

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

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### 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”.<sup>1</sup> Its original German version<sup>2</sup> 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.<sup>3</sup> 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 And yet, all of these developments and changes notwithstanding, our study is not outdated but remains in many respects instructive (2).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 study<sup>4</sup> pleaded for a public law complement to the European standardisation policy on the one hand and to the Directive on product liability of 1985<sup>5</sup> on the other. To be sure and also

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

<sup>2</sup> 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).

<sup>3</sup> 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.

<sup>4</sup> 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’.

<sup>5</sup> 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 92/59<sup>6</sup> on general product safety, as adopted in 1992 nor its amended version, Directive 2001/95<sup>7</sup>, 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,<sup>8</sup> can hardly be overestimated. It seems equally significant, that the revision of the New Approach, as undertaken in 2008,<sup>9</sup> has in principle respected the need to accompany “market-making” by regulatory policies. The two regulations 764/2008<sup>10</sup> and 765/2008<sup>11</sup> and the Decision 768/2008<sup>12</sup> 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/EEC<sup>13</sup> and is now, after the adoption of the Lisbon Treaty, envisaging quite dramatic changes.<sup>14</sup> The EU rules on product liability as enshrined in Directive 85/374, remained untouched. Three major reports from the European Commission<sup>15</sup> explored the need for reform and – at the end – found it to be superfluous.<sup>16</sup> 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,

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

<sup>7</sup> 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.

<sup>8</sup> 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).

<sup>9</sup> 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.

<sup>10</sup> 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.

<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> 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.

<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup> 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.<sup>19</sup>

<sup>17</sup> 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.

<sup>18</sup> 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](http://ec.europa.eu/bepa/pdf/monti_report_final_10_05_2010_en.pdf).

<sup>19</sup> 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.<sup>20</sup> 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;<sup>21</sup> 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 general<sup>22</sup>, on personality rights<sup>23</sup> and on constitutionalisation of private law<sup>24</sup> 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

<sup>20</sup> See notes 7-8 *supra*.

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

<sup>22</sup> 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).

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

<sup>24</sup> 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.<sup>25</sup>

- 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.<sup>26</sup> Further research activities were undertaken in the fields of comitology<sup>27</sup>, international standards for the reduction of trade barriers and national concepts for health and safety policy,<sup>28</sup> standardization policy in the frame of the General Agreement on Trade in Services<sup>29</sup>, a comparative analysis of institutions and procedures of risk assessment and risk management and revision of the New Approach on Technical Harmonization and Standards<sup>30</sup>.
- 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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup>

<sup>25</sup> 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).

<sup>26</sup> 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).

<sup>27</sup> 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.

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

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

<sup>30</sup> 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.

<sup>31</sup> 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.

<sup>32</sup> 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).

<sup>33</sup> 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,<sup>34</sup> then on the management of emergency procedures with particular emphasis on the multi-level structure of the EU.<sup>35</sup> In his habilitation thesis he dealt with product safety in the transnational economy.<sup>36</sup> Later research projects, concerned the liability for services<sup>37</sup> and product safety management in the Baltic Sea Alliance.<sup>38</sup>

#### 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

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

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

<sup>35</sup> 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).

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

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

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