1982 Annual Report (5), in financial year 1981 235,000 accidents were surveyed through the NEISS system. In at least 2,000 cases follow-up studies were done. The 1983 and 1984 Annual Reports did not give any figures; it emerges, however, from the CPSC documents cited above (fn. 387), that these figures continue to apply. For all this, though, it should be borne in mind that as the statements by Commissioner E. Sloan to the 1981 Senate Hearings (Hearing before the Subcommittee for Consumer Protection of the Committee on Commerce, Science and Transportation, 1st Dec. 1981, No. 97-87, Washington D.C. 1982, 9 et seq.) confirm, the budget cuts decided at that time had considerable effect here too. On implementation of in-depth investigations, there are detailed product-specific guidelines (CPSC order 901024, 13 January 1983).

³⁸⁹ See *Hoffmann, M.E.*, The Consumer Product Safety Commission: In Search of a Regulatory Pattern, Columbia J. of Law and Social Problems 12 (1976), 393 et seq.

³⁹⁰ Cf. already *Cornell, N.W./Noll, R.G./Weingast, B.*, Safety Regulation, in: Owen, H./Schultze, ch.L. (eds.), Setting National Priorities. The Next Ten Years, Washington, D.C. 1976, 457 et seq., 484 and now *Viscusi, W.K.*, Regulating Consumer Product Safety, Washington D.C./London 1984, 49 et seq.

³⁹¹ See *Cornell, N.W./Noll, R.G./Weingast, B.*, Safety Regulation, in: Owen, H./Schultze, ch.L. (eds.), Setting National Priorities. The Next Ten Years, Washington, D.C. 1976, 457 et seq., 483 and the statement by medical practitioner J. Greensher at the Re-Authorization Hearing before Congress in 1981 (Hearings before the

vary according to the type of product involved, particularly because of geographical differences in product use, to such an extent that the NEISS data allow no conclusions as to priorities for action.³⁹²

Some of these objections are unacceptable to the CPSC, for partly conceptual, partly pragmatic reasons; others have clearly influenced the development and evaluation of the data system. Here it has to be borne in mind that the NEISS was oriented when it was created to the original conception of the CPSC, and that later legislative amendments, budget restrictions and reorientations of the Commission's safety policy inevitably affected the structure of the accident information system. Thus, the decision in favour of an accident coverage system and against the time-consuming evaluation of general investigations of accidents was a result of the endeavour to secure data on product-related hazards as rapidly as possible; the concentration on hospital casualty departments took account (among other things) of the recognition that, for instance, doctors in private practice could hardly be induced to draw up accident reports.³⁹³ Original ideas about the Commission's possibilities of opposing recognized hazards by producing binding standards was certainly too optimistic. As the Commission itself – notably through the “chronical hazards program”³⁹⁴ – filled out its priorities for action and, partly on the basis of its own experience and partly because of internal restrictions, moved towards cooperation with private standardization organizations in working out standards and shifted part of its activities into the area of follow-up market control, the NEISS had to be adapted to these new tasks. On the other hand, while budget restrictions did not exclude refinements to assessment methods, they did *de facto* rule out adoption of proposed cost-intensive improvements.³⁹⁵ Thus, in 1985 the CPSC tried out survey methods aimed at integrating data on accident causes, in particular on product defects or mistakes by product users, into the NEISS.³⁹⁶ But this study was aimed primarily at saving costs on the in-depth investigations. Likewise, the call for the Commission's safety policy to be oriented towards economic rationality criteria was taken into account only in connection with the evaluation of accident data.³⁹⁷

4.3. Mandatory product regulations and product bans

The original expectation that hazards arising from consumer products could primarily be combated by adopting mandatory product standards is particularly striking to a German observer. In Germany, the retreat by government to issuing general clauses in safety law

Subcommittee on Health and the Environment House of Representatives, 97th Congress, 1st Session, H.R. 2271 and 2201, 5 and 13 March 1981, No. 97-4, Washington, D.C. 1981, 21 et seq.).

³⁹² Heiden, E.J./Pittaway, A.R./O'Connor, R.S., Utility of the U.S. Consumer Product Safety Commission's Injury Data System as a Basis for Product Hazard Assessment, *J. of Product Liability* 5 (1982), 295 et seq.; cf. J. Waksberg's reply, CPSC's Hazard Data System: Response to Critique, *J. of Product Liability* 6 (1983), 201 et seq., and the rejoinder by Heiden, E.J./Pittaway, A.R./O'Connor, R.S., Utility of the U.S. Consumer Product Safety Commission's Injury Data System as a Basis for Product Hazard Assessment, *J. of Product Liability* 5 (1982), 295 et seq.

³⁹³ See Verhalen, R.D., The NEISS, in: Commission of the EC, Proceedings of the European Symposium on Product Safety in the EC, Amsterdam 1985, 61 et seq. Brief descriptions which also show the NEISS's further development are contained in each of the CPSC's annual reports (in Part II).

³⁹⁴ See fn. 377.

³⁹⁵ See Verhalen, R.D., The NEISS, in: Commission of the EC, Proceedings of the European Symposium on Product Safety in the EC, Amsterdam 1985, 61 et seq., 67 et seq.; J. Greensher, loc. cit. (fn. 391).

³⁹⁶ See the Commission document Results of a Pilot Study to Collect Causal Data from Victims Treated in Emergency Rooms for Product-Related Injuries from April 15, 1985 to April 28, 1985, (1985).

³⁹⁷ The 1983 Annual Report (II, 6) for the first time contained detailed estimates of accident costs.

and shifting the tasks of regulation and monitoring on to privately organized institutions took place in the 19th century.³⁹⁸ The ramification of institutions of “private-governing” is so firmly established and their professional competence so undisputed that consumer policy initiatives always aim only at reorganization of the cooperative relationships between government agencies and non-governmental self-regulatory bodies and at some pluralization of standard-setting procedures.³⁹⁹ From the viewpoint of German developments, therefore, the CPSA appears as an extraordinarily ambitious project: the private economy’s technological and scientific capability lead was to be compensated for by setting up an independent agency, while at the same time the standard-setting process was to be opened up pluralistically and all those involved were to be offered comprehensive legal protection.

The regulations embodying the original conception of standard setting concern firstly the involvement of the public in determining action priorities through petitions under section 10 CPSA 1972 and tendering for standardization contracts by the offeror process under section 7 (d) - (e) CPSA 1972, and secondly the verification and development of regulations within the Commission pursuant to section 9 CPSA 1972.

4.3.1. Public participation

Section 10 (a) CPSA 1972 gave all interested parties, i.e. individual consumers and consumer organizations, and firms, the right to call upon the Commission to enact, amend or withdraw a product safety regulation. By section 10 (d), such petitions have to be responded to within 120 days. section 10 (e) further provided for enforcement actions in the event of rejection of petitions – though this right was to become available only three years after the CPSA’s entry into force (section 10 (e)). The draftsmen of the bill hoped that these provisions would both cope with the phenomenon of organizational “inertia” and promote the Commission’s readiness to pay attention to publicly expressed safety interests.

In the first three years the number of petitions (and the Commission’s readiness to take all motions – concerning e.g. regulations on earrings, umbrellas and platform shoes – seriously into account) was so great that the petition process proved to be extremely resource-intensive, and at the same time petitioners were in the main disappointed.⁴⁰⁰ Under the impact of the petitions and of the declared objective of section 10 CPSA, the Commission was in four cases prepared to set about setting standards, though the products concerned would not, according to its own scale of priorities based on the NEISS data, have deserved this attention.⁴⁰¹ This readiness led to the Commission’s first spectacular failure.⁴⁰²

Under the second chairman, S.J. Byington, the petition procedure was tightened up in 1977. By that time the difficulties of working out mandatory product standards had become apparent. The petition process had therefore lost its attractiveness, especially to the consumer side. Only business remained active; it used the procedure to secure amendments

³⁹⁸ See *Wolf, R.*, *Der Stand der Technik. Geschichte, Strukturelemente und Funktion der Verrechtlichung technischer Risiken am Beispiel des Immissionsschutzes*, Opladen 1986, 71 et seq., 99 et seq., 114 et seq.

³⁹⁹ See *Brinkmann, W.*, *Die Verbraucherorganisationen in der Bundesrepublik Deutschland und ihre Tätigkeit bei der überbetrieblichen technischen Normung*, Köln/Berlin/Bonn/München 1976.

⁴⁰⁰ For details see *Hoffmann, M.E.*, *The Consumer Product Safety Commission: In Search of a Regulatory Pattern*, *Columbia J. of Law and Social Problems* 12 (1976), 393 et seq., 412; *Schwartz*, 1982, 47 et seq. and the statements by Commissioner R.D. Pittle to the 1977 Congressional Hearings (*loc. cit.*, fn. 375), 248 et seq., 358 et seq.

⁴⁰¹ See above 4.2.1.

⁴⁰² See below 4.3.2.1.

to and exceptions from regulations in force.⁴⁰³ The legislative reaction in 1981 was inevitable: section 10 CPSA was deleted. Since it was now the general provisions of the Administrative Procedure Act that applied, abolition of the special right of petition meant only formal ratification of a change that had already come about.⁴⁰⁴

The same fate was in store for the offeror process pursuant section 7 CPSA 1972. According to the ideas of the National Commission on Product Safety, incorporated in the Senate bill, the tendency by the Commission to follow the industries' ideas too much in working out regulations was to be averted by giving groups not themselves economically interested the opportunity to develop a product standard. section 7 (b) (4) CPSA 1972 complied with these ideas by obliging the Commission to make its intention to adopt a product standard public and call upon "any person" to present suitable proposals. section 7 (d) (2) further provided for the possibility of supporting such work financially.

In four cases, the offeror process led to product regulations (swimming-pool slides, matchbooks, plate glass materials, motor lawnmowers). In only one of these cases, namely lawnmowers, was a consumer organization (the Consumer's Union) active; in two other cases (televisions, Christmas-tree lights) in which non-industrial organizations (the Underwriters Laboratories and the National Consumers' League respectively) were involved, the procedures ended with improvement to the voluntary standards, so that in the Commission's view adoption of a binding rule became superfluous⁴⁰⁵.

The offeror process proved extraordinarily time-consuming, costly and frustrating for all concerned. Commissioner R.D. Pittle openly admitted all these shortcomings in the 1977 Congressional hearings.⁴⁰⁶ But he saw ways of making the procedure effective: through more precise guidelines from the Commission, improved cooperation with the offeror in working out standards, and adequate financial support for the work of non-commercial organizations. According to the testimony of D.A. Swankin, who headed standardization work on Christmas-tree lights for the National Consumers' League, in this case Pittle's ideas were largely realized, with great practical success.⁴⁰⁷ However, no further testing of these improvements presented itself. The provisions on the offeror process were withdrawn in 1981.⁴⁰⁸

4.3.2. Individual standards and typical regulatory problems

In the years 1973-1984, the CPSC issued only some 22 binding product regulations (only 7 of them based on the CPSA), some three regulations on information requirements and some 7 product bans.⁴⁰⁹ These figures look rather modest. Whether they in fact reveal the Commission's inefficiency and/or the inadequacy of the act itself could be decided only from a comparison with the cost and time incurred by private standardization organizations,

⁴⁰³ See *Schwartz, T.M.*, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq., 54.

⁴⁰⁴ Cf. 4.1.2.2. above and the observations in Merrill, 1981, 1360, 1363 et seq. on the role of petitions in the area of carcinogenic substances.

⁴⁰⁵ See *Schwartz, T.M.*, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq., 61 et seq.

⁴⁰⁶ *Loc. cit.* (fn. 375), 270 et seq., 281 et seq., 285 et seq.

⁴⁰⁷ *Loc. cit.*, 259 et seq.

⁴⁰⁸ See 4.1.2.1. above, at fn. 358. Standards and bans in force can be found from CFR 16, 1000.

⁴⁰⁹ Figures in *Viscusi, W.K.*, *Regulating Consumer Product Safety*, Washington D.C./London 1984, 58 et seq. G.C. Nichols (fn. 342 above) mentions 36 procedures for binding standards and over 100 for voluntary ones.

and a qualitative comparison of results. Account would further have to be taken of the fact that since standards are part of the public (though not purely governmental) system, additional potential for conflict arises, which can continue to act through the judicial controls over standards by the authorities. A generalized evaluation of the CPSA provisions is made still more difficult by the fact that every standard was a response to specific regulatory problems, and that patterns of conflict also varied. There would be no point in retelling the history of every individual standardization process, since any attempt to derive general evaluations from this would inevitably fail. That notwithstanding, the description below should illustrate some problems in setting mandatory standards, on the basis of two well-known spectacular cases.⁴¹⁰

4.3.2.1. The pool slide debacle and the CPSC's product safety philosophy

The legal conditions on which a product rule may be laid down and the criteria it has to meet follow from sec. 9 (b) and (c) CPSA. In their original version, these provisions referred to “unreasonable risk of injury” and “reasonable necessity” for a standard (sec. 9 (c) (2) and (7) CPSA 1972); before issuing a product rule, the Commission was additionally to consider its likely effect on the utility, cost and availability of the products concerned (sec. 9 (f) (1) (C) CPSA). On the basis of these vague expressions, the Commission first of all sought legitimation for its decisions essentially in hazard analyses, rejecting a legal obligation to quantify risks and costs.⁴¹¹ In *Aqua Slide 'N Dive Corp. v. CPSC*,⁴¹² the leeway claimed by the Commission was significantly cut down. The *Aqua Slide* decision concerned the first product standard put through by the Commission, following painful, peculiar experience. The initiatives for regulating swimming-pool slides had been begun by the National Swimming Pool Institute (NSPI, an industry group concerned) and the plaintiff itself (by far the biggest producer) using the petition procedure.⁴¹³ Although according to NEISS survey data the slides were far from being among the riskier groups of products, the Commission decided to embark on a regulatory procedure, in view of the severity of accidents that did occasionally occur. It was at the same time showing what its product safety philosophy was: accidents were attributable to clumsy or incautious but foreseeable types of use. In the offeror process, the NSPI was mandated to work out a standard. Three years went by before it could be announced.⁴¹⁴ In relation to design of slides, the Commission, doubting its own competence, refrained from binding provisions and merely made recommendations. All that was bindingly required was a ladder chain and warning

⁴¹⁰ Comprehensive analyses taking the CPSC's work as touchstone to test divergent regulatory theories are not available. A general survey, primarily from a legal viewpoint, is offered by *Lammantina, L.J.*, *The Consumer Product Safety Act, J. of Product Liability* 4 (1981), 275 et seq; see also *Schwartz, T.M.*, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq., 57 et seq., 73 et seq. An assessment oriented to criteria of cost-benefit analysis, but kept very brief, can be found in *Viscusi, W.K.*, *Regulating Consumer Product Safety*, Washington D.C./London 1984, 71 et seq., 88 et seq. For an illuminating political-science analysis, see *Feldman, L.P.*, *Consumer Protection. Problems and Prospects*, St. Paul/New York/Los Angeles/San Francisco 1980, 58 et seq., 73 et seq. The most comprehensive approach, though confined to the Commission's “chronical hazards program” is in *Merrill, R.A.*, *CPSC Regulation of Cancer Risks in Consumer Products: 1972-81*, *Virginia L. Rev.* 67 (1981), 1261 et seq.

⁴¹¹ See z. B. *Merrill, R.A.*, *CPSC Regulation of Cancer Risks in Consumer Products: 1972-81*, *Virginia L. Rev.* 67 (1981), 1261 et seq., 1279 et seq., with references.

⁴¹² 569 F.2d 831 (5th Cir. 1978).

⁴¹³ The grounds for the petition are illuminating: *Aqua Slide* wanted to avoid a product ban or a compulsory recall under the Federal Hazardous Substances Act (see 569 F.2d 835).

⁴¹⁴ 42 F.R. 2751 (19 January 1976).

notice: “careless slides can cause paralysis”, “careless slides can cause injury”. The Aqua Slide ‘N Dive Corp. opposed these requirements, fearing marketing disadvantages due especially to the indication of the nature of possible, though improbable, injuries.⁴¹⁵

The key legal question in judicial review of the standard was the interpretation of the provisions just cited of sec. 9 CPSA 1972. The Court accepted that the Commission had to assume an “unreasonable risk” even in the case of extremely unlikely but severe injuries; but it reproached it for not having shown “reasonable necessity” for the regulation adopted. The Commission had not, it said, ascertained the economic effects of its regulation,⁴¹⁶ nor tested the effectiveness in practice of chain and warning.⁴¹⁷ Judge Wisdom’s concurring opinion treated the relationship between economic cost and benefit much more decidedly: he agreed with the Commission that the warning signs helped to reduce risks; but these benefits were out of proportion to the costs they would cause.⁴¹⁸ In other respects, the effects on competition had proved considerable, contributing to a monopoly position which was, ironically, now held by the plaintiff itself.⁴¹⁹

The differences in style between the majority opinion and Judge Wisdom’s arguments show how problematic it is to adduce the Aqua Slide decision in calling for the CPSA to be oriented more towards economic rationality criteria. In practice, though, the decision did have this effect,⁴²⁰ contributing to the 1982 amendment to sec. 9 CPSA.⁴²¹

4.3.2.2. Lawnmowers and the indefiniteness of cost-benefit analyses

The regulation of “walk-behind power mowers” too was taken up on petition from an industry group (Outdoor Power Equipment Institute, OPEI) in 1973. In this case, the initiative was aimed at securing official blessing for an already worked out voluntary standard.⁴²² The Commission, however, took the chance to make the award in the offeror process to a consumer organization that had distinguished itself by its activities in this area (the Consumers’ Union, CU). CU finished its work in July 1975. The outcome was controversial: the OPEI criticized all the major technical proposals, as well as the cost-benefit analysis added by the CU.

This essentially explains the duration and intensity of verification of the proposals by the CPSC: the standardization work was practically repeated yet again, with renewed official involvement, and not completed until 15 February 1979⁴²³. In the “findings” justifying the regulations,⁴²⁴ the effects of the Aqua Slide judgment are clearly recognizable. They

⁴¹⁵ 569 F.2d 842.

⁴¹⁶ 569 F.2d 840.

⁴¹⁷ On the effect of warning notices, observations were carried out for two days (loc. cit., 841); the ladder chain was tested by a Commission consultant on his neighbour’s children; “This is not the stuff of which substantial evidence is made” (op. cit., 843).

⁴¹⁸ 569 F.2d 845.

⁴¹⁹ *Schwartz, T.M.*, The Consumer Safety Commission: A Flawed Product of the Consumer Decade, *George Washington L. Rev.* 51 (1982), 32 et seq., 51, fn. 130. The Commission’s attempt to withdraw the regulation in 1981 was opposed by Aqua Slide and not pursued because of the cost of withdrawal proceedings.

⁴²⁰ See also D.D. Bean & Sons Co. v. CPSC, 574 F.2d 643 (1st Cir. 1978) on the partial review of the matchbook standards, and for the history and economic analysis of this regulation *Kafoglis, M.Z.*, Matchbook Safety, in: Miller III. J.C./Yandle, B. (eds.), *Benefit-Cost Analysis of Social Regulation*, Washington, D.C. 1979, 75 et seq. Additionally, see *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

⁴²¹ 4.1.2.1. above.

⁴²² On this see *Schwartz’s* case study, *The Consumer Safety Commission: A Flawed Product of the Consumer Decade*, *George Washington L. Rev.* 51 (1982), 32 et seq., 77 et seq.

⁴²³ 44 F.R. 10024 (15 February 1979), 16 CFR 1205.

⁴²⁴ 16 CFR 1205. 8.

contain a review of estimated numbers and costs of accidents with lawnmowers, an analysis of the effects of the regulation on product costs and an account of the likely effects on accident figures and product costs of the most important safety requirements. This regulation has stood up to judicial review, with one marginal exception.⁴²⁵ What is remarkable here is that the Commission's "safety philosophy", showing in its readiness for "paternalistic" protection of the consumer against his own foreseeable mistakes, was explicitly confirmed, while at the same time cost-benefit analysis acquired more importance.

The risks bound up with lawnmowers are widely known. Accordingly, use leading to injury can be treated as misuse, and the existing safety level taken as a "proper" outcome of consumer demand.⁴²⁶ However, the Court of Appeals, when it was called in, did not accept this argumentation: "Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risks ... There is no evidence ... that (consumers') presumed willingness to defeat protective measures is reasonable".⁴²⁷ This safety philosophy has effects on the basis for cost-benefit analysis. If consumer behaviour were declared to be the criterion for justifying regulatory intervention, then economic analysis as such would be superfluous; willingness to take risks when mowing lawns may very well be "unreasonably" high, having regard to accident insurance and to health protection provisions.⁴²⁸ But leaving these difficulties aside, and comparing merely the (estimated) increase in product cost with the (estimated) effects of the standard on accident figures and the (estimated) savings (though here delay in making a new purchase of a mower made according to the new regulations and the concomitant use of old, hazardous machines would be particularly hard to estimate)⁴²⁹ then again broad room for discretion in decision arises. The CPSC thus saw itself confronted with divergent cost-benefit analyses from the CU and the OPEI. It did a study of its own, which was revised once more following criticisms by the Standard Research Institute, called in by the OPEI⁴³⁰. The Court of Appeals declared itself satisfied with these efforts.⁴³¹ Since on CPSC estimates the cost-benefit analysis came out in favour of adopting the regulation, its legal significance ultimately remained undetermined, and the question whether measures were no longer "reasonably necessary" when their effects on product costs exceeded savings on treating accident victims unanswered. Admittedly, the CPSC success before the courts was wiped out on one important point through a legislative amendment to the regulation by Congress.⁴³²

⁴²⁵ *Southland Mower Co. et al. v. CPSC*, 690 F.2 d 499 (5th Cir. 1980).

⁴²⁶ Cf. esp. *Viscusi, W.K.*, *Regulating Consumer Product Safety*, Washington D.C./London 1984, 94.

⁴²⁷ 619 F.2d 513.

⁴²⁸ See 4.1.3. above, end.

⁴²⁹ See *Lenard, Th.M.*, *Lawn Mower Safety*, in: Miller III, J.C./Yandle, B. (eds.), *Benefit-Cost-Analyses of Social Regulation*, Washington, D.C. 1979, 61 et seq., 69, 71, 73.

⁴³⁰ 690 F.2d 523 et seq.

⁴³¹ 619 F.2d 524 et seq.; for a criticism, see *Viscusi, W.K.*, *Regulating Consumer Product Safety*, Washington D.C./London 1984, 94 et seq.; *Johnson, L.L.*, *Cost-Benefit Analysis and Voluntary Safety Standards for Consumer Products*, Santa Monica, Cal. 1982, 28 et seq., explicitly praises the CPSC's analyses and recommends it to private standardization organizations for imitation.

⁴³² See 16 CFR 1205.5, fn. 1.

4.3.3. Product bans

According to sec. 8 CPSA 1972, products giving rise to an “unreasonable risk of injury” could be “banned” unless some product standard promised appropriate protection. The banning procedure came under the provisions of sec. 9 CPSA 1972 applying to standard setting, but not those of sections 7, 10 CPSA 1972 on petitioning and the offeror process. The possibility of putting through regulations on its own account does much to explain the Commission’s inclination, once the standard-setting procedure had proved unexpectedly complex and conflictual, to opt for the banning procedure. In fact, in at least two cases where issuing or tightening up a standard might have been conceivable, the Commission decided on product bans.⁴³³

The most important field of application of sec. 8 CPSA, however, became the hazards analyzed under the “chronical hazards” program, from health-threatening, especially carcinogenic, chemicals, a case where recourse to sec. 8 CPSA 1972 immediately suggests itself.⁴³⁴ The expectation that product bans might become an important regulatory instrument has however since been deceived, an outcome contributed to by both the outcome of the formaldehyde controversy and the 1981 legislative amendments.

The formaldehyde controversy began in 1976 with initial reports on health complaints from people living in houses treated with urea formaldehyde (UF) foam insulation for energy conservation. A veritable consumer movement developed against UF dangers, further stimulated by medical studies on the possible carcinogenicity of the product.⁴³⁵ The CPSC initiated wide-ranging additional scientific studies, and initially suggested a regulation to oblige manufacturers to provide information on general (not carcinogenic) hazards.⁴³⁶ It was not till 1981 that the Commission threatened to ban urea formaldehyde.⁴³⁷ The proposal for a regulation, which takes up 23 closely printed pages, first of all describes the state of the medical studies and goes on to discuss the economic consequences of a ban. Avoidance of 23 cancer deaths yearly, and of other health risks, were said to be in line with the requirements emerging from the Aqua Slide and Southland Mower decisions and to be

⁴³³ Cf. *Merrill, R.A.*, CPSC Regulation of Cancer Risks in Consumer Products: 1972-81, Virginia L Rev. 67 (1981), 1261 et seq., 1277, fn. 74 and *Schwartz, T.M.*, The Consumer Safety Commission: A Flawed Product of the Consumer Decade, George Washington L. Rev. 51 (1982), 32 et seq., 68 and the example of the “ban on unstable refuse bins”, 42 F.R. 30300, 13 June 1977, amended by 46 F.R. 55925, 13 November 1981, 16 CFR 1301; the refuse bins had according to the Commission's findings led to 21 deaths (20 of them children); the product ban specified the nature of the bins concerned in detail (loc. cit., 1301.1.(b) and (e); cf. also the ban on particular types of children's bicycles under 16 CFR 1500.18 (a) (12), which in turn refers to the requirements for bicycles (43 F.R. 60034, 22 December 1978, 16 CFR 1512); for an illuminating and critical discussion of bicycle regulations cf. *Cornell, N.W./Noll, R.G./Weingast, B.*, *Safety Regulation*, in: Owen, H./Schultze, ch.L. (eds.), *Setting National Priorities. The Next Ten Years*, Washington, D.C. 1976, 457 et seq., 493 et seq.; the standard was essentially confirmed by the decision in *Forester v. CPSC*, 559 F.2d 774 (D.C. Cir. 1977).

⁴³⁴ On the structure of the program, see *Merrill, R.A.*, CPSC Regulation of Cancer Risks in Consumer Products: 1972-81, Virginia L Rev. 67 (1981), 1261 et seq., 1981, 1296 et seq., 1310 et seq. Among the most prominent “victims” of the Commission was the chemical TRIS, which had since 1971, following a standard set by the Commerce Department, been used to treat nightwear to reduce fire dangers. In this case the Commission presented its action as an interpretation of § 2 (q) (1) (A) Federal Hazardous Substances Act (on the dramatic background, see *Merrill, R.A.*, CPSC Regulation of Cancer Risks in Consumer Products: 1972-81, Virginia L Rev. 67 (1981), 1261 et seq., 1323 et seq.). For the losses resulting from the Commission's action, firms involved received, through the 1982 “Tris Act”, compensation amounting to 56 million dollars (references in *Bollier/Claybrook*, 1986, 180).

⁴³⁵ See *Bollier, D./Claybrook, J.*, *Freedom from Harm, Washington, D.C./New York 1986.*, 180 et seq.

⁴³⁶ 45 F.R. 39434 (1980); on this see again *Merrill*, 1981, 1354 et seq. and *Ashford/Ryan/Caldart*, 1983.

⁴³⁷ 46 F.R. 11188 (5 February 1981).

in “reasonable proportion” with the economic drawbacks of a ban.⁴³⁸ On 2 April 1982 the definitive ban was issued,⁴³⁹ which was praised for its scientific justifications, once again spelled out, whereas the Commission’s economic analysis was found to be heavily flawed.⁴⁴⁰

The Court of Appeals, called in by a number of manufacturers concerned,⁴⁴¹ did not go into calculations of the economic benefit of preventing cancer deaths against the cost of banning urea formaldehyde. The Court was able to avoid taking a position on this regulatory aspect because it already regarded “unreasonable risk of injury” as not proven. Measurements of UF burdens had not been effected by random sampling, and where this had been the case, they were often due to installation errors and therefore controllable by a standard. The experimental scientific basis for the assumption of carcinogenic effects was on the whole too narrow, and could not justify the Commission’s risk estimates. The Commission’s 1983 Annual Report⁴⁴² has a brief note on the outcome of the trial, which is very illuminating for its present position: “the Commission voted 3-2 to seek an appeal in the Supreme Court, but the US Solicitor General decided not to ask the Supreme Court to take the case”. But it is not only the outcome of the formaldehyde controversy and the resulting requirements to demonstrate product risks that made the instrument of product bans become unattractive. Legal amendments in connection with the 1981 reauthorization acted in the same direction: product bans could henceforth be issued only under the conditions introduced in sec. 9 CPSA for the binding setting of standards.

4.4. Updating of “voluntary” standards

The explicitly critical attitude to “voluntary” standards that characterized the NCPS Report (“chronically inadequate, both in scope and permissible levels of risk”)⁴⁴³ and was to have determined the regulatory approach in the CPSA 1972 had already changed by the mid-70s; it was finally reversed with the legislative amendments of 1981.⁴⁴⁴ To understand this development and the CPSC’s present support for voluntary standard setting, a few indications as to the structures of private standard setting in the US might be of assistance.

⁴³⁸ 46 F.R. 11200 et seq.

⁴³⁹ 47 F.R. 14366 (2 April 1982).

⁴⁴⁰ On the first aspect see *Ashford, N./Ryan, C.W./Caldart, Ch.*, A Hard Look at Federal Regulation of Formaldehyde: An Assessment of its Health Effects, *Harvard Environmental L. Rev.* 7 (1983), 297 et seq., 360 et seq.; *Fox, E.M.*, Urea Formaldehyde Foam Insulation, *American J. of Law and Medicine* 11 (1985), 81 et seq., 84 et seq., and for an economic analysis *Merrill, R.A.*, CPSC Regulation of Cancer Risks in Consumer Products: 1972-81, *Virginia L. Rev.* 67 (1981), 1261 et seq., 1358 et seq.

⁴⁴¹ *Gulf South Insulation et al. v. CPSC*, 701 F.2d 1137 (5th Cir. 1983).

⁴⁴² II, 103; see also, for a criticism of the judicial critique, *Ashford, N./Ryan, C.W./Caldart, Ch.*, A Hard Look at Federal Regulation of Formaldehyde: An Assessment of its Health Effects, *Harvard Environmental L. Rev.* 7 (1983), 297 et seq., 363 et seq. and *Fox*, 1985, 88 et seq.

⁴⁴³ *Op. cit.*, (fn. 334), 62; see *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, *Texas L. Rev.* 56 (1978), 1329 et seq., 1371 et seq.

⁴⁴⁴ See 4.1.2.1. above.

4.4.1. Standardization organizations and procedures⁴⁴⁵

There are no less than 580 groupings in the US concerned with developing standards, but the number of organizations of national importance is very small. For some influential agencies, standardization activities are part of general representation of professional or economic interests. This is true of the engineering societies (“American Society of Civil Engineers”; “American Society of Mechanical Engineers”; “Institute of Electrical Electronics Engineers”; “Society of Automotive Engineers”); they are “non-profit” organizations with individual memberships, though their standardization activities are supported and influenced by contributions from industry. By contrast, the trade associations represent manufacturers in individual industries. Both the engineering societies and the trade associations not only develop standards themselves but additionally participate in the activities of the most important standardization organizations: the American Society for Testing and Materials (ASTM) and the National Fire Protection Association (NFPA). In view of its particular reputation, special mention should be made of Underwriters Laboratories (UL), an institution promoted by American insurers, dealing among other things with electrical hazards, fire protection and the development of test procedures. The activities of all these organizations are coordinated - which often means stimulated - by the American National Standards Institute (ANSI), which also represents the US in international contexts.

The standardization organizations reacted to public criticism of the quality of voluntary standards in the 1970s by reviewing their procedural arrangements. Thus, standards brought before the ANSI must before being recognized as an “American National Standard” go through a procedure to check whether all those primarily involved have had a chance to express views and raise objections, on whether the standard is “unfair” or ignores “the public interest”; additionally, all standardization proposals are published and, where of direct relevance to consumers, passed on to a “Standards Screening and Revision Committee of the Consumer Council”.⁴⁴⁶ The ANSI’s procedural rules are more specific, and stricter, when it organizes standardization procedures itself. For safety standards, inclusion of workers, authorities, insurers, consumers, and other groups is supposed to guarantee balanced representation of interests (“A consensus does not necessarily mean unanimous acceptance. Votes are weighted rather than counted”),⁴⁴⁷ as well as guaranteeing that standards would actually be applied. All big standardization organizations have similar procedural guarantees. This is the case in particular for the ASTM, which develops detailed “due process” requirements, and has, like, for instance, the NFPA and the UL, set up “consumer sounding boards”.⁴⁴⁸

⁴⁴⁵ On the following, cf. *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, Texas L. Rev. 56 (1978), 1329 et seq., 1336 et seq.; *Hemenway, D.*, Industry-wide Voluntary Product Standards, Cambridge, Mass. 1975, 81 et seq.; *Johnson, L.L.*, Cost-Benefit Analysis and Voluntary Safety Standards for Consumer Products, Santa Monica, Cal. 1982, 6 et seq.

⁴⁴⁶ *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, Texas L. Rev. 56 (1978), 1329 et seq., 1365 et seq.

⁴⁴⁷ For more on the consensus principle see *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, Texas L. Rev. 56 (1978), 1329 et seq., 1361 et seq., and the critical remarks in *Hemenway, D.*, Industry-wide Voluntary Product Standards, Cambridge, Mass. 1975, 89 and in *Opela, M.P.*, The Anatomy of Private Standards-Making Process: the Operating Procedures of the USA Standards Institute, Oklahoma L. Rev. 22 (1969), 45 et seq., 45.

⁴⁴⁸ See *Hamilton, R.W.*, The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health, Texas L. Rev. 56 (1978), 1329 et seq., 1349 et seq., 1384.

4.4.2. The CPSC attitude

In parallel with these reorganization efforts of private standardization associations, attitudes towards “self-regulatory” measures in general changed,⁴⁴⁹ as did the CPSC’s position on voluntary standards in particular. In 1975, the CPSC was already developing forms of cooperation with private standardization organizations⁴⁵⁰ and regulating “employee membership and participation in voluntary standards organizations”.⁴⁵¹ In the statement on the regulation on “Commission involvement in voluntary standard activities” of 1978, the Commission explicitly dissociated itself from the National Commission on Product Safety’s critical observations on voluntary standards,⁴⁵² and at the 1981 Congressional hearings this attitude was confirmed by then Commission Chairman Stuart Statler, who pointed out that in 83 cases the Commission had already collaborated on developing or revising voluntary standards.⁴⁵³ The Underwriters Laboratory additionally stressed that passing on of accident figures by the Commission had already often led to private standardization activity.⁴⁵⁴

The 1978 Regulation just mentioned distinguishes between two forms of official involvement. “Monitoring” of the development of voluntary product standards involves observing the process and influencing it through directed questions and by providing accident figures and the results of in-depth studies. In the case of “participation”, a Commission worker takes part in sessions of the private Standardization Committee, and technical assistance is sometimes provided. The first form of involvement requires approval only from the Commission Executive Director, the second from the Commissioners themselves.⁴⁵⁵ The object of both forms, and the type of support that the Commission can provide,⁴⁵⁶ is fully in line with the CSPA’s general safety policy objectives. Support is accordingly also bound up with particular conditions on the standardization procedure: it should be open to all interested parties and guarantee genuine involvement of consumers and/or small business; it must provide for revisions of standards; actual compliance is important; certification provisions should be worked out and standards themselves be confined to “performance” regulations.⁴⁵⁷ The Commission always keeps its option to issue a mandatory product regulation open, whether to make a voluntary standard generally binding or because a voluntary standard is inadequate from the safety policy viewpoint.⁴⁵⁸

The 1981 legislative amendments did not formally cancel this policy statement, but they did reduce its practical significance, for many reasons. By the new version of sec. 9 (b) CPSA, the Commission must always give preference to voluntary standards where they eliminate or “adequately reduce” the hazards concerned and “substantial” compliance is to be expected. This already guarantees that the Commission will await efforts at voluntary

⁴⁴⁹ See *Katz, R.N.* (ed.), *Protecting the Consumer Interest. Private Initiative and Public Response*, Mass. 1976; Reich, 1984, 123 et seq.

⁴⁵⁰ See e.g. the references in *Hamilton, R.W.*, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety of Health*, Texas L. Rev. 56 (1978), 1329 et seq., 1404 and the testimony by Commission Chairman S.J. Byington to the 1977 Congressional Hearings, loc. cit. (fn. 375), 363 et seq., 373 et seq.

⁴⁵¹ 40 F.R. 26025, 20 June 1975 (for the form in force at present, see 46 F.R. 29930, 4 June 1981, 16 CFR 1031).

⁴⁵² 43 F.R. 19216 (4 May 1978), 16 CFR 1032.1.

⁴⁵³ Op. cit., (fn. 391), 321 et seq., 338 et seq.

⁴⁵⁴ Op. cit., 816 et seq., 823.

⁴⁵⁵ 16 CFR 1032.2 (b) and 1032.3 (a) and (b).

⁴⁵⁶ See 16 CFR 1032.4.

⁴⁵⁷ See 16 CFR 1032.5.

⁴⁵⁸ See 16 CFR 1032.6; cf. 1032.1 (c).

solution and cannot without further ado ignore their outcome. Additionally, the new version of section 9 (c) and (f) CPSA links announcement, and above all enactment, of binding rules with additional requirements. The Commission has not only to show that a product hazard will not be adequately reduced or that observance of a standard would be inadequate; it has further to provide a detailed “regulatory analysis” that must contain cost-benefit analyses of its regulatory proposal and of all alternatives contemplated. The Commission initially responded in 1984 to this change in the framework for its cooperation with standardization organizations through a proposal to supplement the 1978 regulations concentrating on involvement in developing voluntary standards with a procedure to give special recognition to voluntary safety standards already being applied.⁴⁵⁹ The declared aim of this proposal was to encourage application of safety standards and improve consumer orientation towards safety aspects of consumer products. But response to the proposal was discordant, and mainly negative. Industry feared distortions of competition and restrictions on innovation; standardization organisations recalled the Commission’s limited resources for implementing recognition procedures; the Consumer Federation of America protested against the Commission being converted into a sales promotion agency. The Commission decided to withdraw its proposal.⁴⁶⁰ But this did not end efforts to develop standardization policy further. A memorandum of 22 April 1985⁴⁶¹ incorporating suggestions from Commission departments and from public hearings describes and discusses a range of options going from voting rights in setting voluntary standards via systematic announcements of regulatory procedures pursuant to sec. 9 CPSA, up to the conclusion of cooperation agreements with standardization organizations. The Commission decided to use only three of these possibilities: to intensify its involvement in standardization work on products particularly important in its view; to make direct contact with individual manufacturers before producing or amending standards; to refer to standards in its public information.⁴⁶² The practical importance of all these activities is hard for the outsider to estimate. However, thanks to its accident information system and its own technical competence, the Commission should continue to have considerable possibilities of influencing the production and promotion of standards of relevance to safety.⁴⁶³

4.4.3. Standards and product liability

The intensification of “voluntary” standardization in the US cannot be explained solely on the basis of the CPSC’s original powers and its current encouragement of voluntary standards, but is to be attributed essentially to the influence of American liability law. American case law punishes neglect of a binding standard, but also non-compliance with a safety level laid down in a voluntary standard, as in principle “negligence *per se*”.⁴⁶⁴ This

⁴⁵⁹ 49 F.R. 25005, 19 June 1984.

⁴⁶⁰ 50 F.R. 19699, 10 May 1985; the hearings and discussions that led to this decision are documented in the “Briefing Package on Proposed Amendment to Commission Policy Involvement in Voluntary Standards Activities”, 14 December, 1984.

⁴⁶¹ Alternatives for Support of Voluntary Standards.

⁴⁶² Commission Guidance on Voluntary Standards Activities, Memorandum, 28 April 1986.

⁴⁶³ According to a memorandum from D.L. Noble of 14 May 1986, in 1986 15 participation projects and 31 monitoring projects were pursued. The memorandum specifies in each individual case the nature of the hazards involved, and documents advantages and drawbacks to each individual project.

⁴⁶⁴ See *Weinstein, A.S./Twerski, A.D./Pieller, H.R./Donaker, W.H.*, *Product Liability and the Reasonably Safe Product: A Guide for Management, Design and Marketing*, New York/Chichester/Brisbane/Toronto 1978, 56.

sanction manifestly explains industry's willingness to follow voluntary standards;⁴⁶⁵ it likewise explains the interest in having standards recognized by ANSI and making the standardization procedure itself "fair".⁴⁶⁶

On the other hand, compliance with a standard in no way rules out product liability. section 25 CPSA explicitly confirms this principle for binding standards: "Compliance with consumer product safety rules ... shall not relieve any person from liability at common law ..." However clear this position, court practice nevertheless responds in different ways when manufacturers appeal to their compliance with voluntary or with mandatory standards in product liability actions. Standards may, for instance, be adduced to establish the "state of the art" in product safety, or to support or confute expert testimony.⁴⁶⁷ All these forms of observance of standards, however, leave the principle that the courts autonomously determine the level of product safety intact; this principle is not questioned either by efforts at legislative channeling of product liability law.⁴⁶⁸

4.5. Recalls

The recall provisions in the CPSA initially stood in the shadow of preventive standard setting, but soon developed into an important instrument for the CPSC, and took on additional importance after the 1981 restrictions. For European product safety policy, the American example deserves particular attention not only because the New Approach to technical harmonization and standards delegates preventive product safety policy very largely to private standardization organizations, but also because the need for European framework legislation on follow-up market control seems irrefutable.⁴⁶⁹

4.5.1. The CPSA legislative framework

Two provisions in the CPSA deal with response to hazards arising from already marketed products. By sec. 12, the Commission may order seizure and/or public warnings, recalls, repairs, exchange or replacement of "imminently hazardous consumer products". However, the significance of this provision remained marginal.⁴⁷⁰ The Commission has developed its follow-up market policy entirely on the basis of sec. 15. This preference is not surprising: the criteria for intervention in sec. 15 are broadly formulated, the potential for sanctions is rich in alternatives and can be treated flexibly.

⁴⁶⁵ See *Eads, G./Reuter, P.*, *Designing Safe Products. Corporate Responses to Product Liability Law and Regulation*, Santa Monica, Cal. 1983, 40.

⁴⁶⁶ See 4.4.1. above and *Hoffman/Hoffman*, 1980/81, 293, 295.

⁴⁶⁷ See *Hoffmann, S.D./Hoffmann, M.E.*, *Use of Standards in Products Liability Litigation*, *Drake L. Rev.* 30 (1980-81), 283 et seq., 288 et seq., and specifically on automobile standards *Holley, St. C.*, *The Relationship between Federal Standard and Litigation in the Control of Automobile Design*, *New York University L. Rev.* 57 (1982), 804 et seq., 813 et seq.

⁴⁶⁸ See *Dworkin, T.M.*, *Federal Reform of Product Liability Law*, *Tulane L. Rev.* 57 (1983), 602 et seq., 612 et seq.

⁴⁶⁹ See *Joerges, C.*, *Product Safety, Product Safety Policy and Product Safety Law*, *Hanse Law Review (HanseLR)* 2010, 117, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, and for more details *Joerges, C./Micklitz, H.*, *The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy*, *Hanse Law Review (HanseLR)* 2010, 251, 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

⁴⁷⁰ See *Schwartz, T.M./Adler, R.S.*, *Product Recalls: A Remedy in Need of Repair*, *Case Western Reserve L. Rev.* 34 (1984), 401 et seq., 429.

Sec. 15 (a) CPSA provides sanctions against all “substantial product hazards” arising either from failure to comply with a binding rule or from product defect. Every manufacturer, distributor and retailer must by sec. 15 (b) immediately inform the Commission if they obtain information that reasonably supports the conclusion that such hazard is present. On the basis of such reports and/or other sources of information (NEISS accident figures, consumer complaints, in-depth studies etc.), a hearing is held to which all interested circles, including consumers, are invited (see sec. 15 (c) and (d)).

Should the Commission determine after such consultation that a “substantial product hazard” is presented, two measures are possible:

- “notification” under sec. 15 (c), whereby a manufacturer, distributor or retailer may be ordered to inform the general public, notify all manufacturers, distributors or retailers, or mail notice to every person they know to have been sold or delivered the product;
- the further-reaching possibilities of sec. 15 (d), where it seems necessary in the public interest to repair a product, make it fit applicable standards, exchange it or replace it. Additionally, a “corrective action plan”, showing how the order is to be implemented, may be required.

4.5.2. Application of sec. 15 CPSA

The administration of this legal framework has been interpreted and refined by the Commission in its rules on “substantial product hazard reports”⁴⁷¹ and in a number of internal (though publicly accessible) documents. Some elements of this policy have already been brought out:

- (1) the general clause of sec. 15 (a) (2) on defects that lead to “substantial product hazards” has been clarified by the Commission using exhaustive circumlocutions (“a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function”), differentiations (design, manufacture, instructions), examples (“a knife does not contain a defect insofar as the sharpness of its blade is concerned”) and assessment criteria (“... the Commission and staff will consider: the utility of the product involved; the nature of the risk of injury which the product presents; the population exposed to the product and its risk of injury; the Commission’s own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of product liability; and other factors ...”).⁴⁷²
- (2) The obligation laid down in sec. 15 (b) on manufactures, distributors and retailers to report product hazards is regarded by the Commission as an indispensable precondition for its recall policy. It exhaustively commented on this obligation in 1978, defending it against criticism from firms involved.⁴⁷³ The objections are quite understandable. There are fears in particular of negative effects of such reports on product liability suits, and also of deterioration of image and hence of competitive position. The rule dating from 1978 sought to allay these doubts by explicitly treating the report itself as not constituting admission of a product defect.⁴⁷⁴ In 1981 the legislator came to meet the interests of firms involved by making the new version of sec. 6 (b) (5) CPSA provide that in principle

⁴⁷¹ 43 F.R. 34998 (7 August 1978), 16 CFR 1115.

⁴⁷² 16 CFR 1115.4; and exhaustively *Madden, M.S.*, Consumer Product Safety Act, Section 15 and Substantial Product Hazards, *Catholic University L. Rev.* 30 (1981), 195 et seq., 202 et seq.

⁴⁷³ 43 F.R. 34988-34998, 7 August 1978 (on the subsequently adopted rule, cf. in detail *Madden*, 1981, 211 et seq.).

⁴⁷⁴ 16 CFR 1115.12 (a).

information secured under sec. 15 (b) be no longer published.⁴⁷⁵ This legislative amendment, and probably also the Commission's budget difficulties,⁴⁷⁶ led in 1980-2 to a notable decline in the number of reports received. But the Commission's position was not lastingly affected. In 1984 it once more gave detailed justifications for the importance of the reporting duty,⁴⁷⁷ and managed to reverse the trend of the years 1980-2 again.⁴⁷⁸

This strictness cannot be explained by the information function of the reports alone. Procedures under sec. 15 CPSA were inevitably always largely based also on other information sources.⁴⁷⁹ Assuredly, closer observance of the reporting duty would facilitate the identification of hazards. But the importance of the reporting duty seems also to lie in its largely compensating the indefiniteness of the general clause in sec. 15 (a) (2), thus also strengthening the Commission's negotiating position vis-à-vis firms involved when negotiating a recall plan.

- (3) As with all product safety policy instruments, with follow-up market control too priority setting is essential. A 1981 document,⁴⁸⁰ instructive for the Commission's attitude, differentiates three types of injury and of likelihood, in order to set up three types of urgency based on combinations of severity of injury and likelihood of occurrence, to which cases arising can be allocated. But these classifications show that the Commission sees follow-up market control as implementation of the statute, and orients use of its resources towards the objective of preventing hazards; consistent orientation of its policy to the criteria of cost-benefit analysis⁴⁸¹ would give another scale of priorities.
- (4) The great flexibility that sec. 15 (c) and (d) allow the Commission in its response to product hazards is exploited both in notification and in recalls and the drawing up of a "corrective action plan". The intensity of response, its specific shape and its monitoring go according to the type of product and the urgency of the hazard.⁴⁸² A noteworthy point

⁴⁷⁵ See 4.1.2.2. above.

⁴⁷⁶ See *Schwartz, T.M./Adler, R.S.*, Product Recalls: A Remedy in Need of Repair, Case Western Reserve L. Rev. 34 (1984), 401 et seq., 434.

⁴⁷⁷ 49 F.R. 13820, 6 April 1984; see also *Statler, St.M.*, Reporting Guidelines Under Section 15 of the Consumer Product Safety Act. J. of Product Liability 7 (1984), 89 et seq.

⁴⁷⁸ Exact figures can be found in the memorandum from the divisions for "corrective action" and "administrative litigation" of 13 May 1985 and 11 May 1986; for previous years see *Schwartz/Adler*, 1984, 433, fn. 221; *Statler, St.M.*, Reporting Guidelines Under Section 15 of the Consumer Product Safety Act. J. of Product Liability 7 (1984), 89 et seq., 93. However, the courts have cut down on sanctions for breach of the reporting duty. In *Advance Machine Co. v. CPSC*, 666 F.2d 1166 (8th Cir. 1981) and in *Athlone Industries, Inc. v. CPSC*, 707 F.2d 1485 (D.C. Cir. 1983) it was found that the Commission had to impose the fines provided for in sec. 20 CPSA through the courts (on the importance of this decision see *Zollers, F.E.*, The Power of the CPSC to Levy Penalties, American Business Law J. 22 (1985), 551 et seq.). In *Drake v. Honeywell, Inc.* 797 F.2d 603 (8th Cir. 1986) it was decided that breach of the reporting duty did not justify any right of private action.

⁴⁷⁹ See *Schwartz, T.M./Adler, R.S.*, Product Recalls: A Remedy in Need of Repair, Case Western Reserve L. Rev. 34 (1984), 401 et seq., 433 and for the Commission's information sources CPSC Order 9010.34, 4 June 1984, 8 et seq.

⁴⁸⁰ Hazard Priority and Corrective Action Guidelines, 19 January 1981; see also the detailed description of the decision-making procedures in the "Report on Recall Effectiveness Task Force", 25 August 1980, Tab. D and *Madden, M.S.*, Consumer Product Safety Act, Section 15 and Substantial Product Hazards, Catholic University L. Rev. 30 (1981), 195 et seq., 234 et seq.

⁴⁸¹ See 4.1.3. above, end.

⁴⁸² For details see *Madden, M.S.*, Consumer Product Safety Act, Section 15 and Substantial Product Hazards, Catholic University L. Rev. 30 (1981), 195 et seq., 238 et seq. and *Schwartz, T.M./Adler, R.S.*, Product Recalls: A Remedy in Need of Repair, Case Western Reserve L. Rev. 34 (1984), 401 et seq., 437 et seq. (on recalls), 411 et seq. (on notice), as well as, specifically on recalls, the detailed CPSC Order 9010.34 (fn. 478 above).

is the high rate of mutual agreement in the resolution of recalls.⁴⁸³ This can be explained by industry's interest in avoiding adverse publicity and product liability actions, and the Commission's interest in rapidly eliminating product hazards ("safety delayed is safety denied"). Willingness to compromise manifestly did not suffer from the 1981 legislative amendments.

4.5.3. The function of follow-up market control

The history of implementation of follow-up market control under sec. 15 (b) CPSA is one of success. The figures are indeed impressive. Former Commission Chairman S. King reports that between 1973 and 1980 some 2,500 recall actions were carried out, covering 100 million products.⁴⁸⁴ At the 1983 Congressional hearings, Chairman N.H. Steorts was able to point to 3,174 actions on 293 million products.⁴⁸⁵ Commissioner Stuart M. Statler in 1980 called the provisions of sec. 15 CPSA one of the Commission's most effective instruments, that could be used even to solve general product safety problems⁴⁸⁶ – e.g. for an industry-wide recall because of a universally occurring design defect.⁴⁸⁷ But there are limits to this kind of remodelling of sec. 15 CPSA. The primary safety objective of recalls, namely to eliminate hazards arising from already marketed products, can never be fully achieved. The CPSC's implementation studies show this very clearly. Though the success or failure of a recall action cannot simply be read off from the percentage of returned products,⁴⁸⁸ it is nevertheless indisputable that the effectiveness of such actions calls for hard strategic decisions. The type of consumer information must depend on whether manufacturers or retailers have customer lists available; where necessary, suitable public media must be used. The intensity of information must take account of the hazards of the product concerned, but also of the attitudes, inhibitions and efforts of the final consumer. For all the doubts about the achievability of recalls arising from these problems, it should nevertheless be borne in mind that recall actions can be used both to raise standards and to improve safety controls within firms. These feedback effects are also to be taken into account in assessing the "success" of recall arrangements.

4.6. Evaluation of the CPSC

Assessments of the CPSC's performance are as controversial as product safety policy itself. The analyses presented by consumer organizations arrive at positive results: on calculations

⁴⁸³ See *Madden, M.S.*, Consumer Product Safety Act, Section 15 and Substantial Product Hazards, Catholic University L. Rev. 30 (1981), 195 et seq., 227 et seq.; *Schwartz, T.M./Adler, R.S.*, Product Recalls: A Remedy in Need of Repair, Case Western Reserve L. Rev. 34 (1984), 401 et seq., 434. According to figures from former Commission Chairman S. King given to the 1981 Congressional Hearings, loc. cit. (fn. 391), 22, over 90% of procedures under sec. 15 CPSA were settled by mutual agreement.

⁴⁸⁴ S. King, loc. cit.

⁴⁸⁵ Op. cit. (fn. 353), 302, 310, cf. 320 et seq.; see also *Statler, St.M.*, Reporting Guidelines Under Section 15 of the Consumer Product Safety Act. J. of Product Liability 7 (1984), 89 et seq. 92.

⁴⁸⁶ *Statler, St.M.*, CPCS: Only a Beginning, Trial 1980, 77 et seq., 79.

⁴⁸⁷ *Schwartz, T.M./Adler, R.S.*, Product Recalls: A Remedy in Need of Repair, Case Western Reserve L. Rev. 34 (1984), 401 et seq., 439, fn. 260.

⁴⁸⁸ As stated again in the Recall Effectiveness Study, Loren Lange, Office of Strategic Planning, May 1978; the 1980 Report (fn. 479 above) additionally points to a number of other relevant factors: the significance of the proportion returned depends on how many products are still being used at all, how many have been privately repaired following a warning and how many have been simply thrown away.

by A.K. Lower/A. Averyt/D. Greenberg,⁴⁸⁹ the falling trend in home and leisure accidents has been speeded up (twofold) by the Commission's activities; in the years from 1978 to 1983 alone, the CPSC is said to have prevented 1.25 million serious injuries and deaths, and saved consumer's costs of some 3.5 billion dollars. W.K. Viscusi⁴⁹⁰ arrives at an opposite finding: the falling accident figures merely continued (even though more strongly) a trend that has not been significantly influenced by the CPSC. It is hardly surprising that there are also studies with findings in between the two results cited.⁴⁹¹

The problems with evaluations like this arise because they have to identify and quantify factors, which allow the trend in accident figures and the way the CPSC's activities influence them to be explained. All the studies mentioned use simplifying, if not speculative, assumptions for this. More illuminating, though likewise controversial, are analyses of individual measures and of them put together. The Commission itself undertakes these analyses of results, which however largely use estimates for the period after full implementation of a measure. Thus, for instance, the rule on children's cots is supposed to have prevented 50 deaths per year, the ban on TRIS in children's nightclothes to have averted 500 possible cancer cases, and the lawnmower regulation to have reduced annual injuries by 60,000.⁴⁹² For the CPSC's cooperation with standardization organizations and for recall actions⁴⁹³ there are similarly impressive figures.⁴⁹⁴ Critics of the Commission have questioned these success claims in individual studies. The careful analysis of the Mattress Flammability Standard 1973⁴⁹⁵ by P. Linneman⁴⁹⁶ finds that a reliable pronouncement on the standard's effects is impossible. Admittedly, this is a case of adoption of a voluntary standard, already 80% observed by the industry, and moreover the Commission seems to have been prevented from adopting an alternative solution to the problem (namely implementation of a standard on self-extinguishing cigarettes).⁴⁹⁷ W.K. Viscusi has checked all binding standards, in part summarily and in part in detail, for their effects. His analysis of the 1973 Poison Preventive Packaging regulation⁴⁹⁸ concentrates on figures for child poisonings by aspirin. He disputes the success claimed by the Commission for compulsory childproof containers; the poisoning rate, he says, fell generally, and the relatively better figures for the product covered by the regulation could be attributed to counterproductive side effects of the regulation in other areas (on the use of non-regulated medicines and "lulling" effects in handling them).⁴⁹⁹ The phenomena mentioned by Viscusi

⁴⁸⁹ Lower, A.K./Averyt, A./Greenberg, D., *On the Safe Track: Death and Injuries Before and After the CPSC*. A Consumer Federation Report, Washington, D.C. 1983.

⁴⁹⁰ Viscusi, W.K., *Regulating Consumer Product Safety*, Washington D.C./London 1984, 271 et seq. and *idem*, *Consumer Behaviour and the Safety Effects of Product Safety Regulation*, *J. of Law and Economics* 28 (1985), 527 et seq.

⁴⁹¹ Zick, C.D./Mayer, R.N./Snow, L.A., *Does the Consumer Product Safety Commission Make a Difference? An Assessment of Its First Decade*, *JCP* 9 (1986), 25 et seq.

⁴⁹² CPSC figures to the 1981 Congressional Hearings, loc. cit. (fn. 391), 431; also 419, 426.

⁴⁹³ For 1981 cf. loc. cit. (fn. 492), 427; cf. also the 1983 Congressional Hearings, loc. cit. (fn. 353), 318 et seq.

⁴⁹⁴ The individual estimates may be added together. Thus, for 1981, the Commission arrives at a reduction, in relation to mandatory and voluntary standards, by 300 deaths and 125,000 injuries (loc. cit., fn. 391, 412); for 1983, 450 deaths and 248,000 injuries are claimed (loc. cit., fn. 353, 309).

⁴⁹⁵ 38 F.R. 15095 (8 June 1973).

⁴⁹⁶ Linnemann, P., *The Effects of Consumer Safety Standards: The 1973 Mattress Flammability Standard*, *J. of Law and Economic* 23 (1980), 461 et seq., 469.

⁴⁹⁷ Bollier, D./Claybrook, J., *Freedom from Harm*, Washington, D.C./New York 1986, 173; the standard has since been supplemented, see 16 CFR 1632 (1985).

⁴⁹⁸ 38 F.R. 21247 (7 August 1973), 16 CFR 1700.

⁴⁹⁹ Viscusi, W.K., *Regulating Consumer Product Safety*, Washington D.C./London 1984, 77 et seq.; see also *idem*,

certainly exist; however, it seems speculative to use them as evidence in an argument like his. The Commission's positive findings are, at any rate, supported by studies by the American Academy of Pediatrics.⁵⁰⁰ In the case of the standard for children's cots,⁵⁰¹ even Viscusi has to admit an improvement in accident figures by 10%;⁵⁰² a demonstration that this is in line with a trend operating in any case can scarcely be provided.

These conflicting analyses cannot and will not be definitively assessed here. The controversies at any rate show how ambitiously research on effects must be designed if it is not only to determine involvement of the regulated products in accidents, but also clarify other possible influencing factors and take side effects of regulation into account. The CPSC can at any rate show that such complex analyses of effects as lastingly to question its results have not so far been presented.

Consumer Behaviour and the Safety Effects of Product Safety Regulation, *J. of Law and Economics* 28 (1985), 527 et seq., 539 et seq.

⁵⁰⁰ See figures by *Greensher/Mofenson* to 1981 Congressional Hearings, loc. cit. (fn. 391), 81.

⁵⁰¹ 38 F.R. 129 (21 November 1973), 16 CFR 1508.

⁵⁰² *Viscusi, W.K.*, Consumer Behaviour and the Safety Effects of Product Safety Regulation, *J. of Law and Economics* 28 (1985), 527 et seq., 552.

The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy⁺

*Josef Falke** and Christian Joerges**

Abstract Deutsch

Dieser Artikel behandelt die verschiedenen Möglichkeiten der Europäischen Gemeinschaft, national unterschiedliche Gesetze zu harmonisieren. Der Artikel konzentriert sich hierbei auf den Bereich der Produktsicherheit. Nachdem analysiert wurde, inwieweit die EG über die hierfür notwendigen Kompetenzen verfügt, wird ein Schwerpunkt auf das Allgemeine Programm vom 28. Mai 1969 zur Beseitigung der technischen Hemmnisse im Warenverkehr gelegt. Die fünf darin angeführten Methoden zur Harmonisierung – von der totalen Harmonisierung bis hin zur gegenseitigen Anerkennung von Tests – werden erläutert und teilweise mit Beispielen belegt. Die Realisierung des Programms verlief jedoch schleppend und Ziele wurden nur unzureichend erreicht. Ein dahingehend neuer Versuch der EG in Hinblick auf die Harmonisierung wurde durch eine Richtlinie über Bauprodukte im Jahr 1978 angeregt. Allerdings ist dieser gescheitert.

Anschließend stellt der Artikel die Kritik an der vertikal orientierten europäischen Harmonisierungspolitik dar und widmet sich dem Problem der Umsetzung von Richtlinien in nationales Recht. Weiterhin wird auf die Bedeutung des GATT-Abkommens über technische Handelshemmnisse eingegangen.

Danach fokussiert sich der Artikel auf den Wechsel in der Harmonisierungspolitik, welche sich von einer vertikalen zunehmend zu einer horizontalen Herangehensweise entwickelt. Anhand von Beispielen (Richtlinie zur Sicherheit von Spielzeugen, Pilotexperiment bezüglich eines Gemeinschaftlichen Informationssystems bei Unfällen) wird verdeutlicht, wie der Verbraucherschutz solch eine Horizontalisierung bewirkt und wie bei gefährlichen Produkten vorgegangen werden muss. Daran anknüpfend, schließt der Artikel mit einer Analyse der Produkthaftungsrichtlinie und ihrem (beschränkten) Nutzen für die Harmonisierung im Bereich der Produktsicherheit.

⁺ This article has originally been published in 1991 as Chapter III, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 4, EUI Working Paper Law No. 91/13.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

Abstract English

This Article deals with the different ways of law approximation methods by the EC and hereby concentrates on the area of product safety. After analyzing the competences of the EC to do so, focus is put on the General Programme of 28 May 1969 which aims at removing technical barriers to trade. The five methods of harmonization the programme offers – from complete harmonization to mutual recognition of tests – will be outlined and some of them are accompanied with examples. In general, the programme has been realized only partially and the implementation took longer than anticipated. A new attempt of the EC in order to harmonize national legislation was put forward by a directive on construction products in 1978 transferring legislative powers to the Commission. However, this effort failed.

The article then depicts the criticism which is voiced with regard to the vertical harmonization by the EC and the problem of implementing the relevant directives into national law. Furthermore, the importance of the GATT-Agreement on Technical Barriers to Trade is stressed.

Finally, focus is placed upon the change of harmonization policy which shifts from vertical to horizontal approximation of laws. By means of several examples (Safety of Toys Directive, Pilot Experiment for a Community Accident Information System), it is shown how consumer protection leads to such a horizontalization and what has to be done with hazardous products. Tying in with the latter, the article closes with discussing the Product Liability Directive and its (limited) effects on harmonizing product safety.

The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy⁺

*Josef Falke** and Christian Joerges**

Introduction

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

Despite these varied effects on the Community on the development of product safety law, it nevertheless remains difficult to specify the nature of these influences more exactly, recognize the consequences of the integration process for law in Member States and find answers to the questions of what product safety policy tasks the Community ought to take upon itself and what instruments it ought to employ in so doing. Jurists are accustomed to approach such questions by seeking to clarify and demarcate the competencies of Community and Member States. However obvious and unavoidable this way of doing things may be, it rapidly emerges that the legal framework set by the EEC Treaty leaves the Community with enormous latitude, and can hardly define the priorities of Community policy (1.1.). Since Community law determines the process of Europeanization of product safety policy only to a very limited extent, it is tempting to fall back on economic and political-science theories in explaining the actual course of this process. But attempts to date to reconstruct the process of European integration using economic models or political structural analyses have scarcely gone beyond the development of relatively abstract hypotheses on the effects of the general European policy framework conditions (1.2.). In view of this vagueness not only in the law but also in sociological integration research, it is

⁺ This article has originally been published in 1991 as Chapter III, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 4, EUI Working Paper Law No. 91/13.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

presumably justified in analysing Community practice to start from the political programmes on a long-term basis that the Community has taken as a guide in influencing product safety law: the 1969 General Programme on removing technical barriers to trade, and the programmes to protect and inform consumers (2. and 3.). It is the fate of political programmes, and not only where the Community is concerned, to lag behind original expectations when it comes to realization. But the Community's responses to discrepancies between its original programmatic conceptions and the actual course of the integration process will be gone into further in other contributions to that special issue.

1. Framework conditions for the Europeanization of product safety policy

The Community's competencies are not all-embracing. Its legislative acts in principle operate indirectly in Member States. The Community has genuine administrative powers in only a few policy areas. All this influences both the orientation and the implementation of Community policy. All the same, these general framework conditions do not constitute insuperable legal barriers to the Community's possibilities of affecting product safety law.

1.1. The openness of the legal framework

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

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

¹ Cf. esp. ECJ case 120/78, judgment of 20 February 1979, ECR [1979] 649 - Cassis de Dijon; on which see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

² For more details see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³ Cf. *Röhling, E.*, *Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt*, Köln/Berlin-/Bonn/München 1972, 95 et seq., and more recently *Collins, Ph./Hutchings, S M*, Articles 101 and 102 of the EEC Treaty: Completing the Internal Market, *ELR* 11, 1986, 197 et seq.

This cautiousness is hardly surprising. It is one of the indications that the limits to Community action in fact cannot be determined purely “legally”.⁴

The Community’s powers to take measures to approximate laws on product safety under Art. 100 EEC cannot *de facto* be limited by binding the Commission to particular integration policy objectives. There have of course been repeated attempts to derive the limits to Community competence specifically in areas of “social regulation” (chiefly health, consumer protection and the environment) from the requirement in Art. 100 EEC that law approximation measures should have to do with the market.⁵ But it cannot be denied that differences in product safety law constitute non-tariff barriers to trade and therefore “directly affect the establishment or functioning of the Common Market”. This realization leads directly to the position that in order to avert emergent regulatory differences the Community can exert a shaping influence “even in anticipation of the development of new legal areas”.⁶ If as is the prevailing view today the law-making competencies of Art. 100 EEC are taken in connection with the preamble and to Art. 2 EEC,⁷ and further bearing in mind that in drafting directives the Community can lay claim to very wide discretion,⁸ then it is hard to identify any definitive legal bounds to product safety policy harmonization at all. Moreover, in addition to the instrument of the directive, the Community has by Art. 235 EEC a second and likewise very far-reaching power to act. This provision may as the ECJ has confirmed⁹ be taken advantage of where directives do not offer an “adequately effective means” to attain treaty objectives.

The demonstration that no unambiguous bounds to the Europeanization of product safety law can be derived from Art. 100 and 235 EEC does not admittedly say all that is to be said about the questions of “dynamic” interpretation of these provisions. It may be very hard to drive unambiguous criteria for the delimitation and control of European law-making activity from differences between the Community legal system and Member States’ constitutions. But one indirect consequence, which is hard to grasp in formal legal terms, is equally irrefutable: entry by the Community into areas of social regulation has to lead to a conflict of objectives between a law approximation policy oriented merely towards market integration as such and a legislative policy oriented towards the substantive quality of regulations.¹⁰

⁴ Cf. also the reports on the Commission’s present consideration of activation of Articles 101 et seq. EEC, in *Collins, Ph/Hutchings, M.*, Articles 101 and 102 of the EEC Treaty: Completing the Internal Market, ELR 11 1986, 198 et seq.; *Pipkorn, J.*, Kommentar zu den Artt. 101 und 102 EWGV, in: v.d. Groeben, H./v. Boeckh, H./Thiesing J./Ehlermann, C.-D. (Eds.), Kommentar zu EWG-Vertrag, 3rd edition, Baden-Baden 1983, Art. 101, para. 24.

⁵ From the German literature, see e.g. *Kaiser, J.H.*, Grenzen der EG-Zuständigkeit, EuR 1980, 97 et seq., 102 et seq.; *Börner, B.*, Die Produkthaftung oder das vergessene Gemeinschaftsrecht, in: Grewe, W.G. (Ed.), Europäische Gerichtsbarkeit und nationale Verfassungsgerichtsbarkeit, FS zum 70. Geburtstag von Hans Kutscher, Baden-Baden 1981, 43 et seq.

⁶ *Taschner, H.C.*, Kommentar zu Art. 100 EWGV, in: Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D. (Eds.), Kommentar zum EWG-Vertrag, 3rd ed., Baden-Baden 1983, Art. 100, para. 23.

⁷ Cf. *Close, G.*, Harmonization of Laws: Use or Abuse of the Powers of the EEC-Treaty, ELR 1978, 461 et seq.; *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 6 et seq., 15 et seq., and for the analogous case of environment policy *Rehbinder, E./Stewart, R.*, Environmental Protection Policy, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), Integration Through Law. Europe and the American Experience, vol. 2, Berlin/New York 1985, 21 et seq., with other references.

⁸ Cf. only *Langeheine, B.*, Kommentar zu den Artt. 100 bis 102 EWGV, in: Grabitz, E. (Ed.), Kommentar zum EWG-Vertrag, München 1986, Art. 100, para. 13, with other references.

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

¹⁰ Cf. *Everling, U.*, Möglichkeiten und Grenzen der Rechtsangleichung in der Europäischen Gemeinschaft, in: FS Reimer Schmidt, Karlsruhe 1976, 101 et seq., 170 et seq.; *Langeheine, B.*, Kommentar zu den Artt. 100 bis

The Community's powers under Articles 100 and 235 EEC are in principle also suited for compensating for the absence of genuine powers of direct action and administration by the Community. The most obvious way to reach uniform administrative practice is to harmonize the conditions for recognizing national administrative acts.¹¹ The objective connection between approximation of laws and harmonization of administrative practice is undeniable, particularly in the area of product safety law. Admittedly, such coordination is enormously complicated in practice, especially since, as M. Seidel rightly stresses¹², it affects the political "quality" of the integration process: it means an "approfondissement" of the integration process, legal reservations against which are not justified, but can at the same time be perceived by Member States as a threat to their sovereignty and by national administrations as a restriction on their powers.

1.1. Excursus into integration theory

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

1.2.1. The economic theory of federalism and the opposing economic interests in connection with Europeanization of product safety law

The economic theory of federalism seeks, in its normative part, to answer the question of what regulatory tasks can more rationally ("economically") be handled centrally and which better at a decentralized level. "Positive" federalism theory then tries to identify the factors that actually determine the actions of those involved in politics, and bases recommendations for political strategies on this positive analysis.¹³ Normative arguments for centralization (federalization) of regulatory activities apply where the costs and advantages of a measure cannot be confined to a particular jurisdiction ("externalities"), where regulatory differences can be strategically exploited by economic actors, starting off a regulatory "race to the bottom" ("prisoner's dilemma"), where duplication of

102 EWGV, in: Grabitz, E. (Ed.), *Kommentar zum EWG-Vertrag*, München 1986, Art. 100, para. 54; *Seidel, M.*, Grundsätzliche Regelungsprobleme bei der Verwirklichung des Gemeinsamen Marktes, in: Magiera, S. (Ed.), *Entwicklungsperspektiven der Europäischen Gemeinschaft*, Berlin 1985, 169 (170 et seq.); *Bruha, Th./Kindermann, H.*, Rechtssetzung in der Europäischen Gemeinschaft, *Zeitschrift für Gesetzgebung* 1 (1986), 293 et seq., 302 et seq.

¹¹ Cf. *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin/Bonn/München 1972, 156 et seq.

¹² *Seidel, M.*, Grundsätzliche Regelungsprobleme bei der Verwirklichung des Gemeinsamen Marktes, in: Magiera, S. (Ed.), *Entwicklungsperspektiven der Europäischen Gemeinschaft*, Berlin 1985, 169 et seq.

¹³ From the extensive literature, see *Rose-Ackerman, S.*, Does Federalism Matter? Political Choice in a Federal Republic, *J. of Political Economy* 89 (1981), 152 et seq.; *Noam, E.*, The Choice of Governmental Level of Regulation, *Kyklos* 35 (1982), 278 et seq.; *Mashaw, J.L./Rose-Ackerman, S.*, Federalism and Regulation, in: The Urban Institute, *The Reagan Regulatory Strategy*, Washington, D.C. 1984, 111 et seq.; *Fix, M.*, Transferring Regulatory Authority to the States, in: The Urban Institute, *The Reagan Regulatory Strategy*, Washington, D.C. 1984, 153 et seq.

administrative tasks (e.g. in the area of research) causes superfluous costs (“diseconomies of scale”), where the scale advantages of uniform regulation outweigh the chances of innovative product design and where federalization weakens the influence of interest groups.¹⁴ While such normative considerations can, *cum grano salis*, be transferred to the European situation notwithstanding the institutional differences between the Community and the US, this is much less true of the positive analysis. The current federalism debate presupposes an already economically integrated market, a parliamentary democratic constitution for the “central government” and the existence of a federal administration with a wide range of tasks. It is on this institutional framework that the assumptions about interests and about the behaviour of industry, unions, consumers and State and federal political actors are based, which in turn underlie hypotheses about the chances for a federal take-over of regulatory tasks from individual States or about the – at present more topical¹⁵ – efforts at decentralization. The Community situation differs from the US one in several respects. This is true firstly as regards the process of political opinion-forming and decision-making. Political actors, who are according to the assumptions of economic theory oriented either to the expectations of a particular clientele (“constituency politics”), or to more general regulatory attitudes and programmes (“electoral politics”) lose part of their possibilities of self-presentation and influence, which are guaranteed only nationally, if they involve themselves in dealing with regulatory task at European level.¹⁶ Likewise different are the interests and influence possibilities of European business, which has a degree of integration comparable with the US in only a few areas and therefore finds it enormously harder to develop a uniform position on uniformization of product safety requirements. The two aspects mentioned are also connected with the different underlying assumptions of American federalism and of European integration. Explanations for the emergence of American federalism largely relate to situations concerning the introduction of new regulations or their generalization, whereas the Community as a rule finds itself facing already firmly established regulations that tend to differ in nature and intensity.¹⁷

The differences between the American and European situations mentioned make it hard to transfer “positive” theorems of federalism theory. They do not, however, *a priori* preclude their adaptation to the specific conditions of European integration. For the area of environment policy, which is a related one to the issue of Europeanizing product safety law, E. Reh binder and R. Stewart¹⁸ have tried just that. In the model they use as the basis for

¹⁴ *Mashaw, J.L./Rose-Ackerman, S.*, Federalism and Regulation, in: The Urban Institute, The Reagan Regulatory Strategy, Washington, D.C. 1984, 115 et seq.

¹⁵ *Fix, M.*, Transferring Regulatory Authority to the States, in: The Urban Institute. The Reagan Regulatory Strategy, Washington, D.C. 1984, 153 et seq.

¹⁶ For more details see *Pelkmans, J.*, The Assignment of Public Functions in Economic Integration, JCMS 21 (1982), 97 et seq., 116 et seq.; *idem*, Market Integration in the European Community, Den Haag/Boston/Lancaster 1984, 173 et seq. This fits the thesis developed by *Scharpf, F.W.*, in 1985 that willingness to convey powers of action to the Community was opposed by Member States’ governments “own institutional interests” (Die Politikverflechtungs-Fälle: Europäische Integration und deutscher Föderalismus im Vergleich, PVS 26 (1985), 323 et seq.)

¹⁷ Cf. *Heller, Th./Pelkmans, J.*, The Federal Economy: Law and Economic Integration and the Positive State: The U.S.A. and Europe Compared in an Economic Perspective, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), Integration Through Law. Europe and the American Federal Experience, vol. 1, book 1, Berlin/New York 1986, 245 et seq., esp. 397 et seq.; also *Slot, P.*, Technical and Administrative Obstacles to Trade in the EEC, Leyden 1975, 153. *Scharpf, F.W.*, Die Politikverflechtungs-Fälle: Europäische Integration und deutscher Föderalismus im Vergleich, PVS 26 (1985), 323 et seq., 34 et seq.) calls the Community relationships with Member States a case of “policy overlap” that is nearer to German federalism than to the American model.

¹⁸ *Rehbinder, E./Stewart, R.* Environmental Protection Policy, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.),

their analysis of the integration process, they use the Nation State as the sole political actors. For the integration policy behaviour of the States they assume on the one hand identification with the interests of the domestic economy and on the other a loyalty towards protective standards applying in their own legal system. This hypothesis says that faced with a Europeanization of legal standards the States will weigh up its advantages and drawbacks for the competitive position of their own industries, but that they cannot simply make compromises arrived domestically between economic interests and interests in social protection available. For so-called product regulation,¹⁹ the interest position for “protection States” and “risk States”²⁰ looks like this: as long as the protection States can exclude imports from risk States using Art. 36 EEC, the chances for harmonization are good. The protection States will support it if the production costs caused by their domestic standards are higher, setting up different production lines would be uneconomic and they can see opportunities on the foreign markets; the risk States will agree to the tightening up of standards where they expect advantages from access to markets in the protection States; finally, for pure “import States” the decision depends only on their own political calculations of the costs and benefits of a raised level of protection. Admittedly, the initial position changes where and to the extent that the restrictions of Art. 36 EEC have been lifted in favour of the principle of free market access in the protection State and/or products from the risk State merely need to be specially marked. On such conditions, a risk State has in principle no longer any reason to agree to the tightening up of product regulations.

E. Rehbinder and R. Stewart themselves stress the limits to the explanatory capacity of their model.²¹ These limits arise firstly from the complexity of the economic interest situation. These interests are as a rule not even homogeneous within the economy of a single Member State. The effects of a harmonization measure on firms involved in each case depend on the internationalization of the economy, the size of the domestic market, their own competitive position, the costs involved in changing their output and expectations of the economic prospects – and it may, as the example of the car industry shows, even pay to exploit different product standards to seal off regional sub-markets and set up a sectorally differentiated price policy.²² But not only the complexity of economic interests but also the “intrinsic logic” of political opinion-forming processes makes it hard to develop general hypotheses. In their negotiations at European level States need not concentrate on a particular product regulation, but can try to purchase gains in one sector through

Integration Through Law. Europe and the American Experience, vol. 2, Berlin/New York 1985, 9 et seq.; *Rehbinder, E./Stewart, R.* also apply their model as a starting point for analysing the US federal system; in the revisions of the model this necessitates (op. cit., 177 et seq., 277 et seq.), however, they do not go any further into the state of American federalism theory.

¹⁹ *Rehbinder, E./Stewart, R.*, like the American literature on the whole (cf. only *Mashaw, J.L./Rose-Ackerman, S.*, Federalism and Regulation, in: The Urban Institute, The Reagan Regulatory Strategy, Washington, D.C. 1984, 129 et seq.), distinguish between product regulations and process regulations (the third usual category of industrial safety regulations can be left out of consideration of environment protection). For *Rehbinder, E./Stewart, R.*, product regulation involves only the product requirements necessitated on grounds of environment protection; but regulations motivated by consumer policy grounds also belong to this category. By “process regulations” are meant environmental provisions relating to production processes; they may be neglected for our purposes.

²⁰ Since they are dealing with environmental protection, *Rehbinder, E./Stewart, R.* talk about “environment States” and “polluted States”.

²¹ *Rehbinder, E./Stewart, R.*, Environmental Protection Policy, in: Cappelletti, M./Secombe, M./Weiler, J. (eds.), Integration Through Law. Europe and the American Experience, vol. 2, Berlin/New York 1985, 322 et seq.

²² Cf. *Joerges, Ch./Hiller, E./Holzscheck, K./Micklitz, H.W.*, Vertriebspraktiken im Automobilersatzteilsektor, Frankfurt/Bern/New York 1985, 345 et seq. and 2.4.1 and 2.4.3 below.

concessions in another. Political objectives within a government are just as unhomogeneous as business interests. The conduct of negotiations often depends on what department is responsible, how “high” the political value of the subject involved is rated and what influences the negotiators are exposed to. Awareness that a new regulation can in any case not be strictly monitored may facilitate acceptance. And last but not least, in agreements on product regulations the object is often a uniformization of regulatory methods, and therefore wishes for change have to deal with administrative inertia even apart from their political and ideological content.

In the meantime, integration of the viewpoints referred to a differentiated economic model that nevertheless has explanatory power has not been achieved.²³ But this finding is not a merely negative statement. What it means is instead that especially bearing the economic interest situation and political-opinion forming processes in the Community in mind, uniform behaviour patterns cannot be expected and the chances of carrying broadly based integration strategies through are slight. Instead, having regard to the economic and political starting conditions, fragmentary advance and pragmatism in negotiation, adapted to the area concerned, are to be expected. In other words, the difficult conditions of integration policy encourage an incrementalism which has a tendency to obstruct the development of a coherent European safety law.²⁴

1.2.2. Legal structures and political decision-making processes

Political research into integration has an ambitious past to look back on. Looking back, it is evident that the expectation of functionalism, and of neo-functionalism too, that the political integration process would involve objective, functional interdependences and gradually extend to increasingly wider sectors, underestimated the contingencies of political developments.²⁵ The centre of interest in political research on Europe therefore shifted to the Community’s decision-making structures²⁶ and analyses of individual policy areas.²⁷ A repeatedly confirmed finding of political analyses is, as Joseph Weiler has shown,²⁸ in

²³ This is *Rehbinder/Stewart’s* very surprising conclusion, given the nature of their presentation of the economic integration model as the starting point for their considerations: Environmental Protection Policy, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), *Integration Through Law. Europe and the American Experience*, vol. 2, Berlin/New York 1985, 315.

²⁴ For the – relative – success of traditional harmonization policy and on the heterogeneity of “vertical” and unsuccessfulness of “horizontal” European safety regulations see 2.7, 2.8 and 3 below.

²⁵ See the literature survey in *Behrens, P.*, *Integrationstheorie - Internationale wirtschaftliche Integration als Gegenstand politologischer, ökonomischer und juristischer Forschung*, *RabelsZ* 45 (1981), 8 et seq. and the references in *Rehbinder, E./Stewart, R.*, *Environmental Protection Policy*, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), *Integration Through Law. Europe and the American Experience*, vol. 2, Berlin/New York 1985, 316 et seq. and *Krislov, S./Ehlermann, C.-D./ Weiler, J.*, *The Potential Organs and the Decision-Making Process in the United States and the European Community*, in: Cappelletti, M./Seccombe, M./Weiler, J.(eds.), *Integration Through Law, Europe und the American Federal Experience*, vol. 1, book 2, Berlin/New York 1986, 3 et seq., 6 et seq.

²⁶ As an example, see *Bulmer, S.*, *Domestic Politics and European Policy Making*, *JCMSt* 32 (1983), 349 et seq.

²⁷ Specifically on the programme for eliminating technical barriers to trade, see *Dashwood, A.*, *Hastening Slowly: The Community’s Path Towards Harmonization*, in: Wallace, H./Wallace, W./Webb, C. (eds.), *Policy Making in the European Community*, 2nd ed., London 1983, 177 et seq., and on environment policy the references in *Rehbinder, E./Stewart, R.*, *Environmental Protection Policy*, in: Cappelletti, M./Seccombe, M./Weiler, J. (eds.), *Integration Through Law. Europe and the American Experience*, vol. 2, Berlin/New York 1985, 265 et seq.

²⁸ *Weiler, J.*, *The Community System. The Dual Character of Supranationalism*, *Yearbook of European Law* 1 (1981), 267 et seq; *idem*, *Community, Member States and European Integration: Is the Law Relevant?*, *JCMSt* 31 (1982), 39 et seq.; *idem*, *Supranational Law and the Supranational System: Legal Structure and Political Process in*

striking contradiction with the developments of the Community's legal structure: whereas in political decision-making processes a replacement of supranational elements by intergovernmental bargaining processes is unmistakable, the supranational legal structures have developed into a European constitution which finds its expression specifically in the doctrines of direct effect, primacy and prior effect of European directives. The originality of Weiler's analysis is that he sees the presumed contradictions between the patterns of political decision-making and the legal structures as two characteristics of the European integration process that mutually determine each other. The discrepancies between the political and legal structures have not acted centrifugally, but created an equilibrium situation that maintains the Community.²⁹

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

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

The ways technical barriers to trade manifest themselves and their consequences will first be gone into (2.1.), then the general programme for their removal (2.2.) and the methods of harmonization it provides (2.3.). Analysis of selected directives and proposals for directives

the European Community, Ph.D. Dissertation (European University Institute, Florence) 1982.

²⁹ *Scharpf's* 1985 characterization of the relationship between the Community and the Member States as a case of "policy overlap" very largely coincides with *Weiler's* analysis. Like *Weiler*, *Scharpf* too explains the unanimity rule on the basis of Member States' situations (and their governments "own institutional interests", see fn. 16 above). However, *Scharpf* is interested only in the political conditions, which, despite the unanimity rule, impose constraints towards consensus formation at European level (he mentions specially the density of regulation already attained, which excludes exit options and continually makes follow-up decisions unavoidable, *Scharpf, F.W.*, *Die Politikverflechtungs-Fälle: Europäische Integration und deutscher Föderalismus im Vergleich*, PVS 26 (1985), 323 et seq., 337 et seq.), whereas *Weiler's* analysis centres around the relationship between the conditions for political agreement and the Community's legal structures.

³⁰ Fn. 10 in 1.1 above.

³¹ Cf. *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 251, Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

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

2.1. Manifestations of technical barriers to trade, and their consequences

Following abolition of customs duties and quantitative restrictions between Member States, technical barriers to trade³² attracted public attention. The General Programme to remove technical barriers to trade in goods was aimed at removing obstacles arising from differences in legal and administrative provisions in Member States of relevance to the quality of products.

For many goods, there exist special requirements on production, import, marketing or use that may, because of their differing nature from one country to another, hamper free movement of goods. Among these are all administrative measures by Member State authorities that ensure compliance with these regulations. Of particular importance economically are the numerous, often very detailed, intercompany technical standards, aimed at both raising safety in using technical products and especially at rationalizing business processes and increasing productivity through mass production. Technical legal regulations often have decades of tradition behind them; it is often not easy to separate the objective of protecting particular legal values on grounds of public safety and order from attempts to fence off markets. This is, however, not the place to go into attempts by particular industries to take advantage of industrial property rights and technical standards to fence off their markets and avoid price and quality competition.³³

Technical standards and trade regulations for a product that differ from one country to another may also hamper trade without having been deliberately created for protectionist reasons, but instead out of a desire to create uniformity, raise the safety of appliances or protect consumers, the environment or workers. Those particularly affected are foreign suppliers without enough economic strength to produce separate product lines to meet each set of national requirements. They are alleged to have their international competitiveness notably cramped, in particular through insufficient possibility of exploiting the advantages

³² In general on technical barriers to trade see esp. *Nunnenkamp, P.*, Technische Handelshemmnisse - Formen, Effekte und Harmonisierungsbestrebungen, *Außenwirtschaft* 38 (1983), 373 et seq.; *Page S.A.B.*, The Revival of Protectionism and its Consequences for Europe, *JCMSt* 20 (1981), 17 et seq. and *Slot, P.*, Technical and Administrative Obstacles to Trade in the EEC, Leyden 1975. See also OECD, *Consumer Policy and International Trade*, Paris 1986.

³³ Cf. *Pelkmans, J.*, Market Integration in the European Community, Den Haag/Boston/Lancaster 1984, 175-8. For the pharmaceutical industry see *Stuyck, J.*, Product Differentiation in Terms of Packaging, Presentation, Advertising, Trade Marks, etc. An Assessment of the Legal Situation Regarding Pharmaceuticals and Certain Other Consumer Goods, Antwerpen/Boston/London/Frankfurt 1983 and *Reich, N.*, Parallelimporte von Arzneimitteln nach dem Recht der Europäischen Gemeinschaft, *NJW* 1984, 2000 et seq.; for car spare parts cf. *Joerges, Ch./Hiller, E./Holschek, K./ Micklitz, H.W.*, Vertriebspraktiken im Automobilersatzteilsektor, Frankfurt/Bern/New York 1985.

of larger-scale mass production. Additionally, the price effects of non-tariff barriers and therefore the degree of protection for domestic suppliers are allegedly harder to estimate than for customs duties. The impenetrability and complexity of technical barriers to trade and the possibility of changing them rapidly are said to create considerable information costs and to hinder planning of production and investment. Domestic industrial firms are said to unavoidably have considerable influence on the shaping of technical standards.

A number of additional factors influence the extent to which differing technical standards and trade regulations lead to economic problems.³⁴ Flexibility in adaptation is greater for expanding markets and in the early stage of a product cycle. Differences in standards hit harder the more costly it is to alter a product. Suppliers with the highest turnover on given markets play more or less the role of “standards leaders”.

The economic effects of protectionist measures in general, including duties, levies, quotas and technical or administrative barriers to trade³⁵ have frequently been discussed.³⁶ Among those repeatedly mentioned are higher prices to consumers, restriction of quality competition, loss of economic adaptiveness and medium- to long-term dangers to jobs protected in the short term by protectionist measures.

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

The General Programme of 28 May 1969 for the elimination of technical barriers to trade which result from disparities between the provisions laid down by law, regulation or administrative action in Member States³⁷ aims at harmonizing national regulations that have to be met in marketing and using particular important selected products, through directives under Art. 100 EEC. The mutual recognition of national regulations was out of the question as a procedure in principle, since it can be considered only for cases where regulations are more or less equivalent, particularly as regards objects of legal protection and costs of production.³⁸ The programme consists of four resolutions and a Gentlemen’s Agreement.

³⁴ Cf. *Gröner, H.*, Umweltschutzbedingte Produktnormen als nichttarifäres Handelshemmnis, in: Gutzler, H. (Ed.), *Umweltpolitik und Wettbewerb*, Baden-Baden 1981, 143 et seq., 153-155.

³⁵ On 6 November 1978, in a letter to Member State governments, the Commission complained of the rising protectionism within the Community, mentioning as major examples the following restrictive measures that led principally to complaints at restrictions on free movement of goods:

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

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

³⁶ More recently, see OECD, *Consumer Policy and International Trade*, Paris 1986; OECD, *Costs and Benefits of Protection*, Paris 1985; *Lorenz, D.*, Liberale Handelspolitik versus Protektionismus - Das Schutzargument im Lichte neuer Entwicklungen der Außenhandelstheorie, in: *Neuer Protektionismus in der Weltwirtschaft und EG-Handelspolitik*, Jahreskolloquium 1984 des Arbeitskreises Europäische Integration, Baden-Baden 1985, 9 et seq.; *Schultz, S.*, Der neue Protektionismus - Merkmale, Erscheinungsformen und Wirkungen im industriellen Bereich, in: *Neuer Protektionismus in der Weltwirtschaft und EG-Handelspolitik*, Jahreskolloquium 1984 des Arbeitskreises Europäische Integration, Baden-Baden 1985, 35 et seq.; *Gutowski, A.*, (Ed.), *Der neue Protektionismus*, Hamburg 1984; also *Hasenpflug, H.*, *Nicht-tarifäre Handelshemmnisse. Formen, Wirkungen und wirtschaftspolitische Beurteilung*, Hamburg 1977.

³⁷ OJ C 76, 17 June 1969, 1.

³⁸ For detail on law approximation as a procedure for eliminating technical barriers to trade, see *Seidel, M.*, *Die*

Two Council resolutions contain a *timetable* for eliminating barriers to trade in the industrial sector³⁹ and in foodstuffs⁴⁰; the latter area will not be gone into any further below. According to this very ambitious but utterly unrealistic programme, the Council was to decide on 114 harmonization directives for industrial products in three six-monthly periods between mid-1969 and the end of 1970⁴¹; the decisions were each to be taken within six months of presentation of the draft. Regulations were planned above all for motor vehicles, agricultural tractors and machinery, measuring instruments, electrical machinery and equipment, pressure vessels, fertilizers, dangerous preparations, lifting equipment and lifts and other miscellaneous goods.

A further resolution⁴² provided for the *mutual recognition of national inspections*, which are conditions for the marketing of many products. The principle of mutual recognition, applies, however, only in so far as national rules for marketing are equivalent or have been rendered so by Community harmonization measures.

To *adapt directives to technical progress*, two simplified procedures are provided for:⁴³ in cases of particular importance, the Council will decide on a Commission proposal, by qualified majority. Otherwise the Commission will be empowered to enact amending provisions, but in doing so must call in a committee on which Member States are represented. Should the committee support the Commission's proposed regulation by qualified majority, then it may be enacted; otherwise the Council will decide by qualified majority within three months. Should it not do so, the Commission itself may decide.⁴⁴

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

The Council resolution of 21 May 1973⁴⁷ supplemented the General Programme for the elimination of technical barriers to trade in industrial products, because of the intensification of internal Community trade and the increasingly more pressing (or

Problematik der Angleichung der Sicherheitsvorschriften für Betriebsmittel in der EWG, NJW 1969, 957 et seq.; *idem* Die Beseitigung der technischen Handelshemmnisse, in: Angleichung des Rechts der Wirtschaft in Europa, Kölne Schriften zum Europarecht, vol. 11, Köln/Berlin/Bonn/München 1971, 733 et seq.

³⁹ OJ C 76, 17 June 1969, 1.

⁴⁰ OJ C 76, 17 June 1969, 5.

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

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

⁴³ OJ C 76, 17 June 1969, 8.

⁴⁴ For details on this see *Zachmann, K.*, Das Ausschlußverfahren zur Anpassung der EG-Richtlinie an den technischen Fortschritt, DIN-Mitt. 56 (1977), 293 et seq.

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

⁴⁶ Directive 83/189/EEC of 28 March 1983, OJ L 109, 26 April 1983, 8. For details see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

⁴⁷ OJ C 38, 5 June 1973, 1.

publicized) problems connected with environment and health protection, adding such sectors as motorcycles, packaging, toys, equipment and machinery for building sites, petrol additives and fuel oil. Finally, in its resolution of 17 December 1973 on industrial policy⁴⁸ the Council presented a thoroughly revised timetable for the elimination of technical barriers to trade in industrial product. More than 100 additional directives were to be adopted in the four-year period up to the end of 1977.⁴⁹

2.3. The methods of harmonization provided for in the General Programme

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

- a) “Complete” solution: in this procedure, also known as *total harmonization*, national regulations are completely replaced by Community ones. In complete harmonization, only products that fully conform with directives may be marketed in the Community. The full harmonization approach means the biggest loss of sovereignty for Member States, places particular requirements on political consensus formation and requires comprehensive detailed regulations at Community level, but it means the furthest-reaching harmonization. This approach has so far been chosen, apart from the foodstuffs area, in directives on hazardous substances and preparations, cosmetics and medicaments.
- b) “Alternative solution”: this procedure, better known as *optional harmonization*,⁵¹ leaves up to suppliers the freedom to choose between orienting their products to national law or to the Community-law requirements. Products meeting the Community requirements cannot be refused access to the market in any Member State. This approach, the prevailing one in the area of industrial products, does ease political agreement, but has drawbacks from the viewpoints of harmonization and also of product safety. The number of recognized rules is increased, so that it is harder to compare what is offered. Where safety standards differ, a manufacturer that avoids higher standards which in general mean higher costs, can secure competitive advantages.⁵² Optional harmonization thus tends, given significant differences in safety and a sizeable volume of cross-border trade in the products concerned, to promote a reduction in the level of safety. The reasons adduced in favour of the Community regulation in cases of optional harmonization –

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

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

⁵⁰ E.P. Doc. 15/68, VI, reprinted in BT-Drs. V/2743, 22 March 1968, 13 et seq.; for details on this see *Slot, P.*, Technical and Administrative Obstacles to Trade in the EEC, Leyden 1975, 80-89; cf. also *Lauwaars, R.H.*, The Model Directive on Technical Harmonization, EUI-Colloquim Papers, DOC IUE 169/86 (COL 82), 2 et seq. Also very instructive on total and optional harmonization is Part B of the agreement between CEN and the Commission on cooperation between CEN and the Commission of the European Communities as regards the Commission's work in the area of harmonization of different technical legislation of Member States and the application of harmonized Community directives, DIN-Mitt. 53 (1974), 200.

⁵¹ *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 79 and *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980; *Seidel, M.*, Die Beseitigung der technischen Handelshemmnisse, in: Angleichung des Rechts der Wirtschaft in Europa, Köln Schriften zum Europarecht, vol. 11, Köln/Berlin/Bonn/München 1971, 733 et seq., 742 et seq.; *Eiden, C.H.*, Die Rechtsangleichung gem. Art. 100 des EWG-Vertrages, Berlin 1984, 61 et seq.

⁵² On this see *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 79 and *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 45.

longer manufacturing series, better use of output, greater rationalization – do not apply to many small- and medium-size firms that market their goods only domestically. In favour of optional harmonization, it may be said that Member States have more leeway to take national peculiarities into account, and that national adaptation to technical progress is possible without amending the directive while nevertheless, because the market is opened up for products that meet the Community standard, consumer choice is increased and competition among manufacturers stepped up.

- c) “Reference to technical standards”: On this method, directives refer, in order to specify safety requirements, to harmonized technical standards worked out by standardization bodies.⁵³ This method of harmonization has so far been applied only in the low-voltage Directive,⁵⁴ though the European Parliament⁵⁵ and the ESC⁵⁶ had picked it out in their opinions on the draft general programme as the most promising solution. The Economic and Social Committee stressed that reference to technical standards was particularly suitable for sectors where there was experience in harmonizing technical standards, and offered the biggest possibilities for elastic adaptation to the demands of technical progress and for the introduction of new technical ideas. Almost pre-empting the new approach to technical harmonization and standards, the ESC says:

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

The legal literature had fleshed out this method of harmonization by the early 70s, fairly clearly setting forth the outline of the new approach.⁵⁸ While sliding reference to the successively newest version of a standard was rejected as inadmissible,⁵⁹ as being a

⁵³ For more details on reference to technical standards see the chapter on Germany (*Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3. OOO), the discussion of the Low Voltage Directive (*Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>) and that of the new approach (*Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3 Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>).

⁵⁴ Directive 73/23/EEC, OJ L 77, 26 March 1973, 29. The draft of the Low Voltage Directive was presented by the Commission on 12 June 1968 (OJ C 91, 13 September 1968, 19), only a few weeks after the General Programme for eliminating technical barriers to trade, which it had proposed to the Council on 7 March 1968 (OJ C 48, 16 May 1968, 24). On the Low Voltage Directive see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

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

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

⁵⁷ Op. cit. – Cf. also *Seidel, M.*, Die Beseitigung der technischen Handelshemmnisse, in: *Angleichung des Rechts der Wirtschaft in Europa*, Köln Schriften zum Europarecht, vol. 11, Köln/Berlin/Bonn/München 1971, 733 et seq., 745 et seq.

⁵⁸ Cf. esp. *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 104-118, 143-160. More recently, see also *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 82-91.

⁵⁹ *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen

conveying of law-making powers to privately organized standardization organizations, the preferred model was for directives only to prescribe compliance with basic requirements, with technical standards merely being cited to determine these basic requirements. Accordingly, manufacturers are not bounded by the technical standards, but can show compliance with the basic requirements otherwise than by meeting standards.⁶⁰ The directive should lay down the general requirements in a general clause embodying a rebuttable presumption that these requirements have been met by anyone who has complied with a particular technical standard in its latest version.⁶¹ Where a manufacturer departs from the general clause, the onus is on him to prove that the generally formulated requirements of the general clause, which alone is *legally* binding, have nevertheless been met. Conversely, the authorities have the onus of showing that though technical standards referred to have been complied with, basic requirements set out in the general clause are not met.⁶² In order that technical standards should not remain “merely a non-binding indication and aid to interpretation showing the specific content of the basic requirements in the individual case”⁶³ thereby bringing the success of harmonization into question, Member States should “take all necessary measures to ensure that administrative authorities recognize goods as meeting the basic requirements if they comply with the standards decided on by the Commission following consultation of the Standards Testing Committee”.⁶⁴

While its proponents presented as an advantage that standardization in this procedure in principle remains a matter for industry,⁶⁵ critics adduce constitutional reservations, complaining that in view of the existential importance of environmental and consumer protection for our society today, a regulation can be tenable that leads to industrial organizations’ wide-ranging powers of decision in determining the level of safety in manufacturing and utilizing technical products.⁶⁶

- d) “Conditional mutual recognition of tests”: Where harmonization fails because Member States hold to their own safety regulations, products from one Member State should be exportable to another on the following two conditions:
- that the exported product complies with manufacturing provisions applying in the country of import;
 - that competent authorities in the country of export carry out checks according to the methods applying in the country of import⁶⁷.

Wirtschaftsgemeinschaft, Berlin 1973, 111 et seq.; *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 72-75. *Röhling* rejects any form of reference to technical standards as unacceptable. (*Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 112-132)

⁶⁰ *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 115 et seq.

⁶¹ In the formulation by *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 82-91.

⁶² Cf. *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980, 88.

⁶³ *Starkowski, R.*, Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 116.

⁶⁴ Op. cit., 151.

⁶⁵ Op. cit., 152.

⁶⁶ *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 114.

⁶⁷ BT-Drs. V/2743, 14.

- e) "Mutual recognition of tests": Here checks carried out in one Member State are *automatically* recognized as valid by all Member States. This solution can be considered where in a given branch of industry there is very far reaching correspondence between technical and administrative regulations in force, so that prior harmonization of national legal provisions seems superfluous.⁶⁸

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

2.4.1. General survey

The programme to eliminate technical barriers to trade has to date been converted into law in only fragmentary fashion and with considerable delays⁶⁹. Table 1 gives a picture of the number of Commission proposals for directives, Council directives and Commission directives on adjustment to technical progress for the years from 1968 to 1986.

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

<i>Year</i>	<i>Commission proposals</i>		<i>Council directives</i>		<i>Difference between cols. 2 and 4</i>	<i>Commission adaptation directives^{II}</i>	
	abs. (1)	cum. (2)	abs. (3)	cum. (4)		abs. (6)	cum. (7)
1968	18	18	-	18	18	-	-
1969	13	31	1	1	30	-	-
1970	5	36	9	10	26	-	-
1971	7	43	11	21	22	-	-
1972	12	55	3	24	31	-	-
1973	12	67	11	35	32	1	1
1974	33	100	14	49	51	2	3
1975	15	115	12	61	54	1	4

⁶⁸ This solution should not be confused with the resolution on mutual recognition of tests (see the explanations in fn. 42 above) since there harmonization of legal provisions and equivalence of tests is assumed. Generally on the mutual recognition of certification and tests see *Seidel* who stresses that trust in other Member States' administrative actions is justified only where certification and tests are equivalent. (*Seidel, M.*, Die Beseitigung der technischen Handelshemmnisse, in: Angleichung des Rechts der Wirtschaft in Europa, Kölne Schriften zum Europarecht, vol. 11, Köln/Berlin/Bonn/München 1971, 733 et seq., 748-750); see also *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 142-160.

⁶⁹ On this see also *Pelkmans, J./Vollebergh, M.*, The Traditional Approach to Technical Harmonization: Accomplishments and Deficiencies, in: Pelkmans, J./Vanhenkelen, M. (eds.), Coming to Grips with the Internal Market, Maastricht 1986, 9 et seq.

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

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

1976	13	128	21	82	46	4	8
1977	6	134	15	97	37	1	9
1978	11	145	15	112	33	5	14
1979	8	153	11	123	30	9	23
1980	25	178	10	133	45	1	24
1981	22	200	7	140	60	5	29
1982	5	205	7	147	58	14	43
1983	6	211	8	155	56	7	50
1984	8	219	16	171	48	7	57
1985	5	224	4	175	49	12	69
1986	11	235	19	194	41	5	74

By the end of 1986 the Council had adopted 194 directives on the adaptation of Member States' legal and administrative provisions on trade in industrial products. Since 1974 it has had average "arrears" of some 50 Commission proposals for directives. By the end of 1970 only 10 directives had been adopted. According to the original 1969 Programme, the figure should have been over 100. It was not till June 1978 that adoption of the hundredth directive on elimination of technical barriers to trade in industrial products could be hailed.⁷⁰ The directives adopted as a "package" in September 1984⁷¹ had on average been before the Council for decision for nine and a half years.

Most directives contain minutely technically detailed regulations⁷² and do not differ significantly in content from technical standards. This entails long preparatory periods, considerable possibilities of influence by the expert industrial circles involved, overloading the high-level political decision-making procedure in the Council with technical details and a pressing compulsion to adapt the directives to technical progress (or sometimes to advances in knowledge). By the end of 1986 the Commission had already adopted 74 directives on adaptation to technical progress.⁷³

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

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

<i>Area</i>	<i>Council</i>	<i>Commission</i>
-------------	----------------	-------------------

⁷⁰ Bull. EG 6-1978, 7 et seq.

⁷¹ OJ L 300, 19 November 1984, 1-187.

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

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

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

	<i>directives</i>	<i>adaptation directives</i>
<i>Vehicles</i>	58	23
<i>Chemical products</i> ^{II}	33	16 ^{III}
<i>Measuring devices</i>	30	10
<i>Agricultural tractors</i>	24	2
<i>Construction machines and appliances</i>	11	5
<i>Electrical appliances</i>	8	5
<i>Textile products</i>	5	1
<i>Pressure vessels</i>	5	0
<i>Motorcycles</i>	4	0
<i>Lifts and lifting devices</i>	3	2
<i>Cosmetics</i>	3	10 ^{IV}
<i>Miscellaneous</i>	8	0
TOTAL	192	74

Of 192 directives, 145 are in the four areas of motor vehicles, agricultural and forestry vehicles, measuring devices and chemical products. The first three sectors mentioned are particularly favourable for approximation of laws. In the area of measuring devices, the Community can in its harmonization work call upon far-reaching international agreement regarding and measurement.⁷⁴ In the vehicle sector, it can largely refer back to technical directives from the ECE in Geneva - the Economic Commission for Europe, a United Nations regional organization. This means not only a saving of time for the Commission but a possibility for European vehicle manufacturers to offer their products on a market wider than just the Community without costly special adaptations.⁷⁵

2.4.2. Total harmonization – directives on hazardous substances

A special place is occupied by the directives that follow the principle of total harmonization, on hazardous substances and also on fertilizers and cosmetics. By contrast with most of the directives, they concern areas not normally regulated by technical standards. The directives in the area of classification, packaging and labelling of dangerous substances and preparations⁷⁶

^{II} Hazardous substances, lacquers and paints, medicaments, planthealth products, fertilizers, detergents; except for cosmetics.

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

^{IV} Including four Commission directives on methods of analysis for verifying the composition of cosmetics.

⁷⁴ Cf. *Lukes, R.*, Die Zulässigkeit nationaler Rechtsvorschriften für technische Gegenstände und Stoffe nach Gemeinschaftsrecht, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 194 et seq., 196.

⁷⁵ Cf. *Henssler, H.*, Einige Aspekte des Abbaus technischer Handelshemmnisse im Kraftfahrzeugsektor, in: *Götz, V./Rauschnig, D./Zieger, G.* (Ed.), *Umweltschutz und internationale Wirtschaft*, Köln/Berlin/Bonn/München 1972, 173 et seq., 175 et seq.; *Lukes, R.*, Die Zulässigkeit nationaler Rechtsvorschriften für technische Gegenstände und Stoffe nach Gemeinschaftsrecht, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 194 et seq., 196.

⁷⁶ Starting with Council Directive 67/548/EEC of 27 June 1967 on the classification, packaging and marking of

were based on preliminary work done by the ILO, the Council of Europe and the OECD but not yet reflected in national legislation. Here the Community has given Member States a lead.⁷⁷ This is true particularly of the sixth amendment to Directive 67/548/EEC⁷⁸, which is the basis for chemicals laws in the Member States.

In contrast, the regulations restricting marketing and use of certain dangerous substances and preparations,⁷⁹ much more detail in application, almost always go back to initiatives by Member States barring dangerous substances on grounds of health protection or public safety, or introducing restrictions on their use. Quite clearly, these are ad hoc regulations, though made with considerable delays.⁸⁰ The underlying Directive 76/779 contains no criteria for including substances in the annex to the Directive. If hazards appear (and bans or restrictions are issued in Member States), a unanimous Council resolution, on a Commission proposal and following opinions from the European Parliament and the Economic and Social Committee, must be adopted, though speedy mandatory measures would really be necessary to ward off severe health risks.⁸¹ A ban issued by one Member State and a Commission proposal for a ban give manufacturers and traders enough time to sell off the dangerous substances quickly in countries that have not yet applied the protective clause.⁸²

2.4.3. Optional harmonization – Directives in the automotive sector

The most detailed regulations at Community level are for the vehicle market,⁸³ which is also of paramount economic importance for internal trade.⁸⁴ All directives are based on the

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

⁷⁷ Cf. *Braun, F.*, Nationale Rechtsvorschriften für Anlagen, Geräte und Stoffe in der Gemeinschaft, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 176 et seq., 179 et seq.

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

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

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

⁸¹ Accordingly, the Commission undertook a new advance in 1983, in order to make amendments to the annex possible using the Regulatory Committee Procedure, COM (83) 556 final of 26 September 1983. In the meantime, with strengthening of the Commission's implementing powers by the Single European Act (for details see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 4.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>) it has proposed the even quicker and more flexible procedure of the Advisory Committee, which provides only for informative consultation of Member States' representatives, COM (87) 39 final of 30 January 1987. Cf. also the corresponding proposal for a directive on the classification, packaging and labeling of hazardous preparations, OJ C 41, 19 February 1987, 17 et seq. See also *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 239-241.

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

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

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

principle of optional harmonization. In 1982, the Commission checked the extent to which Member States had bindingly prescribed compliance with Community standards domestically and to which manufacturers voluntarily followed the Community provisions.⁸⁵ The finding was that except in Italy, where Community standards are mandatory, and in The Netherlands, manufacturers still largely have a choice between domestic provisions and Community directives. Manufacturers largely apply about half the directives, especially those on environment protection and active safety. Otherwise, they apparently prefer national provisions. The Community standards have practically no effect where technical specifications are not legally regulated by national standards. Accordingly, manufacturers are only partly exploiting the oft-proclaimed advantages of longer production runs. The differing national provisions are apparently advantageous for dividing up and fencing off markets and preventing parallel imports.⁸⁶

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

The delays are attributed to the so-called Third Country problem;⁸⁸ which being interpreted signifies the fear that goods from third countries might take advantage of EEC type approval to secure easier access to the common market. In the Council, even after adoption of 15 directives long blocked because of this problem⁸⁹ and after adoption of the regulation on the strengthening of the common commercial policy and in particular on protection against prohibited commercial practices,⁹⁰ it was not possible, on the same day, to overcome differences of opinion in the vehicle sector as to whether third-country products should secure access to the Community type-approval systems introduced by the harmonization directives. By its international undertakings, the Community is obliged where reciprocity is guaranteed to give imported products equally favourable treatment with Community products.⁹¹

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

⁸⁶ In general on market delimitation in the automotive sector see *Joerges, Ch./Hiller, E./Holzscheck, K./Micklitz, H.W.*, *Vertriebspraktiken im Automobilersatzteilektor*, Frankfurt/Bern/New York 1985. See also the report on behalf of the Committee for industry, currency and industrial policy on the automotive industry of the European Communities of 8 December 1986, EP-Doc A2-171, 86, point 7. This product differentiation despite optional harmonization should be separated from the "Third country problem" which arises particularly clearly in the automotive sector; on this see the references in fn. 88-91 below.

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

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

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

⁹⁰ OJ L 252, 20 September 1984, 1.

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

While harmonization work in the vehicle sector was initially aimed mainly at advantages of long production runs, for a long time now other aspects have been coming to therefore, since new production techniques allow flexible adaptation to different technical requirements. These aspects include noise levels, air pollution, fuel consumption and passenger safety. On 30 March 1984 the European Parliament adopted a resolution introducing a programme of Community measures to promote road traffic safety, and also called for an integrated programme including measures regarding vehicle construction and equipment, road construction and road signs and road traffic regulations.⁹² Among proposals are the obligatory equipping of all private cars with laminated windscreens, headrest and fog glass, anti-lock braking systems in all lorries and other safety devices, and the laying down of minimum standards on a large number of safety aspects, including quality of car tyres and rigidity of the passenger compartment, mandatory technical checks by independent test centres, and measures to remove vehicles with design faults from the market. It is clear that the originally largely commercially oriented policy to guarantee free movement of goods is gradually being overshadowed by an integrated policy on road traffic safety and aspects of environment and consumer protection, even though the Council still remains closed to the idea of an integrated programme to promote road traffic safety.⁹³

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

<i>Regulatory object of directive</i>	<i>Date of proposal^I</i>	<i>Date of Adoption of directive (planned)^{II}</i>	<i>Date of Adoption of directive (achieved)</i>	<i>Lag in months^{III}</i>
<i>Type approval</i>	7/68	1/70	2/70	1
<i>Admissible noise level and exhaust equipment</i>	7/68	1/70	2/70	1
<i>Measures against air pollution by petrol engines</i>	10/69	7/70	3/70	0
<i>Containers for liquid fuel and its safe transport</i>	7/68	1/70	3/70	3
<i>Licence plate fixtures</i>	un-published	1/70	3/70	3

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

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

^I Sometimes a directive was preceded by several drafts; the date here is that of the last draft.

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

^{III} Figures in brackets indicate the lag behind the original date in the 1969 General Programme.

<i>Steering equipment</i>	2/69	7/70	6/70	0
<i>Doors</i>	12/68	7/70	7/70	1
<i>Equipment for sound- level marking</i>	8/68	1/70	7/70	7
<i>Rear-view mirrors</i>	8/68	1/70	3/71	14
<i>Brakes</i>	12/68	7/70	7/71	13
<i>Radio interference removal for petrol-driven vehicles</i>	un-published	1/70	6/72	29
<i>Measures against the emission of pollutants by diesel engines</i>	12/71	7/70	8/72	25
<i>Internal equipment</i>	12/71	7/74 (7/70)	12/73	0 (42)
<i>Security equipment against unauthorized use</i>	7/72	New	12/73	-
<i>Behaviour of steering gear in collisions</i>	9/72	7/74 (7/70)	6/74	0 (48)
<i>Strength and anchoring of seats</i>	5/73	1/75	7/74	0
<i>Projecting edges</i>	12/73	1/75	9/74	0
<i>Reverse gears and speedometers</i>	8/74	1/76 (1/70)	6/75	0 (66)
<i>Number plates</i>	8/74	1/76	12/75	0
<i>Safety belt anchorage</i>	8/74	1/76	12/75	0
<i>Lighting and signalling installations</i>	6/74	1/75 (1/70)	7/76	19 (79)
<i>Rear lamps</i>	1/74	1/75	7/76	19
<i>Contour lights, side lights, rear lights and brakelights</i>	12/74	1/75	7/76	19
<i>Direction indicators</i>	12/74	1/75 (1/70)	7/76	19 (79)
<i>Rear-numberplate lighting</i>	12/74	1/75	7/76	19
<i>Main-beam and dipped headlights</i>	12/74	1/75	7/76	19
<i>Fog lights</i>	12/73	1/75	7/76	19
<i>Towing equipment</i>	12/74	1/77 (7/70)	5/77	5 (83)
<i>Rear fog lamps</i>	12/76	1/75	6/77	30
<i>Reversing lights</i>	12/76	1/77	6/77	6
<i>Parking lights</i>	12/76	1/77	6/77	6
<i>Safety belts and restraints</i>	12/74	1/76	6/77	18
<i>Driver view field</i>	12/75	1/77 (1/70)	9/77	9 (93)
<i>Marking of starting equipment, telltale lights and indications</i>	11/76	1/77	12/77	12
<i>Defrosting and demisting equipment for glass surfaces</i>	11/76	1/77	12/77	12
<i>Windscreen wipers and washers</i>	11/76	1/77 (1/70)	12/77	12 (96)
<i>Internal heating</i>	12/76	1/77	6/78	18
<i>Wheel covers</i>	12/76	1/77	6/78	18
<i>Headrests</i>	12/74	1/76	10/78	34
<i>Fuel consumption</i>	1/80	New	12/80	-
<i>Engine performance</i>	1/80	New	12/80	-

<i>Safety windscreens</i> ^{IV}	9/71	7/74 (7/70)	not yet adopted	-
<i>Pneumatic tyres</i> ^V	12/76	1/76 (7/70)	not yet adopted	-
<i>Weights and dimensions of particular vehicles</i> ^{VI}	12/76	1/77	not yet adopted	-

2.5. Safeguard clauses – Response to Member States reservations

A number of directives contain safeguard clauses⁹⁴ allowing Member States to intervene should despite compliance with Community standards a hazardous situation suddenly arise calling for immediate action. Such safeguard clauses are necessitate to the extent that the Community provisions lay down rules for marketing and handling products Community-wide that take from Member States the right to appeal to Art. 36 EEC and take measures to protect the health and safety of persons.⁹⁵ The relevant provision usually runs:

(1) If a Member State has good grounds for believing that an item of equipment represents a hazard to safety or health, although satisfying the requirements of this Directive and the relevant separate Directives, it may temporarily prohibit the marketing and use of that item of equipment in its territory or make them subject to special conditions. It shall immediately inform the other Member States and the Commission thereof, giving the reasons for its decision.

(2) The Commission shall consult the other Member States concerned within six weeks, then give its opinion without delay and take the appropriate steps.

*(3) If the Commission considers that technical modifications to the Directive or the relevant separate Directives are necessary, such modifications shall be adopted, by either the Commission or the Council (...); in this event the Member State which has taken the safeguard measures may retain them until such modifications come into force.*⁹⁶

^{IV} Commission proposal of 20 September 1971, OJ C 119, 16 November 1972, 21.

^V Commission proposal of 31 December 1976, OJ C 37, 14 February 1977, 1.

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

⁹⁴ A comprehensive survey is given by Krämer, L., EWG-Verbraucherrecht, Baden-Baden 1985, para. 242-246.

⁹⁵ This is the ECJ's consistent case law; for more details on this see Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, Hanse Law Review (HanseLR) 2010, 289, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁹⁶ Thus Art. 20 of Directive 84/532/EEC (common provisions on machines and appliances for use in construction), OJ L 300, 10 November 1984, 111. Identical or similar formulations can be found in Art. 21 of Directive 84/530/EEC (common provisions for gas installations), OJ L 300, 19 November 1984, 95; Art. 24 of Directive 84/528/EEC (provisions for lifting and conveying equipment), OJ L 300, 19 November 1984, 72; Art. 23 of the sixth amendment to Directive 67/548/EEC on the classification, packaging and marking of hazardous substances, OJ L 259, 15 October 1979, 10; Art. 10 of Directive 78/631/EEC (pesticides), OJ L 206, 29 July 1978, 13; Art. 12 of Directive 75/117/EEC (electrical equipment for use in explosive atmospheres), OJ L 462, 30 January 1976, 45; Art. 12 of Directive 76/768/EEC (cosmetics), OJ L 262, 27 September 1976, 169. Member States' temporary measures are confined to a maximum duration of 6 months, unless the Commission finds adjustment of the Directive necessary, as with Art. 9 of

The safeguard clauses are thus designed for cases where after a Community provision has been enacted a hitherto unknowable or unrecognized hazard appears. The Member State, as responsible for the safety and health of its citizens and for other objects of legal protection, is allowed to take the necessary quick action. At the same time, the notification of the Commission and other Member States and the involvement of the Committees to adapt the relevant directives to technical progress is aimed at securing amendment of the latter to cope with the hazard situation and bring Community law up to date with the hazardous situation that has emerged, so as to avoid obstacles to trade. A Member State that reacts more critically than others to hazardous situations can thus provide an impetus for the tightening up of Community standards. However, it must supply justification for temporary departure from Community law, and accept the fact that its intervention may not be lastingly confirmed by the Commission or in the committee procedure. Where despite contrary decision by the relevant Community bodies a Member State maintains its special measures, the Commission may bring it before the ECJ for infringement of Art. 30 EEC. Those who doubt that exercise of national police intervention powers is accessible to subsequent coordination through a binding Community procedure⁹⁷ are refuted by the fact that Member States, in agreeing to the directive, have also agreed to verification of any further-reaching protective measures that may be necessary in accordance with the procedure laid down in the safeguard clause, so as to maintain the stock of Community law already arrived at. There is much to suggest that this question of principle remains hidden in the background and that the safeguard clause procedure can be used pragmatically in a political negotiating process to adapt Community law to new hazard situations.

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

With its proposal for a directive on construction products,⁹⁸ the Commission embarked in 1978 on the since abandoned attempt to develop an alternative to the cumbersome policy of harmonization through vertical, product-related Council directives.⁹⁹ A framework directive

Directive 73/173/EEC (solvents), OJ L 189, 11 July 1973, 7; Art. 9 of Directive 74/150/EEC (licences for agricultural and forestry tractors), OJ L 84, 28 March 1974, 10; Art. 9 of Directive 70/156/EEC (licences for motor vehicles), OJ L 42, 23 February 1970, 1. On the protection clause in the Low-Voltage Directive, see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2.3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁹⁷ Thus *Seidel, M.*, Die Beseitigung der technischen Handelshemmnisse, in: *Angleichung des Rechts der Wirtschaft in Europa*, Köln Schriften zum Europarecht, vol. 11, Köln/Berlin/Bonn/München 1971, 733 et seq., 754.

⁹⁸ OJ C 308, 23 December 1978, 3. For details on the basic problems raised by this proposal for a directive see *Grabitz, E.*, Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften, Berlin 1980. See also *Bub, H.*, Internationale Harmonisierung im Bauwesen, *DIN-Mitt.* 58 (1979), 669 et seq.; *idem*, Normung und Zulassung der Baustoffe und Bauteile aus europäischer Sicht. Güteanforderungen, Prüfungen, Kennzeichnung, Güteüberwachung, *DIN-Mitt.* 61 (1982), 63 et seq.; *Blachère, G.*, Normung und gesetzliche Bestimmungen auf dem Gebiet des Bauwesens, sofern sie die nationalen, europäischen und internationalen Normen betreffen, *DIN-Mitt.* 61 (1982), 284 et seq.; *Lindemann, G./Reihlen, H./Seyfert, H.J.*, Bauvorschriften im Wandel. Technische Bestimmungen - Baunormen und EG-Richtlinien, *DIN-Mitt.* 63 (1984), 179 et seq.; *Börner, B.*, Die Harmonisierung der Regeln der Technik in der EWG, in: *Studien zum deutschen und europäischen Wirtschaftsrecht*, vol. 1, Köln/Bonn/München 1973, 231 et seq., 245 et seq., was already proposing basic directives from the Council with implementing directives from the Commission as a transitional solution until European standardization bodies are in a position to produce recognized European standards.

⁹⁹ The 1978 proposal has since been replaced by the proposal for a directive on construction products following the

from the Council was to contain common definitions for all construction products and lay down general rules on the form of implementing directives; these implementing directives were, pursuant to Art. 155 EEC, fourth indent, to be enacted by the Commission, with feedback through a committee made up of Member State representatives (regulatory committee procedure). Implementing directives were to lay down more specific requirements for individual products or types of product, and guarantee that buildings produced using materials complying with the implementing directives would meet the generally recognized requirements, including safety requirements. These requirements relate to reliability, safety, hygiene, comfort and economy of buildings, and to specific properties of products.¹⁰⁰ Conformity of construction products with implementing directives was to be verified and established through an EEC type approval certificate (Art. 8-12), an EEC type examination certificate (Art. 13-17), EEC type conformity checks (Art. 18-21) or through EEC self-certification (Art. 22-26); procedures were to be laid down in the individual implementing directives.¹⁰¹

The reasons for the failure of this ambitious project are not entirely clear. Besides Member States' reservations at such far-reaching transfer of powers to the Commission¹⁰² and Parliament's mistrust of the excessive influence for Government representatives in the committee procedure,¹⁰³ rejection of central bureaucratic detailed regulation by industrial circles involved was not that also important, as well as special characteristics of the construction industry which, by comparison with other technical areas, is relatively localized and displays special local and regional traditions. As well as these political reasons, there were legal reservations regarding the proposed delegation arrangements, since all essential basic decisions were not left to the Council, but would be given over to the Commission without its having any specific, detailed framework.¹⁰⁴ It is noteworthy that the Commission did not seek to follow the model of the Low-Voltage Directive,¹⁰⁵ but wanted to lay down the specific products standards itself in implementing directives. Here, however, it can always

principles of the new approach to technical harmonization and standards, OJ C 93, 6 April 1987, 1. On this proposal see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

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

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

¹⁰² Cf. *Braun, F.*, Nationale Rechtsvorschriften für Anlagen, Geräte und Stoffe in der Gemeinschaft, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 176 et seq., 181.

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

¹⁰⁴ In detail, see *Grabitz, E.*, *Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften*, Berlin 1980, 48-55.

¹⁰⁵ As for instance e.g. *Bub, H.*, *Internationale Harmonisierung im Bauwesen*, DIN-Mitt.58 (1979), 669 et seq., 673-675.

point to the fact, by contrast with electrical sector, only a few construction products are covered by international or European technical standards.¹⁰⁶

Quite apart from the failed attempt to secure far-reaching powers to issue implementing directives, the Commission is working on bringing out Eurocodes for the construction industry, a set of European regulations based on result of work by major international technical and scientific associations for the design, dimensioning and construction of buildings and engineering structures.¹⁰⁷ By contrast with the failed proposal for a directive on construction products of 1978, the 1987 proposal for a directive on construction products, with its strengthening of standardization committees and of the procedure of conformity certification, implies above all a strengthening of industrial circles involved. Because of the comprehensive competence of the proposed Standing Committee for the construction industry, the position of Member States ought if anything to be strengthened, even though from the purely legal point of view they can assert their influence only through an advisory committee rather than a regulatory committee.

2.7. Criticisms of the classical concept of integration

Along the road towards the new approach to technical harmonization and standards, criticism of the classical Community concept of integration were an important step. As described, the Community has for years pursued the aim of eliminating barriers to free movement of goods through vertical directives laying down uniform standards for particular products or groups of products, thereby providing firms with a broader area of action and at the same time creating uniform protective standards. By Art. 36 EEC, individual Member States may, as long as they comply with the principle of proportionality and non-discrimination, take measures to protect the health and life of people, and other objects of legal protection. These measures may have restrictive effects on free movement of goods. Harmonization directives pursuant to Art 100 EEC were intended to “communitarize” these protective policies, since if they continued to be on a national basis market integration might be hampered. Along these lines the Community, in its endeavour to create the internal market, pursued a highly fragmented product safety policy, structurally subordinated to internal market policy.¹⁰⁸ The criticisms of the classical integration concept¹⁰⁹ related mainly to the following points:

- The results of harmonization work concerned only a few areas of industry¹¹⁰ and had in some sectors remained practically insignificant, considering the enormous number of

¹⁰⁶ Cf. *Lindemann, G./Reihlen, H./Seyfert, H.J.*, *Bauvorschriften im Wandel. Technische Bestimmungen - Baunormen und EG-Richtlinien*, DIN-Mitt. 63 (1984), 179 et seq., 184 et seq. See also point 11 of the explanatory statement on a proposal for a directive on construction products, COM (86) 756 final/3 of 17 February 1987, 6, according to which 15% of national draft standards reported under the information directive on standards and technical regulations related to construction products, but only 3% of existing international standards.

¹⁰⁷ For more on this see *Breitschaft, G.*, *EUROCODES für das Bauwesen*, DIN-Mitt. 63 (1984), 136 et seq. In general on European standardization in the construction industry see *Kiehl*, *Der Beitrag der europäischen Normung zur Harmonisierung im Bauwesen in Europa - Stand und Zukunftsaussichten*, DIN-Mitt. 66 (1987), 467 et seq.

¹⁰⁸ On the uneven harmony between internal market and product safety policy cf. *Reich, N.*, *Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften*, Baden-Baden 1987, para. 116.

¹⁰⁹ A first comprehensive criticism can be found in the ESC's opinion on the issue of barriers to movement of goods and harmonization of relevant legal provisions, of 21 November 1979, OJ C 72, 24 March 1980, 8 et seq.; a balance sheet of the criticisms precedes the new approach, COM (85) 19 final of 31 January 1985, 3 et seq.; cf. also *Pelkmans, J./Vollebergh, M.*, *The Traditional Approach to Technical Harmonization: Accomplishments and Deficiencies*, in: *Pelkmans, J./Vanhenkelen, M.* (eds.), *Coming to Grips with the Internal Market*, Maastricht 1986, 9 et seq., 25 - 27.

¹¹⁰ Cf. Table 2 above.

technical regulations and standards in all Member States. For the Federal Republic of Germany, France, Britain and Italy alone, technical standards are estimated to total some 50,000.¹¹¹ In 1984 alone, 1,418 DIN standards¹¹² and 609 British Standards¹¹³ appeared, while in the same year – one of the most successful – the Council, under the programme to eliminate technical barriers to trade, adopted 16 directives and the Commission a further 7 on adaptation to technical progress.¹¹⁴ Clearly, the figures are not simply comparable, since some of the national standards served to take over international or European standards¹¹⁵ and as a rule national standards have, at any rate by comparison with European standards and with the relevant directives, a much narrower area of application.¹¹⁶ It is nevertheless clear that the Community cannot, even if it concentrates on a few industries of particular importance to Community internal trade, keep up with the speed and intensity of regulation in the Member States. This is particularly true where it tries to go into technical, detailed regulations, specific to particular products.

- Even where directives were adopted, they often, as in the automotive sector,¹¹⁷ regulated only particular aspects, whereas other aspects largely continued to get in the way of a genuine internal market.
- The procedure for developing and testing draft directives, and particularly the decision-making procedure, is extremely cumbersome and time-consuming. According to ESC indications,¹¹⁸ it takes more than three years between publication of a draft in the Official Journal and final adoption. The 15 directives adopted by the Council as a “package” on 17 September 1984 had been before it for decision for an average of nine years, much too long a period to be able to respond quickly and flexibly to new needs and to steadily accelerating technological advance. This criticism must of course be qualified by the observation that even at national or European level the conclusion of standardization procedure often takes a considerable time.¹¹⁹ Conversion of directives in Member States takes at least another year and a half, and is often delayed still further.¹²⁰
- The frequently used procedure of optional harmonization, while it facilitates compromise in the Council, is often not enough to bring about a genuine internal market. Here the ESC made the suggestion, apparently never taken up, that optional harmonization solutions should in general be time-limited and be regarded as only a halfway house on

¹¹¹ *Lukes, R.*, Die Zulässigkeit nationaler Rechtsvorschriften für technische Gegenstände und Stoffe nach Gemeinschaftsrecht, in: *Recht und Technik. Rechtliche Regelungen für Anlagen, Geräte und Stoffe im deutschen und im europäischen Recht*, Studienreihe des Bundesministers für Wirtschaft, Nr. 53, Bonn 1985, 194 et seq., 198.

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

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

¹¹⁴ Cf. Table 1 above.

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

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

¹¹⁷ See the comments under 2.4.3 above.

¹¹⁸ OJ C 72, 24 March 1980, 9.

¹¹⁹ According to the procedure for producing DIN standards, some three years go by between an application for standardization and submission of finished DIN standard: *DIN (ed.)*, *Handbuch der Normung*, 5th ed., Berlin/Köln 1981, vol. 1, 2-5.

¹²⁰ See the comments under 2.8 below.

the road to full harmonization, in order to allow certain Member States and manufacturers enough time to adjust gradually.¹²¹

- Only part of the barriers to trade that actually exist can be dealt with by directives, since Art. 100 EEC presupposes that legal or administrative provisions in the area exist in at least one Member State, or that there are plans likely to lead to the creation of a trade barrier. Harmonization of inter-company technical standards by directives is possible only where technical norms are referred to by at least one Member State in legal or administrative provisions.¹²² The Commission summarized the position in 1980 as follows:¹²³

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

- If directives are not confined to setting forth results to be achieved, but bindingly prescribe detailed technical specifications of design, they may hamper technical progress.¹²⁴
- The unanimity requirement of Art. 100 EEC is indivisible, and therefore applies not only to the laying down of basic safety requirements in respect of the protective policies Member States may legitimately pursue under Art. 36 EEC, but also to the regulation of detailed technical requirements. The unanimity requirement is suspended only where adaptation of directives to technical progress has been entrusted to the Commission, in collaboration with a committee of Member State representatives. But it is well known that the attempt to give the Commission the power, pursuant to Art. 155 EEC, fourth indent, to enact implementing regulations failed.¹²⁵ This solution would have meant both gaining time and giving the Council the needed leeway to work out the underlying political principles more clearly. A prominent feature of work in the regulatory committees is the common endeavour of specialists and technicians represented not to let failure to agree in committee leave the decision to politicians and diplomats on the Council with no

¹²¹ OJ C 72, 24 March 1980, 12.

¹²² Langeheine, B., Kommentar zu den Artt. 100 bis 102 EWGV, in: Grabitz, E. (Ed.), Kommentar zum EWG-Vertrag, München 1986, Art. 100, para. 18-23; Starkowski, R., Die Angleichung technischer Rechtsvorschriften und industrieller Normen in der Europäischen Wirtschaftsgemeinschaft, Berlin 1973, 54-56.

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

¹²⁴ Pelkmans, J./Vollebergh, M., The Traditional Approach to Technical Harmonization: Accomplishments and Deficiencies, in: Pelkmans, J./Vanhenkelen, M. (eds.), Coming to Grips with the Internal Market, Maastricht 1986, 9 et seq., 25.

¹²⁵ This is provided for in the draft Directive on construction products, OJ C 308, 23 December 1978, 3; on this cf. the comments under 2.6 above. This solution of delegation was once again suggested by the ESC, OJ C , 24 March 1980, 11.

technical competence. In votes, there is strikingly high proportion of concurring opinions, and in most cases even unanimity.¹²⁶

2.8. Difficulties with conversion into international law

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

Tables 4, 5 and 6 give a picture of the actions for treaty breaches brought by the Commission under Art. 169 EEC¹³⁰. The actions start with a letter to the governments of Member States concerned calling on them to take a position on the non-conversion of a directive in into national law, or else on an alleged breach of the EEC Treaty or of a regulation. The number of such letters grew from 97 in 1978 to 503 in 1985, that is, they quintupled.¹³¹ If the accusation hereupon eliminated, the Commission presents a recent opinion: here the rise was threefold, from 68 in 1979 to 233 in 1985. Whereas on the long-term average six out of ten cases were resolved in the initial clarificatory stage before presentation of the reasoned opinion, in around four out of ten cases the Court of Justice had to be called in because the Member State involved had not complied with the Commission's reasoned opinion. In all procedural stages, some 40% of cases concern the sector of the internal market and industry, i.e. the conversion of directives on elimination of technical barriers to trade or on infringement of free movement

¹²⁶ For details see *Schmitt von Sydow, H.*, *Organe der erweiterten Europäischen Gemeinschaften - Die Kommission*, Baden-Baden 1980, 157-172.

¹²⁷ *Op. cit.*, fn. 123, 14.

¹²⁸ For details see *Ehlermann, C.D.*, *Die Verfolgung von Vertragsverletzungen der Mitgliedstaaten durch die Kommission*, in: *Grewe, W./Rupp, H./Schneider, H.* (Ed.), *Europäische Gerichtsbarkeit und nationale Verfassungsgerichtsbarkeit*, FS zum 70. Geburtstag von Hans Kutscher, Baden-Baden 1981, 135 et seq. On implementation of Community law using the breach of treaty procedure see above all *Krislov, S./Ehlermann, C.D./Weiler, J.*, *The Potential Organs and the Decision-Making Process in the United States and the European Community*, in: *Cappelletti, M./Secombe, M./Weiler, J.* (eds.), *Integration Through Law, Europe and the American Federal Experience*, vol. 1, book 2, Berlin/New York 1986, 3 et seq., 59-88 and *Weiler, J.*, *The European Community System. Legal Structure and Political Process*, Ph.D.Thesis, EUI Florence 1982. See also *Hartley, T.C.*, *The Foundation of European Community Law. An Introduction of the Constitutional and Administrative Law of the European Community*, Oxford 1981, 283-323; *Everling, U.*, *Die Mitgliedstaaten der Europäischen Gemeinschaft vor ihrem Gerichtshof*, EuR 18 (1983), 101 et seq., 105-109, 124; *Evans, A.C.*, *The Enforcement of Article 169 EEC: Commission Discretion*, ELR 4 (1979), 442 et seq.; *Ortlepp B.Ch.*, *Das Vertragsverletzungsverfahren als Instrument zur Sicherung der Legalität im Europäischen Gemeinschaftsrecht*, Baden-Baden 1987.

¹²⁹ See the impressive list of actions for breach that appears monthly in the Community bulletins. It has even happened that the Commission has had to take action simultaneously against all Member States for non-conversion of a particular directive.

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

¹³¹ The decline in 1983 is because in that year the Commission terminated many old actions in order, on grounds of legal security, to replace them by more specific notifications of time-limits.

of goods. Table 5 shows that all Member States have been involved in actions for breach of treaty at all procedural stages, though to differing extents, with Italy, France and Belgium being to the fore as well as Greece, considering its short membership. Table 6 shows that just 70% of actions for breach of treaty relate to faulty conversion or non-conversion of directives.¹³² The breach actions for 1985 relate to 219 different directives, 64 of them laying down standards for industrial products.¹³³ In recent years the number of actions concerning breaches of the EEC Treaty has risen very considerably. Singling out the area of the internal market and industry, these are almost always cases where the Commission complains of breach of Art. 30 et seq. EEC.¹³⁴

Table 4: Actions for breach of treaty begun in the years from 1978 to 1985 by procedural stage, and specifically for questions of the internal market and Industry^I

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

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

<i>Member State</i>	<i>Letters of challenge</i>	<i>Reasoned opinions</i>	<i>Recourse to Court of Justice</i>
Belgium	285	134	62
Germany	173	81	29
Denmark	129	32	11

¹³² In 81% of cases (1978-85) conversion measure had not yet been notified - which mostly indicates that the directive was not yet converted; in 9% measures notified were not in line with a directive, and 10% of actions were brought for faulty application of directives, OJ C 220, 1 September 1986, 16.

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

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

^I Source: Commission, Third Annual Report to the European Parliament on the verification and application of Community Law - 1985, OJ C 220, 1 September 1986, 15.

^{II} Source: Commission, Third Annual Report to the European Parliament on the verification and application of Community law - 1985, OJ C 220, 1 September 1986, 14.

<i>Greece</i> ^{III}	163	63	16
<i>France</i>	421	175	62
<i>Ireland</i>	190	64	21
<i>Italy</i>	420	235	112
<i>Luxembourg</i>	192	66	17
<i>Netherlands</i>	189	66	16
<i>United Kingdom</i>	186	63	19
Total	2,348	979	365

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

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

Between 1978 and 1985 the lion's share of Court of Justice rulings in treaty breach actions, 122 out of 135, were in the Commission's favour, with only 13 in favour of the Member State involved. The Commission boasts the same successful score sheet in the group of cases that is quantitatively by far the largest, and the one of interest here, namely the internal market and industry: 42 cases were decided in its favour, and 5 in favour of Member States involved.¹³⁵

2.9. The GATT agreement on technical barriers to trade

The trade-restricting effect of technical standards is the object of the GATT agreement on technical barriers to trade (the so-called GATT Standards Code) of 12 April 1979, which entered into force on 1 January 1980 and was acceded to by the Community, as well as the most important industrial countries.¹³⁶ The agreement is aimed not only at bringing about a

^{III} Only after 1982.

^{IV} Source: Commission, Third Annual Report to the European Parliament on the verification and application of Community law - 1985, OJ C 220, 1 September 1986, 16.

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

¹³⁶ The GATT agreement on technical barriers to trade is reprinted in OJ L 71, 17 March 1980, 29. By its resolution of 10 December 1979 on the conclusion of multilateral agreements negotiated as part of the trade negotiations from 1973 to 1979, the Council approved the agreement; OJ L 14, 19 January 1980, 36 et seq. To convert the GATT agreement,

universal, equal level of safety, but at eliminating non-tariff barriers to trade caused by different technical requirements or different certification and monitoring procedures. Fair, open application of technical regulations and standards is to be secured through renunciation of mutual discrimination, increased transparency in standard-setting and certification systems, enhanced cooperation in the area of technical standardization and a conciliation procedure. Goods from the territory of one contracting party may not be treated less favourably as regards technical standards and regulation or certification and control procedures than similar goods from another contracting party or goods of domestic origin (Art. 1, 5.1, 7.2). The contracting parties undertake to use relevant international standards, in so far as they exist, as a basis for their own standardization work (Art. 2.2). This may be regarded as a reference to the international state of the art as embodied in international technical standards. However, the technical standards produced by the ISO and IEC are not explicitly mentioned. As with Art. 6 EEC, the contracting parties are allowed wide-ranging autonomy in the area of safety regulations: "... for reasons of national security, to prevent misleading practices, to protect the safety and health of the person, the life and health of animals and plants or the environment, because of significant climatic or other geographical factors or because of fundamental technological problems" (Art. 2.2).

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

their central government offices will recognize test results, conformity certificates or conformity marks from competent offices in the territories of other contracting parties, or accept certificates made out by manufacturers on the territories of other contracting parties even where test methods differ from their own, as long as they are convinced that the methods applied on the territory of the manufacturing contracting party are adequately suitable for determining correspondence with relevant technical regulations and standards.

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

the Council decision of 15 January 1980 on the provisions for laying down and applying technical regulations and standards, OJ L 14, 19 January 1980, 36, was adopted. On the GATT standards code cf. esp. *Middleton, R.W.*, The GATT Standards Code, J. of World Trade Law 14 (1980), 201 et seq. and *Nusbaumer, J.*, The GATT Standards Code in Operation, J. of World Trade Law 18 (1984), 542 et seq.; also *Sweeney, R.E.*, Technical Analysis of the Technical Barriers to Trade Agreement, Law and Policy in International Business 12 (1980), 179 et seq. and *Bourgeois, J.H.J.*, The Tokyo Round Agreements on Technical Barriers and on Government Procurement in International and EEC Perspective, CMLR 19 (1982), 5 et seq., 7-11.

¹³⁷ In the interests of industrialized countries, performance-oriented standards, by comparison with design requirements, impede too speedy transfer of technology. Cf. also *Middleton, R.W.*, The GATT Standards Code, J. of World Trade Law 14 (1980), 201 et seq., 207.

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

3. Approaches to a horizontally oriented product safety policy

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

3.1. Consumer protection and information programmes

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

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

As well as many indications on the promotion of consumer safety and health in harmonizing legal regulations for individual products, the second programme contains a basis for a horizontal product safety policy which – against the background of increasing awareness of the limits to interventionist interference at the policy formation and programme implementation stage¹⁴¹ – stresses informative guidance and the provision of incentives to

¹³⁸ Nusbaumer, J., The GATT Standards Code in Operation, J. of World Trade Law 18 (1984), 542 et seq., 545.

¹³⁹ First and second programmes on consumer protection and information policy (OJ C 92, 25 April 1975, 1; OJ C 133, 3 June 1981, 1). For the survey see Krämer, Verbraucherpolitik, in: Groeben, H./Thiesing/Ehlermann, C.-D. (Ed.), Kommentar zum EWG-Vertrag, vol. 2, 3. Aufl., Baden-Baden 1983, 1631 et seq. An interim report can be found in: Commission of the European Communities, Zehn Jahre Verbraucherpolitik der Gemeinschaft. Ein Beitrag zum "Europa der Bürger", Luxembourg 1985.

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

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

- Community action already requisite and not replaceable by measures by other actors;
- positive effects on Community internal trade;
- contribution to the economic and monetary integration of Europe;

cooperation over intervention. As regards product safety, in part to facilitate identification of priorities, two information systems are proposed: a Community system of information on accidents in connection with the use of particular products, other than in occupational activity or road traffic, and one for rapid exchange of information on hazards arising in the use of consumer goods.¹⁴²

In broad areas, Community consumer protection policy has had results that lag far behind the programmatic intentions. Among reasons given for this are economic decline, the view that consumer protection is part of Member State rather than Community competence, the unanimity requirement for law approximation pursuant to Art. 100 and 235 EEC, and the concentration on vertical harmonization.¹⁴³ For a long time successes were achieved essentially only where product-specific regulations were issued to guarantee free movement of goods that also involved protection of consumer health and safety.¹⁴⁴ The principle of pursuing consumer policy “piggyback” fashion to other policies cannot immediately be transferred to horizontal product safety policy. This is one explanation for why it was only fairly late that the Community developed systems to survey accidents and hazards in handling products, and adopted the product liability directive.

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

- Laying down of binding health and safety standards for manufacturers and suppliers, introduction of a general safety duty;
- cooperative action among national authorities responsible for consumer product safety;
- creation of Community institutions to monitor health and safety hazards arising in using consumer products;
- Community information and education on home and leisure product safety.

-
- adequate staffing and financial resources.

On this see *Bourgoignie, T./ Trubek, D.*, Consumer law, common markets and federalism in Europe and the United States, Berlin, Walter de Gruyter, 1987. On criticism of the production and implementation of directives in connection with the programme on eliminating technical barriers to trade cf. 2.7 above.

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

¹⁴³ Commission communication to the Council on a new impetus to consumer protection policy, COM (85) 314 final of 23 July 1985, points 4-9. For an exhaustive analysis *Bourgoignie, T./ Trubek, D.*, Consumer law, common markets and federalism in Europe and the United States, Berlin, Walter de Gruyter, 1987, 200-219.

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

¹⁴⁵ New impetus (op. cit., fn 143), points 19-28. On the Commission communication, cf. the Council resolution of 23 June 1986, OJ C 167, 5 July 1986, 1 et seq., and *Stellungnahme von BEUC*, BEUC-News, No. 46/1985, 7-10 and *Héloire, M.-Ch.*, Gemeinschaftspolitik in bezug auf die Verbraucher: die Konditionen eines neuen Impulses, Europäische Zeitschrift für Verbraucherrecht 1987, 1 et seq., 7-10.

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

- Amended proposal for a directive on the safety of toys;¹⁴⁶
- directives on products which appearing to be other than they are, endanger the health or safety of consumers;¹⁴⁷
- intensification of cooperation and information exchange with and among national authorities responsible for consumer product safety;¹⁴⁸
- interim report on the system for the rapid exchange of information on dangers arising from the use of consumer products, and initial proposals to extend the system¹⁴⁹;
- extension of the demonstration project on a Community accident information system¹⁵⁰;
- communication to the Council on the integration of consumer policy in the other common policies¹⁵¹;
- communication to the Council on safety of consumers in relation to consumer products¹⁵²;
- communication from the Commission on a Community information and awareness campaign on child safety.¹⁵³

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

Some peculiarities are displayed by the proposal for a framework directive on safety of toys of 1983,¹⁵⁴ which replaced an initial proposal from 1980.¹⁵⁵ The toy industry is characterized by considerable international integration, and markets an extraordinarily varied range of products. Over 60,000 types of toys are at present marketed. These often have very short development periods, so that there is only a very limited time between development and

¹⁴⁶ In OJ C 282, 8 November 1986, 4, on 2 October 1987 the Commission presented another amended version, COM (87) 467 final. See also the observations in 3.2 and in *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

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

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

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

¹⁵⁰ For more on this see 3.3 below.

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

¹⁵² COM (87) 209 final, 8 May 1987.

¹⁵³ COM (87) 211 final, 11 May 1987.

¹⁵⁴ OJ C 203, 29 July 1983, 1-11.

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

marketing of a product, thus intensifying safety problems. Community-wide, some 2 million children per year have accidents when playing with toys.

What is aimed at is total harmonization, since children's health and safety ought not to be protected to different extents in different Member States. Toys must meet a detailed catalogue of safety requirements which – in line with the variety of risks – relate to physical and mechanical risks, flammability, chemical hazards, explosion risks, electrical risks, hygiene and radioactivity (Annex II). If it is not proper use that is to be taken as a basis, but the usual mode of use and foreseeable misuse by children under normal circumstances (Art. 2 (1)).

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

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

According to the 1980 first draft,¹⁵⁷ the technical standards to be observed for individual risks among those mentioned in the general safety objectives should be laid down in guidelines from the Council itself. The proposal for a directive contained general safety objectives and at the same time detailed annexes with Community technical safety standards, on testing of physical and mechanical properties and on the flammability of toys (Annexes V and VI); further directives on common technical standards concerning chemical, toxicological, electrical and other risks were contemplated (Art. 4 (1)). The initial attempt at broad reference to technical standards failed because no satisfactory technical standards for toy safety existed at European level, and because European standardization bodies did not get on with their work quickly enough, and were exposed to criticism from Member States regarding the quality of their work.

The European Parliament in particular wanted reference to technical standards instead of a description of technical characteristics and test methods in the annexes to the directives.¹⁵⁸

The Commission thereupon split its proposal, bringing three proposals before the Council in July 1983 for directives on toy safety. These were a framework directive containing general objectives for toy safety from all viewpoints¹⁵⁹ and two specific implementing directives on the mechanical and physical properties¹⁶⁰ and the inflammability of toys.¹⁶¹ The proposed

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

¹⁵⁷ OJ C 228, 8 September 1980, 10.

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

¹⁵⁹ OJ C 203, 29 July 1983, 1-11.

¹⁶⁰ OJ C 203, 29 July 1983, 12-14.

¹⁶¹ OJ C 203, 29 July 1983, 14-16.

implementing regulations referred – subject to particular amendments – to two European standards. Compliance with them was to be made binding (Art. 4 (1)). Departure was to be possible where toys were manufactured according to new technologies and the general safety regulations were complied with (Art. 5 (1)).

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

3.3. Pilot experiment for a Community accident information system

The first important foundation stone towards the establishment of a horizontal Community product safety policy was the Council's decision of 23 July 1981 on the "implementation of a pilot experiment relating to a Community system of information on accidents involving products outside the spheres of occupational activities and road traffic".¹⁶³ The pilot experiment was carried out from 1 January 1982 onwards for a period of 30 months and was to cover accidents in the home and its immediate proximity requiring medical treatment, and supply information on identification of the accident, its location, products involved, type of accident, type of injury, activity in progress at time of accident, its outcome and arrangements relating to the victim. The intention was to cover 320,000 cases per year, distributed proportionately over Member States according to population, from hospitals, poison emergency centres and doctors. The object was to set up a Community system to collect information on home accidents in order to establish priorities for appropriate proposals to prevent accidents involving products.¹⁶⁴ All the States that have an information system for the systematic assessment of accidents in fact understood the setting up of the system as a building-block towards a more comprehensive product safety policy.¹⁶⁵

The pilot experiment, which left Member States free as to the mode of their participation (Art. 2 (2)), ended with a relative failure,¹⁶⁶ because only Britain, the Netherlands and Denmark

¹⁶² OJ C 282, 8 November 1986, 4 in the amended version of 2 October 1987, COM (87) 467 final. For more details see the comments in *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

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

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

¹⁶⁵ Cf. *OECD*, Data Collection Systems Related to Injuries Involving Consumer Products. Report by the Committee on Consumer Policy, Paris 1978.

¹⁶⁶ The final report on the results of the pilot experiment –published as an annex to the Commission's proposal for a

really took part,¹⁶⁷ while other Member States either did not take part at all¹⁶⁸ or supplied only fragmentary information.¹⁶⁹ Given the extremely tight financing, a representative data survey was never in question. Nevertheless, the pilot experiment did, taking experience acquired in the US with the NEISS into account¹⁷⁰ and including data from Member States that have an appropriate survey system, allow a more or less well founded estimate of home and leisure accidents. It was that there are in the European Community annually more than 30,000 deaths and some 40 million injuries from accidents outside work and traffic. Hospital treatment costs and sickness insurance costs alone amount to more than 30 million ECU annually.

On the basis of experience with the pilot experiment, the Commission once again, on 7 January 1985, proposed the setting up of a “Community system of information on accidents in which consumer products are involved”.¹⁷¹ Despite the favourable opinions from the Economic and Social Committee¹⁷² and the European Parliament¹⁷³, all the Council managed to arrive at with its decision of 22 April 1986 concerning a “demonstration project with a view to introducing a Community system of information on accidents involving consumer products”,¹⁷⁴ was to introduce a further demonstration project, this time limited to 5 years. Basic information is to be obtained from the casualty departments of hospitals selected by Member States in agreement with the Commission; in full operation, between one (Luxembourg) and 13 (Federal Republic of Germany) hospitals per Member State are to be covered. The object is involvement of 90 hospitals and collection of data on 400,000 to 900,000 cases per year, distributed over Member States in proportion to population.¹⁷⁵ In duly justified circumstances, the Commission may accept information from alternative sources of an equivalent value. Member States may also forward *additional* information from poison antidote centres, family doctors, insurance companies or other information sources. The Commission is responsible for assessing data from the whole Community, uniformly coded; it may carry out detailed studies on the most serious and/or most frequent accidents (Art. 4 (1)). A maximum amount of 7 million ECU is provided for implementing the demonstration project for the first three years.¹⁷⁶

Council decision introducing a Community system of information on accidents in which consumer products are involved, COM (84) 735 final, 7 January 1985 – rather complacently glosses over this. But see the report by the European Parliament Committee on the environment, public health and consumer protection on this Commission proposal, PE DOC A 2-183/85, 12 December 1985, p. 10.

¹⁶⁷ That is, the Member States that already had a more or less developed system for monitoring accidents arising in using products; Britain has been running the “Home Accident Surveillance System” (HASS) since 1976 (cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 2.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>), the Netherlands have been doing studies since 1981 for the “Privé Ongevallen Registratie Systeem” (PORS, in force since 1983), and Denmark has since 1978 been involved in Scandinavian projects for surveying home and leisure accidents. A survey is provided by the Commission of the European Communities, Proceedings of the European Symposium on “Product Safety in European Community”, Brussels, 17-18 May 1984, 60-120.

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

¹⁶⁹ Belgium, France, Ireland and Italy.

¹⁷⁰ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁷¹ OJ C 117, 11 May 1985, 4.

¹⁷² OJ C 188, 29 July 1985, 9.

¹⁷³ OJ C 68, 24 March 1986, 189.

¹⁷⁴ OJ L 109, 26 April 1986, 23.

¹⁷⁵ Op. cit., fn. 105, Annex I.

¹⁷⁶ This amount is regarded by the ESC (loc. cit., fn. 103), point 1.7, as utterly inadequate – understandably, since ignoring initial costs one arrives at less than 8 ECU per case, assuming coverage of only 300,000 cases per year on

The Council adopted the Commission's objective of using the information for "promoting improvements in product features, their standards, their proper use by consumers and consumer information and education aimed at preventing accidents"¹⁷⁷, but decided against the proposed documentation and information centre to make all non-confidential information accessible to those interested, which would have been important for achieving its goal,¹⁷⁸ and instead of annual reports called only for a final report.¹⁷⁹ This decisively restricts the possibilities of arriving at any specific action during the again extended test period. The conveying of as speedy as possible information to circles involved, possible withdrawal of goods from the market and in general the urgency of action on an accident information system had been underlined by the European Parliament¹⁸⁰ and the Economic and Social Committee in their opinions, the latter putting it particularly emphatically.¹⁸¹ Indeed, it has to be said that today the link-up between accident surveys and other areas of product safety policy has not yet been achieved. Priority ought to go not to the building-up of the most perfect possible accident information system in the 1990s, but to rapidly converting already available data into Community-wide action before completion of the demonstration project. This would mean making all non-confidential information collected available to interested circles, namely public authorities, manufacturers, traders, users, standardization bodies and the Standing Committee on standardization questions. Funds for the necessary in-depth studies on particularly hazardous areas found should already be made available. It is well known that only a small proportion of home and leisure accidents surveyed have causes attributable to use of consumer products.¹⁸² Such accident-causing products¹⁸³ ought where possible to be recorded, along with any marks they may bear, their condition at the time of the accident and detailed information on how it happened, if improvement of hazardous products on a voluntary basis, or the establishment of suitable safety standards with priority in proven hazard areas or where necessary the publication of warnings or the commencement of recall campaigns is to be achieved. In designing the in-depth studies, representatives of standardization workers should be brought in, to guarantee that information of importance to standard setting is in fact collected.¹⁸⁴

average, for data collection, evaluation and administration.

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

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

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

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

¹⁸¹ Loc. cit., fn. 171, point 1.6.

¹⁸² Even though the much played up finding of the HUK study for the Federal Republic (*Pfundt*, , Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 190 - for more details see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>), that 99% of home and leisure accidents result from more or less serious mistaken actions, is not entirely confirmed by the other information systems.

¹⁸³ Cf. the list drawn up by the HASS of products, articles and characteristics in the household area with most frequent involvement in accidents requiring hospital treatment, described in the Commission's preliminary draft, submitted in May 1986, for a multi-year action programme on consumer safety and on measures to prevent home and leisure accidents (1987-91), 20 et seq. For a comparison see *Pfundt, K.*, Bedeutung und Charakteristik von Heim- und Freizeitunfällen. Ergebnisse von 90.000 Haushaltsbefragungen, Köln 1985, 163-5.

¹⁸⁴ On the above see *Falke, J.*, What Should Be the Content of an E.E.C. General Directive on the Safety of Technical Consumer Goods, BEUC Legal News No. 16 (Nov./Dec. 1986), 16 et seq., 19. On the connection between accident information systems and technical standardization cf. also *Micklitz, H.W.*, Perspectives of a European Directive on Safety of Technical Consumer Goods, Report to the ECRSA Conference on "Product Safety in the European Community", Amsterdam 1984, 17.

The Commission intends as part of its research and development programme for 1987 to 1991 to coordinate and promote in-depth research work on the following priority areas: poisonous substances (especially child-proof seals), articles for children, playground devices and amusement parks, sport articles, do-it-yourself appliances, fire safety and products developed specially for the elderly and the handicapped.¹⁸⁵

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

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

The Community has through its measures to eliminate technical barriers to trade, and still more through the new approach to technical harmonization and standards with its reference to standards and mutual recognition of certificates¹⁸⁷ and also through ECJ case law on freedom of movement of goods – namely that a product legally manufactured and marketed in one Community country must in principle be admitted into all other Community countries, irrespective of contrary national regulations, which cannot be legitimated by Art. 36 EEC¹⁸⁸ – contributed to the marketability of products. However, with a few exceptions,¹⁸⁹ it is not taking any measures for Community-wide intervention against product hazards. Altogether, it is left up to Member States to restrict or prohibit trade in suitable fashion on their territory where serious hazards arise from a product. For products to which Community safety standards apply, they must here use the safeguard clause procedure.¹⁹⁰

The reverse side of the Cassis de Dijon principle, according to which anything legally manufactured and marketed in one Member State may be marketed without restriction everywhere in the Community, leads to the political maxim that a product must be removed from the market in all Member States where serious risk has been found in one Member State,

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

¹⁸⁶ Thus the European Parliament’s proposed amendment to the proposed system for information exchange on product hazards, OJ C 182, 19 July 1982, 116 et seq. (117); it takes up a formulation from the first and second programmes on consumer protection and information. On the legal position in the Community and the individual Member States cf. *Stuyck, J.*, Withdrawal and Recall of Dangerous Products in the EEC, in: Commission of the European Communities Proceedings of the European Symposium on Product Safety in the European Community, Brussels, 17-18 May 1984, 35 et seq.; *Krämer, L.*, Zum Rückruf von Produkten in der Europäischen Gemeinschaft, DAR 1982, 37 et seq.; *idem*, Product Recalls in the European Community, BEUC, Legal News 2/(1982), 2 et seq. On the legal position in the OECD countries and the OECD’s position, cf. *OECD*, Recall Procedures for Unsafe Products Sold to the Public. Report to the Committee on Consumer Policy, Paris 1981.

¹⁸⁷ For details see the comments in *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹⁸⁸ More details in *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹⁸⁹ Cf. the directives restricting the marketing and use of certain hazardous substances and preparations, on which see 2.4.2 above, esp. fn. 79; cf. also the Directive on products which, being other than they appear to be, endanger consumer health and safety, OJ L 192, 11 July 1987, 49. See also *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 239-241.

¹⁹⁰ Cf. 2.5 above.

leading to a recall or a marketing ban.¹⁹¹ Behind this lies the general idea that free movement of goods should benefit only products that do not constitute a hazard to consumer safety or health.¹⁹² If a product could be recalled or banned from the market in one Member State but simultaneously freely marketed in others, this would be incompatible with the objective of creating a Community-wide level of comparable product safety and of guaranteeing free movement of goods only where this does not adversely affect the rightful protection of consumer safety and health.¹⁹³ A common market for products necessitates, if new border controls are not to be introduced because of the possibility of resale and parallel imports, a Community instrument for eliminating hazards arising from products.¹⁹⁴ The Council decision of 2 March 1984 “introducing a Community system for the rapid exchange of information on dangers arising from the use of consumer products”¹⁹⁵ does not aim at introducing this sort of Community follow-up market control. Instead, all Member States are to be informed as rapidly as possible of urgent steps taken by one Member State (if possible only after consulting the producer, distributor or importer)¹⁹⁶ to prevent, restrict or attach particular conditions to the marketing or use on its territory of a product, or product group, because of a serious and immediate risk which that product or product group presents for the health or safety of consumers when used in normal and foreseeable conditions (Art. 1 (1)). The information system applies to all products intended for use by consumers except those intended exclusively for professional use or those subject under other Community instruments to equivalent notification procedures (Art. 2). It has since been clarified that only medical specialties falling under Directives 75/319/EEC and 81/851/EEC and notifications on animal diseases and residues in foodstuffs and fresh meat pursuant to Directives 64/432/EEC

¹⁹¹ For details on this, discussing it as a legal principle, see *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 247-251. See also *Kögler, G./Krämer, L.*, Brauchen wir ein Gesetz über den Rückruf gefährlicher Produkte?, ZRP 1982, 320 et seq.; *Domzalski, Y.*, The Interpol of the Consumer Association, in: Commission of the European Communities, Proceedings of the European Symposium on Product Safety in the European Community, Brussels, 17-18 May 1984, 18 et seq., 28.

¹⁹² The present position is bitterly described by *Domzalski, Y.*, (The Interpol of the Consumer Association, in: Commission of the European Communities, Proceedings of the European Symposium on Product Safety in the European Community, Brussels, 17-18 May 1984, 30) as follows: “If there is one field in which the Community principle of ‘free movement’ is fully implemented, then it is without a doubt that of dangerous products”.

¹⁹³ *Krämer, L.*, (EWG-Verbraucherrecht, Baden-Baden 1985, para. 250) describes examples where recalls remain restricted to individual Member States. On the related problem of banning particular hazardous substances, cf. 2.4.2 above.

¹⁹⁴ For details on this see *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 251, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

¹⁹⁵ OJ L 70, 13 March 1984, 16 et seq. For details on this see *Milas, R.*, La signification juridique de l'institution d'un système communautaire d'échange rapide d'informations sur les dangers découlants de l'utilisation de produits de consommation, RMC 1984, 71 et seq. See also *Pauli, A.*, EG-weites Informationssystem über gefährliche Konsumgüter, PHI 1984, 130 et seq.; *Falke, J.*, What Should Be the Content of an E.E.C. General Directive on the Safety of Technical Consumer Goods, BEUC Legal News No. 16 (Nov./Dec. 1986), 16 et seq., 20 et seq. The European Parliament, which initially took a negative attitude to the Commission proposal (OJ C 172, 13 July 1981, 135 et seq.), indicated its agreement only once the existing informal information exchange among European countries under OECD auspices proved in the case of the denatured Spanish oil, from which hundreds of people died and thousands were poisoned in summer 1981, to be inadequate. See the European Parliament resolutions on the Commission proposal, OJ C 182, 19 July 1982, point 3. In July 1985 the Commission, pursuant to Art. 4 of the decision, decided the details of its implementation, communicated as Annex II to the interim report on the system for the rapid exchange of information on dangers arising from the use of consumer products, COM (86) 562 final, 24 October 1986.

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

and 82/894/EEC have an equivalent Community notification procedure¹⁹⁷. The safeguard clause procedure contained in many product-related directives¹⁹⁸ cannot be regarded as an equivalent notification procedure, as not being aimed at equally rapid exchange of information, as applying only to products complying with the harmonized standards, and finally as being intended, over and above urgent temporary intervention, to lead to revision of the Community standards themselves. The point of the system is rapid exchange of information in the case of serious, immediate danger requiring immediate action, not long-term risks in the case of which the adjustment of product-specific requirements has to be considered.¹⁹⁹ For foodstuffs, which formally fall under the scope of the decision, the informally introduced and, according to report, well-functioning system has been retained and not administratively blended with the non-food area.²⁰⁰

The Commission, under which an advisory committee is set up to implement the decision (Art. 7), is the central relay station for information. It receives notification of emergency measures taken, verifies it and telexes it to the competent authorities of the other Member States (Art. 1 (3)). These have to inform it without delay of any measures they may have taken following receipt of the information; the Commission in turn forwards this information to the competent authorities of other Member States (Art. 3). At the request of authorities supplying the information, it may in justified cases be treated as confidential (Art. 6). By March 1988 the Council is to decide in the light of experience obtained whether to continue or revise the system, initially restricted to 4 years (Art. 8 (2)).

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

One point that should be verified is whether the information exchange should remain confined to sovereign governmental urgent measures. It is likely that voluntary recall or warning campaigns by manufacturers and importers, not infrequently in response to pressure from government agencies²⁰⁴ or consumer organizations or the media, are commoner than governmental marketing bans or restrictions. Government agencies more often act in an advisory capacity rather than with repressive police measures in monitoring the safety of

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

¹⁹⁸ Cf. 2.5 above.

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

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

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

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

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

²⁰⁴ In this connection, cf. the cooperation between manufacturers and the Institute for Research and Standards in Ireland and the Consumer Safety Unit of the Department of Trade and Industry in Britain, and above all the British Code of Practice on action concerning vehicle safety defects.

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

Important supplementary functions or initiatives, correction and information are performed by the efforts of the consumer associations to set up information networks on product hazards.²⁰⁷

All too often the authorities merely react to public pressure or else keep important information from the public or minimize hazardous situations. Since 1981 the BEUC has, with its BEUC Communications, set up a sort of Interpol system for hazardous products. By mid-1985 some 140 different products had been indicated as hazardous, though without distinction as to whether the case concerned a ban or warning from a public body, a voluntary recall by a manufacturer or a comparative test of goods.²⁰⁸ In view of the practice by multinational concerns of selling off hazardous products and chemicals in Third World countries that have been banned in industrialized countries, the worldwide activities of the IOCU (International Organization of Consumers' Unions)²⁰⁹ deserve particular attention.

3.5. The product liability Directive

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

The main lines of the Directive can be summarized as follows.²¹² The manufacturer²¹³ of a product – except for primary agricultural products and game (Art. 2) – is liable, even without

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

²⁰⁶ More details in *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 251, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

²⁰⁷ On the activities of BEUC and IOCU, see *Domzalski, Y.*, The Interpol of the Consumer Association, in: Commission of the European Communities, Proceedings of the European Symposium on Product Safety in the European Community, Brussels, 17-18 May 1984, 18 et seq.

²⁰⁸ Cf. *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 154.

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

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

²¹¹ OJ L 210, 7 August 1985, 29.

²¹² On the product liability directive in general see *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, 54 et seq; *Schmidt-Salzer, J.*, Kommentar EG-Richtlinie Produkthaftung, vol. 1: Deutschland, Heidelberg 1986; *Taschner, H.C.*, Die künftige Produzentenhaftung in Deutschland, 1986; *Hollmann, H.H.*, Die EG-Produkthaftungs-Richtlinie. DB 1985, 238 et seq., 2439 et seq.; *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq.; *Reich, N.*, Product Safety and Product Liability. An Analysis of the EEC Council Directive of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, J. of Consumer Policy 9, (1986), 133 et seq.; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 86-112; *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 320-330; *Schmidt-Salzer, J.*, Die EG-Richtlinie Produkthaftung, BB 1986, 1103 et seq.; *Schlechtriem, P.*, Angleichung der Produkthaftung in der EG. Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25.7.1985, VersR 1986, 1033 et seq.; *Storm, P.M.*, Rechtsangleichung durch die EG-Produkthaftungs Richtlinie?, PHI 1986, 112 et

fault, for damages caused by a defect in the product (Art. 1). The requirements as to proof are strict: the injured person has to prove the damage, the defect and the causal relationship between defect and damage (Art. 4).²¹⁴ Liability cannot be excluded by contractual provision and is unlimited in extent, though Member States may set a limit, of at least 70 million ECU for a given producer, for deaths or personal injuries caused by identical items with the same defect (Art. 16 (1)). The Directive does not apply to property damage in the industrial sphere; even property damage to non-commercial consumers is not compensated for fully, but only above a threshold of 500 ECU (Art. 9 (b)). Member States' provisions relating to non-material damage remain unaffected (Art. 9, last sentence). Manufacturers are not liable where the product complies with mandatory regulations issued by the authorities (Art. 7 (d)). Liability does not extend to development hazards, that is, to defects that could not be discovered given the stage of scientific and technical knowledge at the time of its manufacturing (Art. 7 (e)), unless a Member State explicitly so provides (Art. 15 (1)(b)). Liability is extinguished 10 years after marketing of the specific product causing the damage (Art. 11). Having regard to the latency period of up to 30 years between the action of chemicals and other harmful substances such as asbestos and the manifestation of damage and other after-effects, this is a very significant exclusion of liability, especially since in that sort of situation the conditions for tortious liability ought normally to be absent.

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

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

- a) the presentation of the product;*
- b) the use to which it could reasonably be expected that the product would be put;*
- c) the time when the product was put into circulation.*

Accordingly, defectiveness of a product follows not from its lack of fitness for use, but from a lack of the safety that the public is entitled to expect.²¹⁶ The use of the "informed public" as the reference point provides courts in Member States with considerable leeway in putting the

seq.; *Pauli, A.*, Die EG-Produkthaftpflicht-Richtlinie und ihre Umsetzung in der BR Deutschland, PHI 1986, 153 et seq.; *Lorenz, W.*, Europäische Rechtsangleichung auf dem Gebiet der Produzentenhaftung. Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25. Juli 1985, ZHR 151 (1987), 1 et seq.; *Frietsch, E.*, EG-Richtlinie über Produkthaftung und deren Umsetzung in das deutsche Recht, DIN-Mitt. 66 (1987), 135 et seq.; *Budde, E./Reihlen, H.*, Die EG-Richtlinie zur Produzentenhaftung aus der Sicht der Ersteller technischer Regeln, DIN-Mitt. 66 (1987), 63 et seq.; *Whittaker, S.*, The EEC Directive on Product Liability, Yearbook of European Law 5 (1985), 233 et seq.

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

²¹⁴ This distribution of the onus of proof is called by *Taschner, H.C.*, in Die künftige Produzentenhaftung in Deutschland, NJW 1986, 611 et seq., 613 et seq., a "Magna Charta to protect industry against unjustified claims". For criticism see *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 153 et seq.; *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 328, with references to the potentially considerable effects in the area of regulatory practice outside the Courts.

²¹⁵ Cf. the tenor of Art. 1 of the French law No. 83-660 of 21 July 1983 on consumer safety: "Products and services must under normal conditions of use or any other conditions of use reasonably foreseeable by the expert offer the level of safety that can legitimately be expected, and may not endanger the health of persons". - Cf. the comments in *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

²¹⁶ As the sixth recital in the product liability Directive explicitly says.

norm into practice. “The relevant safety expectations within the meaning of Art. 6 (1)”, conclude Brüggemeier and Reich,²¹⁷ “are precisely what the courts find to be necessary in the individual case in terms of hazard protection, in the interest of protecting the integrity of the citizen of the Common Market”.

Different definitions of safety expectations by courts in individual States cannot be ruled out.²¹⁸ In view of the differing legal traditions and divergent safety philosophies in Member States, any farther-reaching attempt at harmonization would probably be in vain. Consideration should however be given to whether an information system on relevant decisions by national courts²¹⁹ might not restrain excessive divergence. Such an information system would also help with deciding in 1995 on a secure basis of knowledge as to the inclusion of agricultural products and development risks, and as to the liability restrictions for damage resulting from deaths or personal injury (cf. Art. 15 (3) and Art. 16 (2)). Even before this second stage of the harmonization process, it would also provide further indications of product hazards, possibly useful for setting standards.

The directive’s concept of defect is, even though this terminology²²⁰ is not used, oriented towards foreseeable misuse. Accordingly, a manufacturer cannot get off with the defence that the specific use of the product did not correspond with proper use; otherwise, by restrictively defining use he could decide as to the defectiveness of his product and thus as to his own liability. Conversely, not every misuse counts against the manufacturer, but only misuse that could be foreseen.²²¹

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

Among the grounds for exclusion of liability, the provisions of Art. 7 (d) are significant for our purposes. A manufacturer of a defective product that has caused damage can exculpate himself by showing that the defect is due to compliance of the product with mandatory regulations issued by the authorities. This does not include technical standards from private standardization organizations, since they are not issued by the public authorities and compliance is not mandatory. Nor does this change where technical standards have by way of sliding reference, such as under the German Appliances Safety Act or the Low Voltage Directive or the new approach to technical harmonization and standards, been made an integral part of a product safety regulation. In this case all that is legally relevant for the manufacturer are the basic safety requirements, or the general safety obligation of the

²¹⁷ Brüggemeier, G./Reich, N., Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 150.

²¹⁸ Taschner, H.C., Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, Art. 6, para. 5-7, regards the danger of divergent decisions by the courts of different Member States as rather a theoretical one. He bases himself not only on the possibility of preliminary rulings from the ECJ, which favours uniform practice (op. cit., para. 7), but also on an exhaustive list of examples of product defects from Member States’ case law (op. cit., p. 88-96).

²¹⁹ Brüggemeier, G./Reich, N., Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 150 et seq.

²²⁰ Cf. Joerges, C., Product Safety, Product Safety Policy and Product Safety Law, Hanse Law Review (HanseLR) 2010, 117, 2.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

²²¹ Cf. Taschner, H.C., Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, Art. 6, para. 16-18; Schmidt-Salzer, J., Kommentar EG-Richtlinie Produkthaftung, vol. 1: Deutschland, Heidelberg 1986, Art. 6, para. 141-148; Hollmann, H.H., Die EG-Produkthaftungs-Richtlinie. DB 1985, 238 et seq., 2393 et seq.

Appliances Safety Act;²²² compliance with the relevant technical standards merely justifies the rebuttable assumption that the binding safety requirements have been met. In order not to hamper technical progress, when sliding reference is used departure from technical standards is allowed, sometimes explicitly, if the same safety is achieved in other ways.²²³ In this case the onus of proof that products meet the basic safety requirements is on the manufacturer.²²⁴ In other words, compliance with particular European or national technical standards to which the Community or Member State legislator has referred does not allow the manufacturer to apply the exclusion of liability under Art. 7 (d).²²⁵ As an argument for this, Taschner²²⁶ adds:

Manufacturers in a particular industry, normally the authors of such technical standards, may not, by issuing standards that exclude liability, make themselves the masters of their own liability.

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

Positive and negative lists issued by the authorities do not constitute grounds for exclusion from liability under Art. 7 (d). Use of an admissible food additive (in the case of positive lists), or of a non-prohibited additive in the case of cosmetics (in the case of negative lists) is freely open to the manufacturer, but not bindingly prescribed; positive and negative lists are

²²² § 3 (1) (1) GSG.

²²³ Thus § 3 (1) (2) GSG.

²²⁴ On the above cf. the 3rd and 4th basic principles in the new approach to technical harmonization and standards, OJ C 136, 4 June 1985, 1 et seq. (3). See further the comments in *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²²⁵ So also *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, *PHI* 1986, Art. 7, para. 24-35; *Briggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, *WM* 40 (1986), 149 et seq., 152 et seq.; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 95a; *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 325; *Frietsch, E.*, EG-Richtlinie über Produkthaftung und deren Umsetzung in das deutsche Recht, *DIN-Mitt.* 66 (1987), 135 et seq., 137; *Hollmann, H.H.*, Die EG-Produkthaftungs-Richtlinie. DB 1985, 238 et seq., 2394 et seq.; *Schlechtriem, P.*, Angleichung der Produkthaftung in der EG. Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25.7.1985, *VersR* 1986, 1033 et seq., 1036 et seq.; *Lorenz, W.*, Europäische Rechtsangleichung auf dem Gebiet der Produzentenhaftung. Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25. Juli 1985, *ZHR* 151 (1987), 1 et seq., 12. The only divergent view as far as can be seen is from *Budde, E./Reihlen, H.*, Die EG-Richtlinie zur Produzentenhaftung aus der Sicht der Ersteller technischer Regeln, *DIN-Mitt.* 66 (1987), 63 et seq., 66, who however generously overlook the characteristic of the bindingness of standards and *Schmidt-Salzer, J.*, Kommentar EG-Richtlinie Produkthaftung, vol. 1: Deutschland, Heidelberg 1986, para. 99-104, for the case where interpenetration or statutory regulation with various intercompany sets of regulations and administrative practice put manufacturers concerned into a position that is identical with a mandatory statutory norm.

²²⁶ *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, *PHI* 1986, Art. 7, para. 26.

²²⁷ *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, *PHI* 1986, Art. 7, para. 25 and 33.

aimed merely at ruling out the use of particular hazardous substances, but not at bindingly prescribing a particular way of producing a product.²²⁸

According to Art. 7 (e), a manufacturer is not liable where he shows that the “state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered”. The manufacturer cannot exculpate himself by showing that he complied with the state of scientific and technical knowledge.²²⁹ The state of scientific and technical knowledge is in Art. 7 (e) a criterion not for the manufacturer’s action but for the recognizability of the defect. What is decisive is not the individual manufacturer’s actual possibilities of knowledge but whether anyone at all could recognize the defect because the scientific and technical aids objectively existed.²³⁰ Since scientists and technologists exchange information worldwide, it is not the scientific and technical expertise available in the manufacturer’s country that accounts.²³¹ Nor is it relevant whether the science and technology are generally recognized and generally available.²³² Science lives on the methodical encouragement of doubt, and constantly re-defines technical risks; to see it as the administration of presumably established stocks of knowledge is to misunderstand it. Accordingly even potential hazards expressed in outsider views but scientifically justified are to be taken into account.²³³ Before marketing a hazardous substance – development risks are relevant above all for the chemical and pharmaceutical industries – all investigations into the state of science and technology that may provide information to determine side-effects and after-effects are to be employed, or to be taken into account. This does not of course remove the dilemma that the research laboratories of industry, which frequently have a monopoly of knowledge, do not necessarily see their task as being the publication of scientific knowledge and the advancement of science.²³⁴ All in all, this probably means that the product liability directive’s contribution to harmonizing the level of product safety will remain limited.²³⁵ Important questions of liability

²²⁸ Particularly incisive is *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 325; see also *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, 1986, Art. 7, para. 31; *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 153; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 95.

²²⁹ But see *Kretschmer, F.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie, PHI 1986, 34 et seq., 35; by contrast *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, 54 et seq., 55.

²³⁰ *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, Art. 7, para. 44; *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 153.

²³¹ *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, Art. 7, para. 45.

²³² But see *Taschner, H.C.*, Die EG-Richtlinie zur Produzentenhaftung und die deutsche Industrie. Eine Erwiderung, PHI 1986, Art. 7, para. 45. Cf. also *Schmidt-Salzer, J.*, Kommentar EG-Richtlinie Produkthaftung, vol. 1: Deutschland, Heidelberg 1986, Art. 7, para. 133-148, who wishes to go further and focus on whether knowledge of the relevant hazard has become general knowledge among experts in the area concerned. He however takes it that the legal meaning and purpose of Art. 7 (e) is to clarify that in principle tortious liability should continue to apply to development risks (op. cit., Art. 7, para. 139-142).

²³³ Cf. *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 153; *Reich, N.*, Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften, Baden-Baden 1987, para. 106.

²³⁴ Instructive examples in *Krämer, L.*, EWG-Verbraucherrecht, Baden-Baden 1985, para. 326.

²³⁵ On this see *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 155; *Schmidt-Salzer, J.*, Die EG-Richtlinie Produkthaftung, BB 1986, 1103 et seq.; *Schlechtriem, P.*, Angleichung der Produkthaftung in der EG.

law are not harmonized; apart from the non-material damages and development risks already mentioned, and property damage in the commercial area, this also applies to recalls and to product monitoring. This means that the harmonization of product liability aimed at in the Directive has remained largely unachieved; it was regarded as necessary because “existing divergences may distort competition and affect the movement of goods within the Common Market and entail a different degree of protection of the consumer”²³⁶. The exclusion of compensation claims for damage to commercially used property means, in view of the fact that the major proportion of product liability cases handled through insurance companies falls into the commercial sector,²³⁷ that the differing cost burden on manufacturers in individual Member States because of differing liability regulations remains unaffected. In the case of damage to non-commercial users too, the goal of harmonization has been achieved only in embryo. In the case of property damage the injured person will, in order to get around the excluded own risk, which is anything but a petty amount, have recourse to the general law of tort. In the case of personal injury too, in order to assert claims to a solatium, he will likewise have to proceed under the relevant general law of tort.²³⁸ One should not however lose sight of the fact that the product liability directive ought to lead to an improvement in consumer safety especially in countries where today product liability is still regulated on a pure basis of tortious liability, with a corresponding burden of proof on the injured person.

Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25.7.1985, VersR 1986, 1033 et seq., 1043; *Storn P.M.*, Rechtsangleichung durch die EG-Produkthaftungs Richtlinie?, PHI 1986, 112 et seq., 116-218; *Pauli, A.*, Die EG-Produkthaftpflicht-Richtlinie und ihre Umsetzung in der BR Deutschland, PHI 1986, 153 et seq., 154 et seq.; *Lorenz*, Europäische Rechtsangleichung auf dem Gebiet der Produzentenhaftung. Zur Richtlinie des Rates der Europäischen Gemeinschaften vom 25. Juli 1985, ZHR 151 (1987), 1 et seq., 36 et seq. The limited success of the harmonization is explicitly admitted in the second-last recital to the Directive: “Whereas the harmonization resulting from this cannot be total at the present stage but opens the way towards greater harmonization”.

²³⁶ First recital to the Product Liability Directive.

²³⁷ According to a letter from the HUK Association to the Federal Minister of Justice of 15 November 1979, p. 3, 75% of damage involving liability for industrial products is accounted for by claims from industrial contractual partners, mainly because of subsequent damages arising because of defects in preliminary products supplied.

²³⁸ *Brüggemeier, G./Reich, N.*, Die EG-Produkthaftungs-Richtlinie 1985 und ihr Verhältnis zur Produzentenhaftung nach § 823 Abs. 1 BGB, WM 40 (1986), 149 et seq., 155.

The New Approach to Technical Harmonization and Standards, its Preparation through ECJ Case Law on Articles 30, 36 EEC and the Low-Voltage Directive, and the Clarification of its Operating Environment by the Single European Act⁺

*Josef Falke^{**} and Christian Joerges^{*}*

Abstract Deutsch

Der Artikel analysiert die Neuorientierung der Gemeinschaftspolitik zum Aufbau eines Binnenmarktes für Produkte und die neuen Ansätze zu einer horizontalen europäischen Produktsicherheitspolitik. Er beschreibt die wichtigsten Vorläufer der neuen Binnenmarktpolitik, nämlich die Rechtsprechung des EuGH zur Warenverkehrsfreiheit seit dem Urteil im Fall Cassis de Dijon und die Regelungstechnik der Niederspannungsrichtlinie. Im Einzelnen wird dann die Neue Konzeption zur technischen Harmonisierung und Normung analysiert. Dabei beschränkt sich die Gemeinschaft darauf, in ihren Richtlinien grundlegende Sicherheitsanforderungen festzulegen, und überlässt es den Europäischen Normungsorganisationen, diese in technische Spezifikationen zu übertragen, die den Produzenten einen sicheren Weg zur Einhaltung der grundlegenden Sicherheitsanforderungen aufzeigen. Die Einheitliche Europäische Akte hat zu wichtigen Änderungen in den rechtlichen Rahmenbedingungen für die europäische Produktsicherheitspolitik geführt. Die abschließende Überprüfung der Neuen Konzeption an den Vorgaben des EWG-Vertrages behandelt die Einbeziehung der europäischen Normungsorganisationen in den Prozess der gemeinschaftlichen Rechtsetzung und das institutionelle Gleichgewicht zwischen Rat und Kommission.

⁺ This article has originally been published in 1991 as Chapter IV, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 4, EUI Working Paper Law No. 91/13.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 “Sozialregulierung im Welthandel” (social regulation in world trade) in the Collaborative Research Centre 597 “Staatlichkeit im Wandel” (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

Abstract English

The Article analyses the reorientation of Community policy on achieving the internal market for products and the new efforts on a horizontal European product safety policy. It describes the most important precursors of the new internal market policy, namely ECJ case law on Articles 30 and 36 EEC since the Cassis de Dijon judgement, and the regulatory technique of the Low Voltage Directive. It then analyses in detail the new approach to technical harmonisation and standards, whereby the European Community restricts itself in its directives to setting “essential safety requirements”, leaving it to European standardisation bodies to convert these safety requirements into technical specifications. The Single European Act has brought important changes in the legal framework conditions for the European product safety policy. The concluding legal evaluation of the new approach regarding its compatibility with the EEC Treaty is dealing with the inclusion of standardisation organisations in the Community’s law-making process and with the institutional balance between Council and Commission.

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

*Josef Falke^{**} and Christian Joerges^{*}*

Introduction

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

The description of law approximation policy under the general programme to remove technical barriers to trade of 1969² has repeatedly confirmed the notion that internal market policy must always include coverage of product safety policy implications of legal harmonization measures. Let us recall only the spread of escape clauses in relevant Community directives,³ the collapse of initiatives in the area of construction products⁴ the lack of success in efforts to supplement harmonized product standards in the automotive

⁺ This article has originally been published in 1991 as Chapter IV, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 4, EUI Working Paper Law No. 91/13.

^{**} Josef Falke, Professor at the Centre for European Law and Politics at the University of Bremen; co-ordinator (with Christian Joerges) of the Project A1 "Sozialregulierung im Welthandel" (social regulation in world trade) in the Collaborative Research Centre 597 "Staatlichkeit im Wandel" (transformation of the state). He works in the fields of European law, environmental law, labour law, world trade law and legal sociology.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center "Transformation of the State" (SfB597).

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

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

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

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

sector with an integrated safety policy programme⁵ and the general resistance to a “horizontal” European product safety policy.⁶ The problems with internal market policy can clearly not be explained exclusively by the fact that Member States seek to assert their own economic interests in negotiations on legal approximation measures; they point at the same time to the fact that the issue of product safety is felt as a politically sensitive area where political actors resist delegating powers of action and decision to the Community.

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

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

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

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

⁸ Op. cit. (fn. 1), 14 et seq.

⁹ OJ L 77 of 26 March 1973, 29.

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

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

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

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

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

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

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

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

^I Calculated from the European Court reports and communications regarding the ECJ's work.

^{II} Case 7/68, Judgment of 10 December 1968, ECR [1968] 634 et seq.

^{III} Case 8/74, Judgment of 11 July 1974, ECR [1974] 834 et seq./Dassonville.

^{IV} Case 120/78, Judgment of 20 February 1979, ECR [1979] 649 et seq./Cassis de Dijon.

^V Case 178/84, Judgment of 12 March 1987, published in NJW 1987, 1133 et seq./Beer Purity Ordinance.

<i>Plants</i>	3
<i>Other products</i>	12
<i>Not product-specific</i>	9

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

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

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

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

It was first with the "Dassonville" judgment¹¹ that the ECJ undertook a comprehensive definition of the central concept of measures having equivalent effect. This basic rule has been repeated by the Court in large numbers of later judgments, and continues to be the basis for the case law; the Commission too observes it in bringing actions for breach of treaty against Member States. It says:

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

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

¹¹ Case 8/74 judgment of 11 July 1974, ECR [1974] 837/Dassonville. On this see the note by *Willinghausen*, EuR 1975, 322 et seq.

¹² Case 8/74 judgment of 11 July 1974, ECR [1974] 837 (852)/Dassonville.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

With its underlying pro-integration approach, the Court has given this exceptional provision a narrow interpretation in several respects. Among the principles that can be taken as established are: Art. 36 covers only situations of a non-economic nature and cannot be understood as an escape clause against the economic effects of the opening up of markets⁴⁸; the list of objects of protection in Art. 36 EEC is exhaustive and cannot be extended by conclusions from analogy, Art. 36 EEC is not intended to reserve particular fields for the exclusive competence of Member States.⁴⁹

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

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

⁴⁶ Case 249/81 Judgment of 24 November 1982, ECR [1982] 4005 (4021-4023). See the note by *Rabe*, EuR 1983, 341-343.

⁴⁷ For details on the relationship between technical standards and Art. 30 EEC cf. *Leclercq, S.*, Les Articles 30 et suivants CEE et les Procédures de Contrôle prévues par la Directive 83/189/CEE, RMC 1985, 6 et seq., 12-23. Cf. also *Röhling, E.*, Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt, Köln/Berlin-/Bonn/München 1972, 33-55.

⁴⁸ Case 7/61, Judgment of 19 December 1961, ECR [1961] 695/ Commission v. Italy.

⁴⁹ Continuing case law: case 35/76, Judgment 15 December 1976, ECR [1976] 1871 (1886)/Simmenthal; case 5/77, Judgment 5 October 1977, ECR [1977] 1555 (1576)/Tedeschi; case 153/78, Judgment 12 July 1979, ECR [1979] 2555 (2564)/Commission v. Germany.

⁵⁰ Case 5/77, Judgment of 5 October 1977, ECR [1977] 1555 (1576)/Tedeschi; case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 (3388)/Denkavit; case 227/82, Judgment of 30 November 1983, ECR [3883 (3904)/ van Bennekom; case 28/84, Judgment of 3 October 1985, ECR [1985] 3097 (3123)/Mischfuttermittel; case 247/84, Judgment of 10 December 1985, ECR [1985] 3887 (3903 et seq.) Léon Motte. See also *Wägenbaur, R.*, Kommentar zu den Artt. 30 bis 36 EWGV, in: v.d. Groeben, H./v. Boeck, H./Thiesing, J./Ehlermann, C.-D., (Eds.), Kommentar zum EWG-Vertrag, 3. Aufl., Baden-Baden 1983, Art. 36, para. 12-17.

⁵¹ As in case 4/75, Judgment of 8 July 1975, ECR [1975] 843 (859)/Rewe-Zentralfinanz.

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

1.2.2. Proportionality controls by the ECJ

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

⁵² Very instructive on this is case 251/78, Judgment of 8 November 1979, ECR [1979] 3369 (3389 et seq.)/Denkavit, which also contains an indication that the Council should in harmonization use the method of gradual advance covering individual points.

⁵³ Case 272/80 Judgment of 17 December 1981, ECR [1981] 327 (3291)/Biologische Producten. Cf. answer to the Written Question No. 1928/84, OJ C 233, 12 September 1985, 5.

⁵⁴ For details cf. *Gormley, L.W.*, Prohibiting Registrations on Trade within the EEC. The Theory and Application of Articles 30-36 of the EEC Treaty, Amsterdam/New York/Oxford 1985, 154-174.

⁵⁵ Cf. case 73/84, Judgment of 27 March 1985, ECR [1985] 1013 (1025)/Mischfuttermittel.

⁵⁶ Case 104/75, Judgment of 20 May 1976, ECR [1976] 613 (634 et seq.)/de Peijper.

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

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

On the basis of Art. 36 EEC, the Dutch prohibition on nisin as a conservation additive for processed cheese intended for the Dutch market was found to be justified:

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

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

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

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

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

⁶⁰ Case 174/82, Judgment of 14 July 1983, ECR [1983] 2445 (2460-2464)/Sandoz. In an observation on this judgment, *Meier*, RIW 1983, 866, suggests the presumptive rule that in all cases where national provisions on marketability allow exceptions for goods intended for export, there is a presumption that the consumer protection provisions involved are not necessary.

A particularly illuminating judgment regarding the far-reaching powers that the Court allows Member States in the area of preventive health protection is the one in case 97/83.⁶¹ This says that Member States are free to set threshold values for microbiological substances in milk to protect particularly sensitive consumers that may be well below the endangerment levels for normal consumers discussed by scientists but not established with certainty. Account may also be taken here of national usage regarding storage of milk products between purchase and consumption.

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

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

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

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

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

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

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

consumed as far as possible⁶⁶ was rejected as insufficient. It was necessary to justify the exclusion of particular substances on grounds of specific hazards.

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

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

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

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

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

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

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

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

⁷⁰ Op. cit., para. 16 et seq.

⁷¹ Op. cit., para. 17-22.

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

Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits – the low-voltage Directive⁷² – with its new harmonization technique of sliding reference to harmonized standards, became the model for the new approach to technical harmonization and standards,⁷³ after it had for years been regarded by many officials in governments and the Commission as an original sin that ought not to be repeated⁷⁴. With annual output worth some 80,000 million ECU in 1981, Community internal trade in electrical appliances amounted to some 35,000 million ECU; an estimated 70% of turnover in the electrical sector comes under the low-voltage Directive.⁷⁵

2.1. Peculiarities of the electrical sector

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

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

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

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

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

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

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

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

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

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

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

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

2.2. A conspectus of the Low-Voltage Directive

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

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

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

Art. 2 lays down the basic requirements for marketable electrical products. Electrical equipment may be marketed only if “having been constructed in accordance with good engineering practice in safety matters in force in the Community, it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made”. The reference to the state of the art – good engineering practice – means that what applies is technical development at a given point in time, not widespread recognition and a proof in practice of particular rules – which would mean that the rule would always lag behind steadily advancing technical development, as with the reference to “generally recognized rules of art” in the German Appliances Safety Act.⁸¹ The affirmative statement that in the event of a differing level of safety technology in individual Member States all ought to apply the highest level⁸² does not fully bring out the graded harmonization machinery of the Directive, which had to be developed because the desired success in harmonization at an enhanced safety level could not be secured simply by having requirements on products follow directly from such a formulaic prescription.

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

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

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

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

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

⁸² *Op. cit.*, 149. *Schmatz, H./Nöthlich, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1610, 9.

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

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

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

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

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

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

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

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

⁸⁴ Communication on the application of the low-voltage Directive (op. cit., fn. 73), point 3.3.

⁸⁵ The list of centres is published in OJ C 184, 23 July 1979, 1.

⁸⁶ Case 815/79, judgment of 2 December 1980, ECR [1980] 3583/ Cremonini v. Vrankovich. Cf. Hartley, 1982. Also illuminating is case 123/76, judgment of 14 July 1977, ECR [1977] 1449/Commission v. Italy.

⁸⁷ Communication on the application of the low-voltage Directive, (op. cit., fn. 73).

⁸⁸ COM/III/1412/83 - Rev. 3.

2.3.1. Harmonized standards

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

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

The Commission publishes the harmonized standards in the Official Journal; this publication is for purposes of information and thus has a purely declarative function.⁹⁰ The list published in September 1984 summarized harmonized standards agreed up to that date⁹¹. The 94 harmonization documents⁹² covered extend to the following areas:

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

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

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

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

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

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

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

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

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

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

Following the ruling in the *Cremonini v. Vrankovich* case, it was clarified⁹⁶ that type B departures are not admissible, since no discrepant national standards apply alongside the harmonized standards. Nor could type A divergences continue to claim any validity alongside a harmonized standard, since compliance with discrepant national safety provisions operates as a presumption of compliance with the general safety objectives only where no harmonized standards pursuant to Art. 5 or no safety requirements published pursuant to Art. 6 exist. They can be adduced only in connection with the safeguard clause procedure of Art. 9.

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

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

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

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

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

⁹⁸ Op. cit., point 2.3.1.

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

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

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

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

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

2.3.2. Equivalence of safety level

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

¹⁰⁰ Cf. 3.3 below.

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

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

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

been established for the whole area of application of the low-voltage Directive.¹⁰⁴ It is conceivable that in this transitional period national standards will in one Member State or another continue to apply which lag behind the requirements of Art. 2 taken together with Annex I, that is, the general safety objectives. In this case, it should be ensured that the safety level prescribed in the importing Member State is not reduced. The importing country cannot however require the same safety also to be achieved by the same means, nor can it call for any higher degree of safety than required by Art. 2 and Annex I.¹⁰⁵

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

2.3.3. Safeguard clause procedure

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

2.3.4. The CENELEC certification agreement

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

¹⁰⁴ According to industry figures, harmonized standards already existed for over 90% of turnover in equipment covered by the low-voltage Directive; cf. COM III/1412/83 - Rev. 3, point 2.4.1.

¹⁰⁵ On the foregoing cf. the closing speech by Advocate-General *J.-P. Warner* in case 815/79, ECR [1980] 3583 (3624 et seq.); cf. also *Hartley, T.C.*, Consumer Safety and the Harmonization of Technical Standards: the Low Voltage Directive, ELR (1982), 55 et seq., 59.

¹⁰⁶ Communication on application of the low-voltage Directive (op. cit., fn. 73), point 6.3.

¹⁰⁷ COM III/1412/83 - Rev. 3, point 2.5.2.2.

that country additionally mean an indisputable commercial advantage. Accordingly, it is in the interest of manufacturers to secure the national mark of every Member State in which they wish to market their products. The CENELEC certification agreement of 11 September 1973 in the version of 29 March 1983¹⁰⁸ (CCA) facilitates the acquisition of such marks without needless repetition of tests. A manufacturer who has already secured a conformity mark on the basis of the prescribed tests may by submitting the tests result on a form secure the mark of another office too, in a rapid, informal procedure.¹⁰⁹ There are agreements between the test centres on initial inspection of the place of manufacture and on monitoring of the manufacturing process and of marketing. Where a manufacturer so desires, he can on the basis of one test acquire national conformity marks for all Member States more or less automatically. The Commission energetically supports this agreement, which it regards as an advance on the system of mutual recognition of conformity marks and certification in the low-voltage Directive and as making introduction of a Community mark practically superfluous.¹¹⁰ What is ultimately decisive is the initial test which does not necessarily have to be done in the manufacturer's country.

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

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

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

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

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

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

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

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

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

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

organization were recognized by the others. The CB certificate as such does not give entitlement to application of a test mark, but merely facilitates the securing of other national test marks among the CEE member countries.

Public supervision, government influence or even any sort of consumer involvement are scarcely conceivable in the CENELEC certification system. There is only very restrictively any competitive situation among individual test centres, or mutual verification. It is clear that in the case of certification marketing interests outweigh verification of compliance with standards. An international certification system ought, besides the necessary cross-cooperation among certification centres, to require that certification be centralized in the individual Member States, precise requirements be placed on the staffing and equipment of centres, clear test criteria worked out and ample consensus reached among centres involved as to the target safety standard. The requirements would have to be strict. Once conformity marks have been conferred, marketing restrictions can be arrived at only through a time-consuming, rather cumbersome safeguard clause procedure.

For certification questions arising in implementing the new approach, reports ought to be useful on the extent to which use is made of certification by manufacturers even outside the industrial use of products, and what precautionary measures ought to or can be taken against misuse.¹¹⁶

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

Finally, it should be considered whether the form of sliding reference to technical standards chosen in the low-voltage Directive does not constitute inadmissible delegation of public tasks to private standardization bodies. The ECJ has not dealt explicitly with this question, but has not expressed any doubt as to the admissibility of the reference technique employed in the low-voltage Directive.¹¹⁷ The possible criticism has been brought out very succinctly by E. Röhling,¹¹⁸ in specific reference to the low-voltage Directive, and can be summarized as follows:

Sliding reference to technical standards in their current version is alleged to constitute inadmissible delegation of sovereign powers to non-sovereign organizations, since the tasks transferred go far beyond mere implementing powers, Community agencies are allowed practically no influence on the production of the technical standards and the balance between Community institutions is encroached upon. Reference to standards can allegedly not be justified even on the ground that it is a very technical matter, regulation of which would present Community institutions with insoluble tasks. Given that only vague, undisputed general safety objectives are laid down, standard-setting bodies are alleged to decide by themselves as to the extent of hazards the public is to be exposed to. Community institutions, moreover, are not so much allowing themselves in the case of application of reference standards to be guided by consideration of the hazardousness of the individual products, but more by the extent to which international standards exist for the given areas, or at least international standardization bodies are viable. The standard-setting bodies are

¹¹⁶ Cf. COM III/1412/83 – Rev. 3, point 2.6.4.

¹¹⁷ Case 123/76, judgment of 14 July 1977, ECR [1977] 1449/Commission v. Italy; case 815/79, judgment of 2 December 1980, ECR [1980] 3583/Cremonini v. Vrankovich.

¹¹⁸ Röhling, E., *Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt*, Köln/Berlin-/Bonn/München 1972, 122-127. Reservations are also expressed by Grabitz, E., *Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften*, Berlin 1980, 78 et seq.

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

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

3. The new approach to technical harmonization and standards

The development of a strategy aimed at guaranteeing the conditions for marketability of goods on European markets is among the essential legal requirements for the renewed efforts to bring about the internal market. The new approach to harmonization policy is justified above all by the principle of “equivalence” of safety policy objectives in Member States, supported by the *Cassis de Dijon* Judgment of 1978, which should made possible mutual recognition of national provisions¹²¹ and permit the generalizability of the reference technique first practised in the 1973 low-voltage Directive.¹²² But the political impulses and preliminary conceptual work go much further back.¹²³ Both the European Parliament¹²⁴ and the Economic and Social Committee¹²⁵ had already recommended the reference method in their resolutions or opinions on the general programme to eliminate technical barriers to trade of 1969, as an alternative to the “traditional” method of approximation of laws.¹²⁶ In

¹¹⁹ Cf. 5 below.

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

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

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

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

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

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

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

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

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

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

3.1. The Information Directive of 20 March 1983

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

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

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

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

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

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

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

¹³² See 2.4 above, as well as 5.1 below.

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

¹³⁴ On this cf. 5 below.

¹³⁵ OJ L 109, 26 April 1983, 8.

non-governmental appendage, namely national technical standards.¹³⁶ The directive was also innovative because of the measures by which it sought to oppose the emergence of technical barriers to trade. Art. 8 obliges Member States (and Art. 4 national standardization bodies) to “immediately communicate to the Commission any draft technical regulation” (and national standards programmes and draft standards).¹³⁷ This information is to enable the Commission to seek European solutions for the area concerned and initiate negotiations on such solutions. The legal instrument the information Directive gives it for this purpose is a time-limited anticipation of the primacy doctrine,¹³⁸ which replaces the “Gentlemen’s Agreement” of 28 May 1969.¹³⁹ The Commission or a Member State can cause adoption of technical regulations to be delayed for six months (Art. 9 (1)) and the Commission even by 12 months, if it announces an intended directive (Art. 9 (2)). Art. 7 (1) obliges Member States to ensure that standards are suspended for a period of six months if production of a European standard is intended. It is noteworthy that the information Directive “institutionally” restricts the primacy claim of European law by taking Member States’ interests into account and giving standards institutions too a possibility of collaboration.¹⁴⁰ These opportunities of influence are guaranteed by the Standing Committee of Member States’ representatives set up by Art. 5, which shall be consulted on all important matters and may deal with any questions it finds important (cf. Art. 6 (5) and (6)). National and European standardization organizations may be represented on the Committee themselves directly through experts or through advisers; in other respects they are recognized by Art. 6 (1) as permanent interlocutors. Member States’ safety policy interests are taken into account by Art. 9 (3), which grants Member States the right “for urgent reasons relating to the protection of public health and safety” to introduce effective national provisions immediately. The objectives of Europeanization of technical regulations and standards and the institutional innovations in the information Directive already adumbrate important components of the new approach. The information Directive itself admittedly means in the first place that the Commission has taken a very considerable burden of work upon itself. Following entry into force of the Directive on 1 January 1985, the Commission had by May 1986 already received 80 relevant communications, brought about the postponement of procedures in 32 cases and announced the adoption of directives in 10 cases.¹⁴¹ Evidently, however, the “information ethics” documented in these figures is still not enough. At any rate, the Commission pointed out in a communication of 1 October 1996

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

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

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

¹³⁹ OJ C 76, 17 June 1969, 9.

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

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

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

This assessment is confirmed by the proposals submitted by the Commission on 20 February 1987. By these, the scope of the information Directive is to be considerably expanded, extending in future to farm products, foodstuffs and fodder, medicaments and cosmetics;¹⁴⁴ at the same time, it is intended that the Standing Committee set up by Art. 5 of the information Directive should be involved in working on standardization contracts (Art. 1 (2)). The postponement periods in Art. 9 of the Directive are not extended. However, in future, communication of a proposal for a directive to the Council (and not only announcement of a corresponding “intention”) would bring on the postponement obligation (Art. 1 (3)(b)). The Commission’s explanatory document of 13 February 1987¹⁴⁵ stresses that the postponement periods resulting from the announcement to Member States of an intention and the communication of proposals for directives to the Council are not to be added together.

3.2. Harmonization of safety objectives and their implementation in standards

The overstraining of the Community’s law-making capacities by procedures under Art. 100 (1) EEC has led to the trying out of three¹⁴⁶ strategies to unburden it. All are to be continued under the new approach too. In accordance with the extensive interpretation of Art. 30 EEC¹⁴⁷ advocated by the Commission following the Cassis de Dijon decision,¹⁴⁸ in areas where reliance can be placed on mutual recognition of national regulations and

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

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

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

¹⁴⁵ COM (87) 52 final, point 9.

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

¹⁴⁷ Cf. 1.1.2 above, text on fn. 26.

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

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

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

This addition has led to considerable hesitation and controversies. Pelkmans, for instance, warns¹⁶¹ that it endangers the whole planning of the new approach and ought therefore to be

¹⁴⁹ See point 65 in the White Paper (fn. 1).

¹⁵⁰ See 1.2.3 above and point 64 in the White Paper (fn. 1).

¹⁵¹ Cf. the proposal for a directive on construction products, OJ C 308, 23 December 1978, 3 and *Falke, J./Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>, and the ESC's opinion on problems of barriers to trade and the harmonization of relevant legal provisions, OJ C 72, 24 March 1980, 8.

¹⁵² Op. cit. (fn. 1), point 70.

¹⁵³ Cf. *Falke, J./Joerges, C.*, The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

¹⁵⁴ OJ L 77, 26 March 1973, 29.

¹⁵⁵ Op. cit. (fn. 1), points 65, 68.

¹⁵⁶ Op. cit. (fn. 122), 5.

¹⁵⁷ Cf. 2.2 above.

¹⁵⁸ *Schmatz, H./Nöthlichs, M.* Gerätesicherungsgesetz, Kommentar und Textsammlung. Sonderausgabe aus dem Handbuch Sicherheitstechnik, Berlin, Kennz. 1610, 11, 13, cf. 17 et seq.

¹⁵⁹ Op. cit. (fn. 122), 11.

¹⁶⁰ Council resolution of 7 May 1985, OJ C 136, 4 June 1985, 2.

¹⁶¹ *Pelkmans, J.*, Opheffing van technische Handelsbelemmeringen. Pilot-Studie in opdracht van het Verbond

understood merely as a call for involvement of national certification centres in cases where neither European or national standards guarantee the safety of a product.¹⁶² The European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy called in its report on technical harmonization and standards in the Community¹⁶³ for the deletion of this addition, and an April 1986 question by one MEP¹⁶⁴ suggested that it be treated as non-mandatory. The answer to this question, communicated by Lord Cockfield on behalf of the Commission,¹⁶⁵ makes the legal position clear and yet seems to dodge the issue:

As far as the requirements on the precision of safety objectives are concerned, the addition is "only a comment intended to define the relationship between the essential safety requirements (point B III) and the means of proof of conformity and effects (point BV3). An essential aspect of the harmonization arrangements proposed by the Commission in its communication of 31 January 1985 is that the manufacturer would be able to choose between certification by a third party on the basis of the essential requirements, on the one hand, and the declaration of conformity with standards, on the other hand. It is therefore a choice that makes it possible to retain the optional nature of standards, which is the basic feature of the 'new approach'.

The Commission in no way takes the view that this principle will necessarily lead the Council to adopt directives laying down very detailed essential safety requirements, since the testing bodies appointed by the Member States to check the conformity of manufactured products with the essential requirements normally have expertise based on lengthy experience which holds out the assurance that the obligations deriving from a directive that has clearly formulated the standard of safety to be attained by the products in question will be correctly interpreted and applied.

It will also be possible for suitable informal procedures to be established in each case, so as to allow satisfactory cooperation between the appointed certification and testing bodies, thus ensuring that the provisions of the directives in question are correctly and uniformly applied ... The Commission considers, at all events, that such a question should be examined in connection with each specific case, rather than form the subject of a general discussion on the interpretation of the Council resolution of 7 May 1985".

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

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

¹⁶² Cf. 3.3 below.

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

¹⁶⁴ OJ C 19, 26 January 1987, 5.

¹⁶⁵ Op. cit., 5.

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

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

The second draft directive submitted on the basis of the new approach concerns the safety of toys.¹⁶⁹ Art. 2 (1) lays down a general safety obligation whereby manufacturers must bear in mind the foreseeable use of toys and the “normal behaviour of children”. This general safety obligation is specified in Annex II, initially in “general principles”, according to which children are to be protected not only against risks due to the construction and composition of the toy, but also, where design measures are not possible, against those inherent in its use.¹⁷⁰ The lengthy Annex II lays down requirements on physical and mechanical properties, flammability, chemical properties, explosion, electrical properties, hygiene and radioactivity. Annex IV additionally contains differentiated requirements as to warnings concentrating partly on the age of children, partly on the nature of the toys and partly on risks involved. All categories of risks and warnings were contained in the Commission’s proposal for a directive of 3 July 1980,¹⁷¹ from which they were taken over into the proposal for a framework Directive of 23 June 1983.¹⁷² The 1980 draft dealt in Annexes V and VI with Community standards for physical and technical properties and for the flammability of toys, but in 1983 corresponding standards were incorporated into separate directives.¹⁷³ A simplified procedure for amending these mandatory standards had been provided for both in 1980 (Art. 17) and in 1983 (Art. 13). The regulatory technique of the draft as now submitted thus builds on preliminary work already done. This continuity emerges particularly clearly from the fact that the binding standards in the 1980 and 1983 drafts merely took over provisions from the European standardization organizations, seeking to make them mandatory even though not yet formally adopted at the time by the national standards organizations. These draft standards have since been developed into mandatory European standards. Article 5 of the new proposal can therefore now refer to the very regulations that previous drafts sought to make legally binding.¹⁷⁴

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

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

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

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

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

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

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

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

The Commission's most recent project to date,¹⁷⁵ the proposal for a directive on construction products,¹⁷⁶ is likewise a resumption of a long-discussed project.¹⁷⁷ The development is very easy to follow, because the original draft provided for wide-ranging "implementing powers" for the Commission pursuant to Art. 155, fourth indent, and (partly) because of that provoked considerable resistance from business circles involved. On the other hand the circumstances that had at the time induced the Commission to take advantage of these regulatory powers have not changed: there are still hardly any European or international standards for construction products, and the multiplicity of existing national standards on them relates to differing national statutory provisions on buildings.¹⁷⁸ In these circumstances, the Commission's proposal cannot apply the new approach the way the model directive assumes. The safety requirements in the construction products Directive contain "essential requirements to which construction works, i.e. buildings and civil engineering works, have to conform, and which may influence the specific characteristics for products" relating to such points as stability, safety in case of fires, hygiene, health, the environment, safety in use, durability, protection against noise and energy saving.¹⁷⁹ The Commission explicitly stresses that it would not in general be possible on the basis of these requirements "to establish directly a presumption of conformity with the essential requirements by means of a type-examination carried out by an approved body".¹⁸⁰ Since the regulatory lacunae between the "essential requirements" and actual construction products will not in the foreseeable future be closed by European standards either, the Commission proposal provides for "European technical approval". Approval bodies authorized by Member States should, "on the basis of common approval guidelines for the product" in coordination with approval bodies in other States issue "European technical approval" on the legal basis of this directive (Annex II, (3) (1) and (6)). The multiplicity of regulatory proposals through which the Commission has sought to apply the new approach confirm the doubts of earlier commentators on the realizability in practice of the model directive,¹⁸¹ but also corresponds to the pragmatically syllable statements by

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

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

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

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

¹⁷⁹ According to the list in Annex I.

¹⁸⁰ Op. cit. (fn. 178), point 10.

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

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

It should be noted that these internal differentiations inevitably affect a further area already mentioned in the preparatory document to the new approach¹⁸³ and now specifically stressed in the proposal for a directive on construction products:¹⁸⁴ the abandonment of detailed design specifications in favour of “performance” standards. The distinction between “performance” and design is evidently intended not merely to paraphrase the difference between “safety objectives” and their “specifications”, but at the same time to refer to a more general competition-policy dimension of the debates on the regulatory technique of product safety law. The preferability of performance standards is because as repeatedly asserted in the US, such provisions leave room for technical innovation and make it harder to turn the standard-setting process into a way of warding off competition.¹⁸⁵ The theoretically clear distinction between performance and design standards has come in the practice of standard setting repeatedly to lead to wellnigh unsolvable demarcation problems. It may, moreover, prove questionable from a safety policy viewpoint where and in so far as alternative design solutions are not conceivable.¹⁸⁶ Accordingly, the draft toy Directive, to the extent that it deals with chemical properties of toys, contains threshold values for particular substances and references to relevant prohibitions in Community law.¹⁸⁷ The explanatory statement on the proposal for a directive on simple pressure vessels points out, in connection with restrictions relating to materials, a further problem with performance standards:¹⁸⁸ the more the leeway open to the manufacturer is cut down, the more urgent and at the same time more difficult becomes the development of suitable certification procedures and mutual recognition of conformity certifications.

3.3. Proof of conformity, mutual recognition, certification¹⁸⁹

The internal market and competition policy interests pursued through the retreat from approximation of laws to harmonization of basic requirements are met by the new approach through its opening up to manufacturers a range of ways of showing the safety conformity of their products patterned on the low-voltage Directive.¹⁹⁰ Section B VIII and V of the model directive of 7 May 1985¹⁹¹ offers them the following alternatives:

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

¹⁸² See fn. 165 above.

¹⁸³ Op. cit. (fn. 122), 5.

¹⁸⁴ Op. cit. (fn. 176), Art. 5 (2).

¹⁸⁵ See Klayman, 1982, 104 et seq.

¹⁸⁶ Op. cit., 105 et seq.

¹⁸⁷ Op. cit. (fn. 169), Annex II (3).

¹⁸⁸ Op. cit. (fn. 167), 9.

¹⁸⁹ A general survey is given by *Volkman, D.*, *Aktivitäten in der EG auf dem Gebiet der Zertifizierung und Qualitätssicherung*, DIN-Mitt. 66 (1987), 419 et seq.

¹⁹⁰ See 2.2 above, text in fn. 84.

¹⁹¹ Fn. 160.

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

Conformity is attested by

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

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

3.3.1. Recognition of national standards

Reference to national standards is explicitly termed a “transitional measure” in the model directive (Section B V (1) (b)). Nevertheless, this recognition of national standards is of fundamental importance. It corresponds to the assumption, contained in the Commission’s White Paper¹⁹³ and repeated in the explanatory material on the new approach,¹⁹⁴ that the objects of national safety provisions mostly coincide and that one may therefore take the equivalence of differing mandatory provisions and voluntary standards as a basis. Where this confidence derives from, why the statements in the general programme on elimination of technical barriers to trade of 28 May 1969 that harmonization measures are indispensable¹⁹⁵ have since been superseded, is not entirely clear. The technical safety development in the electrical sector, which the regulatory technique of the low-voltage Directive could take as a basis,¹⁹⁶ has, after all, not happened in other sectors. This is amply confirmed by the difficulties in delimiting the “essential safety objectives” from mere “manufacturing specifications” in the Commission’s new proposals for directives;¹⁹⁷ and the proposal on construction products, above all, shows that a basic pattern of “equivalent” safety objectives that merely have to be specified by standards is by no means achievable without further ado, still less presumable.

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

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

¹⁹³ Op. cit. (fn. 1), point 65.

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

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

¹⁹⁶ 2.1 above.

¹⁹⁷ 3.2 above.

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

3.3.2. Mutual recognition of conformity certificates and certification procedures

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

The model directive largely ignores the thorny question of how equivalence of national safety certificates can be guaranteed. It merely lists a number of different means of attestation²⁰¹ (certificates and marks of conformity issued by a third party, results of tests by a third party, manufacturer's declarations of conformity and surveillance systems), but does not specify the requirements that these certification bodies have to meet.²⁰² It is only with the directives and proposals for directives submitted on the basis of the new approach that we come upon more precise regulatory proposals, meant as examples, on the certification issue.

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

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

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

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

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

²⁰² *Op. cit.* (fn. 160), section VIII.

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

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

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

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

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

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

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

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

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

²⁰⁸ Fn. 176 above.

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

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

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

3.4. Safeguard clause procedure and follow-up market controls

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

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

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

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

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

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

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

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

The new directives or proposals for directives respond differently to this regulatory lacuna in the Model Directive. The Directive for simple pressure vessels²¹⁵ contains provisions on review of the recognition of standards (Art. 6) and on information of the Commission on unilateral measures (Art. 7), but in no way guarantees their applicability Community-wide. The safeguard clause in the proposal for a directive on construction products²¹⁶ likewise deals only with the need to amend standards and approvals decisions, without making it clear how a justifiably adopted protective measure by one Member State can be made applicable Community-wide. By contrast the proposal for a toy directive²¹⁷ aims at Europeanizing follow-up market controls. Article 7 (1) obliges all Member States to take "all appropriate measures to withdraw" unsafe toys "from the market and prohibit their placing on the market" and to inform the Commission of such measures. This information is aimed not only at revision or supplementation of standards; the Commission is instead to verify the justifiability of national measures and inform other Member States, while according to the 1986 proposal it should if national measures prove justified remind other Member States of the need to take similar action (Art. 7 (4)).²¹⁸ The Directive on airborne noise emitted by household appliances²¹⁹ likewise "walks on two legs": Art. 9 regulates the procedure for reviewing European standards and national standards or technical regulations,²²⁰ while Art. 7 obliges Member States to take steps to secure correction of faulty information from manufacturers.²²¹

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

²¹⁵ Op. cit. (fn. 166).

²¹⁶ Op. cit. (fn. 176), Art. 21.

²¹⁷ Op. cit. (fn. 169).

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

²¹⁹ Op. cit. (fn. 210).

²²⁰ On this differentiation see 5.3 below.

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

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

3.5. Improving the position of European standards

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

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

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

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

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

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

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

²²⁶ Op. cit., 15.

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

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

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

²²⁸ On this see 3.1 above.

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

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

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

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

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

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

²³¹ See also the figures in *Reihlen, H.*, Europäische Normung - eine Bilanz und eine Vorschau, DIN-Mitt., 63 (1984), 4 et seq.

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

²³³ See the report by *Mohr, C.*, CEN-Generalversammlung 1985, DIN-Mitt. 65 (1986), 47-48. and fn. 175 above.

²³⁴ Cf. *Seidel, M.*, Regeln der Technik und europäisches Gemeinschaftsrecht, NJW 1981, 1120 et seq., 1121; *Seidel, M.*, Grundsätzliche Regelungsprobleme bei der Verwirklichung des Gemeinsamen Marktes, in: Magiera, S. (Ed.), Entwicklungsperspektiven der Europäischen Gemeinschaft, Berlin 1985, 169 et seq.

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

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

The restructuring of legal harmonization policy not only leads to a "functional" involvement of private organizations in the Community's law-making process, but also affects the relationship between Member States, Council and Commission. The Council's role will according to the ideas of the model directive be confined to laying down the basic safety objectives. This means that Member States are no longer to be involved directly ("in legislative policy") in transposing the new directives. This limitation of their possibility of influence explains the setting up of a Standing Committee pursuant to Section IX of the Model Directive, identical with the one set up by the 1983 information Directive. Pursuant to Art. 6 of the information Directive, it is to be involved in discussion of standardization projects²⁴⁰ and may be brought into the standstill procedure under Art. 8 (2) of that Directive; it is now also brought into managing the list of standards (Section VI (2)), is to be consulted in the safeguard clause procedure (Section VII (2)) and furthermore, "any question regarding the implementation of a Directive may be submitted to the Committee" (Section X (2)). But for all that, the Commission's legal prerogative remains clear. As regards the Committee's function in managing the list of standards, Section X of the Model Directive says in syllabic fashion that "the object of the consultation of the Committee ... is more to provide for a forum for the discussion of the objections ... than to carry out a systematic examination of the entire contents of the standards". Its formal powers are described unambiguously. The Committee cannot, by contrast with "management" and "regulatory" committees, compel the Council through its vote to reformulate its decision,

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

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

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

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

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

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

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

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

The Single European Act (SEA)²⁴³ provides for some important changes to the framework conditions for a policy to bring about the internal market and guarantee product safety. Art. 8 a²⁴⁴ contains the central objective of progressively establishing the internal market by 31 December 1992, and lists the additions to the Treaty that are to permit the accomplishment of the ambitious political programme contained in the White Paper on completing the internal market.²⁴⁵ The supplementations of the Treaty relate essentially to harmonization measures, leaving the existing rules on free movement of goods before approximation of laws unaffected. The internal market, on the realization of which the new instruments are to

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

²⁴² Cf. 5.2 below.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

avoidance pursuant to Art. 173 EEC,²⁶⁶ and no regulation on simplified appeal to the Court by the Commission or another Member State would have been required.

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

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

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

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

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

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

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

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

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

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

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

such objects of legal protection as those listed in Art. 36 EEC. If it has not responded to newly emerging hazardous situations not yet covered by harmonization measures, there is *ipso facto* no Community regulation, and Member States are, if the Community does not act, not prevented from taking protective measures themselves in response to the new risk. If the case is one of intensification of a hazardous situation already covered by Community law, Member States must aim at raising the Community level of protection.²⁷⁰

A manageable distinction is required between harmonization measures under Art. 100 a to complete the internal market on the one hand, and environment protection and industrial safety arrangements on the other, since Art. 118 a and 130 t allow Member States to introduce or maintain higher protection even in a harmonized area without further substantive or procedural restrictions,²⁷¹ whereas Art. 100 a (4) makes appeal to industrial safety or environment protection dependent on the conditions described. The relevant point is the primary object of the measure.²⁷² If it is concerned primarily with creating the internal market, that is, with the free movement of goods, persons, services and capital in the various Member States with as little restriction as possible from different standards, then appeal to increased industrial safety or environment protection is possible only under the restrictive conditions of Art. 100 a (4). If instead a measure has to do primarily with the working environment within the meaning of Art. 118 a or with environmental protection within the meaning of Art. 130 r, that is, so to speak, with raising the "quality of life" in the Community, then Member States are not subject to any further restrictions if they wish to bring in higher levels of protection of industrial safety or of the environment.

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

4.2. Art. 100 b – mutual recognition

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

²⁷⁰ On this issue, in connection with vehicle catalysers and lead-free petrol, see *Steindorff, E.*, *Umweltschutz in Gemeinschaftshand?*, RIW 1984, 767 et seq. and *Ress, G.*, *Luftreinhaltung als Problem des Verhältnisses zwischen europäischem Gemeinschaftsrecht und nationalem Recht. Überlegungen zu einem Alleingang der Bundesrepublik Deutschland bei der Einführung des Katalysatorautos und des bleifreien Benzins*, FS Hundertfünfzig Jahre Landgericht Saarbrücken, Köln 1985, 355 et seq.

²⁷¹ See the statements by *Zuleeg, M.*, *Vorbehaltene Kompetenzen der Mitgliedstaaten der Europäischen Gemeinschaft auf dem Gebiet des Umweltschutzes*, NVwZ 1987, 280 et seq., 283-286 on the principle of best possible protection of the environment, applied by him.

²⁷² See *Reich, N.*, *Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften*, Baden-Baden 1987, para. 176. On the practical significance of this allocation see the instructive example in *Reich, N.*, *Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften*, Baden-Baden 1987, para. 180.

²⁷³ See *Reich, N.*, *Förderung und Schutz diffuser Interessen durch die Europäischen Gemeinschaften*, Baden-Baden 1987, para. 174; *Seidel, M.*, *Die Bedeutung des Art. 100a der Einheitlichen Europäischen Akte für die zukünftige Entwicklung des Gemeinschaftsrechts*, Vortrag auf der CLA/CCMA Konferenz über die Einheitliche Europäische Akte und die Zukunft der Rechtsangleichung in der EWG, Brüssel, 18.11.1986, 71.

The Conference wishes by means of the provisions in Article 8a to express its firm political will to take before 1 January 1993 the decisions necessary to complete the internal market defined in those provisions, and more particularly the decisions necessary to implement the Commission's programme described in the White Paper on the Internal Market.

Setting the date of 31 December 1992 does not create an automatic legal effect.

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

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

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

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

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

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

4.3. Conferment of implementing powers on the Commission

Finally, the Single European Act provides for a supplement to Art. 145 EEC.²⁷⁷ According to this the Council has, apart from certain exceptional cases not mentioned in detail, to confer upon the Commission powers to implement regulations adopted. By decision of 13 July 1987, the Council laid down the procedures for the exercise of implementing powers conferred on the Commission,²⁷⁸ thereby limiting the number of different committee procedures to which the Council may in future resort in conferring implementing powers, with the existing structure of some 300 committees remaining unaffected (see Art. 4 of the decision). In its proposal²⁷⁹ the Commission had, referring back to practice to date,²⁸⁰ provided for three different types of committees of national experts, namely “advisory committees” as purely consultative bodies, “management committees”, so far brought in particularly in the area of agricultural regulations for products coming under a common organization of the market, and “regulatory committees”, till then used mainly in the area of adapting directives to technical progress. The European Parliament, in its endeavours to strengthen the Community’s executive powers while concomitantly expanding Parliament’s control powers, recommended only the procedures of the Advisory Committee (preferred in the context of Art. 100 a) and the Management Committee).²⁸¹ The Council decision, now heavily attacked by the European Parliament,²⁸² provides for no less than seven different Committee procedures. The details of the four basic procedures and their variants are contained in the following table.

Procedures for exercise of implementing powers conferred on the Commission

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

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

²⁷⁸ OJ L 197, 18 July 1987, 33.

²⁷⁹ OJ C 70, 25 March 1986, 6 et seq.

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

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

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

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

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

context is not explicitly mentioned but is usually set up in the case of safeguard clause procedures, or not, each Member State can bring the Commission's decision before the Council within a set period. The Council may within a set period and by qualified majority take a different decision (variant a) or (variant b) confirm, amend or abrogate the Commission's decision, with the Commission's decision been taken as abrogated where the Council has not taken a decision within a set period. In the latter case, and with variant (b) in the regulatory committee procedure, a block on the application of Community law is possible where the Council cannot arrive at a majority for a decision.

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

In the procedure of management and regulatory committees, the Council was hitherto able to take the delegated power on itself again in the event of unresolvable disagreement of the Commission with the Committee, i.e. with the majority of Member States' government representatives. These powers of recourse for the Council have so far been of theoretical nature. The real influence on the Commission takes the shape of prior pressure to adapt and of a more or less diffuse basic consensus of national experts and the relevant Commission officials among themselves. This explains why the committees, which have in some cases been operating for many years now, have only rarely rejected Commission proposals, fairly rarely abstained from an opinion and often even voted unanimously.²⁸³ This "filter of expert consensus" is not provided for in the case of the safeguard clause procedure, which is in the main highly controversial politically or at any rate very sensitive for the protection policies of Member States concerned.

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

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

²⁸³ *Schmitt von Sydow, H.*, *Organe der erweiterten Europäischen Gemeinschaften - Die Kommission*, Baden-Baden 1980, Art. 155, para. 52; more fully, *idem.*, 160-166.

²⁸⁴ On this see *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 251, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>; on the significance of Art. 100 a (4) of the SEA cf. point 4.1 above.

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

In the course of preparing the low-voltage Directive²⁸⁵ the advocates and opponents of the reference technique had exhaustively discussed the pros and cons of including standards organizations in the Community's legislative process. The uncontroversial starting points for these debates were the principle of limited individual empowerment whereby the Community could exercise only the powers allocated to it in the EEC Treaty, and the related principle of institutional equilibrium which in particular requires observance of the relationship depicted in the Treaty between Commission and Council.²⁸⁶ Both principles have to do with the upholding of the rule of law and of democracy, from which it also follows that these principles prohibit the assignment elsewhere of Community legislative tasks.

The proponents of the low-voltage Directive referred above all to the legally non-binding nature of standards; the prohibition on delegation would not be broken if and because the specification of safety objectives laid down in the Directive would ultimately be under the control of governmental bodies, and also because the safeguard clause procedure of Art. 9 did not rule out emergency measures.²⁸⁷ But this argument has two weak points. Firstly, the structure of the low-voltage Directive gives harmonized, international and national standards (and conformity certificates issued by a national body) considerable legal importance, merely because conformity with the standards is a basis for presuming compliance with the safety objectives in the Directive and thus a right to access to Member State markets.²⁸⁸ This legal effect can be removed only through the safeguard procedure provided for the purpose. A second, graver objection is directed against the merely formalistic interpretation of the prohibition on delegation. Especially in the case of the low-voltage Directive, it is indisputable that its safety objectives open up very considerable leeway for standardization organizations²⁸⁹ and that the level of safety is in practice essentially determined by private standards.²⁹⁰

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

²⁸⁵ OJ L 77, 26 March 1973, 29.

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

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

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

²⁸⁹ Cf. 3.2 above at fn. 158.

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

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

These changes take the force away from the objections raised against the low-voltage Directive, but do not remove the problem of delegation. By contrast with what has often been asserted in the literature,²⁹² the controversy that broke out over the low-voltage Directive has not been clarified even by the ECJ judgment in case 815/79.²⁹³ While in its decision the ECJ urged Member States to comply with the low-voltage Directive,²⁹⁴ it did not explicitly address itself to the issue of the prohibition on delegation. The sole relevant decision, as far as we can see, of the ECJ is from long ago. It concerned the delegation of decision-making powers of the High Authority on private-law “financial arrangements” set up pursuant to Art. 53 ECS. The ECJ drew a distinction: “clearly defined executive powers” are unobjectionable; “discretionary powers” instead “bring about an actual transfer of responsibility”, “since it replaces the choices of the delegator by the choices of the delegate”.²⁹⁵ But these statements do not offer much help in deciding either. By contrast with the situation in Art. 53 ECSC, cooperation between the Community and European standards organizations is based not on a particular provision of the EEC Treaty but only on the Council resolution of 16 July 1984.²⁹⁶ Above all, however, it is hard to draw a line between mere “executive powers” and inadmissible “transfers of discretionary powers”,²⁹⁷ and in the case of the delegation issue with reference to standards, where what counts is the relationship between formal decision-making powers and actual possibilities of influence, it can be applied only in the form of a description of general trends. The more precisely safety objectives are set forth in directives and standardization orders to European standardization organizations are formulated, and the more intensive the substantive checking of standards in recognition and safeguard clause procedures and those regarding conformity certificates from national bodies, the easier is it to throw out the objection that the new approach means impermissible transfer of legislative powers.²⁹⁸

²⁹¹ 3.2. above at fn. 160 et seq.

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

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

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

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

²⁹⁶ OJ C 136, 4 June 1985, 2.

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

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

5.2. The institutional balance between Council and Commission

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

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

²⁹⁹ 3.4 and 3.6 above.

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

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

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

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

³⁰⁴ Op. cit., 1173.

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

regulatory committee procedure, but is at the same time an objectively obvious consequence of the delegation of implementing powers that include discretion.

The wide-ranging debate on shifting decision-making powers to “non-Treaty” bodies carried on in connection with the development of committee procedures, which always concerned the admissibility of restrictions on the Commission’s autonomy of decision,³⁰⁶ ignored the consequences of extensive delegation of “implementing powers” for the political legitimation of Community law. But now that both the practice of delegation has become established and at the same time highly articulated machinery to protect Member States’ influence has been developed, employment of these controls must also be in line with the nature of the delegation concerned. A normative interpretation of the principle of “balance”, which sees this principle as one of maintaining Member States’ possibilities of influence, can be combined with the analytical observation that the Community, wherever it creates supranational legal structures, has to allow Member States possibilities of involvement in its decision-making process.³⁰⁷ But now the Final Act of the governmental conference on the Single European Act has explicitly asked the Council “to give the Advisory Committee procedure in particular a predominant place”, specifically “for the exercise of the powers of implementation ... within the field of Art. 100 a”³⁰⁸, and the European Parliament has firmly supported this proposal.³⁰⁹ Even these statements were already lagging behind the Commission’s original intentions on amendment of Art. 145 EEC,³¹⁰ and also presuppose the powers of action remaining to Member States pursuant to Art. 100 a (4). Now the Council decision of 13 July 1987³¹¹ has politically (even if not legally) strengthened the position of Member States in the “advisory committee” procedure, and above all abandoned the favouring of this type of committee in connection with activities oriented towards bringing about the internal market. This development quite meets the legal reservations regarding the Council’s depriving itself of its powers by transferring decision-making powers in extremely sensitive questions of legislative policy to the Commission, under the title of mere “implementing powers”.

5.3. The way forward

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

³⁰⁶ Apart from the authors’ mentioned in fn. 297, see also e.g. *Bertram, Ch.*, Das Verwaltungsausschußverfahren, Diss. jur. Bonn 1967.

³⁰⁷ *Falke, J./ Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 1.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

³⁰⁸ Cf. 3.6, fn. 241 and 4.3 above.

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

³¹⁰ Cf. *Glaesner, H.J.*, Die Einheitliche Europäische Akte, *EuR* 21 (1986), 119 et seq, 146 et seq.

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

³¹² *Op.cit.* (fn. 281); on the conditions for this sort of foundation see *Lauwaars, R.H.*, Auxiliary Organs and Agencies in the E.E.C., *CMLR* 17 (1979), 367 et seq, and *Hilf, M.*, Die Organisationsstruktur der Europäischen

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

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

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

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

³¹⁴ Fn. 232 above.

The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy⁺

Christian Joerges^{} and Hans-W. Micklitz^{**}*

Abstract Deutsch

Der Artikel beschäftigt sich mit den Auswirkungen, die der „new approach“ auf die europäische Politik zur Produktsicherheit hat. Die Autoren kritisieren, dass es auf europäischer Ebene einen flickenartigen Standard in der Produktsicherheit gibt, da die EG Regelungen zur Produktsicherheit lediglich in Ergänzung zu den Richtlinien gemäß dem „new approach“ vorsieht. Deshalb fordern die Autoren, dass mit dem Setzen eines einheitlichen Standards begonnen wird. Sie empfehlen, bei der Festlegung dieses Standards die Bürger zu beteiligen, denn schließlich seien auch sie es, die von einer ungenügenden Produktsicherheit betroffen seien.

⁺ This article has originally been published in 1991 as Chapter V, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 5, EUI Working Paper Law No. 91/14.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

^{**} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

Abstract English

The article deals with the effect the new approach has on the development of a European product safety policy. The authors criticize that the standard of product safety on European level is very vague and inconsistent because the EC just adds (where needed) product safety regulations to their legislation according to the new approach. Thus, they demand of the European legislator to follow a uniform practice on product safety. They recommend to take the point of view of the consumers into account by strengthen their participation in the process of standardization of safety regulations because they are after all affected by a low level of product safety.

The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy⁺

Christian Joerges and Hans-W. Micklitz***

Introduction

The declared primary objective of the new approach to technical harmonization and standards is to overcome the stagnation in law approximation policy and thus promote the realization of the European internal market. Our survey of the most important aspects of the new approach has, however, already shown that the regulatory technique of reference to standards continually comes up against problems of product safety policy. Let us mention only the controversies about the degree of perception of the “basic safety requirements”,¹ the unsolved problems of recognition of national certification,² the decision-making powers of Member States under the safeguard clause procedure³ and the endangerment of internal market policy through the reservations in Art. 100 a (4) SEA.⁴ The following sections will go beyond these already visible points of contact to systematically consider the effects of the new approach on the beginnings of a European safety policy. It will not question the principle of the regulatory aspects of the new approach, but instead seek to bring out the ensuing problems the Community will have to solve if it is to push through its new harmonization policy.⁵

⁺ This article has originally been published in 1991 as Chapter V, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 5, EUI Working Paper Law No. 91/14.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SFB597).

^{**} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

¹ Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

² Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³ Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.3 and 3.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴ Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 4.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵ That the Commission is itself in principle aware of these implications as documented by the Commission communication of 23 July 1985, “A new impetus for consumer policy”, COM (85) 314 final, point 19 et seq., Commissioner Varfis’ answer to EP question N° 2778/85, OJ C 277 of 3 November 1986 and the Commission communication to the Council on “Inclusion of consumer policy in the other common policies” of 24 October 1986, COM (86) 540 final, 5 et seq.; and the ensuing Council resolution of 15 December 1986, OJ C 3, 7 January 1987, 1.

1. Product safety obligations

Wherever it harmonizes areas of law that (also) involve the safety of products the Community must lay down a binding or optional European safety level. Here, the “traditional” method of approximation of laws has led to a many-faceted range of product safety duties. The low-voltage Directive⁶ provides for protection only given “proper use”. The medicaments Directive⁷ uses the same standard. By contrast, the consumer policy programmes of 1975 and 1981 used the terms “normal” or “foreseeable”.⁸ This formulation was taken up both in the preamble to the Directive on cosmetics⁹ and in the decision on the exchange of information on product hazards,¹⁰ whereas the “new impetus for consumer protection policy” speaks only in general terms of the “need” to set “safety requirements at Community level”.¹¹ The product liability Directive,¹² finally, refers to the justified safety expectations of users “taking all circumstances into account”, in particular the “reasonably” foreseeable use. The relevant formulations in the model Directive of 4 May 1985¹³ are kept vague: “... products ...may be placed on the market only if they do not endanger the safety of persons, domestic animals or goods when properly installed and maintained and used for the purposes for which they are intended”. Furthermore, “in certain cases, in particular with regard to the protection of workers and consumers, the conditions set out in this clause may be strengthened (foreseeable use)”. The indefiniteness of this text results from the fact that “intended” use is introduced as the normal criterion, but the rule-exception relationship reversed again because the reference to protection of workers and consumers applies to almost all conceivable goods, and furthermore the tightening up of safety obligations in the areas mentioned is only a prospective possibility, and finally because such obvious differentiations as those by age of users concerned are lacking. In any case the structure of the model Directive shows the Community’s general tendency to orient the level of protection in consumer goods to “foreseeable” use. Furthermore, even the first two directives or proposals for directives submitted on the basis of the model Directive introduced an unavoidable differentiation. While the Directive for simple pressure vessels seeks to guarantee the safety of persons, domestic animals and goods only given “proper use”¹⁴, toy manufacturers have to take “foreseeable” use into account, bearing in mind the “normal behaviour of children”, and also take account of differences in children’s ages.¹⁵

⁶ OJ L 77 of 26 March 1973, 29 (Art. 2); cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁷ OJ L 147 of 9 June 1975, 1.

⁸ *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁹ OJ L 262, 27 September 1976, 169.

¹⁰ OJ L 70, 13 March 1984, 6; cf. Chapter, 3.4 above.

¹¹ Commission communication to the Council (fn. 5 above), COM (85) 314 final, point 21.

¹² OJ L 210, 7 August 1985, 29 (Art. 6); cf. for more detail *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

¹³ OJ C 136, 4 June 1985, 1, Section B II.

¹⁴ OJ L 220, 8 August 1987, (Art. 2 (1)), 148.

¹⁵ Cf. Art. 2 (1) and Annex II to the proposal for a directive on safety of toys, OJ C 282, 8 November 1986, 4.

The framework of the model Directive is of fundamental importance in other respects too. It takes account of the fact that the reference method leaves the Community legislator's responsibilities for product safety unaffected and that harmonization covering broad groups of products presupposes the laying down of appropriate safety duties. The question whether this insight, still expressed in the model Directive in relatively open, and above all non-mandatory, formulations, is to lead to the positive introduction of a Community general clause on product safety will be returned to later.¹⁶

2. Internal market policy priorities and the demonstration project on accident information systems

The list of "criteria for choosing priority areas", attached to the model Directive of 7 May 1985 and aimed at explaining its intended scope,¹⁷ mentions mainly regulatory criteria. In principle, the new approach will be appropriate only where it is genuinely possible to distinguish between "essential requirements" and "manufacturing specifications" where the requirements for protecting safety make "inclusion of large numbers of manufacturing specifications" unnecessary,¹⁸ and where, as with many "engineering products and building materials" not yet covered by Community regulations, essential safety requirements can be defined for a "wide range of products". The Commission White Paper¹⁹ sets the rather legislative criteria of the model Directive in a more ambitious integration policy context. The legislative technique of reference to standards is ascribed far-reaching functions: it is to enable the Community to create an expanding and flexible internal market, to increase the competitiveness and innovative capacity of European industry and promote the introduction of new technologies. If the regulatory technique of the new approach is to be understood from the viewpoint of the ambitious policy perspectives of the White Paper, then law approximation projects brought in will be oriented towards industrial policy priorities. But even where the practice of harmonization policy is pragmatically oriented towards the chances of implementing harmonization measures, tensions between internal market policy and product safety policy priorities can be foreseen. For product safety policy, the Community has with the "demonstration project on a Community accident information system"²⁰ created a mechanism which can, by collecting and assessing data on the number and severity of accidents, supply (among other things) knowledge about hazards arising from consumer goods and therefore contribute to clarifying where safety policy action is needed.²¹ The discrepancies between internal market priorities and product safety policy

¹⁶ *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

¹⁷ *Op. cit.* (fn. 13), 8 et seq.

¹⁸ In this connection see the Commission communication to the Council and the European Parliament "Completing the internal market: Community foodstuffs law", COM (85) 603 final of 8 November 1985, 2.

¹⁹ Completing the internal market, Luxembourg 1985, point 60 et seq.

²⁰ OJ L 109, 26 April 1986, 23; cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²¹ Cf. *Joerges, C.*, Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, and *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

priorities again bring up a conflict of objectives that already marked “traditional” approximation of laws.²² The sixth recital and Art. 1 (2) of the decision on the demonstration project, however, at the same time show a way that would at least allow this conflict of objectives to be dealt with: findings of accident research should be used in defining safety objectives and drawing up standards. This might be done by, for instance, carrying out in-depth studies on product risks preferentially in areas where the Commission has ordered a new standard or in which it has been presented with objections regarding the safety conformity of standards or certifications. This kind of feedback would of course assume that the Commission and the Standing Committee already set up by the information Directive of 28 March 1983²³ and now entrusted also with the coordination tasks connected with the new standardization policy²⁴ would cooperate with the committees active in the area of product safety policy.²⁵

3. The primacy claim in the new approach and Member States’ safety interests

Even assuming the admissibility in Community law of reference to standards,²⁶ this does not mean that applicability of this regulatory technique is guaranteed. Experience shows that transposing directives into national law is a thorny process that has at all stages, from incorporation of the directives into national legislative acts up to judicial and administrative practice in Member States, to reckon with varied resistance.²⁷ In the case of the new approach to technical harmonization and standards, additionally, a regulatory technique justified on internal market policy considerations and unfamiliar to many Member States is to be pushed through against other legal traditions and political demands.²⁸ Even now a whole range of lines of resistance on safety grounds can be discerned.

3.1. Conflict potential

Following the model of the low-voltage Directive of 19 February 1973,²⁹ directives adopted on the basis of the new approach are to secure full harmonization of the areas and types of

²² Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 1.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

²³ OJ L 109, 26 April 1983, 8 (Art. 5).

²⁴ Cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²⁵ Cf. apart from the Advisory Committee pursuant to Art. 7 of the decision on a demonstration project (fn. 20) also Art. 7 of the decision of 2 March 1984 on the exchange of information on hazards arising with the use products (fn. 10).

²⁶ Cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²⁷ This has been showing frequently and in detail: cf. only Eiden, *Rechtsangleichung* 1984, 76 et seq.

²⁸ Fn. 13 above; cf. also *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 1.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

²⁹ Cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ

risks covered.³⁰ They are therefore to be “directly effective”, have primacy over contrary national law and “block” legislative activity. But all these doctrines on the effects of European directives, though recognized in principle, may cause considerable difficulties of application in practice. Extension of the doctrine of direct effect to directives is a reflection of shortcomings in transposition in Member States; the doctrine therefore merely states that individuals may appeal against application of national law to the anti-Community conduct of the national legislator.³¹ But the ECJ has now linked direct effect in favour of individuals with the conviction that “the relevant obligation (on the Member States) is unconditional and adequately precise”.³² Accordingly, in the case of the new approach, controversy over the functions of the “essential safety requirements”³³ can affect the applicability of the new directives. If in future the Community makes the safety objectives sufficiently precise “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”³⁴, the chances for the application of the European law increase; on the other hand, precise specification of safety objectives makes it harder to secure consensus when adopting new directives and weakens the attractiveness of the regulatory technique to standardization organizations.

In applying the doctrine of primacy and blocking effect and also in connection with actions for breach of treaty brought by the Commission under Arts. 169 and 30 EEC, similar difficulties are foreseeable. The ECJ has given to understand that primacy of European law cannot depend on whether the primary motivation was internal market policy or safety policy,³⁵ and it follows from the judgment in the *Cremonini v. Vrankovich* case³⁶ that Member States must if they wish to assert their interests keep to the procedures provided in the directives. These directives can and should, however, provide only a presumption of safety conformity of products bearing the relevant certifications. Controversy on the appropriate level of safety of products is therefore ultimately to be decided on the basis of the criteria laid down in the directives.³⁷ The wider is the leeway for interpreting objectives

case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³⁰ Cf. Section B II 1 of the Model Directive (fn. 13).

³¹ Cf. e.g. ECJ case 9/70, judgment of 6 October 1970, ECR [1970], 825/Traunstein Finance Office; case 33/70, judgment of 17 December 1970, ECR [1970] 1213/Italian Ministry of Finance; case 41/74, judgment of 4 December 1974, ECR [1974] 1337/Home Office; case 102/79, judgment of 6 May 1980, ECR [1980] 1473/Commission v. Belgium. A full description of the case law up to 1982 can be found in Oldenbourg, 1984, 50 et seq.; on the interpretation of the doctrine of direct effect taken as a basis here, see also Karoff, 1984, 659 et seq.

³² According to the formula in case 148/78, judgment of 4 May 1979, ECR [1979] 1629, 1642, para. 23/Ratti; on the more generous tendencies in earlier judgments see Karoff, 1984, 663.

³³ Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³⁴ Section B III 1 of the Model Directive (fn. 13).

³⁵ Case 148/78, op. cit. (fn. 31), 1644.

³⁶ Case 815/79, judgment of 2 December 1980, 3583.

³⁷ On the procedure see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>, and on the similar situation with the low-voltage Directive *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 2.3.3. Online available at:

left in the new directives, the greater is the chance for Member States to secure their safety policy positions in substance in the new procedures even once they have formally transposed a directive. Explosive problems can continue to arise where a Member State takes additional measures to protect safety interests and decisions therefore have to be taken on the “blocking effect” of the new approach. The ECJ decisions *in rebus* Ratti³⁸ and Grunert³⁹ indicate that the Court wishes to base the “blocking effect” of Community law primarily on specific contradictions between the content of directives and Member States’ legal provisions, and the ban on legislative action in an area dealt with by the Community assumes that the Community has also actually pursued its policy.⁴⁰ This again raises the question whether the Community ought not, in the interest of applicability of the new approach, to develop a more comprehensive product safety policy.

3.2. Functions of the safeguard clause procedure

All situations of dispute mentioned always ultimately come down to the same point, namely whether the regulatory technique of reference to standards can establish itself not only as a strategy for internal market policy but also as a safety policy concept. The procedural provisions in the model Directive guarantee that disputes about the European level of product safety can be brought in not only “preventively” in determining safety objectives and recognizing standards and conformity certificates, but also “responsively” through subsequent objections to decisions taken at Community level, via the safeguard clause procedure.

The safeguard clause procedure, introduced by the model Directive, had to go beyond the usual type of safeguard clause, given the merely presumptive effects of recognition of standards and of conformity certifications. Its function is, though the typical wording of the safeguard clause may not make this explicit, to give Member States possibilities for action in the event of hazards not yet recognized when a Community standard was adopted.⁴¹ The practice has become that Member States are through their representatives on the administrative or regulatory committees being allowed decision-making powers in safeguard clause procedures.⁴² The model Directive departs from these examples in both

<http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>. On recourse to Art. 36 EEC see also *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³⁸ *Op. cit.* (fn. 32).

³⁹ Case 88/79, judgment of 12 June 1980, ECR [1980] 1827.

⁴⁰ Cf. Waelbroeck, 1982, 548 et seq.; *Weiler, J.H.H.*, *Supranational Law and the Supranational System: Legal Structure and Political Process in the European Community*, Ph.D. Thesis (European University Institute, Florence) 1982, 79 et seq.; *Rehbinder/Stewart*, 1985, 40 et seq. On the corresponding interpretation of Art. 36 EEC by the ECJ cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴¹ Cf. *Falke, J./Joerges. C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf> and Krämer, 1985, para. 246, who describes and criticizes the contrary practice in the case of the Directive on cosmetics (fn. 9).

⁴² Cf. for more Krämer, 1985, para. 236 and *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the

respects: not only new objections can be considered in the safeguard clause procedure, but also all findings already arrived at can be questioned, and the Commission is alone to decide as to the justifiability of any objections.⁴³ This means that all the difficulties of reaching agreement that the Council was to free itself of according to the new approach must under the safeguard clause procedure be solved by the Commission, which is to undertake the actual fine tuning of product safety policy differences among Member States. Even setting aside legal reservations regarding such broad delegation of decision-making powers to the Commission,⁴⁴ it seems scarcely conceivable that the safeguard clause procedure in the model Directive can be developed into a routine measure with short periods of decision and that Member States will rely on its possibilities for protecting their rights. These as consequences for both follow-up market controls⁴⁵ and the cooperation between the Standing Committee and committees at Community level in the area of product safety policy.⁴⁶

3.3. Majority decisions pursuant to Art. 100 a (4)

As a scratch test of the applicability of the reference technique of the new approach to Member States' product safety law we may take the power given to Member States, following ratification of the Single European Act,⁴⁷ by Art. 100 a (4) to keep to their own safety law against harmonization measures adopted only by qualified majority. The Commission can presume "arbitrary discrimination" or "disguised restraint of trade" pursuant to Art. 100 (4), second sentence, and the ECJ establish misuse of the rights under Art. 100 a (4), first sentence, pursuant to Art. 100 a (4), third sentence, only where the Community regulations in fact take account of Member States' interests in protection. Harmonization measures decided by qualified majority must therefore apply the relatively highest standard if the unity of the common market is not to be endangered. The Single European Act's provisions on environment protection may have the same effect, in so far as product regulations simultaneously take account of environmental and consumer policy interests. By Art. 130 t, Member States may take more stringent protective measures even where the Council has decided unanimously, as long as the measures are "compatible with the Treaty".

clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴³ On the more restrictive shape given to the Commission's powers in the safeguard clause procedure in the low-voltage Directive see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2.3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴⁴ On the objections see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴⁵ See 4 below.

⁴⁶ Cf. *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

⁴⁷ Bull. EEC, Suppl. 2/86; cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

Controversies as to the meaning of Art. 100 a (4) will seem hypothetical only on the assumption that only outvoted Member States may assert their rights arising out of this provision,⁴⁸ and that at any rate in the case of directives laying down only essential safety objectives the unanimity principle will *de facto* not be departed from. Irrespective of this, however, it is possible to link systematic conclusions with Art. 100 a (4). If even qualified majority decisions of the Council do not bind Member States, or only to a very limited extent, how are the Commission's sole rights of decision under the safeguard clause procedure to be justified? Such objections can be refuted only with the argument that Art. 100 a (4) is a special arrangement not in itself compatible with the supranational structures of Community law, which does not change the binding effect of directives adopted pursuant to Art. 100 (1) EEC and leaves the Council's powers of delegation pursuant to Art. 155, fourth indent, EEC unaffected. In its decision-making practice, the Commission will nevertheless not be able to avoid taking account of the sensitivity of Member States to interventions in their safety law on grounds of internal market policy, expressed in Art. 100 a (4).

3.4. Compliance with standards

Probably the most problematic aspects in practice of the reference to standards favoured by the model Directive as a regulatory instrument for safety policy arise from the difficulties of imposing standards that are not legally binding. A comparison with the move from mandatory to voluntary standards in the US is instructive. The American Consumer Product Safety Commission plays an active part in developing voluntary safety standards; it pays attention to their effects on competition and to the involvement of consumer organizations in standardization procedures, and verifies the content of standards produced and compliance with them.⁴⁹ The model Directive and the agreement between the Commission and the European standards organizations admittedly contain a number of procedural guarantees (in part still in need of precise specification).⁵⁰ But the only control mechanisms the Commission can use preventively to affect actual compliance with standards are the recognition procedures for standards and for conformity certificates; it can affect the practice of national certification centres only indirectly through the provisions contained in the directives or proposals for directives on simple pressure vessels, toys and construction products.⁵¹ These limited possibilities of influence are in line with the internal market policy perspectives of the new approach, according to which the point is to ensure free

⁴⁸ However, see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 4.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴⁹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁵⁰ Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵¹ For more details see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3.2. Furthermore, on the lacunae in protection that may result from diverging certification practices, see the opinion of the Consumer Advisory Committee of 22 March 1985, *STO/7/85*, 5.

movement of goods in the Community, so that what matters is only the equivalence of standards and conformity certificates recognized by the Community. But this internal market policy perspective neglects the decisive question from the product safety policy viewpoint, namely how a move to voluntary standards can be combined with actual guarantees of safety interests.

4. Regulatory lacunae in the model Directive in the case of emergency measures and follow-up market controls

The model directives and the directives or proposals for directives on simple pressure vessels, toys and construction products explicitly recognize Member States' power to take directly effective measures in the interests of protecting safety.⁵² A Member State that takes advantage of this possibility has to have recourse to the safeguard clause procedure. But the legally critical cases are not those where a Member State loses, since then it must accept the Commission decision, but instead the Commission's possibility of imposing measures it finds justified Europe-wide.

The pressure for action arising in such cases is irresistible, for both economic and legal policy reasons. Unilateral measures by a Member State encroach on the unity of the internal market which is the very point of the new harmonization policy. Unilateral measures are, moreover, admissible only in accordance with the safety objectives of directives. Where the Commission has found such measures to be legally justified, this implicitly means that Member States that do not share the Commission's interpretation and do not follow the measures it recommends are disregarding the product safety duty under Community law.

The model directive's laconic formulation that the Commission has to "remind" such Member States of their duty to act⁵³ in no way guarantees, even if taken over into individual directives,⁵⁴ a uniform application of follow-up market controls within the Community. In the case of such controls Member States apply administrative powers that the Community can influence only indirectly.⁵⁵ As with mutual recognition of administrative acts in general and of national conformity certificates in particular,⁵⁶ the Community must seek to bring about uniform practice by Member States in follow-up market control.

The more recent relevant directives or proposals for directives have in principle taken account of this perception. The proposal for a Directive on "products which, appearing to be other than they are, endanger the health or safety of consumers"⁵⁷ had provided for

⁵² For details see *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵³ Section B VII 2 of the Model Directive (fn. 13).

⁵⁴ In the Directive on simple pressure vessels (fn. 14, Art. 7) not even this was done; cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵⁵ Specifically on technical safety law see Seidel, 1971, 753 et seq. and in general Rengeling, 1977, 19 et seq. 25 et seq.

⁵⁶ Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵⁷ OJ C 272, 28 October 1986, 10.

implementation of a Community-wide prohibition (Art. 2), obligations on Member States to apply such bans (Art. 3) and provisions for Europeanizing nationally decided bans (Arts. 4 and 6). However, the since adopted directive⁵⁸ lacks these provisions, as does the Directive on simple pressure vessels.⁵⁹ The Directive of 1 December 1986 on airborne noise emitted by household appliances⁶⁰ differentiates in the monitoring of national decisions between objections by Member States to European standards and disputes as to national standards and regulations (Art. 9); this differentiation shows what resistance the Europeanization of control measures has to reckon with even when “only” the enforcement of Community provisions is involved.⁶¹ The proposal for a Directive on toys,⁶² finally, must, in addition to provisions on bans and recalls (Art. 7 (1), first sentence) and on Europeanization of such decisions by Member States (Art. 7 (1), second sentence, (2) - (4)), contain criteria for the recognition of national test centres (Annex III). The danger of “subsequent” splitting of the common market through single-handed administrative action in implementation of Community regulations can be opposed by the Commission only if it moves to bring about intensive cooperation among competent centres in Member States and in the Community. From all this, the recall issue provides the plainest proof that realization of the European internal market must involve Europeanization of product safety law. The more decisively the Community applies the conditions for the free marketability of products by making product safety obligations uniform, the more pressing becomes the need to harmonize control measures whereby Member States comply with these duties. We shall return to the practical consequences of these connections.⁶³

5. Reference to standards and manufacturer liability

For manufacturer liability in accordance with the Directive of 25 July 1985,⁶⁴ the new harmonization policy is not of direct legal importance. The legal liability duty of product safety in Art. 6 of the Directive is to be interpreted autonomously by the civil courts. It will neither be tightened up nor slackened off through the product safety obligations of new directives. European or national standards a manufacturer must comply with to market his products do not exclude liability in civil law pursuant to Art. 7 d of the Directive. Nor is this “state of science and technology” which by Art. 7 e limits manufacturer liability, identical with the state of European and national standards.⁶⁵

The legal independence of product liability and product regulation does not, however, in any way rule out *de facto* mutual influence, which can indirectly have considerable legal

⁵⁸ Op. cit. (fn. 14), Art. 4.

⁵⁹ Cf. fn. 53.

⁶⁰ OJ L 344, 6 December 1986, 24.

⁶¹ On the question of the differentiations in Art. 9 see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁶² Fn. 15 above.

⁶³ *Joerges, C./Micklitz, H.*, Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

⁶⁴ OJ L 210, 7 August 1985, 29.

⁶⁵ Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

effects. American law provides the clearest example of this, as being the furthest developed both in the area of product liability and in that of standard setting by federal agencies. Thus, detailed concepts for taking safety aspects into account in product planning have been extrapolated from the exhaustive case law on design faults.⁶⁶ It is indisputable that product liability procedures offer information of relevance not only legally but also technically, which can be used by Government agencies,⁶⁷ standardization organizations and individual firms. Admittedly, empirical studies have shown that while firms react to the excessive damages imposed under American law, these reactions concentrate often on developing strategies to deal with damage suits.⁶⁸ Standardization organizations seem neither ready nor able to make use of the dynamic development of manufacturer liability systematically in their work.⁶⁹ Conversely, both the standards set by federal agencies and voluntary standards of the standardization organizations play a considerable part in product liability actions, both to establish the state of the art and to demonstrate technically feasible alternatives.⁷⁰ Comparably intensive interactions between product liability law and product safety law are unknown in Community Member States⁷¹ and cannot be expected even after the product liability Directive is converted into national law.⁷² Nevertheless, directed measures to increase the degree of effectiveness of the product liability Directive for European product safety policy are entirely conceivable. Thus, systematic exploitation of the case law and of documents of relevant actions in Member States could clarify whether the safety law demonstrated by European conformity certifications is accepted or whether the case law is questioning the integrative objectives of the new approach through autonomous and/or divergent safety requirements. It is however equally conceivable to use them in the direction of Europeanizing standards, in the procedures for recognition of standards and conformity certificates and finally in the bringing of recall actions.

6. Involvement of consumers in technical standardization

The new approach to technical standardization confers on the European standardization organizations CEN/CENELEC the task of defining the European safety standards, or *de facto* “the European level of safety”, on the basis of defined safety objectives which have to

⁶⁶ Weinstein/Twerski/Piehler/Donaher, 1978, esp. 136 et seq.

⁶⁷ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 4.2 in fn. 57. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶⁸ Eads/Reuter, 1983, VIII et seq., 21 et seq., 24 et seq., 69 et seq., 92 et seq., cf. Joerges, C., Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review* (HanseLR) 2010, 117, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁶⁹ Cf. Johnson, 1982.

⁷⁰ For a systematic evaluation of the American case law in this connection see Hoffman/Hoffman, 1980-81, 283 et seq.; cf. also Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 4.4.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷¹ The German debate, still the relatively the most fruitful, is confined to legal and normative considerations (cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; about France cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 1.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; and England Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 2.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>).

⁷² Cf. Falke, J./Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

be converted into specific mandates. The privatization of the law-making process goes hand in hand with opening up of the standardization procedure for interested circles, including consumers. Consumer involvement is aimed at providing democratic legitimacy for the new regulatory approach.⁷³ Participation can only succeed where the consumer interest is brought in to actual standardization. The organization of this involvement thus stands in the centre of interest. However, conceptual and organizational weaknesses of consumer involvement suggest a rather pessimistic view regarding the attainment of the ambitious goal. Conversely, it would be false to draw the conclusion from foreseeable difficulties, which are perhaps removable only conditionally, that consumer involvement at Community level should be rejected. For the possibilities that have been opened up offer chances to influence the standard-setting process that did not so far exist. Consumer involvement has to live with the constant dilemma of on the one hand being measured against expectations it can perhaps never meet, and therefore having a sort of alibi function, and on the other of grasping the opportunity offered, however limited are the resources.

6.1. Basic questions of consumer involvement

Consumer involvement in standardization exists in some Member States, such as the Federal Republic of Germany, France and Britain, and has done for several decades.⁷⁴ Without seeking to define the exact starting point for consumer involvement,⁷⁵ all three countries have points in common which take on importance in assessing consumer involvement under the new approach. All three have in the course of the consumers' movement intensified involvement in the 1970s, and all three are at the same time the only countries in the European Community that have "organized" involvement, namely the DIN Consumer Council,⁷⁶ the AFNOR Consultative Committee and the Consumer Advisory Committee. Studies on whether the opening up of the procedure to consumers has led to different contents for standards are not available. The only so far known study on consumer involvement was done in the Federal Republic of Germany.⁷⁷ Questions to groups involved in standardization – industry, government and consumers – indicated a basically positive (self-) image. The consumer involvement was felt to have led to a change in the content of standards. Nevertheless, the authors diagnose structural defects that ought to be removed.

⁷³ Micklitz, *Produktsicherheit* 1986, 109 et seq. The question was discussed on 4/5 June 1987 at a meeting of the Community's "European Forum on Consumer and European Standardisation", cf. Bosserhoff, 1987, *Europäisches Forum*.

⁷⁴ Survey in Lukes, 1979, 48 et seq. (France), 123 et seq. (Great Britain); see also Reich/Micklitz, 1981, 99 et seq.; Bosma, 1984, 34 et seq.

⁷⁵ In France consumers were included following the first major restructuring of standardization during the Second World War, see Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; specifically on consumer involvement, Art. 5 of the decree of 24 May 1941, printed in Germon/Marano, 1982, 111. In Britain the Advisory Committee was set up in 1946; see Bosma, 1984, 41. On consumer involvement in DIN see Brinkmann, 1976, and Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 3.4.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁶ On the work of the Consumer Council see Bosserhoff, 1980, 670 et seq.; *idem*, 1984, 1 et seq.; cf. also Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., *Examples of Product Safety Legislation*, *Hanse Law Review (HanseLR)* 2010, 137, 3.4.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁷ See Schatz, 1984, 178 et seq.

6.1.1. Privatization and participation

In its agreement on cooperation with CEN/CENELEC⁷⁸ the Commission transferred the cooperation between State and business begun with the agreement between DIN and the German Government to European level.⁷⁹ Since the Community is not a State and since CEN/CENELEC merely brings together the national standards organizations, specific Community problems arise about which there is no experience at national level. While the Commission is by Council decision of 16 July 1984⁸⁰ formally legitimated to reach agreement with standardization organizations, it cannot conclude any legally binding agreements providing for delegation of Community powers to private standardization organizations, since this is not provided for by the Rome treaties. The “general guidelines on cooperation” were therefore arrived at, and could *de facto* develop the same legal quality as an international treaty or a “memorandum of agreement”.⁸¹ CEN/CENELEC are being asked to do too much in applying the general guidelines, since the representatives of the European economy in fact do not sit on them.⁸² Specifically, the question arises whether consumer involvement should be brought about through national contributions in the CEN/CENELEC standardization committees or at European level through the European consumer organizations existing there.

The general guidelines contain no specifications on this. All that is laid down is that “the Commission will as appropriate contribute to the establishment of suitable arrangements”. But the agreement between the German Government and DIN⁸³ does not contain any provisions on involvement of interested circles either. In para. 1 (2) DIN merely undertakes to take the public interest into account. It is only the notes that make it clear that this provision is among other things aimed at an increase of consumer protection in standardization.⁸⁴

What the new forms of cooperation at national and European level have in common is not only that the functional delegation of legislative powers is bound up with the decision not to set substantive regulations,⁸⁵ here in connection with consumer safety and health, but that the opening up of the procedure to particular interested circles (consumers) is not bound up with any formally guaranteed rights.⁸⁶ The “suitable arrangements” mentioned in the

⁷⁸ Printed in DIN-Mitt. 64 (1985), 78 et seq.

⁷⁹ Micklitz, Perspectives, 1984, published in a revised version in CMLR 23 (1986), 617 (621 et seq.).

⁸⁰ Printed in DIN-Mitt. 63 (1984), 681.

⁸¹ See *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸² On the prospects for this sort of restructuring see Reihlen, 1984, 7.

⁸³ Printed in DIN-Normenheft 10, Grundlagen der Normungsarbeit des DIN, 1982, 49 et seq.; for more details in the agreement between DIN and the Federal Government of Germany see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸⁴ Grundlagen der Normungsarbeit des DIN (op. cit. fn. 80), 54.

⁸⁵ On the function of reference to standards in the GSG see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf> and on safety objectives under the new approach *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁸⁶ In the Federal Republic of Germany procedural rights were laid down following the standards agreement when setting up the DIN Consumer Council, which leads Bopp-Schmehl/ Heibült/Kypke, 1983, 172 et seq. to make the

general guidelines are worked out in a procedure that involves only the Community administration and the standards organizations (CEN/CENELEC). Those whose right to speak is at stake may, to be sure, be heard, but have a weak position in the negotiating process. For what requirements can be deduced from “real involvement” and from support from the Commission “as appropriate” for the establishment of “suitable arrangements”? That sequence of phrases shows the openness of a process the object of which is no less than to legitimize the new approach.

On 11 December 1987 the Commission took an official position on consumer involvement in standardization.⁸⁷ It pressed for strengthening of consumer participation at national level, in order to ensure that consumer interests could be input into the position of national representations on CEN/CENELEC. What the way forward is to be at European level is on the other hand left open. The Commission wishes to arrive at “an agreement with CEN/CENELEC on a new way of working”. Whatever this may mean, institutionally solid consumer participation does not at any rate seem to be within immediate grasp. One year later on 4 November 1988 the Council confirmed the Commission’s position by enhancing the necessity to push for an effective consumer participation at the Member States level and by watering down consumer participation at the Community level*. The conclusion of an “agreement” is no longer mentioned; instead reference is made to a priority programme for consumer fairs and to seminars. We can safely assume that this type of activity will strengthen the consumer input at best marginally should be held to increase the consumer input in standardization.

Involvement understood in this way, without substantive provisions and without procedural guarantees, cannot remain without consequences for the consumer input to standards. For if the conditions of consumer involvement are partly determined by the standards organizations, the obvious thing to do is channel the consumer interests in standardization in accordance with the criteria set by business of the proportionality of consumer representatives, the technical relevance of their contributions and feasibility,⁸⁸ in order to exclude alternative (non-professional as being lay, non-technical as being sociological, and non-feasible as being economically expensive) product concepts from standardization.⁸⁹ The whole of consumer protection thus becomes subordinated to the existing goals of standardization and can be brought about only in a piggyback procedure unless other vehicles can be found, in other words, unless the goal is necessary for other reasons than those of health or safety protection. In this way, safety policy becomes integrated into internal market policy. Alternative product concepts, humanized technology as the object of product safety law, are placed institutionally under a constraint to provide justification. Safety objectives that go beyond the “generally accepted state of the art” will be accepted only where consumers can show that existing practice has led to severe accidents. This sets the framework for consumer involvement in private standardization. The privatization does not mean participation truly worthy of the name.

following statement: “The demonstration that this function has been carried out did not follow substantive criteria of assessment of standards, but compliance with particular procedural rules ...” Conversely it should be borne in mind that the standards agreement could not have been concluded before the parties had agreed on consumer involvement.

⁸⁷ COM(87)617 final, 11 December 1987.

* OJ No. C 293, 1, 17 November 1988.

⁸⁸ Convincingly, Kypke, 1983, 213.

⁸⁹ See Brüggemeier/Falke/Holch-Treu/Joerges/Micklitz, 1984, 8 et seq.

6.1.2. The consumer interest in standardization⁹⁰

Consumers want better products, safer products. Consumer demands regularly lengthen the manufacturer's proceedings. They call for a little "more" than the manufacturers are prepared to give. This is in line with the institutional framework for consumer involvement. Separate product concepts, in order to avoid the word "alternative", could be brought about only in an offeror process,⁹¹ but not as an appendix to standardization oriented towards the needs of business. The slight experience with the American offeror process has at any rate shown that consumers can if given the chance arrive at their own conceptions of product safety. In Community Member States there have not so far been many attempts to develop technical standards from the consumer's "own" point of view. Even differentiated models of the determination of the consumer interest concentrate on the manufacturer's perspectives and seek to load their position with consumer policy significance.

Bosma⁹² has dealt comprehensively with the issue. She demands that an adequate consumer orientation in standards answer three questions:

- (1) Should the final consumer be directly involved in standardization, and if so, how can such a commitment effectively be organized? Who can adequately represent the consumer, or also, who speaks "for" the consumer in the relevant bodies?
- (2) Where is the needed scientific background to come from for choosing priorities that take account of individual households or society as a whole?
- (3) Where is the necessary scientific mechanism to come from in order to analyse the needs, wishes and behaviour of individual consumers?

In order to arrive at an answer on the basis of these three questions, Bosma splits consumer interest into three categories:⁹³ consumer interest and marketing, consumer interest and product technology, consumer interest and product information. Bosma includes under marketing, among other things, requirements on consideration of foreseeable misuse in design, but also for possible recall or else liability in the event of defectiveness of a product.⁹⁴ Consumer requirements on product technology would be expressed through the requirement for a technology assessment (especially with new technologies), an estimate of the social consequences of the introduction of new or modified products and a quality assessment by the relevant testing agencies.⁹⁵ The interest in adequate product information is stated to require provision of special safety marks.⁹⁶

This ambitious concept of determination of the consumer interest is in Bosma's view too much for the individual consumer.⁹⁷ The latter, as often not being able at all to articulate wishes or sometimes even know what they are, far less being in a position to set priorities, would have to be represented on the relevant bodies by experts. Bosma does not fail to see the problems facing realization of this kind of concept, but feels that an intensive process of

⁹⁰ See Bosma, 1984, 16 et seq.

⁹¹ *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.1.2.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁹² As well as Bosma, 1984, 16 et seq., see Bosma, 1985, 9 et seq.

⁹³ Bosma, 1984, 17, 19, 22.

⁹⁴ *Op. cit.*, 18.

⁹⁵ *Op. cit.*, 20 et seq.; similar considerations by Venables, 1982.

⁹⁶ Bosma, 1984, 23.

⁹⁷ *Op. cit.*, 25.

scientific study (processing of surveys, etc.)⁹⁸ could permit adequate establishment of the consumer interest in standardization.

It would be attractive to differentiate the model proposed still further or even develop it towards an (alternative) consumer concept of consumers themselves. It is attractive because the proposed categories for including sociological findings as to the behaviour of consumers, the acceptance of environmental technologies, etc. are very inviting. The job is valuable and necessary and should be done, but there are a number of structural problems that should be borne in mind. The concept does not so far take account of the specific conditions for determining the consumer interest at European level. If even nationally it is hard to determine “the” consumer interest, then at European level differences in familiarity with technical dangers also enter in, as well as differences in technical solutions to deal with the danger. These social and technical differences have led to different safety philosophies in the Community which now have to be combined within the standards organizations. Consumers are afraid, and can cite examples, that standardization oriented towards creation of an internal market will lead to a reduction in the level of safety.⁹⁹ Though effective consumer involvement might help to avert this risk, there should still be consideration of whether it is all desirable to make the various safety philosophies in the Member States uniform. Thinking by both political and technical bodies is only at its outset. Already, however, it can be seen that work in standardization bodies does not aim at levelling out differing safety philosophies and regulatory approaches, but wishes to let them continue to exist side by side.¹⁰⁰

Another thing that seems problematic from the European viewpoint is the scientific presentation of consumer participation favoured by Bosma. In a European organization of consumer involvement this would lead to a predominance of the industrial countries, Germany, France, and Britain, while southern European countries, with their experiences of handling technology, would be excluded.¹⁰¹ The opening up of the prospect reveals the internal contradictoriness of the idea of making consumer involvement scientific. Consumer organizations have to meet the requirements on professionalism in contributions in standardization bodies; this is only the way they can stand up in argument. At the same time, this necessity cuts them off from their rank and file, since consumer organizations in developed industrial countries derive their body of experience also from sources that do not meet the demand to be scientific, or do so only partly. The tendency to make it scientific may in the long term affect the very foundations of consumer work, and lead in Germany, France and Britain to more technology-oriented consumer advice, but at European level the differences are liable to continue for a long time. What should be done therefore is to develop a model that does not rule out non-professional experience, particularly in the southern European countries, in handling technology, but includes it in an integrated concept of involvement in standardization.

⁹⁸ Bosma, 1985, 9.

⁹⁹ Bosma, 1984, 12.

¹⁰⁰ On this see 6.3.3 below.

¹⁰¹ At the same time the non-inclusion of southern European countries in the decision-making process was used as an argument against the admission of consumer observers; see 6.3.1 below.

6.1.3. Chances of consumer involvement

In view of the multiplicity of tasks assigned to European consumer involvement in standardization, the question arises where consumer are to get the ability to do the job in substantive terms. Questionnaires to national consumer representations in standardization organizations in European Community Member States have recently confirmed what will surprise no one: even at national level there is a shortage of experts and of the requisite financial resources.¹⁰² Experts are likely to be available in significant quantity only if consumer organizations start having more recourse to technicians in their field work. But this would lead to a fundamental restructuring of the direct contact between the organizations and consumers. Consumer organizations are traditionally bound up with personal product consultancy. The use of new media promises a considerable lightening of the burden, but at the same time offers opportunities for conflicts among organizations. For ecotrophologists would be replaced by technicians who not only handle media control product consultancy but at the same time have a broad range of work on handling complaints.¹⁰³ At the same time, only a step like this can create the conditions for gradually increasing the number of experts. However, even this kind of restructuring cannot solve the financial problems of consumer organizations. Effective consumer involvement in standardization will always remain dependent on governmental subsidies.

The present problems arising for standardization from the involvement of consumers have been summarized by the DIN Consumer Advisory Council's office in a manual.¹⁰⁴ Honorary work on behalf of consumers in standardization committees continually impinges on the recurrent structural pattern of "reasons for standardization – person – object of standardization – asserting of interest". In detail:

Whether there are *grounds* for standardization is decided ultimately by the manufacturers. Consumers are therefore dependent on the goodwill of the other side if they wish to encourage standardization of a particular product. The situation looks somewhat brighter in the area of safety standards, since the Appliances Safety Act has given consumers the necessary stiffening to push safety standardization forward. For this very reason, there is a need to press at European level for stronger obligations on manufacturers, importers and traders to market only safe products.¹⁰⁵ Even inside safety standards, consumer representatives ought to take priority decisions in order to make it possible to find a standardization project that will pay. It is in this very decision that the scarcity of resources comes into play.

The manual then sets out clearly the compromises that the DIN Consumer Council has to engage in so as even to find *consumer representatives* that would commit themselves to standardization work. Accordingly, the DIN Consumer Council has even accepted people not employed in a consumer institution. The principle applied is that people must have sufficient technical knowledge, which is not to be understood as actual specialization, be motivated, be legitimated to speak on behalf of consumers and be able to defend their position in DIN working committees.

¹⁰² Bosma, 1984, 34 et seq. carried out a survey of those involved in standardization and continually came to the same findings.

¹⁰³ On such considerations see Micklitz, 1985, 177 et seq.

¹⁰⁴ Printed in Bosserhoff, 1984, 7 et seq.

¹⁰⁵ See Joerges, C./Micklitz, H., Completing the New Approach through a European Product Safety Policy, *Hanse Law Review* 2010, 383, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art07.pdf>.

The requirements on the person in each case depend quite largely on the *object of standardization*. However, consumer representatives rarely get beyond the position of “informed laymen”, measured by the standards of the other side. In order to meet the requirements on the professionalism of contributions, the manual provides methodological indications for working out a consumer standpoint. If the problem is localized (safety, health), consumer protection objectives have to be defined in detail. Consumer representatives should have recourse here to complaints, accident statistics, tests of goods, etc. Particular difficulties face consumers when it comes to determining the actual level of safety. This is where the shortcomings of making things scientific become particularly clear. For empirical studies and scientific assessments are often replaced by mere exchange of experience, reference to test reports or comparable standards from other countries. If the grounds for standardization are present, the right people found and the object for standardization specified, the question still arises how the consumer side is to assert its position in the relevant committees.

Experience in DIN confirms the need to utilize the procedural rights formally allowed to the full. The DIN manual could act as a model for working out procedural guarantees at European level.

Experience with consumer involvement at national level and the structural problems of consumer involvement pointed out by the DIN Consumer Council suggest the conclusion that the chances for European consumer involvement should be regarded rather skeptically. If experts are lacking even at national level, where are they to be got from at European level? The financial problems are considerably increased by the high travel costs. The structural problems of consumer involvement diagnosed in the DIN manual must each be increased by the dimension of coordinating consumer interests Europe-wide so that at every level – reason for standardization, person, object of standardization, strategies to follow – mechanisms have to be provided to ensure that national consumer interests are reconciled. Nevertheless, it would be over-hasty to deny consumer involvement in European standardization work all prospect of success *a priori*. European involvement at the same time offers consumers chances to assert their interests that cannot be found in the same way at national level. A decisive step in this direction would be to break into the organizational structure of CEN/CENELEC by involving *European* consumer organizations in the standardization process. This kind of direct influence from the European angle would give consumers something of an edge over business, which must first coordinate its interests through national organizations. Moreover, consumer involvement ought not to be incorporated in the organizational structure CEN/CENELEC but the opposite: it should be established independently of the standardization organizations. This very trend is emerging in the development of involvement so far.¹⁰⁶

But the institutional advantages can be fully utilized by consumer representatives at European level only if they divide up tasks and capacities and concentrate their forces to take advantage of the resources from twelve Member States that they can now draw on. This means setting up a “professional organization” of consumer representatives at European level, since this is the only way to guarantee an adequate definition of the consumer interest in the sense of Bosma’s idea. This kind of professionally organized consumer involvement would have to take measures to ensure adequate taking of the interests of South European consumers into account.

¹⁰⁶ See 6.2 below.

6.1.4. Consumer access to public information

The chances for effective consumer involvement depend largely on how far consumer representatives can back up their position in the relevant committees with information. As well as mobilizing information sources of their own, they will have to depend here on access to information compiled either nationally or by Community institutions. The Commission has now considerably expanded its information policy in this very area of standardization of product safety, so that direct access by consumer representatives here is of considerable importance. The information procedure in the field of technical standards and regulations¹⁰⁷ might provide consumer representatives in the area of safety standardization with an overview of national differences and at the same time give them ideas as to which national safety standard should be favoured as the European solution.¹⁰⁸ The Community system for rapid exchange of information on hazards arising from consumer products¹⁰⁹ and the Community information system on accidents caused by consumer goods¹¹⁰ theoretically create the conditions for bringing statistically supported information into the standardization process.

In fact, all three projects hinder consumer access to the information. The information procedure in the field of technical standards and regulations treats information received as confidential.¹¹¹ The European consumer representatives have no access to the CEN/CENELEC database. At most they can secure information from the national representations of consumers on the standards organizations. The Community system for rapid exchange of information on dangers arising in using consumer goods excludes the consumer from the beginning. Where a national authority so desires, information is treated confidentially in justified cases.¹¹² The accident information system, which is perhaps even more important, does not provide for any possibility of using accident statistics in standardization procedures before the end of the model project in 1989.¹¹³ This may change, especially if sources of danger that suddenly arise make Community-wide regulation necessary. It is, though, very striking that all three projects bar consumers from access to the information.

6.2. The existing organization structure of consumer involvement¹¹⁴

Since December 1982 and April 1983 respectively, the four organizations represented on the Consumer Consultative Committee (CCC) (BEUC, the European Trade Union Conference, the Association of Community Family Organizations and the European Community of Consumer Cooperatives) have been sending observers to various technical committees of the European standardization bodies CEN and CENELEC. This started with exhaustive discussions between the Commission, CEN and CENELEC and the European

¹⁰⁷ OJ L 109, 26 April 1983, 8 et seq.

¹⁰⁸ On the chances for the information project see Micklitz, *Perspectives*, 1984, 33 et seq.

¹⁰⁹ OJ L 70, 13 March 1984, 16 et seq.

¹¹⁰ OJ L 109, 26 April 1986, 23 et seq.

¹¹¹ Fn. 103 above, Art. 8 (4).

¹¹² Fn. 105 above, Art. 6.

¹¹³ Fn. 106 above, Art. 8.

¹¹⁴ The following statements are based on two reports drawn up by the BEUC for DG XI today Consumer Policy Service, to give an account of the utilization of contributions: report on the involvement of European consumers in European standardization, BEUC/2111/84, 26 October 84 (cited as BEUC 1984) and report on standardization, STD/20/85, 31 December 1985 (cited as BEUC, 1985, Report).

consumer organizations on the form of possible involvement by European consumers. Ultimately those involved agreed to direct collaboration of European consumers in standardization, although it long seemed as if CEN/CENELEC would not be prepared to accept direct involvement since this would mean a brake in CEN/CENELEC's organization structure. Without pressure from the Commission it would not have come to direct involvement of European consumer representatives in standardization. The Commission pays some of the expenses: its contribution was 60,000 ECU in 1984, 40,000 in 1985 and 90,000 in 1986. In October 1983 the Commission (DG XI) and BEUC signed an agreement on the involvement of European consumers in European standardization.¹¹⁵

6.2.1. Consumer Advisory Committee, working group on standards and secretariat for coordination

The Consumer Consultative Committee (CCC) has for many years had a working group on standards that was brought into negotiations between the Commission and CEN/CENELEC. The way towards a financing of European consumer involvement by the Commission became free only when the four members of the CCC had agreed to locate coordination of European consumer involvement in BEUC. The coordination secretariat is formally independent, with BEUC merely providing the institutional framework.

To give a closer definition of the tasks of the coordination secretariat, it is needful to keep the three organizations involved, BEUC (as the contractual partner of the Commission), the CCC and the coordination secretariat separate. The BEUC has taken over merely formal competence. It has given an undertaking to the Commission to: coordinate the positions of European national standardization organizations in the area of standardization; secure information on standardization from European and national consumer organizations and pass it on; pay travel expenses for experts taking part in CEN/CENELEC meetings; hold coordination meetings on standardization in order to arrive at a common position for European consumers on standardization questions, provide for contacts between Commission offices, the standardization organizations and consumer organizations in order to secure active and effective cooperation of European consumers on questions of European standardization; take other measures suitable for contributing to the efficiency of consumer involvement in the work of CEN and CENELEC. Similarly, BEUC is obliged to bring interim reports and annual reports before the Commission. *De facto*, however, this work is done not by BEUC, but by an employee paid by the Commission who directs the coordination secretariat.

The CCC's interest is to draw as clear a demarcation line as possible between the area of work of the European coordination secretariat and the work of the CCC working group on standards.¹¹⁶ The coordination secretariat is to coordinate participation by consumer representatives in CEN/CENELEC (selection, appointment, reimbursement of expenses, training, coordination) and in national standardization bodies, to give technical support to the CCC in its discussions and supply technical reports on specific topic at the request of Commission offices. The work of the working group on standards is to concentrate on the following three fields: verification of new Commission initiatives in the area of standardization policy; verification of proposals for directives in the area of standardization and any setting of minimal requirements in the area of consumer protection; evaluating the

¹¹⁵ Printed in BEUC, 1984, Annex I.

¹¹⁶ See XI/371/86, 22 May 1986, ccc/17/86 "Beteiligung der Verbraucher an den Normungsarbeiten".

annual report of the coordination secretariat. In other terms, the CCC working group on standards formulates policy and the coordination secretariat (BEUC) implements it. The working group on standards would thus as hitherto, and like the other CCC working groups, also prepare opinions for subsequent adoption by the plenary sessions. In addition to policy formulation, the working group on standards also wishes to exercise a supervisory function over the coordination secretariat, which cannot necessary be reconciled with the CCC's range of tasks to date.

6.2.2. Consumer observers on technical committees

Only representatives of test institutes or members of independent research institutes act as consumer observers on the technical committees of CEN/CENELEC. Without this ever having become public, it seems to be clear inside the CCC that representatives of consumer committees in national standards organizations can at any rate not act as observers.¹¹⁷ This does not rule out their inclusion as experts in coordination meetings. However, this prior decision by the CCC illustrates a certain skepticism regarding the independence of consumer representations institutionally involved in national standardization organizations. The differing perspectives of testing and scientific institutions may be decisive here. For while consumer representatives on national standardization organizations are supposed to find generally accepted solutions together with the manufacturers, the testing and scientific institutes may take the product standardized into consideration relatively free from such economic compulsions. The number of consumer observers on CEN/CENELEC technical committees has steadily risen since work began.¹¹⁸ In 1984 European consumer representatives were sending four observers to nine technical committees. In 1985 it was eight to ten committees. Of these, however, only four committees were really active in 1985. Altogether, their 58 committees in CEN, eight of which do not work, in seven of which consumers are involved and 34 of which would be of interest to consumers. CENELEC has 34 committees on 3 of which consumers are involved, while seven would be of interest. This assessment is based in a selection according to the following criteria:¹¹⁹ safety considerations, influence of standards on competition, consumer information, performance criteria, energy aspects. In fact the possibilities for European consumer associations to send observers are considerably restricted. First of all, one has to find an observer prepared to take the job on. This observer has to provide information on the state of work on a particular CEN/CENELEC committee, name the most important points for discussion, reflect the various standpoints of manufacturers and the national standardization organizations, form an opinion of his own and above all send a report to the coordination secretariat after each meeting.¹²⁰

To avoid misunderstandings, it would seem appropriate to give some further explanations of the number of committees set up by CEN/CENELEC. Behind each technical committee there is a whole range of products. When European consumer associations send an observer to TC 61 (safety of household appliances), he has to cover the whole product range of

¹¹⁷ BEUC, 1984, 9 and Annex II (minutes of the meeting on problems of consumer involvement in European standardization work of the Consumer Advisory Council, BEUC 162/83, 15 November 1983, 6(g)).

¹¹⁸ As well as the BEUC report (fn. 111 above) see Consumer Participation in Standards Work, STD/17/86, 15 May 1986.

¹¹⁹ BEUC, 1984, Annex II (fn. 114 above), 6 (f).

¹²⁰ Op. cit., 3.

electrical appliances to be found in the home. The gamut runs from washing machines, dryers, electric cookers, toasters, refrigerators, freezers, coffee mills, clocks and irons to massage appliances, sunray lamps and sewing machines. And this list is by no means complete. A comparison with national sets of standards might lead to the result that European standards are much broader in content than differentiated national standards.

6.2.3. Observers' coordination meetings

One of the most important tasks of the Coordination Secretariat is to hold coordination meeting with consumer observers and national consumer experts on the individual committees.¹²¹ Since it is incumbent on the consumer observer to represent the interests of consumers in individual Member States, he must be informed and advised by national consumer experts in order to be able to intervene appropriately in CEN/CENELEC meetings. Accordingly, the coordination meetings are the core of European consumer participation. Theoretically, there is an entitlement to raise new projects for CEN/CENELEC standardization through the coordination meetings. In practice, the coordination meetings serve mainly to tackle problems "brought back" by the observer from meetings of the technical committees. The Coordination Secretariat then has the task of drawing up an agenda, inviting the experts from the various Member States and distributing the necessary papers in advance. Since the national experts' work is honorary, the success of the coordination meetings depends largely on voluntary commitment by the experts. At the same time, the greatest commitment is useless if the information flow among national consumer experts is not adequately organized.

6.3. Practice to date with consumer participation in CEN/CENELEC

European consumer representatives can now look back on two and a half years of practical experience. The reporting duty placed upon BEUC by the Commission offers a good basis for making an initial analysis from an internal viewpoint. This seems all the more important because thinking is at present going on in DG XI about how consumer involvement is to be organized in future.

6.3.1. Procedural questions

Observers on CEN/CENELEC technical committees meet a number of procedural obstacles at the start of their work that do not yet seem to have been removed. This annoyance can ultimately be removed only by written procedural guarantees, a conclusion that can be confirmed from experience with the DIN Consumer Council.¹²²

The first appearance of consumer observers on the technical committees regularly led to the question of what status the observer ought to have on the technical committees.¹²³ This was even though CEN/CENELEC had informed the relevant committees of the inclusion of consumers in standardization through a circular. *De facto*, the consumer representatives faced the burden of justifying why they wanted to take part in the work.

¹²¹ BEUC, 1984, 4 et seq.; BEUC, 1985, Report, 14 et seq.

¹²² 6.1.3 above.

¹²³ BEUC, 1984, Annex II (fn. 113 above), 2.

While these problems were more or less rapidly solved in course of time, much more complex obstacles faced consumer representatives when it came to putting forward their position in discussion. Two areas proved particularly important: involvement in drawing up the agenda and inclusion of consumer positions set down in writing in the organized information flow within CEN/CENELEC. An example may illustrate this.

The commitment of the consumer representatives on the CENELEC Committee on Safety of Household Appliances (TC 61) very quickly brought out the need to think about the extent to which technical standards ought in principle to take account of the fact that children are not always under supervision (the so-called exclusion clause).¹²⁴ At the coordination meeting in May 1984, the decision was taken to set a debate going in TC 61. At the next TC 61 meeting in June 1984, the Coordination Secretariat's request was however rejected. Observers had according to the Committee Chairman no possibility of bringing forward a paper in the Technical Committee. According to CENELEC procedural rules this was open only to the Secretariat and to national delegations. An exception might be made for consumer observers if the Commission asked CENELEC to consider a corresponding proposal.¹²⁵ Despite this unpromising beginning, the Coordination Secretariat, at the request of the observer, went further into the question. At the January 1985 coordination meeting a letter to the Chairman of TC 61 was drafted. The next meeting of TC 61 in May 1985 showed, however, that the paper had not been distributed.¹²⁶ The Coordination Secretariat thereupon decided to approach the President of TC 61 and urge that the letter be distributed. This letter was distributed to Committee members, with the agreement of the CENELEC Executive Secretary. At the next meeting of TC 61 in October 1985 the President then made it clear that henceforth written comments of the consumer observer would automatically be passed on to TC 61 members.¹²⁷ Altogether, then, it took more than a year in order merely to secure formal access to the debating forum, without a single substantive word yet having been spent on the actual issue.

More fundamental in nature are the problems arising from the low participation by consumer observers, from only four Member States. For the committees ask observers for legitimation of their claim to speak on behalf of the European consumer when only four, or even three, consumer delegations out of 12 Member States were involved in coordinating a consumer standpoint.¹²⁸ The structural weaknesses are imputed to the consumers themselves and additionally the task is imposed on them of specifically insuring inclusion of South European countries. This position may be used positively as an argument for asking the Commission for suitable financial contributions in order to organize this process. The remaining point is the difficulties that have arisen in the case of contracts issued to CEN/CENELEC by the Commission. With one exception,¹²⁹ consumers have not been included in the terms of the contract. And even this one Community measure happened more or less by chance, because the European Consumer organizations had got wind of the Commission's intention in time. Practical problems with the technical committees arose particularly because the remit given by the Commission was often so imprecisely worded

¹²⁴ For details on the substantive issue see 5.3.3 (2).

¹²⁵ BEUC, 1984, Annex VIII: Protocol of the meeting of CENELEC, Oslo, 18-22 June 1984.

¹²⁶ BEUC, 1985, Report, Annex 1 d: Co-ordination Meeting on Electrical Household Appliances TC 61, Brussels, 12 September 1985.

¹²⁷ BEUC, 1985, Report, Annex II b: Minutes of the Meeting of CENELEC TC 61, Athens, 1-3 October 1985.

¹²⁸ CCC's observers report on meeting of CEN TC 62 – Gas Convector Heaters, London 12-13 March 1986.

¹²⁹ BEUC, 1985, Report, 19; what is meant is TC 48 Safety of Gas Water Heaters, on which see Note for file, op. cit., Annex III a.

that the Technical Committee saw itself compelled to give the decision on what the remit involved back to the Community.¹³⁰ It should be noted in passing that the Commission is giving contracts to CEN/CENELEC before safety objectives under the new approach have yet been specified.

6.3.2. Information and coordination

Since consumers are cut off at European level from Community information sources, the need to build up an internal information network and coordinate incoming information Community-wide takes on even greater importance. The importance of this task was just as clear to the CCC working group on standards as it was to BEUC when it set up the Coordination Secretariat. But the Coordination Secretariat has neither the financial nor staff resources to build up this information and coordination network itself. Instead, it is dependent on cooperation by national experts on coordination committees and on their information sources in their home organizations.

A clear tendency to professionalization¹³¹ has emerged, which pursues more or less the following course: if an observer has been found for a technical committee of importance to European consumers, the Coordination Secretariat assembles the information to put the observer in a position to get a picture of the state of work in the technical committee. This is the only guarantee that the observer can recognize his possibilities of influencing the ongoing procedure.¹³² If problems arise in the technical committee, the observer approaches the Coordination Secretariat and asks for the calling of a coordination meeting. The Coordination Secretariat prepares the meeting, sends round all necessary material and/or asks for it from members of the coordination meeting. While in the initial stages the members of the coordination meeting sought to assess the problems arising on the basis of their experience, a procedure has now been developed in which one of the members undertakes to produce a background paper which, according to the topic, assesses either specific scientific research or ad hoc surveys within national consumer organizations.¹³³ This background paper is used by the observer, following decision in the coordination meeting, for submission to the technical committee.

The intensity of information exchange between the observer and the national representatives or experts in the coordination committee depends strongly on the activity of the technical committee. In other terms, CEN/CENELEC determines the rate of the consumer work. Besides current information and coordination needs, the Coordination Secretariat has begun a number of in-depth studies. These serve on the one hand the objective of proceeding in product-related fashion, as was the case with the study by the

¹³⁰ BEUC, 1985, Report, 11; *op. cit.*, Annex II f: Report by Mr. Bosserhoff on CEN/TC Gas Water Heaters, which seeks to specify the requirements on the wording of terms of reference; Bosserhoff put his criticism into practice and drew up a proposal of his own for giving a Community remit to CEN/TC 48; *op. cit.*, Annex III b: Resolutions taken at the 1st Meeting of CEN/TC 52/WG in Berlin, 1985-09-25/27, which lists the shortcomings of the terms of reference in specific form.

¹³¹ Cf. e.g. the minutes of the first coordination meeting, BEUC, 1984, Annex II (fn. 114 above) and of the meeting of 10 June 1986: Minutes of the CCC Coordination Meeting June 10, 1986. In both meetings a number of problem areas were touched on; the later minutes show the growth in self-confidence by their precise listing of relevant material questions.

¹³² This had at the outset proved a great obstacle, BEUC, 1984, Annex II (fn. 114 above) 2.

¹³³ BEUC, 1985, Report, Annex VI: STD/12/85, Maximum Surface Temperatures of Heating Appliances by D. Grose, Consumer Association, June 1985 and BEUC, 1985, Report, Annex VII: STD/33/85 Analysis of a Survey concerning Electrical Functional Toys by A. Lange - Stümpfig, DIN-Verbraucherrat, 1985.

Consumer Association on the “bicycle market in the Community”¹³⁴ but also through work directed at making up for shortcomings in knowledge on consumer participation, particularly in Southern European countries.¹³⁵ Attempts were also made to provide regular information through a newsletter on the state of standardization work.¹³⁶ However, this proved difficult, for two reasons. Firstly, the circle of interest is small, so that it appeared better to incorporate this newsletter into the general BEUC journal,¹³⁷ and secondly this path was blocked because the CCC insists on independence of the Coordination Secretariat. Despite all the tendencies towards professionalization, so far there is no intact infrastructure to which the Secretariat can have recourse. Accident studies are not recorded centrally, nor can the Secretariat have access to the specific knowledge of safety standards accumulated particularly in test institutions. The only internal information network available to date – BEUC Interpol¹³⁸ – is not included in the work,¹³⁹ which would in any case be possible only if an overall concept for building up an information and coordination network were available.

6.3.3. Material questions

The intention is not to provide a stock-taking¹⁴⁰ of work to date, but merely to illustrate the points at dispute in the individual technical committees.

- (1) The starting point for the CEN TC 100 working group is a remit from the Commission to CEN:¹⁴¹

Initially, to determine the requirements for tactile hazard indications on packages intended as containers for substances and preparations classed as hazardous by national authorities; further, to work out standards for means to permit the perception of hazards by touching, in order in particular to comply with Art. 15 (2) and (3) of Directives 79/831 and 78/63.

These terms of reference from the Community are aimed at combating accident risks from chemicals in the household using the safety technique of instruction, specifically through a tactile indication of hazard. But this safety philosophy was opposed not only by the consumer side, but also by some national standards organizations that called for special protective devices – child resistant closures.¹⁴²

This conflict was resolved when the members of the technical committee agreed to treat special protective devices as a separate thing from tactile hazard indication systems, requiring separate standardization.¹⁴³ This compromise was facilitated by

¹³⁴ AGV, Der Fahrradmarkt in der Europäischen Gemeinschaft, 1986.

¹³⁵ So far, reports are available on consumer participation in Italy and Greece.

¹³⁶ The first edition is printed in BEUC, 1984 as Annex XI.

¹³⁷ Due to scarce resources BEUC stayed away from the further publication of the journal.

¹³⁸ See the description of the system by Domzalski, 1984.

¹³⁹ Interestingly enough, this has on several occasions been called for by the Germans, BEUC, 1984, Annex II (fn. 114 above), 3 (a) on the part of the AGV.

¹⁴⁰ This attempt is made indirectly by Bosserhoff, who presented a strategy paper to the working group on standards of the Consumer Advisory Council: Consumer-orientated proposal for a priority programme for the drawing-up of European Standards within the competence of CEN/CENELEC, printed in BEUC, 1985, Annex VIII a, STD/22/85. Bosserhoff presented his ideas in a revised version at the European Forum on consumer standardization (op. cit., fn. 70), cf. Bosserhoff, 1987, Prioritätenprogramm.

¹⁴¹ BEUC, 1984, Annex VI: Reports of meetings of CEN TC 100, Doc. IV; Report Brussels 25-27 June 1984, 1.2.

¹⁴² BEUC, 1984, Annex VI (fn. 137 above), Doc. I: Report Paris 26-28 January 1983 (without naming the countries).

¹⁴³ BEUC, 1984, Annex VI (fn. 137 above), Doc. III: Report of the fifth meeting of CEN TC 100 (without figures).

the need to develop a marking system as rapidly as possible in the specific interest of the poorly sighted. Ultimately, however, no agreement could be reached on the basis of this compromise either. It proved impossible from the industry viewpoint to develop a uniform method,¹⁴⁴ which had always been the priority goal of the consumer organizations. The latter had carried out a survey through the CCC that had brought out the interest in a uniform method guaranteeing the unambiguous nature of the information.¹⁴⁵ The working group temporarily suspended its work and asked the Commission to lay down the requirements for standardization in precisely worded terms of reference. The consumer side drew the conclusion from the failure of TC 100 that technical committees themselves were not in a position to secure compromises as to safety philosophy (safety technique of instruction versus protective devices). Only a suitably precisely worded remit that the consumer side would play a part in drawing up could prevent safety policy from failing to advance because “commercial circles involved” cannot agree.¹⁴⁶

- (2) One of the important points at dispute in Technical Committee 61 (safety of electrical household appliances) is the so-called exclusion clause.¹⁴⁷ This states that electrical safety standards do not take account of the special hazards arising in children’s rooms, kindergartens, etc. in which small children or old and infirm people are present without supervision. In such cases additional requirements are necessary:¹⁴⁸

Except in so far as this standard deals with electric toys, it does not take into account the special hazards which exist in nurseries and other places where there are young children or aged or infirm persons without supervision; in such cases additional requirements may be necessary.

The consumer side has now raised the question of the extent to which safety standards meet additional requirements, or whether the protection of children or old people is no longer guaranteed where they are present without supervision in kitchens or other rooms in the home where there are electrical appliances.¹⁴⁹ The suppliers’ side sought to downplay the accusation by referring to standardization practice, in which safety is guaranteed even without such supervision.¹⁵⁰ Consumers again found themselves in a position of having to offer proof that the level of safety was not sufficient. In fact the consumer representatives managed to find that the exclusion clause had been adduced in a number of cases as an argument against the introduction of comprehensive protection measures.¹⁵¹ Thus, protection against access to current carrying parts is tested with the “standard test

¹⁴⁴ BEUC, 1984, Annex VI (fn. 137 above), Doc. III, 2.3.

¹⁴⁵ BEUC, 1984, Annex VI (fn. 137 above), Doc. III, 3.3.

¹⁴⁶ BEUC, 1984, 11 et seq. and Op. cit., Annex IV: CEN TC 100 - Tactile danger warning systems STD/17/85, 1 August 1985.

¹⁴⁷ BEUC, 1984, Annex IX: Minutes of the Co-ordination Meeting of Consumer Experts on CENELEC TC 61 - 8 May 1984, 122/84, 3.

¹⁴⁸ Scope of HD 254:S:3, printed in: Draft letter from the CCC observer to CENELEC TC 61 to the Chairman of CENELEC TC 61, in: BEUC, 1985, Annex V.

¹⁴⁹ 1. Entwurf eines Briefes, BEUC, 1984, Annex X 2.

¹⁵⁰ BEUC, 1985, Report, Annex II a: Report of the Meeting of CENELEC 61, Copenhagen, 7-9 May 1985. The representative of the DIN Consumer Council adopted the standpoint of the German industry, BEUC, 1984, Annex IX (74), 3.

¹⁵¹ BEUC, 1984, Annex X, 5-7, from which the examples are taken.

finger”, based on an “average” adult finger. This test may well not constitute adequate protection for many adults, but certainly does exclude children. This leads to considerable hazards from ventilator heaters or other flow heaters accessible to children. Nevertheless, CEN/CENELEC continues to reject the introduction of a child-sized test finger. No special child resistant closure is provided for in the case of spindryers and washing machines. Sockets on the front of electric cookers likewise have no protection for children, though this is already prescribed in the case of gas cookers. Surface temperatures of electrical appliances are another problem area. A large number of appliances provide no protection even against severe burns. The consumer side is not claiming that all appliances ought to be so hazard free that no parental supervision is necessary. However, avoidable hazards ought to be removed and electrical safety standards ought to take foreseeable conditions of use (not merely proper use) of particular appliances into account. On the basis of these considerations, the consumer observer, following consultation with national consumer experts in several coordination meetings, proposed a revision that positively asks for foreseeable misuse to be covered in the design of electrical appliances that might present a danger to children and old people.¹⁵²

This standard takes account of foreseeable misuse (other than gross misuse) of equipment by users of all ages and also, so far as is reasonable, of the fact that the equipment covered by the standard may be used where there are young children and elderly persons.

The suppliers’ side rejected this proposal, but at the same time had to admit that the present text of the exclusion clause did not at any rate reflect practice in safety standardization. It therefore seems to be possible that the consumer side may at least partly succeed with its move. At present, the wording proposed by the British Consumer Advisory Committee is before TC 61 for debate:¹⁵³

So far as practicable, this standard deals with the common hazards presented by appliances which are encountered by all persons in and around the home. However, except in so far as this standard deals with electric toys, it does not in general take into account the use of appliances by young children or infirm persons without supervision; for such use additional requirements may be necessary.

It is not yet clear whether the compromise proposal will be adopted. At any rate, the compromise formula, also supported by the IOCU Testing Committee,¹⁵⁴ means a considerable step back from the original position. For the consumer side gives up the inclusion of foreseeable misuse and contents itself with the much softer formulation “common hazards”, which is in turn in need of interpretation. On the positive side, there is now a much clearer formulation of the circumstances in which safety standards provide *no* protection for unsupervised persons. The scope has been reduced to children only, to avoid discrimination of old people. The arguments over the exclusion clause make clear the need at European level for a safety philosophy along the lines of DIN 31000. This project, which has been

¹⁵² BEUC, 1985, Report, Annex V (fn. 144 above).

¹⁵³ BSI Technical Committee LEL/161 Safety of electrical appliances, STD 18/86.

¹⁵⁴ See its letter of 21 July 1987 to the Chairman of the working group IEC TC 61.

worked on since April 1985, has involved European consumer representatives since June 1986.¹⁵⁵

- (3) Often, however, difficulties arise even among national consumer representatives in agreeing on a uniform safety philosophy. Thus, the consumer's protection against electric shock must be weighed against his interest in being able to do repair and maintenance work himself.¹⁵⁶ Even if one in principle supports a right of access by consumers, it remains to be decided whether consumers are to be explicitly encouraged to do work themselves and what protective measures are at all possible if consumers are to be allowed to do repairs or maintenance. Likewise, the question of the protective level for surface temperatures of household electrical appliances remains open. The British consumer representatives want the maximum limit brought below 50 degrees, while the German side does not even support a maximum of 80 degrees.¹⁵⁷ The list of examples could be extended, though the conclusion ought not to be drawn from the disagreements that the consumer side is unable to develop a uniform European safety philosophy.

6.4. Proposals for extending consumer involvement in standardization

The present organization of technical standardization is regarded by all those involved, the Commission, CEN/CENELEC and also the Consumer Consultative Committee and the Coordination Secretariat, as a transitional stage. The policy of the new approach seems to have led to the insight by all those involved that in the long term consumer involvement in standardization must be institutionalized. It is not yet foreseeable, however, how it will end up looking. Several proposals are available, but discussions have barely begun.

6.4.1. The Bosma proposal¹⁵⁸

In her report for DG XI, Bosma proposed the setting up of a consumer advisory committee for technical standardization, to be attached to the Standing Committee. The object is to guarantee access to European standardization activities by consumer interests, through institutional collaboration between the Consumer Advisory Committee for Technical Standardization and the Standing Committee. The committee is to be made up of representatives of European consumer organizations (though it is not said, this probably means CCC members) and European consumer research institutions such as Swoka, INC, Swoka, INC, Stiftung Warentest, Husholdningsrad, CRIOC.¹⁵⁹ While European consumer organizations should provide the *political* input, Bosman assigns to the research institutions listed the task of making the necessary technical know-how available. Accordingly, the Consumer Advisory Committee on Technical Standardization would in this conception

¹⁵⁵ However, since June 1986 an observer has been sitting on CEN TC 144, Minutes of the CCC Coordination Meeting, June 19, 1986 STD/28/86, 3 July 1986.

¹⁵⁶ BEUC, 1985, Report, Annex I d: Co-ordination Meeting 12 September 1985 (fn. 124 above), 2 and Annex II b: Minutes of the meeting of CENELEC, Athens 1 - 3 October 1985, STD/40/85, 23 October 1985, 6.

¹⁵⁷ See the background paper by D. Grose, BEUC, 1985, Report, Annex VI (fn. 130 above) and the letter from the German Consumers Association to the coordination meeting in London, 16/17 1985, 10 January 1985. BEUC, 1985, Report, Annex I d: Co-ordination Meeting 12 September 1985 (fn. 124 above), 2 and Annex II b: Minutes of the meeting of CENELEC, Athens 1 - 3 October 1985, STD/40/85, 23 October 1985, 6.

¹⁵⁸ See Bosma, 1984, 60 et seq.; and esp. Bosma, 1985, 22 et seq., especially the organigram, 29.

¹⁵⁹ Bosma, 1985, 23.

represent the collective European political and technical expertise of the consumer side. It should among other things have the following tasks:¹⁶⁰

- To point out to the Standing Committee developments of special interest to the consumer side, and make the necessary expertise available to the Standing Committee for it to assert the consumer interest;
- to develop consumer priorities in European standardization;
- to formulate a consumer safety policy, taking particular account of technical standards;
- to list special research studies needed for consumer desires and needs to be recognized in standardization;
- to make contacts with consumer representations on national and international standards organizations.

To be able to cope with the multiplicity of tasks, the Advisory Committee would in Bosma's view¹⁶¹ have to have especial technical committees assigned to it: (1) food and nutrition; (2) household chemicals; (3) transport, in particular cars; (4) house and building materials including furniture; (5) electrical and electronic products. These technical committees are to provide the Advisory Committee with the necessary technical information, draw up background reports and develop specific proposals, in other words, do the hard technical work.

Correspondingly, these technical committees should also include experts with relevant experience in those areas. Bosma¹⁶² is thinking, apart from test institutions, above all of independent research institutes dealing with specific aspects of a product (ergonomics, safety). She then raises the question whether it would not be advisable also to include specialists from industry in the work of the technical committees. Though she does not ultimately answer the question, she is clearly thinking of an "ideology-free discussion" since the technical committees are to have the task only of supporting the Advisory Committee on standardization in its work. It would be incumbent on the Advisory Committee for standardization to delegate observers to the technical committees of CEN/CENELEC and to maintain contacts with the Standing Committee.

Bosma wishes to locate the Secretariat of the Consumer Advisory Committee on standardization in DG XI. At the same time, she advocates formalization of the consultative relationships between the Standing Committee and the Consumer Advisory Committee on Technical Standardization.

6.4.2. The thinking in DG XI¹⁶³

DG XI has put forward a proposal of its own for the organization of consumer participation in standardization. It is similarly contemplating setting up a special consumer advisory committee for technical standardization. This is, however, to consist of CCC members, and no subdivision into special technical committees is contemplated. As before, actual administrative work is to be done by a secretariat to be located outside DG XI. "Political control" of the Consumer Advisory Committee for technical standardization is to be handled by the CCC working group on standards. DG XI is thinking of a division of tasks

¹⁶⁰ Op. cit., 23 et seq.

¹⁶¹ Op. cit., 25 et seq.

¹⁶² Op. cit., 27.

¹⁶³ Annex to the Minutes of the Meeting of the CCC Working Group on Standardization, June 30, STD/27/86, 3 July 1986.

as already similarly proposed by the CCC.¹⁶⁴ This would give the CCC working group on standards the task of formulating policy, while the Consumer Advisory Committee for technical standardization would flesh out these outlines with technical content, with assistance from the Secretariat. There are no plans for formalizing the relationships between the Standing Committee and the CCC.

6.4.3. Assessment

It is striking that neither proposal takes account of the outstanding importance of safety standards at European level. Consumer safety problems appear as only *one* conceivable case of technical standardization, although experience over the last two years shows that consumer observers on the technical committees overwhelmingly concentrate on safety questions. Bosma's model allows the importance of product safety to be accommodated, since it would be possible to set up a technical subcommittee on product safety that might also possibly involve manufacturers. This way out would not be possible on the DG XI proposal.

Structural problems of consumer involvement arise in each proposal. Firstly, it is unclear why Bosma is so insistent on having the secretariat located in DG XI. This skepticism is all the more important since DG XI evidently has no interest in accommodating the secretariat. Bosma's concept completely lacks any discussion of the CCC as such and its working group on standards. Yet there is an important field here for conflict in the future shaping of consumer participation. DG XI seeks to take account of the institutional framework for consumer participation by seeking to bring the Consumer Advisory Committee on technical standardization under the political control of the CAC working group on standards. But this division of tasks means that the Commission is opening up the possibility of potential conflict between the working group on standards and the new committee. Moreover, the DG XI proposal would ultimately lead to duplication of the work of the CCC, since the Consumer Advisory Committee for technical standardization would have the same expert representatives of the four consumer organizations sitting on it as deal with standardization questions. In the long term, however, thinking the matter through to the end, hiving off standardization issues from the CCC's range of tasks might lead to its weakening. Accordingly, Bosma's proposal seems more convincing: the Consumer Advisory Committee on technical standardization should, alongside the four consumer organizations, also have a place for institutions with years of experience in the area of technical standardization. A final striking point is that neither Bosma nor DG XI in their proposals provide for procedural rules to be laid down in writing concerning either the Standing Committee's relationship to the Consumer Advisory Committee for technical standardization or the Consumer Advisory Committee on technical standardization's relationship to CEN/CENELEC. But this would be one of the major pillars of a formal guarantee structure for consumer participation in European standardization.

¹⁶⁴ See fn. 113 above.

Completing the New Approach through a European Product Safety Policy⁺

Christian Joerges^{} and Hans-W. Micklitz^{**}*

Abstract Deutsch

Die Autoren versuchen in diesem Artikel herauszufinden, wie man die Divergenzen zwischen der Binnenmarktpolitik und dem Verbraucherschutz harmonisieren kann, denn bisher wird die Politik zur Produktsicherheit als Handelshemmnis eingestuft. Zunächst stellen sie fest, dass die Politik der gegenseitigen Anerkennung keine Alternative für die Entwicklung einer einheitlichen Produktsicherheit ist, da dadurch Unternehmen diskriminiert würden, die sich freiwillig höheren Sicherheitsbestimmungen unterwerfen; das Gleiche gilt für die vertikale Harmonisierung, die zu einer Überlastung des Gemeinschaftsgesetzgeber führen würde. Sie schlagen vor, einen Ständigen Ausschuss zum Produktsicherheitsrecht einzusetzen, der die verschiedenen Regelungen der Mitgliedstaaten koordiniert und an der Entscheidungsfindung in der Kommission teilnimmt. Außerdem wollen sie die Beteiligung der Verbraucher an der europäischen Normung erhöhen. Schließlich schlagen sie eine systematische Nachmarktkontrolle vor, die durch eine Kooperation von Mitgliedstaaten und Gemeinschaft gekennzeichnet ist. Aber all diese Vorschläge können erst dann umgesetzt werden, wenn eine Generalklausel zur Produktsicherheit eingeführt wird, die für alle Produktparten verbindlich ist.

⁺ This article has originally been published in 1991 as Chapter VI: Summary and conclusions, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 5, EUI Working Paper Law No. 91/14.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center “Transformation of the State” (SfB597).

^{**} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

Abstract English

In this article the authors try to find a way to overcome the separation of internal-market policy and consumer policy, because the product safety policy has been experienced to be a barrier to trade. First of all they emphasize that mutual recognition as developed in Cassis de Dijon judgment is no alternative to promote the development of a uniform product safety policy because it would discriminate enterprises which follow more stringent safety rules; just as the sectoral (vertical) harmonization because it would overtax the Community legislator. They suggest to set up a *Standing Committee on product safety law* which shall coordinate the policy of the Member States and participate in the decision-making of the Commission. Additionally, they want the involvement of the consumer to be strengthened, in form of a private party like the CEN/CENELEC is for the Standing Committee on technical standards. Finally, the authors mention the idea to start a systematic follow-up market control by cooperation between the Member States and the Community. Nevertheless, the first step has to be the introduction of a general product safety obligation that helps to anticipate standardization in individual sectors, before the previously mentioned steps can be taken.

Completing the New Approach through a European Product Safety Policy⁺

Christian Joerges^{} and Hans-W. Micklitz^{**}*

Introduction

Central to all the analysis in the foregoing chapters was the question of how the connections between the Community's efforts to establish a common market, with their inevitable influence on product safety law, would affect integration. So far, the answers to this question have been anything but encouraging. Although "traditional" harmonization policy has succeeded, at any rate in individual sectors, in exploiting the interests of Member States in the free movement of goods to create uniform safety criteria, the legislative tasks involved in continuing with such a policy exceed the legislative capacity of the Community, if only on account of their scale and the need to bring European rules into line with technical progress.¹ This realization explains the move towards a legal approximation policy that relieves the burden on Community legislators and delegates technical questions relating to safety law to the standards organizations. However, analysis of the "new approach to technical harmonization and standards"² has shown that a retreat by Community legislators to fixing just "essential safety requirements" involves considerable difficulties. It is above all safety policy considerations that have led to ambivalent and unclear points in the program of the model Directive,³ putting at risk the realization of its internal market objectives.⁴ Thus, the theme of the following arguments should already be apparent: if the Community is forced to deal with the effects of its new harmonization policy on product safety law in the Member States, it has to supplement the new approach. For the moment, however, this statement describes merely a need for action, without defining the objectives and instruments with which the Community can counter the danger of internal-market policy being frustrated by product safety policy.

⁺ This article has originally been published in 1991 as Chapter VI: Summary and conclusions, in: Christian Joerges (ed.), *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards* – Vol. 5, EUI Working Paper Law No. 91/14.

^{*} Christian Joerges is Research Professor at the University of Bremen, Faculty of Law at the Centre for European Law and Politics (ZERP) and the Collaborative Research Center "Transformation of the State" (SfB597).

^{**} Hans-W. Micklitz, Professor for Economic Law at the European University Institute, Florence, Lehrstuhl für Privat-, Handels-, Gesellschafts- und Wirtschaftsrecht at the University of Bamberg (on leave).

¹ Cf. Falke, J./Joerges, C., The "traditional" law approximation policy approaches to removing technical barriers to trade and efforts at a "horizontal" European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 2.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

² OJ C 136, 4 June 1985, p. 1. See further Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³ Cf. in particular Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴ Cf. Joerges, C./Micklitz, H., The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review* (HanseLR) 2010, 351, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

I. Product safety policy and product safety law in Member States

The need for coordination of internal-market and product safety policy is ultimately the consequence of safety matters being taken up in the respective legislations of the Member States. The General Program of 28 May 1969 for eliminating technical barriers to trade regarding the movement of goods⁵ was an early response to the “discovery” that the achievement of a common market is hindered not only by tariffs and quantitative restrictions but also by differences in laws and administrative provisions in the Member States - not covered by the prohibition of Article 30 of the EEC Treaty. The differential application and limitation of the program as a result of the provisions for optional harmonization and the introduction of safeguard clauses were also concessions to the safety policy interests of Member States.⁶ A further aim of these instruments, together with the introduction of the regulative and administrative committee procedure under Article 155, fourth indent,⁷ was to relieve the burden on the Community’s legislative process. The new harmonization policy, which confines itself to setting essential safety requirements, represents a continuation of these efforts. The reasoning behind the model Directive does not, however, call into question in principle the legitimacy of government provisions for product safety,⁸ but rather presupposes that the new harmonization policy should be compatible with the safety interests of Member States.

1. Convergences

The comparative survey of the law in the economically most important Member States of the Community and the USA reveals an astonishing convergence of regulatory approaches, which will contribute towards acceptance of the new harmonization policy. An essentially positive attitude was to be expected from the Federal Republic of Germany, because cooperation between government bodies and self-governing industrial organizations in the field of technical safety law has been part of German legal tradition since the 19th century,⁹ and because the Federal Republic also played a major part in implementing the “model” for the model Directive, i.e. the low-voltage Directive of 1973.¹⁰ However, for the United Kingdom and France, the adoption of a regulatory system for product safety law based on the method of reference to standards is anything but obvious. With the CPA 1961, safety legislation in the United Kingdom opted for a government-administered approach to

⁵ OJ C 76, 17 June 1969, p.1; cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁶ Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.3. and 2.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁷ Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.6. and 2.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁸ Cf. the principles in part A of the outline directive (fn. 2).

⁹ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁰ Cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

regulation. This approach was already modified by the 1978 Consumer Safety Act.¹¹ But it was not until 1984 that the White Paper “The safety of goods”¹² made the first move toward a rapprochement with German law, with its proposal for a general product safety obligation to be defined with reference to “sound modern standards of safety”. This convergence is even more obvious in the efforts to strengthen the British standards organizations and ensure their formal recognition by government.¹³ In France the development is less clear, if only because standardization is closely linked, legally speaking as well, with the government administration and because product standardization and the protection of safety interests are regarded as two separate government functions.¹⁴ Furthermore, the Consumer Safety Law of 21 July 1983¹⁵ and its new instruments are as yet virtually untested in practice¹⁶. The argument that developments in France are moving towards the legislative approach of the model Directive thus rests on the assumption that in France too the preventive protection of safety interests is increasingly being approached through cooperation between government administration and AFNOR, whereby the administrative controls provided for in the 1983 Consumer Safety Law are not being fully exploited to regulate the development of safety law. The Commission can be confident that this convergence of developments in the economically most important Member States will influence the Community as a whole, and it can point to the fact that important non-member countries are also increasingly favouring the use of voluntary standards in their product safety policies.¹⁷

2. Divergences

However, the trend towards encouraging voluntary standards does not in itself guarantee the smooth harmonization of their function as regard safety policy. The stable cooperation between government and standards organizations in Germany, which has led to the wide acceptance of the reference method as a means of safety regulation, is the outcome of a long historical process. This process cannot simply be copied, and the role of government administration in cooperation with standards organizations will continue to vary from country to country.¹⁸ In particular, the concrete results of standardization will in all

¹¹ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 2.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹² Cmnd. 9302, HMSO, London, July 1984.

¹³ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 2.4 and 2.6.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁴ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 1.1, 1.4 and 1.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁵ JO 115 No. 168, 2261, 22 July 1983.

¹⁶ Cf. Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 1.2. - 1.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁷ Cf. e.g. the USA, Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 4.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, and the OECD Report “Development and Implementation of Product Safety Measures”, Paris 1986 (as yet unpublished), Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, *Hanse Law Review* (HanseLR) 2010, 137, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁸ The example of the shift from compulsory to voluntary standards as the primary means of regulation in the USA is instructive; the functions of the Consumer Product Safety Commission in monitoring or participating in standardization projects appear to extend considerably beyond the influence exerted by government on the DIN

probability differ. Before the House of Lords Select Committee on European Community consumer policy, the BSI representative emphasized that, particularly where safety standards were concerned, differing national conditions played a considerable role and, moreover, there were substantial differences in the standard of safety within the Community.¹⁹

In addition, there are significant differences in national standardization procedures, particularly with regard to the participation of consumer organizations,²⁰ the coverage of standards work and the actual use of standards in industrial production. Finally, it remains to be seen whether the national standards organizations can develop a common “safety philosophy”, and what effect differences in their general attitude to safety policy will have, for example in their assessment of the functions of accident information systems.²¹ It goes without saying that all these difficulties in ensuring an equal standard of safety in the Community are compounded when the countries “below the olive line”²² and their industrial and administrative infrastructures are taken into account.²³ Accordingly, the importance of the parallels between the traditions of German technical safety law and the strengthening of the standards organizations in the United Kingdom and France should not be exaggerated. The convergences observed are – like the Community’s new harmonization policy – essentially motivated by industrial policy. The linking of standardization and safety policy could once again be called into question in changed political circumstances.

It would be hazardous to assume that the German approach to product safety will automatically provide a model for others, if only because product safety issues repeatedly attract public attention in all Member States in cycles that are difficult to predict, and then prompt widely differing reactions.²⁴ Individual Member States are therefore always likely to resort to special measures to counter certain product risks, to question the appropriateness of the reference method as far as safety law is concerned (or at least to wish to strengthen their control over private standards organizations) and to augment their range

institute (cf. above *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>).

¹⁹ House of Lords, Select Committee on the European Communities, Consumer Policy (Session 1985-85, 15th Report, HL 192), London 1986, p. 158 et seq.

²⁰ On the position in France see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.7.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; on the UK *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.2.1., 2.3.2. and 2.6.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>; for the German Law, see *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.4.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

²¹ The decidedly positive attitude of the BSI to the HASS System (loc. cit., fn. 19, p. 160) corresponds to the recognition accorded to NEISS in the USA (see above, *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.4.2., fn. 125. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>). DIN evidently thinks differently.

²² This formulation was used by a representative of the UK National Consumer Council, loc. cit. (fn. 19), p. 60; all interest groups are agreed on this point (cf. for the assessment of the BSI, loc. cit., p. 159).

²³ It is doubtful whether experience with the low-voltage directive will permit opposite conclusions to be drawn because (a) international standardization is particularly well developed in the field of electrical engineering and (b) there are no empirical surveys of the standard of safety even in the electrical appliances sector (for an anecdotal example of the differences between Italy and the United Kingdom, cf. the hearings of the Select Committee, loc. cit., fn. 19, p. 96 et seq.)

²⁴ Cf. Joerges, C., Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, before 1 and 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

of instruments for product safety policy. Finally, the different situations of “manufacturing” and “importing” countries should also be recalled.²⁵ Since “importing countries” have no influence on the fixing of national standards and can be bypassed at European level as regards both standardization and the recognition procedure,²⁶ and as they need to weigh up only price effects and safety interests when deciding on the level of product safety, they would not necessarily be committed to either the forms or the result of the new regulatory method.²⁷

Consequently, the Community must assume that product safety policy will remain a critical issue within Member States, that the search for appropriate regulatory instruments will continue and that not the issue of legal protection as such, but at most the forms this will take, will be subject to political negotiation. If this diagnosis is correct, there is no real alternative for the Community either but to carry on with *both* elements of its integration policy – internal-market policy *and* product safety policy.

II. Integration policy options

The finding that the integrative force of the new regulatory system in the model Directive will hardly suffice to overcome impediments to the free movement of goods due to differing product safety requirements simply means that the Community has to exert even stronger influence on legal controversies as to the content and form of product safety law than it has already done with its new approach to technical harmonization and standards.

However, this still leaves open the form to be taken by such influence: the Community can either seek to reduce national powers of intervention, or extend its attempts to move towards a “positive” integration of product safety policy.

1. Internal market policy as a deregulation strategy

The results of the Community’s endeavours to implement its consumer policy programmes have been modest.²⁸ This suggests that a Community strategy for the “deregulation” of product safety law in the Member States will have more chance of success than a fresh attempt at “positive” integration. The new harmonization policy has hence been interpreted as heralding such a deregulation strategy.

Probably the most prominent advocate of such an interpretation, or at any rate the most forceful, is the Wissenschaftlicher Beirat (Scientific Advisory Council) of the German Federal Ministry of Economic Affairs.²⁹ It bases its interpretation of the New Approach on

²⁵ Cf. the remarks on the attitude of Canada in the OECD report cited in fn. 17.

²⁶ Cf. Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review* (HanseLR) 2010, 289, 3.3-3.6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

²⁷ Cf. Falke, J./Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 1.2.1, fn. 19 et seq. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

²⁸ Cf. Falke, J./Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

²⁹ Stellungnahme zum Weißbuch der EG-Kommission über den Binnenmarkt, Bonn 1986; see also Joerges, 1988, III 3 a.

the statement contained in the Cassis de Dijon judgment,³⁰ and taken up by the Commission in its communication of 3 October 1980,³¹ to the effect that any product lawfully produced and marketed in one Member State must be admitted to the market of any other Member State.³² In the view of the Beirat, the mutual recognition of safety standards is the consequence of this principle, so the harmonization of safety requirements is not necessary for the establishment of the internal market except in exceptional cases.³³ However, the Beirat bases its thesis not only on the text of the Commission's White Paper but also on independent arguments relating to the competition-policy and regulative functions of the principle of the free movement of goods: in principle (it argues) it is up to the European consumer (not the individual Member State) to decide the standard of quality and safety of products. Therefore it concludes that where governments cannot agree on the harmonization of product standards, competition between products manufactured to different standards is reasonable and, in the long term, the price-performance ratio (or range of products) that best meets consumer demand will prevail.³⁴

However, this is not a valid interpretation of the Commission's White Paper or the case law of the European Court of Justice. The statement quoted by the Beirat from the White Paper is based, as is apparent from the context, on the – albeit problematical³⁵ – assumption that provisions in Member States governing safety are generally equivalent; neither in its Cassis decision nor in any subsequent judgments has the European Court suspended safety requirements in the Member States pursuant to Article 30 of the EEC Treaty regarding imports;³⁶ an obligation as to “mutual recognition” of safety measures taken by the Member States presupposes the harmonization of the preconditions for recognition.³⁷

The position of the Beirat is, however, questionable not just in exegetic and legal terms but also – and especially – in terms of legal policy and integration policy. The first point at issue is the initial normative premise that the decision as to the standard of protection provided by product regulations is in principle to be left to the end-user, whose protection is to be ensured primarily by means of information, obligatory labelling and “strict producer liability”.³⁸ The Beirat does not attempt to justify its regulatory principles vis-à-vis alternative views of product safety policy. If it had done so, it would have become clear first of all that influencing of the safety practice of consumers “in line with market principles” – the only approach envisaged by the Beirat – and obligatory or semi-

³⁰ Case 120/78, Judgment of 20 February 1979, ECR [1979] 649, (§ 14).

³¹ OJ C 256, 3 October 1980, p. 2.

³² Loc. cit. (fn. 29), § 3.

³³ Loc. cit., §§ 4 and 3.

³⁴ Loc. cit., § 4.

³⁵ “Completing the internal market”, White Paper from the Commission to the European Council, COM (85) 310, 14 June 1985, § 58: if safety regulations share the same objectives but differ in the means employed, this may well lead to real differences in the standard of safety.

³⁶ Cf. above Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, Hanse Law Review (HanseLR) 2010, 289, 1.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³⁷ Cf. Falke, J./Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, Hanse Law Review (HanseLR) 2010, 239, 1.1., fn. 11. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>, Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, Hanse Law Review (HanseLR) 2010, 289, 3.3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

³⁸ Loc. cit. (fn. 29), § 4.

governmental product regulation, which are the main targets of the removal of technical barriers to trade, have widely differing objectives and cannot simply be subsumed together as functionally equivalent measures.³⁹ The distinction between “market”, “interventionist” and “self-regulating” regulatory instruments also shows that the standpoint of the Beirat on integration policy has no normative justification and is scarcely feasible in positive terms.

The demand that the Community should at all times enforce the principle of the free movement of goods and promote “intra-Community competition between standards”, even where harmonization of product regulations cannot be achieved, in fact means that enterprises in the “safety countries” will be forced to accept cost disadvantages in competition with enterprises in “risk countries”.⁴⁰ The disadvantaged enterprises may respond to these distortions of competition by exerting political pressure to ease domestic safety regulations or shifting their production to “risk countries” – whatever happens, the “safety countries” would be under pressure to adopt a deregulation policy. Such consequences pose a threat to regulatory measures that are justified in themselves, and are unacceptable, amongst other things because they remove the decision for or against safety regulations from the political decision-making process and place it at the mercy of the strategic calculations of individual countries and enterprises.

The views of the Beirat on integration policy moreover ignore an option that suggests itself, at any rate as a “normative” approach, particularly where there are differences in product regulation, an opinion that is furthermore constantly emphasized in the economic theory of federalism:⁴¹ the performance or coordination of regulatory functions at European level may secure administrative cost benefits and also be “beneficial” where the positive “external effects” of a government measure cannot be confined to a single area of jurisdiction.

However, an integration policy strategy that uses the principle of the free movement of goods as an instrument to deregulate product safety law in the Member States would be not only dubious as a “normative” approach but also scarcely feasible in positive terms. Any lowering of the standard of product safety does not *a priori* meet a genuine interest of “the” European economy.

On the contrary, enterprises in Member States with high standards may even secure competitive advantages from a general raising of the standard of safety. Furthermore, in view of the political sensitivity of safety issues, the Member States cannot call into question their own product regulations just like that. The history of the Single European Act⁴² and also the discussion to date on the New Approach point in the same direction. It was not the “risk countries” which insisted on the proviso of Article 100 (a) (4),⁴³ nor does agreement

³⁹ Cf. Joerges, C., Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review* (HanseLR) 2010, 117, 3 for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁴⁰ For terminology cf. Falke, J./ Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 1.2.1, fn. 20. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁴¹ Cf. Falke, J./ Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review* (HanseLR) 2010, 239, 1.2.1, fn. 14. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁴² EC Bull., Annex 2/86.

⁴³ Cf. analysis by H.J. Glaesner, *L'acte unique européen*, *Revue du Marché Commun* 1986, p. 307 et seq., p. 313 et seq.

to the “reference method” of the New Approach indicate that the “safety countries” are prepared to accept a reduction in the level of safety provided by their standards.⁴⁴

2. Positive integration as an alternative

The “traditional” alternative to the deregulation of safety law in Member States has been the sectoral (vertical) harmonization of their product regulations. This policy has failed because it both overtaxes the legislative capacity of the Community⁴⁵ and blocks the emergence of a coherent European safety policy.⁴⁶ However, the acceptance of these objections to the traditional policy of legal approximation itself raises the question of whether the New Approach in its present form does in fact inaugurate a new epoch in market integration. This skepticism ultimately derives from the fact that the new harmonization policy does not eliminate all the causes of the difficulties in reaching agreement at European level, but simply adopts a new procedure for tackling them: for example, the economic conflicts of interest between Member States remain in spite of the delegation of technical harmonization to the standards organizations.

Although the involvement of technical experts and the majority-voting rules of the standards organizations may make it easier to reach decisions, the Member States can assert their interest when deciding on the implementation of individual directives, defining safety objectives and, in particular, making subsequent use of the safeguard procedures – experience with the low-voltage Directive also shows that provisions for follow-up control are in fact exploited as preventive measures.⁴⁷

In addition, in view of the vagueness and non-binding nature of the provisions of the model directive concerning safety law,⁴⁸ there are likely to be great problems identifying and preventing self-interested policies motivated by protectionism in negotiations on the implementation of new directives. In addition to economic conflicts of interest, political conflicts in the area of product safety policy continue to be disruptive factors. Because of its one-sided bias towards the free movement of goods and its neglect of the safety policy dimension of the integration process, the new standardization policy will not be able to prevent Member States from continuing to develop instruments for product safety law independently and applying them in different ways.⁴⁹

⁴⁴ Cf. opinion of the BSI in the hearings of the Select Committee, loc. cit. (fn. 19), p. 146 et seq., p. 157 et seq.

⁴⁵ For details *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 2.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁴⁶ Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 1.2.1, 2.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁴⁷ Cf. above *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 2.3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴⁸ Cf. *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁴⁹ Cf. in particular *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

III. Towards augmenting the New Approach in terms of safety law

Internal-market policy and consumer policy are handled by different Directorates-General; the original programmes in both policy areas have developed independently in terms of both content and timing.

This applies to the General Programme of 1969 for eliminating technical barriers to trade and the New Approach of 1985, and likewise to the consumer policy programmes of 1975 and 1981. The safety issue links both areas, but in terms of internal-market policy it has been seen primarily as a “barrier to trade”, while in the context of consumer policy it has been proclaimed as a goal in itself, as the “right to the protection of health and safety”. The Commission document “A new impetus for consumer protection policy”⁵⁰ is the clearest expression so far of the endeavour to overcome the separation of internal-market policy and consumer policy. The perspectives set out in this document accord with the results of our analyses: because the new harmonization policy would not be viable as a mere deregulation strategy, because a return to “traditional” legal approximation policy is ruled out, the Community does indeed require a “comprehensive product safety policy”.⁵¹ Coordination of internal-market and consumer policies does not necessarily mean that their specific priorities will be ignored, yet it can improve the chances of success for both areas. With internal-market policy, the aim is to counter any threat posed to the free movement of goods by divergent product safety policies in the Member States; consumer policy can take up this interest and hence at the same time meet the objections to the legitimacy of the Europeanization of product safety law.

1. Coordination mechanisms

The coordination of internal market and product safety policies requires both internal synchronization within the Commission and ongoing cooperation with the Member States. The analysis of the effects of the New Approach on product safety law has already produced concrete proposals for internal coordination at Community level. The main tasks are the development of safety objectives and the preparation of corresponding standards. With its “demonstration project” for accident information system,⁵² the Community has an instrument at its disposal for recording and analysing product hazards. All countries that have set up similar systems make use of the results for their product safety policies and for standardization,⁵³ and the Community’s demonstration project also has these objectives.⁵⁴

⁵⁰ Communication from the Commission to the Council, 23 July 1985, COM (85) 314 final, in particular § 19 et seq.; see also the Communication from the Commission to the Council on “The integration of consumer policy in the other common policies”, 24 October 1986, COM (86) 540 final, § 6 et seq.

⁵¹ COM (85) 314 final, § 19.

⁵² OJ L 109, 26 April 1986, p. 23; cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf> and V, 2.

⁵³ For the USA cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.2. and 4.4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, for the United Kingdom cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.5. and 2.8.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, for the Netherlands, cf. *Rogmans, W.H.J.*, Surveillance of Home and Leisure Accidents in the Netherlands, in: *European Symposium on Product Safety in the European Community*, Amsterdam 1985, 73 et seq.

⁵⁴ *Loc. cit.* (fn. 52), Article 1 (2).

Although it can hardly be expected that new harmonization efforts will be oriented solely towards safety policy priorities dictated by the accident information system, the findings of the latter should be taken into account in decisions on the recognition of standards and attestation of conformity, in safeguard procedures and in the preparation of European standards. Conversely, the accident information system can help to settle doubts and controversies concerning the administration of the new standardization policy, by concentrating resources for in-depth studies of accident risks on those areas in which Community decisions are pending and standardization work has started.

Also worth recalling is the possibility of underpinning harmonization policy by means of a systematic evaluation of product liability procedures in Member States.⁵⁵

With regard to the Member States, the task is to monitor implementation of the reference method, while taking safety policy requirements into account and endeavouring to ensure that safety law develops along lines compatible with the freedom of movement of goods. The information Directive of 28 March 1983⁵⁶ already ensures that the Commission is provided with extensive information on relevant plans in Member States. However, the chances of exerting influence via the “standstill” arrangements in Articles 7 and 9 are limited and do not cover urgent measures motivated by safety policy (Article 9 (3)).⁵⁷ As the new harmonization policy is implemented, the information available to the Community will improve, given the recognition and safeguard procedures and as a result of cooperation with certification bodies in Member States. On the other hand, the concomitant decision-making tasks will become more complicated. These tasks can be approached only through a long-term process of exerting influence to coordinate national developments.⁵⁸

The solution that suggests itself is to establish a *Standing Committee on product safety law* for these tasks, to ensure the ongoing involvement of national bodies responsible for product safety in the Community policy-making process, covering the entire activities of the Community in the field of product safety policy – following the example of the Standing Committee set up under the 1983 information Directive. This Committee could also contribute to the internal synchronization referred to above between internal-market policy and product safety policy, and coordinate the work of bodies charged by the Community with specific tasks in the field of product safety policy.⁵⁹ These tasks are described in more detail below. The decisive point is that Member States be represented on the proposed new committee by representatives and experts responsible nationally for the administration of product safety law. This would lead to the following general division of functions:

⁵⁵ Cf. Joerges, C./Micklitz, H., The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 351, 5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

⁵⁶ OJ L 109, 26 April 1983, p. 8.

⁵⁷ For the functioning of the information directive, see Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁵⁸ Cf. Joerges, C./Micklitz, H., The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 351, 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

⁵⁹ Cf. 3.4.4.1 below for details.

Table 1: Division of functions between the Standing Committee on Technical Standards and Regulations and a Standing Committee on product safety.

<i>Standing Committee on technical standards and regulations (information Directive of 1983 and outline Directive of 1985)</i>	<i>Standing Committee on product safety (future product safety directive)</i>
Cooperation with Member States	Long-term coordination of product safety policy in Member States
Participation in decision-making by the Commission	Participation in decision-making
Legal status: regulatory and/or administrative committee ⁶⁰	Legal status: advisory committee ⁶¹

Cooperation between the two Standing Committees should be provided for in a future product safety Directive, with the details to be regulated by their rules of procedure.

2. Standardization procedures and consumer participation

A method of regulation such as reference to standards cannot be introduced in isolation. It requires adaptation on the part of the institutions concerned and furthermore a framework to meet objections to the legitimacy of this form of regulation. This has already become apparent from the need to ensure equivalence in the working of national certification bodies by means of Community rules.⁶² However, this also applies to the legislative conditions required for the reference method itself. Significantly, the convergence in standardization policies in the Federal Republic of Germany, the United Kingdom, France and at Community level already extends to standardization procedures. In these Member States, government influence on standardization has been secured by agreements with the standards organizations, while consumer organizations have been given the opportunity to participate in the preparation of safety standards for consumer goods.⁶³

The Guidelines agreed between the Commission and CEN/CENELEC on 13 November 1984 are analogous arrangements. The main principles of Community standardization policy are thus: government influence on standardization projects, consumer participation and legal control of standardization results. All these principles still need to be worked out in detail and established as binding rules.

⁶⁰ For reasons, cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.6 and 5.3 above. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁶¹ Cf. also 3.4.4.1 below.

⁶² Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>

⁶³ See refs. in fn. 20, and for the legal justification *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

a. Rights of participation

Particularly urgent with regard to enhancing the status of European standardization⁶⁴ is clarification of the role of consumer participation.⁶⁵ The Community's standardization policy takes a long-term approach. Under Article 6 of the information Directive of 28 March 1983,⁶⁶ the Commission consults with the Standing Committee on technical standards and regulations on the working of the Directive and on standardization priorities. In accordance with Article 6 (7) of the Directive, these discussions are confidential. However, this does not rule out consultation of experts, and the General Guidelines of 13 November 1984 for cooperation between the Commission and CEN/CENELEC⁶⁷ indicate that participation by the European standardization organizations is desirable at this early stage. Such early cooperation is useful in order to ensure mutual coordination of working programs. The same applies to consumer participation, given that the establishment of priorities requires a trade-off between internal-market and safety policy interests. Consumer participation is particularly essential where the granting of standardization mandates is concerned. In accordance with Annex II of the Council Decision of 7 May 1985,⁶⁸ these mandates are intended to ensure the "quality of harmonized standards". They thus interpret and work out in detail the safety objectives of new directives and hence form an integral part of standardization work, in which consumer participation is provided for by Section B (V) (4) of the model directive. However, the main work involved in preparing safety standards will be carried out by the technical committees of CEN/CENELEC. The most important part of consumer participation is hence sitting on these committees.

One of the functions of consumer involvement is to represent safety interests independently of the interests of enterprises, as the parties directly addressed by standards. The performance of this function requires not only participation in standardization work but also access to information relevant to safety policy. The main source of information – the data from the demonstration project on accident information systems – is not public, pursuant to Article 7 (1) of the Council Decision of 22 April 1986.⁶⁹ The exchange of information on hazards arising from the use of consumer goods is also confined by the Council Decision of 2 March 1984 to communication between competent authorities.⁷⁰ These restrictions are not compatible with the requirements of meaningful consumer participation.

⁶⁴ Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.5. and 5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>

⁶⁵ Cf. *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 6. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁶⁶ OJ L 109, 26 April 1983, p. 8.

⁶⁷ Reprinted in *DIN-Mitteilungen* 64 (1985), p. 48.

⁶⁸ OJ C 136, 4 June 1985, p. 3; it should now be added that Article 1 (1) of the Commission's proposal for amending the information directive explicitly provides for involvement of the Standing Committee in preparing standardization mandates (OJ C 71, 19 March 1987, 12; see also *Falke, J./Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.1, fn. 144 and 3.6, fn 240. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>).

⁶⁹ Fn. 52 above; in contrast, Article 7 of the Commission proposal for a Community accident information system (COM (84) 735, 7 January 1985) provided for a publicly accessible documentation and information centre.

⁷⁰ OJ L 70, 13 March 1984, p. 16.

b. Organizational structures

Consumer participation at all stages of standardization work stems from the realization that informed involvement requires continuous collaboration throughout the standardization process. Also essential for informed participation, however, is the establishment of suitable infrastructures. To this end, a forum should first of all be created for European consumers – a Consumers' Consultative Committee on Standardization. The task of this committee would be to ensure that consumers have a say in negotiating standardization mandates in the Standing Committee and to organize the input from the consumer side to CEN/CENELEC. This dual function requires political and technical expertise. In addition to the four member organizations of the Consumers' Consultative Committee (CCC), competent experts from national consumer testing institutes and scientific research establishments therefore need to be involved. The running of the Consumers' Consultative Committee on Standardization should be in the hands of a secretariat, as heretofore. The exact division of tasks between the Committee and the secretariat would need to be set out in rules of procedure. It would be advisable to leave the secretariat in the hands of the BEUC (Bureau Européen des Unions des Consommateurs), as it already has a well-established network of information and contacts with national member organizations. The only legal basis required is for the existence of such a committee, its composition and the establishment of a secretariat.

This means that the scheme outlined above needs to be extended as follows:

Table 2: Involvement of private parties in the Standing Committees on Technical Standards and Regulations and on Product Safety

Commission:	Standing Committee on Technical Standards	Standing Committee on Product Safety and Regulations
Private parties:	CEN/CENELEC	Consumers' Consultative Committee

The General Guidelines of 13 November 1984 provide in principle for access by such a Consumers' Consultative Committee on Standardization to the work of CEN/CENELEC. The revision of CEN/CENELEC rules of procedure to this end could take national models as examples. The rules of procedure of the Standing Committee on Technical Standards and Regulations should provide opportunities for participation.

3. General product safety obligation

The coordination of product safety law in Member States and the elimination of resistance motivated by safety policy considerations to implementation of the new harmonization policy are aims that do not necessarily require the establishment of detailed safety requirements – they are more likely to succeed through a broader form of influence on product safety law in Community Member States. A step in this direction – and one that can be put into effect immediately – has already been announced as part of the “New Impetus” for consumer policy: the introduction of a general product safety obligation.⁷¹ A

⁷¹ Loc. cit. (fn. 50), § 23. More recently, see in detail the Commission Communication on safety of consumers in relation to consumer products, 8 May 1987, COM (87) 209 final.

product safety obligation laid down in Community law would have limited but varied functions. Initially, it would contribute towards the cohesion of product safety and standardization policy by establishing a universally binding fundamental principle.

The model directive, which implicitly presupposes a general product safety policy, is unable to perform this function, if only because it is formulated too vaguely and is not even legally binding.⁷² By imposing a general product safety obligation, the Community would secure the harmonization of existing product safety laws and planned legislation in Member States. However, such an obligation would in particular have an immediate practical impact in all those countries that do not yet have general product safety laws. In such cases, it would provide the competent authorities with grounds for intervention and hence promote adherence to directives and standards. At the same time, it would encourage standards organizations to step up work on safety standards.

Product safety obligations in the various national legislations differ in the way they are formulated. The German Appliances Safety Law (*Gerätesicherheitsgesetz*) refers to “generally recognized rules of the art” (*allgemein anerkannte Regeln der Technik*) and provides protection in the case of “proper use” (*bestimmungsgemäße Verwendung*) – although the basic standards DIN 820, Part 12 and DIN 31.000/VDE 1000 call for “foreseeable misuse” (*voraussehbares Fehlverhalten*)⁷³ to be taken into account. Article 1 of the French Consumer Safety Law⁷⁴ refers to “normal” use (*condition normale*) or use that can be reasonably foreseen by the manufacturer (*condition raisonnablement prévisible*), and “legitimate” consumer expectations. The US Consumer Product Safety Act uses the expressions “unreasonable risk of injury” (for product bans under § 8 CPSA) and “substantial risk of injury” (for recall procedures pursuant to § 15 CPSA), requiring that foreseeable misuse be taken into account⁷⁵. § 3 (1) of the British Consumer Protection Act 1987⁷⁶ follows the model of the product liability Directive (“There is a defect in a product... if the safety of the product is not such as persons generally are entitled to expect...”); but the description of the product safety requirement for the purposes of the criminal law in § 10 (2) says: “...consumer goods fail to comply with the general safety requirement if they are not reasonably safe having regard to all the circumstances...”. Article 14 (a) in the Dutch bill amending the “*Warenwet*” (*Goods Law*) aims to provide protection against hazards arising from reasonably foreseeable use (*overeenkomstig redelijkerwijze te verwachten gebruik*).⁷⁷

⁷² Cf. *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 351, 1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

⁷³ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.5. for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁴ J.O. No. 168, p. 2261, 22 July 1983; cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.2.1. for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁵ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.3. and 4.5.1., for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁶ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 2.4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁷ Tweede Kamer, vergaderjaar 1985-1986, 17495 Nr. 18; on legal developments relating to liability see, comprehensively, *Snijders*, 1987, 147 et seq. and 152 et seq. (specifically on the safety obligation in liability law).

A decision in favour of a European general clause is made easier by the fundamental consensus on safety policy, which is evident in spite of the wide variation among the examples mentioned, and by the limited functions of such a general clause. There is a consensus that safety criteria should not be defined unilaterally by the manufacturer.⁷⁸ This principle, which is common to all modern product safety laws and which is set out, as far as the Federal Republic of Germany is concerned, in the basic safety standards DIN 820, Part 12 and DIN 31.000/VDE 1000, precludes the adoption of the expression “proper use” (*bestimmungsgemäßer Gebrauch*) employed in § 3 of the German Appliances Safety Law.⁷⁹ The general clause is intended to anticipate standardization in individual sectors and help consolidate European legislation. It is also intended to provide for powers of intervention in those Member States that do not possess fully-fledged systems of national standards, and cover products for which there are no safety standards. It necessarily follows from the above that the general clause cannot refer to standards as such.

Finally, in view of the interest of the Community in a safety counterpart to the principle of the free movement of goods, the product safety obligation must extend explicitly to importers and dealers as well. No distinction should be made between importers and dealers in intra-Community trade, since the aim of the efforts to achieve the internal market is precisely to secure a common European standard of safety and mutual recognition of national control measures. On the other hand, the jurisdiction of the various administrations remains confined to their respective territories. The safety loopholes this entails can only be closed by extending the product safety obligation to cover the trade sector.⁸⁰

Accordingly, the question remains as to which alternative to “proper use” should be incorporated in the general clause. Reliable pointers exist for this decision as well. Firstly, the general clause must be formulated so broadly as to cover the safety needs of all consumer groups, particularly children. Consequently, it should take account of “foreseeable misuse”.⁸¹ On the other hand, however, the criterion of foreseeable misuse cannot be assumed to apply to all products without taking their use and users into account. In particular, there is no question that, in addition to the definition of the responsibilities of manufacturers and users, a large number of additional factors are relevant for a normative assessment of risks: the usefulness of the product, the likelihood of harm being caused and the extent of potential hazards, the availability of suitable technical alternatives, and the cost of safety design requirements.⁸² A formulation that provides for distinctions to be made and for all factors relevant for assessing safety to be taken into account is contained

⁷⁸ Cf. *Joerges, C.*, Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, 2.1 for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁷⁹ Cf. for the restricted meaning of § 3 of the *Gerätesicherheitsgesetz (GSG)*, *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸⁰ This conclusion is anyway in line with the development of product safety and liability law; cf. for the unsatisfactory response by German law, *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3.2 and 3.3.7 end. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸¹ Cf. Article 2 of the old proposal for a Directive on toy safety, OJ C 203, 29 July 1983, p. 1; the new draft directive (OJ C 282, 8 November 1986, 4) has changed the formulation but the content remains the same (cf. *Joerges, C./Micklitz, H.*, The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, *Hanse Law Review (HanseLR)* 2010, 351, 1, fn. 15. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>).

⁸² Cf. *Joerges, C.*, Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, 2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

in the product liability Directive,⁸³ which refers to “the safety which a person is entitled to expect”. There are pragmatic considerations in favour of such a criterion. Parallel development of product liability law and safety law would help consolidate Community law, while the Member States should find it easier to agree on a previously accepted standard than to consent to a new formulation. The choice of this criterion is, moreover, in line with the development of the law in the Member States. It accords with French law and the Dutch “Warenwet” bill,⁸⁴ should be reconcilable with the likely application of the British Consumer Protection Act 1987,⁸⁵ and is *de facto* compatible with the legal situation in the Federal Republic of Germany.⁸⁶

4. Follow-up market control

The main practical point of connection between the Community’s internal-market policy and its product safety policy is follow-up market control. The attitude of the Community to this tool represents the acid test of the quality of its new legal approximation policy. The following considerations are intended as suggestions for Community framework regulations on follow-up market control. They first of all explain why in this area a bold harmonization policy that goes beyond mere approximation of existing legal provisions is necessary (3.4.1) and go on to develop proposals that build on the beginnings already present in Community directives or draft directives, as well as on relevant national provisions.

a. Integration policy functions

As far as national product safety policy is concerned, follow-up market control essentially involves penalizing breaches of product safety obligations, responding to newly identified risks and ensuring compensation for financial loss.⁸⁷

All these aspects are also relevant to a European product safety policy. The introduction of a general product safety obligation would be practically meaningless if breaches were not punishable - the legal need for provision for follow-up action is incontrovertible in view of the inevitable gaps in preventive control measures, and any elimination of product risks must, in order to be fair, also ensure compensation for any damage or injury caused.

However, these general safety policy tasks of follow-up market control gain appreciably in importance in the context of the new harmonization policy. The declared aim of the New Approach is to improve the conditions for the marketability of products in the common market. This objective explains the provisions for the equivalence of European standards and national standards (where included in the standards list), the admissibility of attestations of conformity for “products for which the manufacturer has not applied any

⁸³ OJ L 210, 7 August 1985, p. 29 (Article 6); cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.5. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁸⁴ Fn. 74 and 77.

⁸⁵ Though the Act has loosened the originally intended linkage between liability and safety law (see §§ 3, 10 of the bill, reprinted in PHI 1987, 18).

⁸⁶ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁸⁷ Cf. *Joerges, C.*, Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

standard”, and mutual recognition of attestations of conformity issued by national certification bodies⁸⁸. However, these improvements to the conditions governing the marketability of products, which are motivated by competition and internal-market policy considerations, inevitably reinforce the legal need for surveillance of their conformity to safety standards. Here too - as with the product safety obligation - the territorially restricted application of administrative measures means that Member States can react to identified product hazards only within their own territories. Each Member State has therefore to take such action on its own account. In addition to these functions, which are primarily concerned with safety policy, follow-up market control also has genuine internal-market functions, which too have been taken into account in the model directive: easing the burden on the Community’s legislative procedures with the new reference method has its price in terms of integration policy – it allows only the substantiation of market access rights on the basis of “presumption of conformity”, while conceding to Member States the power to check the justification of such presumptions. The dangers that these Member States’ powers pose to the unity of the internal market can be countered only after the event in the safeguard clause procedure. However, this corrective function requires equivalent standards for follow-up market control⁸⁹ if it is to be effective.

The new harmonization policy has thus produced a “regulatory gap” as far as follow-up market control is concerned. This term refers to the inadvertent creation of a need for positive intervention by a policy aimed at market integration.⁹⁰ Indeed, the Member States have neglected the development of follow-up market control as an instrument for product safety policy;⁹¹ now they are under pressure from the “anti-interventionist” principle of the free movement of goods and the “anti-interventionist” reference method to introduce positive regulation. This consequence appears paradoxical only at first sight. It is in line with the logic of an integration policy that does not permit the achievements of a single internal market to be jeopardized again by one-sided and uncoordinated safety policy measures by Member States.

b. Information sources

The intensity with which Member States seek to detect hazards is the essential determinant of the practical importance of their safety provisions, and the well-considered utilization of information is among the essential conditions for rational use of administrative resources. To date, the Community has contributed to controlling the “information input” to follow-up

⁸⁸ Cf. Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁸⁹ Cf. Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.4 for details. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

⁹⁰ Cf. T. Bourgoignie/ D. Trubek, 1987, 3 et seq., 12 et seq. 171 et seq.

⁹¹ Cf. Joerges, C., Product Safety, Product Safety Policy and Product Safety Law, *Hanse Law Review (HanseLR)* 2010, 117, 3.3. (end). Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>, and the description of the legal situation regarding follow-up market control in Member States in Falke, J./ Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

market control essentially only through the decision on exchange of information on product hazards.⁹² It has however begun to build on this pledge. By Articles 12 and 13 of the draft Toy Directive,⁹³ Member States would be obliged to verify observance of toy safety requirements by export checks and inform the Commission on application of the test and supervision procedures.⁹⁴ Similar supervisory measures are provided for in the directive on airborne noise emitted by household appliances.⁹⁵ Article 4 of the Directive on dangerous imitations of consumer goods,⁹⁶ finally, provides at any rate that information on measures by a Member State may be passed on before an “exchange of views” on the justification for them is held.

The most obvious way of systematically advancing from these starting points is offered by the demonstration project on a Community accident information system.⁹⁷ Its data can, as American experience with NEISS shows,⁹⁸ be utilized for follow-up market control. Data from the European accident information system are suitable as a primary information source also because they are collected according to uniform criteria Community wide, so that using them would help to harmonize administrative practice,⁹⁹

However, accident information systems cannot be the sole source of information. Member States must be free to make use of their existing administrative facilities and, for example, to evaluate studies carried out by test institutes. However, a range of information sources should be underpinned by uniform principles: the admissibility of consumer complaints, the admissibility of input from consumer organizations, the obligation to take account of legal judgments concerning product liability, and an obligation on enterprises to provide notification whenever they possess knowledge from which it can be reasonably concluded that the products they market represent a significant hazard.¹⁰⁰

Consideration of legal judgments concerning product liability fulfils a function specifically related to integration policy, because it indirectly¹⁰¹ contributes towards the harmonization of safety law criteria. In contrast, the obligation on enterprises to provide notification primarily furthers safety policy. Especially where serious risks are involved, enterprises will move to eliminate them of their own accord, and for instance voluntarily make recalls.¹⁰² It should not be assumed, though, that the willingness to do so exists throughout

⁹² OJ L 70, 13 March 1984, 16; on the limited scope of this decision and the need to reform it see *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

⁹³ OJ C 282, 8 November 1986, 4, amended proposal of 2 October 1987, COM (87) 467 final.

⁹⁴ On the “Europeanization” of positive decisions cf. 3.4.4 below.

⁹⁵ OJ L 344, 6 December 1986, 24 (Art. 5).

⁹⁶ OJ L 192, 11 July 1987, 49.

⁹⁷ Fn. 52 above.

⁹⁸ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

⁹⁹ Though a prerequisite for this would be removal of the existing prohibitions on using the data (cf. 3.2.1 above, and *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>).

¹⁰⁰ Cf. for US law as a model, *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 4.5.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁰¹ Cf. 3.4.3 below.

¹⁰² Cf. *Falke, J./Joerges, C.*, The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 3.4.

an entire industry or will (or even can) lead to corresponding action on export markets. Nevertheless, the obligation to provide notification would not only meet the safety requirements of consumers but also provide information on inadequacies of standards or deficiencies of national attestations of conformity.

c. Requirements for intervention and instruments for taking action

Public-law product safety duties are intended to provide the competent authorities with possibilities of intervention to ward off product hazards. In legally specifying such intervention rights, general clauses are indispensable. This follows even from the fact that product safety duties in the form of “basic safety requirements” can in principle only set “performance requirements”, but not prescribe definite design characteristics.¹⁰³ This is also in line with the regulatory functions of a general duty of product safety in the sense proposed above. While “legally” the general product safety obligation acts “preventively”, in practice it at the same time turns away from the hopeless attempt to guarantee the safety of consumer goods preventively by specifying particular design requirements. But just because specific prior binding instructions are thus not being given, government must nevertheless remain in a position to meet its responsibilities for product safety by responding to dangers that do become evident. The embodiment of this power of intervention in the form of a general clause in safety law is thus the necessary consequence of abandoning specific governmental product regulations.

But even if Community-law preconditions for the intervention powers of the competent authorities in Member States can thus be laid down only in general form, it is possible, and imperative, to adopt detailed regulations on the instruments of follow-up market control. The Directive on dangerous imitations of consumer goods¹⁰⁴ states that Member States should set up a body with powers to remove, or cause to be removed, products from the market (Article 3). The draft Toy Directive¹⁰⁵ says less specifically that Member States should “take all appropriate measures to withdraw” unsafe toys “from the market and prohibit their placing on the market” (Article 7 (1)).¹⁰⁶

It does indeed seem appropriate to leave Member States the freedom to use institutional solutions that are in line with their various legal traditions. For example, the obvious approach for the Federal Republic of Germany would be to entrust follow-up market control to the industrial inspectorate (Gewerbeaufsicht),¹⁰⁷ while France would do best to maintain the division of functions between the Commission for Consumer Safety and government administration¹⁰⁸ and the United Kingdom should retain the responsibility of

Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

¹⁰³ For this distinction, see *Falke, J./Joerges, C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 3.2. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹⁰⁴ Fn. 96 above.

¹⁰⁵ Fn. 93 above.

¹⁰⁶ Cf. the corresponding provision of Article 7 of the directive on airborne noise emitted by household appliances, fn. 95 above.

¹⁰⁷ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 3.3.7. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹⁰⁸ Cf. *Brüggemeier, G./Falke, J./Joerges, C./Micklitz, H.*, Examples of Product Safety Legislation, *Hanse Law Review (HanseLR)* 2010, 137, 1.5.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

local authorities.¹⁰⁹ Finally, the establishment of independent commissions is also conceivable.¹¹⁰

However, as regards the legal instruments to be made available to these bodies, Community coordination would be advisable. The possibilities are bans, confiscations, recalls, warnings and compensation to consumers affected by recalls.

The type of action taken should depend on the nature and severity of the hazards. Bans or even confiscations are not always necessary, but are not always enough either. It may suffice to have the manufacturer rectify faults. However, it may also be necessary to have products replaced or recalled, with compensation for financial losses. The right to inform the public or demand that the manufacturer or importer provide appropriate information is essential, but the necessity and nature of the information will in turn depend on the seriousness of the product risk. For example, a public information campaign will not be required if the manufacturer is able to identify the customers concerned directly from its files and contact them. This particular example illustrates that the appropriate control measures should best be agreed in conjunction with the manufacturer or importer. A commitment by the enterprise concerned to propose, in the event of significant product hazards, a catalogue of measures for preventing such dangers would normally enable a settlement to be reached, as is shown by the example of US law.¹¹¹

d. The role of the Community in follow-up market control

The development of the law relating to follow-up market control is not an end in itself, but fulfils a dual function in terms of both safety policy and internal market policy. The aim of Europeanizing follow-up market control is to reduce the potential for conflict in the field of safety policy resulting from the objectives of internal market policy¹¹² by Europeanizing the practice of safety law.

aa. Standing Committee on technical standards and regulations and a "Committee on follow-up market control"

The model directive provides for all questions connected with the implementation of new directives to be handled by the Standing Committee on technical standards and regulations. However, the main task of this Committee is to advise on new plans for directives and standards. In addition, the primary function of the safeguard procedure is to examine the quality of European and national standards and, where necessary, ensure that they are

¹⁰⁹ Cf. Brüggeimer, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 2.2.3., 2.3. and 2.4.1. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹¹⁰ Cf. for example the proposals by A. Pauli, 1985, p. 180 et seq.; in the Netherlands, a Parliamentary initiative to supplement the Government Bill amending the "Warenwet" (fn. 77) provides for responsibility to lie with the Minister of Welfare, Public Health and Culture (Tweede Kamer, vergaderjaar 1985-86, 17495 Nr. 22).

¹¹¹ Cf. Brüggeimer, G./Falke, J./Joerges, C./Micklitz, H., Examples of Product Safety Legislation, Hanse Law Review (HanseLR) 2010, 137, 4.5., fn. 154. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art03.pdf>.

¹¹² Cf. Falke, J./Joerges, C., The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, Hanse Law Review (HanseLR) 2010, 289, 3.4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>, and Joerges, C./Micklitz, H., The need to supplement the new approach to technical harmonization and standards by a coherent European product safety policy, Hanse Law Review (HanseLR) 2010, 351, 3. to 4. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art06.pdf>.

developed further. On the other hand, follow-up market control essentially involves executive tasks. The question of whether certain risks require intervention can be considered separately from the question of whether these risks require changes to European or national standards. This distinction could also be taken into account in the institutional arrangements: the Standing Committee on technical standards and regulations should be relieved of executive tasks to allow it to concentrate entirely on problems of legislation and standardization.

The executive tasks are difficult enough. Harmonization of information sources, conditions for intervention and instruments of follow-up market control is a necessary but not sufficient condition for achieving an equal standard of safety throughout Europe. The Community thus requires a body through which differences of opinion between the competent bodies can be argued out and settled. With a view to harmonizing practice in Member States, their inclusion on a "Committee on follow-up market control" is to be recommended here as well. However, since it will be concerned with executive questions, this committee does not need the legal status of an administrative or regulatory committee, but should be set up as a subcommittee of the Advisory Committee on product safety proposed above.¹¹³

Making the administration of follow-up market control institutionally autonomous does not immediately seem to be in line with approaches in the Community's recent legal acts in the area. The Directive on airborne noise emitted by household appliances¹¹⁴ explicitly refers all questions in connection with its implementation to the "Standing Committee set up by Directive 83/189/EEC" (Article 9 (1)).¹¹⁵ The draft Toy Directive¹¹⁶ takes the position that the Commission alone will decide on questions of follow-up market control (Article 7 (4)), and where shortcomings in harmonized standards or gaps in the standards become apparent, provides for consultation of the Standing Committee on technical standards and regulations (Articles 5 and 7 (2)). The directive on dangerous imitations of consumer goods entrusted the Advisory Committee on information exchange on dangers arising from the use of consumer products, set up by decision 84/133 of 2 March 1984, with the tasks of coordinating measures by individual States.¹¹⁷

bb. Decision-making powers of the Commission

The above-mentioned functions of the Europeanization of follow-up market control entail requirements that cannot be met simply by an exchange of information restricted to the authorities concerned, which leaves any reaction to hazards at the discretion of Member States. The Community must therefore go well beyond the Council Decision of 2 March 1984.¹¹⁸ It requires comprehensive information and considerable decision-making powers.

Initially, it needs to be informed of decisions by the competent bodies in the Member States. However, the obligation on Member States to supply information should not be

¹¹³ 3.1 above.

¹¹⁴ Fn. 95 above.

¹¹⁵ On problems of the differential treatment of objections to European standards on the one hand and to national standards on the other, see *Falke, J/Joerges. C.*, The new approach to technical harmonization and standards, its preparation through ECJ case law on Articles 30, 36 EEC and the Low-Voltage Directive, and the clarification of its operating environment by the Single European Act, *Hanse Law Review (HanseLR)* 2010, 289, 5.3. Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art05.pdf>.

¹¹⁶ Fn. 93 above.

¹¹⁷ The reference to the decision (fn. 92 above) can be found in Article 4 of the new directive (fn. 96 above).

¹¹⁸ Fn. 92 above.

confined to cases where positive measures are ordered. It ought also to cover cases where a settlement was reached or where intervention was rejected, since such procedures are no less important for the harmonization of administrative practice, and their justification can be just as questionable as the ordering of positive measures. Decision-making in the Commission and the Advisory Committee on follow-up market control proposed here can also be aided by the findings of the demonstration project on accident information systems as well as by other own sources of information. Consumer organizations should be allowed to approach the Commission, and the “Consumers’ Consultative Committee on Standardization”¹¹⁹ should have access to Commission decisions.

Two types of decision in the area of follow-up market control can be distinguished: responses to urgent measures and definitive decisions on conflicts concerning the justification or necessity of measures. In cases of “serious and immediate risk”, which already have to be notified “immediately” to the Commission under Article 1 (1) of the Council Decision of 2 March 1984, the safety policy function of follow-up market control calls for the Commission to have the authority to order other Member States to take provisional measures. However, such measures should then be discussed with the Advisory Committee on follow-up market control before the Commission takes a final decision. In all cases where no immediate action is required on the part of the Commission, the Committee should be consulted before a decision is taken. Its participation is essential for the development of common assessment criteria in the Community.

IV. Institutional measures to coordinate internal market and product safety policy

The network of committees and cooperative relationships sketched out in the foregoing sections may look over-differentiated and too intricate. Nevertheless, all these proposals are ultimately concerned only with the institutional consequences of two conceptual premises embodied in the Community's objectives for realizing the internal market themselves. The first premise concerns the relationship between internal market and product safety policies. It states that the legal harmonization essential in the interest of free movement of goods in the Community is inseparably linked with the elaboration of a European product safety policy, but that both elements of the integration process, that is, mutual interpenetration of economic sectors on the one hand, and the achievement of closer integration through a European product safety policy on the other, call for separate forward-looking policies and organizational structures. This premise is the basis for the proposals for giving the tasks in internal-market policy and in product safety policy an independent organizational form in different ways, related to the historical separation of these policy areas in the Community. The second premise concerns the Community's relationships with Member States, and states that both for its legal harmonization policy and for the Europeanization of administrative tasks essential in connection with it, the Community is dependent on continuing cooperation with Member States. This need for cooperation is confirmed not only by theoretical analysis of the Community's political system and of specific features of European federalism,¹²⁰ but also by the practice of Community politics, where decision-

¹¹⁹ 3.2.2 above.

¹²⁰ Cf. Falke, J./ Joerges, C., The “traditional” law approximation policy approaches to removing technical barriers to trade and efforts at a “horizontal” European product safety policy, *Hanse Law Review (HanseLR)* 2010, 239, 1.2.

making processes are open at all levels to influence from the Member States. This development has gone hand in hand with the setting up of administrative, regulatory and advisory committees, something that started early in internal market policy, and is also indispensable in product safety policy.

A first conclusion drawn from these premises is the proposal to set up, alongside the Standing Committee on technical standards and regulations created by the information Directive 83/189/EEC, a Standing Committee on product safety.¹²¹ It is indubitable that, in drawing up directives and standardization mandates, safety concerns belong among the most important tasks for the Standing Committee on technical standards and regulations. But whether at national or at Community level, product safety policy is not confined to questions of law-making and standardization. Instead, it belongs much more in the whole context of comprehensive, varied machinery for guaranteeing consumer safety. The Community must in the long term develop such a policy, and will in doing so be dependent on cooperation with the competent bodies and institutions responsible for product safety policy in Member States. Equally, a legal harmonization policy concerned with achieving the internal market has to concentrate on the steps necessary to that end, and thus set its priorities primarily from an economic viewpoint, on which too it will seek the necessary agreements. Accordingly, organizational differentiation between internal-market and product safety policy does not in any way promote competing political projects, but instead aims at easing the burden on both areas and promoting their cooperation.

A second organizational proposal, namely to set up a Consumers' Consultative Committee on standardization,¹²² is connected with the differentiation between internal-market and product safety policy and the Community's relationship with Member States, but is primarily a consequence of the technique of reference to standards favoured in the new harmonization policy. This legal technique links up the European standardization organizations on "functional" law-making tasks. Because of these *de facto* effects of the reference technique, the justification for calls for consumer participation is in principle indisputable. Our proposals for giving shape to this participation are meant to flesh out this concept, so as to take account of the organizational and staff constraints on consumer organizations and formally guarantee them possibilities of collaboration.

The third proposal, namely to set up a separate committee on follow-up market control, is a direct consequence of the distinction between internal-market and product safety policy, but is also connected with the peculiarities of the new legal harmonization method. On our proposal, the tasks of verifying the substance of European and national standards and developing them further should remain with the Standing Committee on technical standards and regulations, since from the functional viewpoint this is a future oriented law-making activity. Follow-up market control is, instead, often concerned with urgent decisions to deal with acute dangers to consumer safety. In each case, what has to be done is implement Community regulations, something for which the Community is *de facto* dependent on cooperation from the competent authorities in Member States. By its very nature, the case is one of nothing less than the Europeanization of administrative tasks. In view of these far-reaching implications, it would seem appropriate to create the organizational prerequisites for setting administrative cooperation between Community and Member States on a permanent footing.

Online available at: <http://www.hanselawreview.org/pdf10/Vol6No02Art04.pdf>.

¹²¹ Cf. 3.1 above.

¹²² Cf. 3.2.2 above.

To conclude, the institutional proposals in this section are set out below in an overview:

Table 3: Overview of Standing Committees in the area of internal-market and product safety policies

	<i>Internal-market policy</i>	<i>Product safety policy</i>
<i>Involvement of Member States</i>	Standing Committee on technical standards and regulations (1983 information directive and 1985 model directive)	Standing Committee on product safety (future Product safety directive)
	Subcommittees for individual directives (e.g. for simple pressure vessels, toys, the building industry)	Committee on accident information systems (Council Decision of 22 April 1986)
		Committee on follow-up market control (future product safety Directive)
<i>Involvement of Non-governmental actors</i>	CEN/CENELEC	Consumers' Consultative Committee on Standardization