The Constitution of Private Governance

In quantity and importance, private standards are rapidly taking over the role of public norms in the international and national regulation of product safety. This book provides a comprehensive overview of the rise, role and status of these private product safety standards in the legal regulation of integrating markets. In international and regional trade law as in European and American constitutional and administrative law, tort law and antitrust law, the book analyses the ways in which legal systems can and do recognise private norms as 'law.' This sociological question of law's recognition of private governance is indissolubly connected with a normative question of democratic theory: can law recognise legal validity and democratic legitimacy outside the constitution, without constitutional political institutions and beyond the nation state? Or: can law 'constitute' private transnational governance?

The book offers the first systematic treatment of European, American and international 'standards law' in the English language, and makes a significant contribution to the study of the processes of globalisation and privatisation in social and legal theory.

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This series of books edited by a distinguished international team of legal scholars aims to investigate the normative and theoretical foundations of the law governing relations between citizens. The context for such investigations of private law systems is set by important modern tendencies in systems of governance. The advent of the regulatory state marks the withdrawal of the state from direct control and management of social and economic activity, and the adoption instead of procedural regulation and co-regulatory strategies that promote the use of private law techniques of ordering and self-regulation in social and economic interactions between citizens. The tendency known as globalisation and the corresponding increases in cross-border trade produce the responses of transnational regulation of commerce and private governance regimes, and these new systems of governance challenge the hegemony of traditional national private law systems. Furthermore, these tendencies towards transnational governance regimes compel an interaction between different national legal traditions, with their differences in culture and philosophy as well as their differences based upon variations in market systems, which provokes questions not only about competing policy frameworks but also about the nature and adequacy of different kinds of legal reasoning itself.

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Volume published with Dalloz, Paris

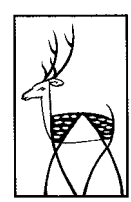
Geoffrey Samuel, *Essai d'épistémologie juridique comparative* (forthcoming)

For the thesis on which this book is based Harm Schepel was awarded the first EUI Alumni Prize for the "best interdisciplinary and/or comparative thesis on European issues" written at the EUI in recent years.

The Constitution of Private Governance

Product Standards in the Regulation of Integrating Markets

Harm Schepel
Kent Law School



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To Phoebe

Contents

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I have made every effort to state law and policy, and to describe major developments, as they stood on 1 January 2004.

Abbreviations

AABB	American Association of Blood Banks
Admin L Rev	Administrative Law Review
AENOR	*Asociación Española de Normalización y Certificación*
AFNOR	*Association Française de Normalisation*
AG	Advocate General
AGA	American Gas Association
AIA	American Institute of Architects
AISI	American Iron and Steel Institute
AJDA	*Actualité juridique- Droit administratif*
AJIL	American Journal of International Law
Am J Comp L	American Journal of Comparative Law
Am J Soc	American Journal of Sociology
Am L Rep	American Law Reports
Am Soc Rev	American Sociological Review
Am U J Int L & Pol	American University Journal of International Law and Policy
Am U L Rev	American University Law Review
ANEC	*Association de Normalisation Européenne pour les Consommateurs*
ANS	American National Standard
ANSI	American National Standards Institute
Antitrust L J	Antitrust Law Journal
AöR	*Archiv des öffentlichen Rechts*
APA	Administrative Procedure Act
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
ASME	American Society of Mechanical Engineers
ASTM	American Society of Testing and Materials
B J Soc	British Journal of Sociology
BOCA	Building Officials and Code Administrators
BOE	*Boletín Oficial del Estado*
BOMA	Building Owners and Managers Association
Brigham Young U L Rev	Brigham Young University Law Review
BSI	British Standards Institute
Cal L Rev	California Law Review
Cam J Econ	Cambridge Journal of Economics
Cardozo L Rev	Cardozo Law Review
CDE	*Cahiers de Droit Européen*
CEN	*Comité Européen de Normalisation*

CENELEC	*Comité Européen de Normalisation Ēlectrotechnique*
CFR	Code of Federal Regulations
Chi J Int L	Chicago Journal of International Law
Chi-Kent L Rev	Chicago-Kent Law Review
Cir	Circuit
CMLRev	Common Market Law Review
CNSI	*Cesky Normalizacni Institut*
Colum J Env L	Columbia Journal of Environmental Law
Colum J Eur L	Columbia Journal of European Law
Colum L Rev	Columbia Law Review
Consumer L J	Consumer Law Journal
Cornell Int L J	Cornell International Law Journal
Cornell L Rev	Cornell Law Review
CPSC	Consumer Product Safety Commission
DIN	*Deutsches Institut für Normung*
DS	*Dansk Standard*
Duke L J	Duke Law Journal
Ecology L Q	Ecology Law Quarterly
ECR	European Court Reports
EJIR	European Journal of International Relations
EJST	European Journal of Social Theory
ELJ	European Law Journal
ELOT	Hellenic Organisation for Standardisation
ELR	European Law Review
Emory L J	Emory Law Journal
Env L J	Environmental Law Journal
Env L Rep	Environmental Law Reporter
EPL	European Public Law
ETSI	European Telecommunications Standards Institute
EuZW	*Europäische Zeitschrift für Wirtschaftsrecht*
FCC	Federal Communications Commission
FDA	Food and Drugs Administration
Florida State U L Rev	Florida State University Law Review
Fordham Int L J	Fordham International Law Journal
Fordham L Rev	Fordham Law Review
FR	Federal Register
Geo L J	Georgetown Law Journal
G Wash L Rev	George Washington Law Review
G Wash U L Q	George Washington University Law Quarterly
Harv J Leg	Harvard Journal on Legislation
Harv L Rev	Harvard Law Review

Hastings Const L Q	Hastings Constitutional Law Quarterly
Hofstra L Rev	Hofstra Law Review
IAFC	International Association of Fire Chiefs
IAPMO	International Association of Plumbing and Mechanical Officials
IBN	*Institut Belge de Normalisation*
ICBO	International Conference of Building Officials
ICC	International Code Council
IFCI	International Fire Code Institute
Ind J Glob L S	Indiana Journal of Global Legal Studies
Ind L J	Indiana Law Journal
Int J Soc L	International Journal of the Sociology of Law
Int Lawyer	International Lawyer
IO	International Organization
IPQ	*Instituto Português da Qualidade*
ISO	International Standards Organisation
JCMS	Journal of Common Market Studies
JCP	Journal of Consumer Policy
JEPP	Journal of European Public Policy
JIEL	Journal of International Economic Law
J Int Econ	Journal of International Economics
J L & Econ	Journal of Law and Economics
J L Econ & Org	Journal of Law, Economics and Organization
J L & Soc	Journal of Law & Society
J Leg S	Journal of Legal Studies
JO	*Journal officiel de la republique française*
J Pol An & Man	Journal of Policy Analysis and Management
J Public Pol	Journal of Public Policy
JfRsozRth	*Jahrbuch für Rechtssoziologie und Rechtstheorie*
JTDE	*Journal des Tribunaux- Droit européen*
JUT	*Jahrbuch des Umwelts- und Technikrechts*
JWT	Journal of World Trade
L & Contemp Prob	*Law and Contemporary Problems*
Law & SocRev	Law & Society Review
LGDJ	*Librairie Générale de Droit et de Jurisprudence*
LIEI	Legal Issues of European Integration
Maryland L Rev	Maryland Law Review
Mich L Rev	Michigan Law Review
Mich J Int L	Michigan Journal of International Law
Minn L Rev	Minnesota Law Review
MLR	Modern Law Review
MoU	Memorandum of Understanding

NCRP	National Council on Radiation Protection and Measurements
NCSBCS	National Conference of States on Building Codes and Standards
NEC	National Electrical Code
NEMA	National Electrical Manufacturers Association
NEN	*Nederlands Normalisatie Instituut*
NFPA	National Fire Protection Association
NJW	*Neue Juristische Wochenschrift*
NMHC	National Multi Housing Council
Notre Dame L Rev	Notre Dame Law Review
NSAI	National Standards Authority of Ireland
NSB	National Standards Body
NSF	*Norges Standardiseringsforbund*
NSPE	National Society of Professional Engineers
NYU Env L J	New York University Environmental Law Journal
NYU J Int L & Pol	New York University Journal of International Law and Politics
NYU J Leg & Pub Pol	New York University Journal of Legislation and Public Policy
NYU L Rev	New York University Law Review
Northwestern J Int L and Bus	Northwestern Journal of International Law and Business
Northwestern U L Rev	Northwest University Law Review
OJ	Official Journal of the European Community
OJLS	Oxford Journal of Legal Studies
ON	*Österreichisches Normungsinstitut*
Opoce	*Office des publications officielles des Communautés européennes*
OUP	Oxford University Press
PMI	Plumbing Manufacturers Institute
PUF	*Presses Universitaires de France*
Rev Fra Sc Po	*Revue Française de Science Politique*
Rev Fra Soc	*Revue Française de Sociologie*
Rev Int Pol Econ	Review of International Political Economy
RIDE	*Revue Internationale de Droit Economique*
RMC	*Revue du Marché commun*
RMCUE	*Revue du Marché commun et de l'Union européenne*
RMUE	*Revue du Marché Unique Européen*
RTDC	*Revue Trimestrielle de Droit Civil*
RTDE	*Revue Trimestrielle de Droit Européen*

Rutgers L Rev	Rutgers Law Review
SAI	Standards Australia International
SBCCI	Southern Building Code Congress International
S Cal L Rev	Southern California Law Review
S Carolina L Rev	South Carolina Law Review
SCC	Standards Council of Canada
Seton Hall L Rev	Seton Hall Law Review
SFS	*Suomen Standardisoimislitto*
SIS	*Standardiseringen i Sverige*
SNV	*Schweizerische Normen-Vereinigung*
Soc & L S	Social & Legal Studies
SSS	Social Studies of Science
Stanford L Rev	Stanford Law Review
Stanford J Int L	Stanford Journal of International Law
Stanford Tech L Rev	Stanford Technology Law Review
ST & HV	Science, Technology & Human Values
STRÍ	*Staðlaráð Íslands*
Syracuse J Int L & Commerce	Syracuse Journal of International Law and Commerce
TC	Technical Committee
Texas L Rev	Texas Law Review
Tort & Ins L J	Tort & Insurance Law Journal
Tulane J Int & Comp L	Tulane Journal of International and Comparative Law
Tulane L Rev	Tulane Law Review
TUTB	European Trade Union Technical Bureau for Health and Safety
U Chi L Rev	University of Chicago Law Review
U Cin L Rev	University of Cincinatti Law Review
U Dayton L Rev	University of Dayton Law Review
UFCA	Uniform Fire Code Association
U Kansas L Rev	University of Kansas Law Review
U Mich J L Reform	University of Michigan Journal of Law Reform
U Penn J Int Econ L	University of Pennsylvania Journal of International Economic Law
U Penn L Rev	University of Pennsylvania Law Review
U Pittsburgh L Rev	University of Pittsburgh Law Review
UCLA L Rev	UCLA Law Review
UL	Underwriters' Laboratories
UNI	*Ente Nazionale Italiano di Unificazione*
USC	United States Code
U Toledo L Rev	University of Toledo Law Review

UTR	*Umwelt- und Technikrecht*
Virginia J Int L	Virginia Journal of International Law
Wake Forest L Rev	Wake Forest Law Review
Washburn L J	Washburn Law Journal
Wayne L Rev	Wayne Law Review
WFCA	Western Fire Chiefs Association
William & Mary L Rev	William and Mary Law Review
Wisconsin L Rev	Wisconsin Law Review
WTO	World Trade Organisation
Yale J Reg	Yale Journal on Regulation
Yale L & Pol Rev	Yale Law & Policy Review
Yale L Rev	Yale Law Review
YEL	Yearbook of European Law
ZfRsoz	*Zeitschrift für Rechtssoziologie*
ZfSoz	*Zeitschrift für Soziologie*
ZHR	*Zeitschrift für das gesamte Handelsrecht*
ZLR	*Zeitschrift für das gesamte Lebensmittelrecht*
ZUR	*Zeitschrift für Umweltrecht*

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Introduction

1. BORDERS AND FRAMES

EARLY LAST CENTURY, the People's Amusement Company operated a playhouse where it provided all sorts of entertainment to the people of Topeka, Kansas. One day, a building inspector saw to his horror that the electrical wiring of the theatre lay bare and was not enclosed in conduit or armoured cable. The People were not amused. Licenses were withdrawn, fines were imposed. The Law had been offended. Or had it? The relevant part of the Kansas Fire Prevention Act of 1915 read as follows:

> All electrical wiring shall be in accordance with the National Electrical Code.

Now, the NEC was, and is, a collection of standards elaborated and promulgated by the National Fire Protection Association, a private organisation of electricians, contractors, manufacturers, fire officials, underwriters and others. And so it was that, in 1919, the electrical wires of the People's Amusement Company made it all the way to the Kansas Supreme Court for a Big Constitutional Question: can the People of a state be bound by regulations that are issued by a private association, the vast majority of whose members are not even residents of the state? The Court's answer in *Crawford* was emphatic:

> [T]he fallacy of such legislation in a free, enlightened and constitutionally governed state is so obvious that elaborate illustration or discussion of its infirmities are unnecessary. If the Legislature desires to adopt a rule of the National Electrical Code as a law of this state, it should copy that rule, and give it a title and an enacting clause, and pass it through the Senate and the House of representatives by a constitutional majority, and give the Governor a chance to approve or veto it, and then hand it over to the secretary of state for publication.[1]

Almost a century on, the dilemmas and questions facing the *Crawford*—court have multiplied and intensified enormously in the face of privatisation and globalisation. Safety standards around the world are written and approved by private and semi-private organisations. In a process greatly accelerated over the last decade or so, these standards are increasingly harmonised either by regional or international federations of

[1] *State v Crawford* 177 P 360, 361 (Kan 1919).

standards bodies, by bilateral joint-development schemes, or by brute exports of standards to foreign markets. This process is partly due to relatively autonomous demands of industry for harmonised standards to facilitate market integration.[2] Large part of it, however, is due to the political co-optation and legal instrumentalisation of standards bodies. From the WTO to the EC to NAFTA, trade agreements put their faith in private standards bodies to achieve the harmonisation of technical specifications that is needed for market integration.[3] In a corresponding process, governments around the world are increasingly replacing their regulations with private standards.

This is a book about the interrelationships between law and standards in the regulation of integrating markets. It deals with the interaction between public and private norms, legal and social norms, and global and local norms. On one level, it is an exercise in the non-existent discipline of 'standards law'. It asks how legal systems deal with standards—how they use standards, how they regulate standardisation, how they incorporate standards. On another level, it is an exercise in what could be called, for want of a less pedantic term, legal constructivism.[4] From the *Crawford*-court to Jürgen Habermas, the dominant position in legal theory and practice is that law cannot accept norms as law if they are not made according to the procedures and passed through the institutions prescribed by law.[5] The sociological question of law's recognition of private governance is indissolubly connected with a normative question of democratic theory: can law recognize legal validity and democratic legitimacy outside the constitution, without constitutional political institutions and beyond the nation state? Or rather: can law 'constitute' private transnational governance?

2. MARKETS, STATES AND ASSOCIATIONS

Standardization is 'a much neglected area of social science research, attracting much less attention than it deserves.'[6] One of the reasons for this, I suspect, is that social scientists like to construct a world according to a series of distinctions—state and market, law and society, public and

[2] Casella, 'Product Standards and International Trade: Harmonization Through Private Coalitions?' (2001) 54 *Kyklos* 243.

[3] See eg Sykes, *Product Standards for Internationally Integrated Goods Markets* (Brookings Institution, Washington, 1995).

[4] For the sophisticated version of the general idea, see Teubner, 'How the Law Thinks: Toward a Constructivist Epistemology of Law' (1989) 23 *Law & Soc Rev* 727; Teubner, 'The King's Many Bodies: The Self-Destruction of Law's Hierarchy' (1997) 31 *Law & Soc Rev* 763.

[5] Habermas, *Between Facts and Norms—Contributions to a Discourse Theory of Law and Democracy* (Polity Press, Cambridge, 1995).

[6] Brunsson and Jacobsson, 'The Contemporary Expansion of Standardization' in Brunsson, *et al*, *A World of Standards* (OUP, Oxford, 2000) 1–2.

private, national and international—that are inherently incapable of capturing or explaining standardisation. Standards hover between the state and the market; standards largely collapse the distinction between legal and social norms; standards are very rarely either wholly public or wholly private, and can be both intensely local and irreducibly global. One of the main themes of the book is that standards can best be seen as links between these spheres and institutions.

2.1 Markets, Hierarchies, and Standardisation

Standardisation has been claimed to be 'a form of regulation just as crucial as hierarchies and markets.'[7] Yet it is by no means obvious that standardisation is distinct from either. Some standards originate purely in 'the market.' Some standards are set by public authorities. The vast majority, however, are written by committees consisting of representatives of various interests and constituencies under the aegis of specialised standards bodies, associations or organisations of various description and composition.[8] Some standards are diffused by market dynamics; some are hierarchically imposed by public authorities. Yet others are diffused by social networking processes, either on efficiency grounds—copying of benchmarks—or on normative grounds—standards might create consumer expectations that producers must fulfil if they wish to compete.[9]

Some standards, most prominently in the information and communications technology sector, ensure compatibility between different products or technologies. Others describe requirements on a product, process or service in order to establish their fitness for purpose and are referred to as quality standards. This category includes standards designed to protect health, safety and the environment, but also those standards conformity with which is designed to convey a message of sheer excellence to consumers. Within this category, design standards describe a product's desired physical characteristics—for example, which materials are to be

[7] Above. Brunsson and Jacobsson go on to make the rather extravagant claim that 'to understand the modern world, we have to know a great deal more about standardization.'

[8] Much of the standards literature is devoted to the comparative advantages of different institutions. See, for example, Farroll and Saloner, 'Co-ordination Through Committees and Markets' (1988) 19 *RAND Journal of Economics* 235; Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990); Knieps, 'Standardization: The Evolution of Institutions versus Government Intervention' in Gerken (ed), *Competition Among Institutions* (MacMillan, London, 1995) 283; Grindley, 'Regulation and Standards Policy: Setting Standards by Committees and Markets' in Bishop, Kay and Mayer (eds), *The Regulatory Challenge* (OUP, Oxford, 1995) 210.

[9] On diffusion models, see Spruyt, 'Actors and Institutions in the Historical Evolution of Standard Setting', Paper presented at the Conference on 'The Political Economy of Standards Setting', (EUI, Florence, June 1998). Cf Spruyt, 'The Supply and Demand of Governance in Standard-Setting: Insights From the Past' (2001) 8 *JEPP* 371.

used or to be avoided. Performance standards describe what a product must be able to do—for example, resist certain temperatures for a certain amount of time. A third category consists of quality management standards, exemplified by the ISO 9000 series. These standards describe procedures to be followed in the production process.[10]

It would be nice if one could lump these characteristics of standards together in two broad categories. Raymund Werle has proposed to divide standards into regulative and coordinative standards. The latter, in this scheme of things, are voluntary compatibility standards, set by market players and diffused through market dynamics. Regulative standards, on the other hand, are mandatory health and safety standards, set by, or under the control of, public authorities, and enforced by imposition.[11] But the world of standards is not so simple. Compatibility standards are sometimes set and enforced by public authorities; health and safety standards often originate in the market and are diffused by benchmarking processes. Most importantly, standards set by committees can be diffused through all three models.

2.2 Markets, States, and Standardisation

Even where public authorities decide to set product standards themselves, it is very rarely the case that they do not, in some way, have to rely on 'private' expertise, institutionalised or not, or enter into consultations or even negotiations with private parties, institutionalised or not. Conversely, even where standards are set by private parties and remain of strictly voluntary application, it is unlikely that public authorities do not exercise some influence over the content and use of these standards—either by the participation of officials in the elaboration and approval of the standard, or because of the threat of public intervention in case the standards were judged to be insufficient for the protection of health and safety or other 'public' values.[12] Standards are almost never either wholly public or wholly private, and neither are standards bodies.

Standards bodies come in many shapes, forms and legal categories. Some are public agencies, some are private trade associations, and most are something in-between. They are locked together, and locked into the public sphere, by co-operation agreements, contracts, membership in umbrella organisations, accreditation arrangements and memoranda of understanding. Some standards bodies are hierarchically subordinated to

[10] For a more extensive classification, see eg De Vries, *Standardization—A Business Approach to the Role of National Standardization Organizations* (Kluwer, Boston, 1999)

[11] See Werle, 'Staat und Standards' in Mayntz and Scharpf (eds), *Gesellschaftliche Selbstregelung und Politische Steuerung* (Campus, Frankfurt, 1995) 266.

[12] See eg Freeman, 'The Private Role in Public Governance' (2000) 75 *NYU L Rev* 543.

the state, others are in overt competition with public agencies—or with other standards bodies—for the 'business' of regulating the production and marketing of goods. They write standards themselves, incorporate references to other standards, and approve, amend or reject standards from other bodies. Together, they form the normative netherworld of acronyms and abbreviations that generates the ISO-EN-BS or ANS-ASTM numbers on your toys, lawn mowers and dishwashers.

2.3 Custom, Technology, and Standardisation

Notwithstanding the tenacity of the imagery of the invisible hand, most people would accept that markets do not, and cannot, function without rules.[13] Markets need rules, says the economist, to sink 'transaction costs.' Markets need rules, says the sociologist, to 'stabilise expectations.' Markets will generate rules and norms 'spontaneously' as they spawn across more and more territory, as social distance grows and complexity increases. Product standards are an important part of these rules.[14] Standards tell manufacturers what to do and tell customers what has been done; standards make components fit together and allow products to be compared. Without widely used and recognised standards, economic life would grind to a halt: it would be much harder, if not impossible, to sell goods, to assemble products, to conclude contracts, or even to get insurance. In that sense, standards constitute markets. The implication is that, left to its own devices, a globalising market will create a demand for global standards and indeed, in some way, generate global standards. In this view, standards spring almost organically from social life.

In another view, which Samuel Krislov calls the 'technocratic' explanation of standards, it is assumed there is an 'optimal' form for physical products:

> Careful, objective study by qualified experts will tease out that form and present is as a verifiable norm. The essence of standards is some neutral, almost definitional finding that stems from the nature of the product itself. Expertise ultimately defines the nature of the goods and what they require.[15]

[13] 'Law, custom, magic and religion' in Polanyi's famous phrase. See Polanyi, *The Great Transformation* (Rinehart, New York, 1944) 55.

[14] In the jargon of 'new institutionalism', standards as social institutions have (a) regulative effects in that they constrain and regularise behaviour; (b) cognitive effects in that they lend a taken-for-granted quality to certain technologies and ways of doing, and (c) normative effects in that they favour co-operative strategies over adversarial ones. See the excellent discussion in Lane, 'The Social Regulation of Inter-Firm Relations in Britain and Germany: Market Rules, Legal Norms and Technical Standards' (1997) 21 *Cam J Econ* 197, leaning on the classic Scott, *Institutions and Organizations* (Sage, Thousand Oaks, 1995) 33 *et seq*. Cf Benezech, 'La Norme: Une Convention Structurant les Interrelations Technologiques et Industrielles' (1996) 75 *Revue d'Economie Industrielle* 27.

[15] Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, Pittsburgh, 1997) 201.

Standards are, in this view, not so much codifications of ways of doing, but the prescription of the best way to do something, finding its roots not in society but in the nature of things. The corollary of this theory is, then, that divergent standards are due to 'protectionist' or at least 'irrational' motives.

In reality, of course, it is very seldom that standards are derived from the customs and practices of social life or deduced from the immutable laws of nature. Standards are products of discussion, negotiation, deliberation and compromise between engineers, manufacturers, academic experts, professionals, trade unionists, representatives of consumer organisations and public officials meeting in boards, committees, task forces and working groups in associations and other organisations. They bring to the table economic, political, moral and technical arguments and ultimately arrive at a solution that will to some extent hurt some groups and in some degree benefit others—consumers or producers, importers or domestic manufacturers. Standardisation is a microcosm of social practices, political preferences, economic calculation, scientific necessity, and professional judgment.[16] Standardisation looks a lot like lawmaking.

Standardisation procedures have developed into a remarkably consistent set of truly global principles of 'internal administrative law'. Partly influenced by legal instruments, partly by the ethics of the engineering and other professions and structured by an extensive process of global reciprocal normative borrowing between the public and private spheres at various levels, these procedures provide *at a minimum* for:

1. Elaboration of draft standards in technical committees with a balance of represented interests (manufacturers, consumers, social partners, public authorities);
2. A requirement of consensus on the committee before the draft goes to
3. A round of public notice and comment, with the obligation on the committee to take received comments into account, and
4. A ratification vote, again with the requirement of consensus rather than mere majority, among the constituency of the standards body, and
5. The obligation to review standards periodically.[17]

[16] See eg Majone, 'Science and Trans-Science in Standard Setting' (1984) 9 *ST & HV* 15; Mai, 'Soziologische Fragen der Technischen Normung' (1988) 11 (2) *Sozialwissenschaften und Berufspraxis* 115; Mayntz, 'Entscheidungsprozesse bei der Entwicklung von Umweltstandards' (1990) 23 *Die Verwaltung* 137; Schmidt and Werle, *Coordinating Technology: Studies in the International Standardization of Telecommunications* (MIT Press, Cambridge, 1998).

[17] See eg ISO/IEC Guide 59 and ISO/IEC Directives Part 1: Procedures; American National Standards Institute, *ANSI Essential Requirements: Due Process Requirements for American National Standards*; Standards Council of Canada, CAN-P–2E, *Criteria and Procedures for the Preparation and Approval of National Standards of Canada*; the European Standardisation Committee, CEN/Cenelec Internal Regulations Part 2: *Common Rules for Standards Work*; DIN 820 and BS 0, the 'standardisation standards' of the German and British standards bodies respectively, and the *Standardization Guides* of Standards Australia and Standards New Zealand.

3. THE BOOK

3.1 Field

'Standards law', I have claimed, is a non-existent discipline. That is not to say, of course, that there is no research done on standards and law. The literature that is available, however, treats standardisation as but an aspect of a particular legal discipline. It is also bizarrely neglected in some countries, jurisdictions and disciplines while receiving almost exaggerated attention in others. There is, thus, a large literature on the subject of standardisation and technical harmonisation in European Community law. But there is close to nothing on the subject of standards in WTO law. There are libraries full of works on standards and administrative law in Germany. But the only two law review articles on the subject in the United States are twenty years old.[18] Lawyers may discuss standards tangentially in tort law, antitrust law, product safety law or even copyright law—but never as a field of interest in itself. The only major works that do so—and they and few and far between—are written by social scientists.[19]

Even more curious perhaps is the absence of any sustained discussion of standardisation in the literature on legal globalisation and the concomitant collapse of the public/private distinction. International lawyers have been warned that, to keep their discipline from falling into oblivion, 'it is necessary to redefine international law to include actors other than States among those who make international norms and who implement and comply with them.'[20] And yet, you'll find nothing at all in the discipline

[18] See Hamilton, 'The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health' (1978) 56 *Texas L Rev* 1329; Hamilton, 'Prospects for the Nongovernmental Development of Regulatory Standards' (1983) 33 *Am U L Rev* 455. Indeed, it is hardly an exaggeration to say that you can learn more about standards in Eastern Asia than about US standards in American law reviews. Cf Burke, 'The Administrative Law of Standardization in the PRC' (1987) 1 *Journal of Chinese Law* 271; Edelman, 'Japanese Product Standards as Non-Tariff Trade Barriers: When Regulatory Policy Becomes a Trade Issue' (1988) 24 *Stanford J Int L* 389.

[19] This includes the splendid Cheit, above n 8, and Voelzkow, *Private Regierungen in der Techniksteuerung: Eine Sozialwissenschaftliche Analyse der Technischen Normung* (Campus, Frankfurt, 1996). Cf Brunsson, *et al*, above n 6; Egan, *Constructing a European Market—Standards, Regulation and Governance* (OUP, Oxford, 2001). The exception is Stuurmans, *Technische Normen en Het Recht* (Kluwer, Deventer, 1995).

[20] Brown Weiss, 'The Rise or the Fall of International Law?' (2000) 69 *Fordham L Rev* 342, 346. For external critique on the discipline's inability to deal with private transnational actors, see eg Cutler, 'Artifice, Ideology and Paradox: The Public/Private Distinction in International Law' (1997) 4 *Rev Int Pol Econ* 261; Sassen, 'The State and Economic Globalization: Any Implications for International Law?' (2000) 1 *Chi J Int L* 109. Cf Delbruck, 'Prospects for a "World (Internal) Law"? Legal Developments in a Changing International System' (2002) 9 *Ind J Glob Leg S* 401, 402 ('In short, international law is in the process of transforming, at least partially, into a World Law or World "Internal" Law extending to states, governmental and non-governmental organizations, and other non-state corporate entities, as well as groups and individuals.')

on perhaps the most important of these private rulemakers. Jody Freeman has announced a similar fate for her own area of expertise:

> Administrative law, a field motivated by the need to legitimize the exercise of governmental authority, must now reckon with private power, or risk irrelevance as a discipline.[21]

And yet, you'll find very little in the discipline on perhaps the most pervasive expressions of private power. Gunther Teubner has described 'global standardization processes' as 'among the most important sources of global law':[22] yet, in his pioneering work on legal globalisation, standards make but the odd cameo appearance.[23] And finally, the only time standards receive a mention in the modern classic on global business regulation by John Braithwaite and Peter Drahos is where they admit that the failure to communicate the importance of what goes in the 'countless little technical committees' of standards bodies is a weakness of their book.[24]

3.2 Method

The book is not about a particular area of law. It is about the interaction of different normative orders on different levels of governance in the broad field of product safety. This has some rather far-reaching consequences for the methodology employed. Most of all, it implies that the analysis cannot be organised and limited according to either the territorial borders or academic categories that normally determine the scope of legal analysis. If globalisation has done anything, it has at least exposed the tools and categorisations of legal analysis to be inadequate to reach a full understanding of the normative fabric of the world.[25]

The thesis deals with trade law, constitutional and administrative law, tort law and competition law. Importantly, it also deals—at improbable length—with what I call the 'internal administrative law' of different standards bodies. There are several reasons for this extravagance. Most obviously, all these areas of law are affected by and implicated in standardisation. More importantly, all these areas of law exert considerable

[21] Freeman, above n 12, 545. Cf Aman, 'The Limits of Globalization and the Future of Administrative Law: From Government to Governance' (2001) 8 *Ind J Glob Leg S* 379 ('The days in which administrative law was focused solely on the government are over.')

[22] Teubner, 'Societal Constitutionalism: Alternatives to State-centred Constitutional Theory?' in Joerges, Sand and Teubner (eds), *Transnational Governance and Constitutionalism* (Hart Publishing, Oxford, 2004) 3.

[23] See eg Teubner (ed), *Global Law Without a State* (Dartmouth, Aldershot, 1997).

[24] Braithwaite and Drahos, *Global Business Regulation* (Cambridge University Press, Cambridge, 2000) 503.

[25] See eg Gessner, 'Global Approaches in the Sociology of Law: Problems and Challenges' (1995) 22 *J Law & Soc* 85; Friedman, 'Borders: On the Emerging Sociology of Transnational Law' (1996) 32 *Stanford J Int L* 65.

influence on standards bodies—on the value of their activities, on their procedures, and on their legitimacy. There is the matter of that mainstay of comparative law—'functional equivalence.' American antitrust law serves, in many ways, much the same purpose and function as does administrative law in France. More generally, in a globalised market, private law may well be able to do more for good governance than public law can. But there is also the matter of national legal systems exerting influence on international standards. The safety of elevators in Mexico may well depend on Oregon product liability law, or on mechanisms of judicial review in Germany.

The book draws on sources ranging from Emile Durkheim to editorials in *ASTM Standardization News*, discusses anything from the WTO Agreement on Technical Barriers to Trade to the California Building Standards Code, and analyses anything from DIN 820 to American constitutional law. On the bright side, there are some limits to the topic. The book deals with product safety standards, and not—or only tangentially—with compatibility or quality management standards or even environmental standards. It does not—or only tangentially—deal with certification and conformity assessment. The book focuses on procedure and not substance. It does not deal with particular industrial sectors or areas of regulation, and it does not evaluate the market share of particular standards, the economic benefit of others, and the dangers to life and limb posed by yet others. Geographically, the book's scope is transatlantic; it focuses on law and standardisation of the European Union and the United States in comparative perspective, with excursions to the law of the WTO, NAFTA and other trade agreements, and to Canada, Mexico, and some Member States of the EU. All I can plead on that score is time and space.

3.3 Structure

The book is loosely divided in three parts. The first part describes the rise of private standardisation in modern governance. Chapter one does so in broad theoretical terms; Chapters two and three do so in terms of specific interactions between political and legal processes and structures in the European Community and in the United States, respectively. The second part maps the universe of the interaction of law and standards in the regulation of integrating markets. After Chapters on the European Community and the United States, Chapter six describes the position of standards in WTO law, and in the free trade regimes of the American hemisphere. Part three is broadly normative, and describes the regulation of standardisation. Chapters seven and eight discuss the status of standardisation in public law in EU and US legal systems; Chapters nine and ten discuss the status of standardisation in comparative tort and antitrust law, respectively. By

way of conclusion, the last chapter evaluates the conditions for, and limits of, the legitimacy of private governance in law.

Without, I hope, detracting from the coherence of the book taken as a whole, I have made an effort to write each chapter as a self-standing essay. I cannot expect many readers to share my passion, if such it is, for all aspects of 'standards law', both public and private, both European and American, and would be surprised, and even a little worried, to hear of anyone who has read through the whole thing. I have tried, then, to make sure that some profit can be had from reading but parts of it. In much the same general spirit, I have tried to write the different chapters in the canons—both methodological and normative—of the traditional fields of enquiry they belong to. This has obvious dangers, especially of detracting from whatever may be the merit of my methodological choice to have standardisation, and not separate legal fields, determine the scope of analysis. But it has some obvious advantages too. Thus, though I would not expect many American public lawyers to agree with my discussion of the status of standards in American constitutional and administrative law, and even less tort lawyers to find that I have added anything to their discipline, I would like to believe that they would find my analysis commensurable to their field. And that, at least, would help to achieve communication.

1

The Rise of Private Governance: Functional Differentiation and Economic Globalisation

1. INTRODUCTION

THE WIDESPREAD SCHOLARLY neglect of the phenomenon of the use of standards in modern market regulation seems all the more striking in the light of the preoccupation of modern theorising in sociology, political science and law with a whole series of processes that standardisation seems to exemplify with force. To repeat a refrain that is becoming more and more familiar: Against the backdrop of the processes of globalisation and differentiation, the state generally loses its centrality in the activity of government—an activity that is now widely re-conceptualised as 'governance.' Law as an instrument of normative ordering becomes more diffuse and is now derived from multiple sources not necessarily limited to the machinery of constitutional lawmaking and exerts validity far beyond the territorial borders of political systems. In this general landscape, standards bodies, public nor wholly private, nationally based but structurally locked into global frameworks, mediating between market demands and legal requirements, would seem to be at least of some interest.

This chapter seeks to give standardisation a place in the debates surrounding modern regulation and governance. It serves two broad purposes. First, it should provide some counterweight to the next two chapters which analyse the rise of private standard setting in the European Union and the United States, respectively, as highly contingent functions of particular interactions of legal and political processes. Second, the chapter provides some general theoretical background for the rest of the book. The ambition here is assuredly not to make any great advances in social theory. Rather, the objective is merely to identify broad trends and to provide some general context for the phenomenon of private standard setting. The chapter starts with a general discussion of the place of associational governance in social theory in the work of Durkheim, Luhmann and

Habermas. It then turns to locate private governance in more specific modern social science debates about governance, globalisation, and scientific expertise. The chapter concludes with a discussion of legal theoretical approaches to private governance.

2. DIFFERENTIATION AND GLOBALISATION: LOGICS OF ASSOCIATIVE GOVERNANCE

2.1 Logics of Associative Governance in Durkheim

It is nearly impossible to find a single strand of sustained thought in contemporary debates about law and governance that is not announced in the work of Emile Durkheim.[1] In particular his celebration of 'professional corporations' seems the logical place to start an exploration of the role of self-regulatory associations in modern governance. Durkheim analysed the division of labour in society in terms of increasing complexity and individualisation. Whereas specialisation of roles leads to increased interdependence, individualisation inevitably involves the erosion of the ties of kinship and community that breed the solidarity which keeps society from disintegrating into a state of *anomie*. In that light, professional corporations were, for him, the only thing standing between a socially integrated society and that '*véritable monstruosité sociologique*', a society composed of an infinite mass of unorganised individuals which an overgrown state tries to limit and restrain.[2] True, Durkheim assigned to these corporations first and foremost a moral function,[3] and his appeal to their self-regulatory capacity can well be explained as a last ditch attempt to salvage something of his case for the spontaneous development of organic solidarity in differentiated society replacing the mechanical solidarity of earlier times.[4] It

[1] Especially since the publication of Cotterrell, *Emile Durkheim—Law in a Moral Domain* (Stanford University Press, Stanford, 1999), neglect of the great French sociologist seems hard to justify in any discussion of the role of law in complex societies. But see Picciotto, 'Introduction: Reconceptualizing Regulation in the Era of Globalization', (2002) 29 *J Law & Soc* 1, 3 (Lamenting the striking absence of discussions of Durkeim, and Marx and Weber, in modern debates about regulation in an introduction to a special issue that does nothing to fill the void.).

[2] Durkheim, *De la Division du Travail Social*, 2nd edn (PUF, Paris, 1930) ii (the 1901 preface to the second edition). For a modern appreciation of the professional group as a vehicle of social cohesion in society, see Gautier, 'Corporation, Société et Démocratie chez Durkheim' (1994) 44 *Rev Fran Sc Po* 836.

[3] Above. See also Durkheim, *Leçons de Sociologie* (PUF, Paris, 1950) 67 ('Ce n'est pas pour des raisons économiques que le régime corporatif me paraît indispensable, c'est pour des raisons morales. C'est que seul il permet de moraliser la vie économique.')

[4] That harsh, Habermas, *Theorie des Kommunikativen Handelns*, 4th edn (Suhrkamp, Frankfurt, 1987) vol II, 130. Harsher still, Alexander, *Theoretical Logic in Sociology, vol 2: The Antinomies of Classical Thought: Marx and Durkheim* (Routledge, London, 1982) 305 (the occupational group is 'a magic formula' for accomplishing 'the complete reversal of differentiation and individualisation.') Cf Hawkins, 'Durkheim on Occupational Groups: An Exegesis and Interpretation' (1994) 55 *Journal of the History of Ideas* 461 (discussing corporations in

is, however, perfectly plausible, and perhaps even necessary, to read his project as being concerned especially with managing social complexity.[5] Dysfunctional regulation for him was as much a moral problem as it was a technical failure of good government:

> Moral or legal rules essentially express social needs which society alone can identify. They rest upon a climate of opinion, and all opinion is a collective matter, the result of being worked out collectively. To be shot of anomie a group must thus exist or be formed within which can be drawn up the system of rules that is now lacking.
>
> Political society as a whole, or the state, clearly cannot discharge thus function. Economic life, because it is very special and is daily becoming increasingly specialised, lies outside their authority and sphere of action. Activity within a profession can only be effectively regulated through a group close enough to that profession to be thoroughly cognisant of how it functions, capable of perceiving all its needs and following every fluctuation in them. The sole group that meets these conditions is that constituted by all those working in the same industry, assembled together and organised in a single body. This is what is termed a corporation, or professional group.[6]

There are two further main themes in Durkheim's vision of self-regulating professional groups that are of particular interest here. The first sees to the relationship between self-regulation and the politico-legal apparatus of the state. Far from being romantic about the spontaneous normative ordering of civil society, Durkheim demanded the corporation to be '*un groupe défini, organisé, en un mot une institution publique*.'[7] He explicitly regarded the corporation as a political instrument of government to be established by law and nurtured by the state.[8] On the other hand, subordination of these corporations to the state is as troublesome as the subversion of the state by professional groups: the two spheres must be and remain distinct and autonomous. Each must do what only it is well equipped to do. We have thus a division of labour in economic regulation:

Durkheim's thinking as an interim measure to institutionalise solidarity in a transitional phase of evolution). See also Habermas, *Die Postnationale Konstellation* (Suhrkamp, Frankfurt, 1998) 130 (commenting on similar 'regressiven Züge einer nach vorne projizierten "Sittlichkeit", die weder dem befreienden Potential der erzwungenen Öffnung einer in Auflösung begriffenen Gesellschaftsformation noch der Komplexität der neuen Verhältnisse gerecht wird' in Hegel and the young, 'noch nicht ganz unsentimentale' Marx.)

[5] Contrast the rather sinister discussion in Kaufman-Osborn, 'Emile Durkheim and the Science of Corporatism' (1986) 14 *Political Theory* 638, with Cotterrell, above n 1, 111, 176 ff. CF Sabel, 'Design, Deliberation and Democracy: On the New Pragmatism of Firms and Public Institutions' in Ladeur (ed), *Liberal Institutions, Economic Constitutional Rights and the Role of Organizations* (Nomos, Baden-Baden, 1997) 101.

[6] Durkheim, above n 2, vii; Durkheim, Halls (tr), *The Division of Labour in Society* (London, Macmillan, 1984) v.

[7] Above, viii.

[8] See especially Didry, 'La Réforme des Groupements Professionnels Comme Expression de la Conception Durkheimienne de l'Etat' (2000) 41 *Rev Fra Soc* 513.

> If it falls to political assemblies to lay down the general principles for industrial legislation, they are not capable of diversifying them according to various types of industry. It is this diversification that is the corporation's proper task. . . . Thus economic activity could be regulated and demarcated without losing any of its diversity.[9]

Corporations and governmental assemblies thus share the business of 'lawmaking': the corporation is to turn itself into a democratic 'public institution' operating according to the same principles and the same logic as the state itself.[10] Democracy is not a function of representation but of communication: Durkheim defines democracy in terms of the quality of decision-making that results from the interaction between the governing agency and the agencies organizing the activities being governed. The state is an organ of social coordination, not a mere medium for the registration of the wills of social majorities.[11] The art of government then consists largely in coordinating the functions of the various self-regulating bodies in different spheres of the economy. And this, in turn, has profound consequences for the qualities of regulatory law. As Cotterrell explains, 'law is increasingly concerned with process rather than substance: not so much with what the various social functions and tasks are as how they are to be related to each other.'[12]

Second, there is a striking prescience in Durkheim's vision of the economy bursting through social and political borders:

> What past experience demonstrates above all is that the organisational framework of the professional group should always be related to that of economic life. It is because this condition was not fulfilled that the system of corporatism disappeared. Thus, since the market, from being municipal as it once was, has become national and international, the corporation should assume the same dimensions. Instead of being restricted exclusively to the artisans of one town, it must grow so as to include all the members of one profession scattered over the whole country, for in whatever region they may be, whether they live in town or in countryside, they are all linked to one another and share a common life. Since this common life is in certain respects independent of any territorial boundaries, a suitable organism must be created to give expression to this life and to regulate its functions.[13]

[9] Durkheim, above n 2, xxviii–xxix. Translated in Durkheim, Halls (tr), above n 6, li.

[10] Cotterrell, above n 1, 179.

[11] Hirst, *Associative Democracy* (Polity Press, Cambridge, 1994) 35. See Durkheim, above n 3, 125 ('Le rôle de l'Etat, en effet, n'est pas d'exprimer, de résumer la pensée irréflechie de la foule, mais de surajouter à cette pensée irréflechie une pensée plus méditée, et qui, par suite, ne peut n'être pas différente.') Cf Cotterrell, above n 1, 159 (discussing how government authority is based in 'mechanisms that optimise the quality of the state's deliberation on behalf of society.') For elaboration of the distinction between corporatism and pluralism, see eg Cawson, *Corporatism and Political Theory* (Blackwell, Oxford, 1986).

[12] Cotterrell, above n 1, 111.

[13] Durkheim, above n 2, xxvii. Translated in Durkheim, Halls (tr), above n 6, l–li.

Durkheim then attached a footnote excusing himself from analysing the international organisation that would necessarily develop above and beyond the national corporation, since only the latter could constitute a 'legal institution.' The former, 'in the present state of European law,' can only result from a series of free contractual arrangements between national corporations.[14]

2.2 Logics of Associative Governance in Luhmann and Habermas

Durkheim's evolutionary functionalism finds its natural successor in systems theory. In the work of Niklas Luhmann, perhaps the most radical and certainly the most influential functional theorist of the latter half of the twentieth century, society differentiates into autonomous self-reproducing social systems consisting of communications. Different systems—politics, law, the economy, science—are operationally closed to each other, each constituting but an 'environment' to the other precisely through the system's self-referential construction of the distinction between system and environment.[15] The modalities of autopoietic closure can be left aside for present purposes. The more pressing question is that of inter-systemic coordination.[16] For Luhmann, 'integration' on the level of society as a whole is impossible: all he offers by way of mechanisms of tying systems together and all of them within society, is 'structural coupling.'[17] Taxation thus couples the economy and politics, the constitution couples politics and law, property and contract couple law and the economy.[18] In related moves, Willke uses technical standards as an example of 'inter-reference' between systems,[19] and Teubner speaks of standards as a 'linkage

[14] Above, xxvii.

[15] See Luhmann, *Soziale Systeme-Grundriß einer Allgemeinen Theorie* (Suhrkamp, Frankfurt, 1984). Cf Luhmann, *Die Wirtschaft der Gesellschaft* (Suhrkamp, Frankfurt, 1988); Luhmann, *Die Wissenschaft der Gesellschaft* (Suhrkamp, Frankfurt, 1990); Luhmann, *Das Recht der Gesellschaft* (Suhrkamp, Frankfurt, 1993) and his swansong, Luhmann, *Die Gesellschaft der Gesellschaft* (Suhrkamp, Frankfurt, 1997).

[16] After all, as the great man himself acidly acknowledged: 'Würde man die moderne Gesellschaft lediglich als eine Menge von autonomen Funktionssystemen beschreiben, die einander keine Rücksicht schulden, sondern den Reproduktionszwängen ihrer eigenen Autopoiesis folgen, ergäbe das ein höchst einseitiges Bild. Es wäre dann schwer zu verstehen, wieso diese Gesellschaft nicht binnen kurzdem explodiert oder in sich zerfällt. Irgendwo und irgendwie müsse doch, so lautet eine naheliegende Einwand, für "Integration" gesorgt werden.' Luhmann, *Die Gesellschaft der Gesellschaft* (Suhrkamp, Frankfurt, 1997) 776.

[17] Above, 100 ff, 778. In systems-theoretical orthodoxy, the choice of words might surprise: 'Faktisch sind alle Funktionssyteme durch strukturelle Kopplungen mit einander verbunden und in der Gesellschaft gehalten.'

[18] Above, 781 ff. Compare Teubner, *Law as an Autopoietic System* (Blackwell, Oxford, 1993) 85 ff.

[19] Willke, 'Societal Guidance Through Law?' in Teubner and Febbrajo (eds), *State, Law and Economy as Autopoietic Systems* (Giuffrè, Milano, 1992).

institution,' elaborated in a scientific discourse but lending themselves to 'translation' into economic, political, ecological or legal discourse.[20]

In any event, the state is not steering anything—the political system is but one subsystem among others, heterarchically tied into a network of structural coupling. Luhmann, in his unforgiving theoretical rigidity, has no time or space for 'organisations' or 'associations' either in the process of differentiation or in the mechanisms for integration.[21] In the hands of Helmut Willke, however, systems theory has a decidedly positive take on neo-corporatism.[22] In his evolutionary scheme, Willke even maintains that *functional* differentiation is followed by a phase of *organized* differentiation, 'um hervorzuheben daß das für die Gesellschaft insgesamt riskante Auseinandertreiben der Funktionsbereiche jedenfalls punktuell und teilweise in organisierten Vernetzungen augefangen wird.'[23] If the problem of differentiation is reconceptualised as being attenuated by capabilities of organisations, the solution is bound to have Durkheimian overtones. In Willke's theory, the 'supervision state' is still capable of integration—albeit from a position of radical heterarchy instead of hierarchy, and even if through indirect rather than direct means. As Habermas summarises with some glee:

> On the one hand, Willke, like Luhmann, sees that the political system has become one subsystem among others. No longer able to claim social primacy, it is relieved of the function of integrating society as a whole. On the other hand, through the back door, Willke reintroduces the state as guarantor of a neocorporatist social integration. As surprising as this answer may be, the question is the logical result of the 'autopoietic turn' taken by systems theory. Indeed, the logic of functional differentiation of society implies that the separate subsystems are reintegrated at a higher level of society. If the decentered

[20] Teubner, 'The King's Many Bodies: The Self-destruction of Law's Hierarchy' (1997) 31 *Law & Soc Rev* 763, 781.

[21] Organisations can only ensure 'operative coupling' which presupposes, and cannot replace, structural coupling. Luhmann, above n 16, 788. But see eg Mayntz, 'Governing Failures and the Problem of Governability: Some Comments on a Theoretical Paradigm' in Kooiman (ed), *Modern Governance—New Government-Society Interactions* (Sage, London, 1993) 9; Brodocz, 'Verbände als strukturelle Kopplung' (1996) 2 *Soziale Systeme* 361. Cf Tacke (ed), *Organisation und Gesellschaftliche Differenzierung* (Westdeutscher Verlag, Opladen, 2001).

[22] Most evidently perhaps in Willke, *Systemtheorie III: Steuerungstheorie*, 3rd edn (Lucius & Lucius, Stuttgart, 2001) 116 ff.

[23] Willke, *Ironie des Staates—Grundlinien einer Staatstheorie polyzentrischer Gesellschaft* (Suhrkamp, Frankfurt, 1992) 183. Cf Willke, 'Three Types of Legal Structure: The Conditional, the Purposive and the Relational Program' in Teubner (ed), *Dilemmas of Law in the Welfare State* (de Gruyter, Berlin, 1986) 280, 286. Cf Teubner, 'Autopoiesis and Steering: How Politics Profit from the Normative Surplus of Capital' in In 't Veld, *et al*, (eds), *Autopoiesis and Configuration Theory: New Approaches to Societal Steering* (Kluwer, Dordrecht, 1991) 127, 134 (describing 'multilingual' formal organizations as 'the most important glue in functionally differentiated society.') See also Mayntz, 'Modernization and the Logic of Interorganizational Networks' in Child, Crozier and Mayntz (eds), *Societal Change Between Market and Organization* (Avebury, Aldershot, 1993) 3 (discussing formal organizations as a *precondition* for differentiation into subsystems.)

> society could not preserve its unity somewhere, it would not profit from the growth in complexity of its parts and would be, as a whole, the victim of gains in differentiation.[24]

Habermas accepts much of the basic tenets of systems theory: functional differentiation leading to increasingly autonomous subsystems, principally the economy—steered by the medium of money, and the administration, steered by the medium of power.[25] The more fundamental process for him, however, is the differentiation of system and lifeworld.[26] That leaves Habermas with the task of finding a mode of social integration that not only ensures inter-systemic coordination, but also, and more importantly, couples systems to the lifeworld. And that he finds in law, the medium capable of transmitting 'structures of mutual recognition', in an abstract but binding form, to 'the complex and increasingly anonymous spheres of a functionally differentiated society.'[27] Indeed, law functions as a 'hinge' between system and lifeworld because of its ability to communicate with the steering media of money and administrative power:

> The lifeworld forms, as a whole, a network composed of communicative actions. Under the aspect of action coordination, its *society* component consists of the totality of legitimately ordered interpersonal relationships. It also encompasses collectivities, associations, and organizations specialized for specific functions. *Some* of these functionally specialized action systems become independent vis-à-vis socially integrated spheres of action, that is, spheres integrated through values, norms and mutual understanding. Such systems develop their own codes, as the economy does with money and the administration does with power. Through the legal institutionalisation of steering media, however, these systems remain anchored in the society component of the lifeworld. The language of law brings ordinary communication from the public and private spheres and puts it into a form in which these messages can also be received by the special codes of autopoietic systems—and vice versa. Without this transformer, ordinary language could not circulate throughout society.[28]

[24] Habermas, *Between Facts and Norms—Contributions to a Discourse Theory of Law and Democracy* (Polity Press, Cambridge, 1995) 342.

[25] Habermas, above n 4. Cf McCarthy, 'Complexity and Democracy: or the Seducements of Systems Theory' in Honneth and Joas (eds), *Communicative Action—Essays on Jürgen Habermas's:* The Theory of Communicative Action (Polity Press, Cambridge, 1991) 119.

[26] Above, vol II, 230 ff.

[27] Habermas, above n 24, 318. Habermas is the first to acknowledge the influence of the legal optimism in Peters, *Die Integration moderner Gesellschaften* (Suhrkamp, Frankfurt, 1993). Fairly good-humoured criticism in Luhmann, '*Quod Omnes Tangit:* Remarks on Jürgen Habermas's Legal Theory' (1996) 17 *Cardozo L Rev* 883.

[28] Above, 354. Emphases in original. Cf Teubner, '*De Collisione Discursum*: Communicative Rationalities in Law, Morality and Politics' (1996) 17 *Cardozo L Rev* 901. See also Willke, above n 23, 206–7 (describing the funtion of law as 'die Institutionalisierung von Bedingungen für die Möglichkeit *kollektiver Kommunikation* in einer hochgradig funktional differenzierten Gesellschaft.')

The political system is conceived as one among several subsystems. Where all else fails, it 'steps in' to ensure social integration through law.[29] Its capacity to do so depends on its being constituted by law. Constitutional democracy, then, is conceived of as the institutionalisation—by legitimate law—of the procedures and communicative presuppositions for a discursive opinion—and will-formation that in turn makes possible legitimate lawmaking.[30] Socially integrative law can find its source only in the formal machinery of constitutional lawmaking. In that light, 'social subsystems, large organizations, associations, and such, which, to a considerable extent, resist legal imperatives', and 'social actors with paraconstitutional bargaining power' are immensely suspect.[31]

To understand the profound disagreement between Durkheim and Habermas on the appropriate institutional responses to social complexity, it is perhaps useful to take a detour to John Dewey's masterpiece, 'The Public and Its Problems': there, Dewey describes 'the state' as a constellation of 'publics,' sets of institutionalised reactions to consequences of behaviour. Once in place, however, the state prevents the emergence of new 'publics':

> The new public which is generated remains long inchoate, unorganized, because it cannot use inherited political agencies. The latter, if elaborate and well institutionalized, obstruct the organization of the new public. They prevent that development of new forms of the state which might grow up rapidly were social life more fluid, less precipitated into set political and legal moulds. To form itself, the public has to break existing political forms.[32]

Durkheim and Habermas have rather similar ideas about the need for democracy to respond to normative as much as to cognitive demands. Both insist on the distinction between the organised and institutionalised mechanisms of identifying and solving social problems on the level of the state, and the spontaneous, diffuse flux of communication in civil society. Both, more importantly, insist on the importance of the interplay between the two spheres.[33] They differ radically, however, in their institutional responses to the strain increased social complexity puts on this model. For Durkheim, social complexity heightens the demands for organised deliberation, for society to create organs to reflect upon itself: hence the diffusion of 'assemblées délibérantes', hence the need for the professional group to become not just the basis of social organisation but of political organisation as well.[34] If the function of the state is to 'focus vague, dis-

[29] Habermas, above n 24, 318.
[30] Above, 457.
[31] Above, 433.
[32] Dewey, 'The Public and Its Problems' in Id, *The Later Works, 1925–1953*, Vol 2: 1925–1927 (Southern Illinois University Press, Carbondale, 1984) 235, 254–55.
[33] Compare Durkheim, above n 3, 113 ff, and Habermas, above n 24, 354 ff.
[34] Durkheim, above n 3, 124, 130.

organised and contradictory opinion in specific regulatory forms',[35] the corporation takes over that function. With Roger Cotterrell:

> The logic of regulation through 'corporations' seems thus identical with that of the state's lawmaking. The same processes of communication and deliberation operate, but Durkheim assumes that communication is likely to be more effective in devolved regulation because of the smaller moral distance between regulators and regulated.[36]

For Habermas, 'the growth of complexity does not automatically imply a shift from the normative to the cognitive.'[37] Indeed, he resists such a move with all his considerable might. His solution, then, is a qualitative leap in the interaction of the constitutional political system and the 'impulse-generating periphery.' The latter is to 'ferret out, identify, and effectively thematize latent problems of social integration which require political solutions,' and then introduce them into the political system via parliamentary or judicial 'sluices'. However, Habermas insists that this take place through 'networks of *noninstitutionalized* public communication' that make possible 'more or less *spontaneous* processes of opinion-formation.'[38] We then have 'resonant and autonomous public spheres' which need to be anchored in the voluntary associations of civil society. The development of such 'lifeworld structures,' granted, can perhaps be stimulated by the political system; for the most part, however, they should, and do, 'elude legal regulation, administrative control, or political steering.'[39] In Habermas, the integration of lifeworld and system depends, in the final analysis, on the very differentiation of political system and the lifeworld.

3. FROM GOVERNMENT TO GOVERNANCE

3.1 Collapsing State and Society

The activity of 'government' logically involves a distinction between who is governing and who is being governed. The conceptual shift in political sociology from 'government' to 'governance' denotes at least the blurring of exactly that distinction. The general idea is that social steering is becoming more and more a property of the interaction of organizations, networks, and associations involving both public and private actors, rather

[35] Cotterrell, above n 1, 156.
[36] Above, 179. Note that Cotterrell continues: 'About the likely quality of deliberation, however, he has little to say.'
[37] Habermas, above n 24, 435.
[38] Above, 358. First emphasis added.
[39] Above, 358–59.

than a product of government control of and intervention in society.[40] This involves a rather dramatic reinterpretation of phenomena that were previously primarily analysed as symptoms of government failure. First, 'social subsystems, large organizations, associations, and such,' and 'social actors with paraconstitutional bargaining power' are now regarded as potential *resources* for effective and democratic governance, rather than as obstacles to the successful implementation of public policies.[41] Second, the processes of deregulation and privatisation are not necessarily seen as indicative of the surrender of politics to the market, or, more generally, of a retreat of the state. Rather, these are signals of a *transformation* of the state's role from 'a role based in constitutional powers towards a role based in co-ordination and fusion of public and private resources.'[42] Belloubet-Frier and Timsit discern a shift from 'exogenous' to 'endogenous' state action:

> L'Etat et son administration n'ont plus, pour se légitimer, à s'affirmer contre et au-dessus de la société civile. Le role premier de l'administration est au contraire, désormais, de favoriser le travail de la société sur elle-même.[43]

After decades where all social problems seemed to be thought of as either government failures to be solved by the market or as market failures to be remedied by the state, civil society has been 'brought back in,' with a vengeance. The world of modern political sociology now looks a lot like Durkheim's world. Paul Hirst, for example, is unapologetically Durkheimian in his restatement of 'organizational society': in modern complex societies, an elaborate division of labour in governance has become inevitable. The way to achieve this, according to Hirst, is to restore

[40] See eg Kooiman (ed), above n 21; Mayntz and Scharpf (eds), *Gesellschaftliche Selbstregelung und Politische Steuerung* (Campus, Frankfurt, 1995); Mayntz, 'Politische Steuerung: Aufstieg, Niedergang und Transformation einer Theorie' in von Beyme and Offe (eds), *Politische Theorien in der Ära der Transformation* (Westdeutscher Verlag, Opladen, 1995), (*Politische Vierteljahresschrift*, Sonderheft 26) 148; Rhodes, 'The New Governance: Governing Without Government' (1996) 44 *Political Studies* 652; Pierre and Peters, *Governance, Politics and the State* (St Martin's, New York, 2000).

[41] See eg Streeck and Schmitter, 'Community, Market, State—and Associations? The Prospective Contribution of Private Interest Governance to Social Order' (1985) 1 *European Sociological Review* 119; Cohen and Rogers, 'Secondary Associations and Democratic Governance' (1992) 20 *Politics & Society* 393; Hirst, above n 11.

[42] Pierre and Peters, above n 40, 25. The thesis of the emergence of the 'regulatory state' has obvious resonances. See Majone, 'The Rise of the Regulatory State in Europe' (1994) 17 *West European Politics* 77; Majone, 'From the Positive to the Regulatory State: Causes and Consequences of Changes in the Mode of Governance' (1997) 17 *J Public Pol* 139. Cf Hancher and Moran, 'Organizing Regulatory Space' in Hancher and Moran (eds), *Capitalism, Culture and Economic Regulation* (Clarendon Press, Oxford, 1989) 271; McGowan and Wallace, 'Towards a European Regulatory State' (1996) 3 *JEPP* 560; Loughlin and Scott, 'The Regulatory State' in Dunleavy, *et al*, (eds), *Developments in British Politics* 5 (MacMillan, London, 1997) 205.

[43] Belloubet-Frier and Timsit, 'L'administration: vers un Nouveau Modèle?' in Timsit, *Archipel de la Norme* (PUF, Paris, 1997) 43, 51–52. Cf Willke, above n 23, 201 ('Gefragt sind nicht mehr Befehlsstrukturen, sondern Einrichtungen des sozietalen Diskurses.')

limited government and devolve the minutiae of governance to civil society, whose organizations are to be politicised and turned into 'constitutionally ordered democratically self-governing associations.'[44] To be sure, the role of self-regulatory associations cannot be the same as it was for Durkheim: in Teubner's words, 'the hierarchy of state versus individual is irreversibly replaced by the heterarchy of different spheres of society.'[45] The role of intermediary associations is, then, not to mediate vertically between the governing and the governed but, rather, to mediate horizontally between politics and other specialized sectors of society.[46] To paraphrase Renate Mayntz, all there can be is steering *within* functionally differentiated society, not political steering *of* society.[47] The successful performance of that task would seem to involve some combination of political steering on the one hand, and social self-organisation and self-regulation on the other; indeed, the more convincing branches of the governance school regard each of these as indispensable for the other to function effectively.[48]

3.2 Globalisation and Governance

The theme of 'governing without government' is particularly salient against the background of globalisation,[49] if only because the latter process obviously exacerbates the conditions leading to the state's decentering and the diffusion of governance structures.[50] Most obviously, globalisation intensifies privatisation. As Alfred Aman notes:

> Markets take on a greater prominence at both international and domestic levels of government, but not because of a philosophical decision to cede power

[44] Hirst, 'Democracy and Governance' in Pierre (ed), *Debating Governance* (OUP, Oxford, 2000) 13, 28. Cf Hirst, above n 11.

[45] Teubner, 'The "State" of Private Networks: the Emerging Legal Regime of Polycorporatism in Germany' [1993] *Brigham Young U L Rev* 553, 556.

[46] Above, 556–57.

[47] Mayntz, above n 40, 165.

[48] See Von Beyme, 'Steuerung und Selbstregelung: Zur Entwicklung zweier Paradigmen' (1995) 35 *Journal für Sozialforschung* 197; Mayntz and Scharpf, 'Steuerung und Selbstorganisation in staatsnahen Sektoren' in Mayntz and Scharpf (eds), above n 40, 9.

[49] See eg Reinicke, *Global Public Policy: Governing Without Government* (Brookings Institution, Washington, 1998); Zürn, *Regieren jenseits des Nationalstaates* (Suhrkamp, Frankfurt, 1998).

[50] Suffice it to refer to Strange, *The Retreat of the State—The Diffusion of Power in the World Economy* (CUP, Cambridge, 1996). See also Hirst and Thompson, *Globalization in Question—The International Economy and the Possibilities of Governance* (Polity Press, Cambridge, 1996). Cf Willke, *Atopia—Studien zur Atopischen Gesellschaft* (Suhrkamp, Frankfurt, 2001). Michael Zürn is right that 'societal denationalization' is a more precise term than 'globalisation', especially to describe the loss of congruence of social and political spaces. See Zürn, 'Democratic Governance Beyond the Nation-State: The EU and Other International Institutions' (2000) 6 *EJIR* 183. On the other hand, concepts are there at least in part to facilitate communication. In that light, the currency of the imprecise term may be reason enough to prefer it over the more precise—and more awkward—term.

> to the private sector. . . . Rather, the market and private actors are more prominent because they can approach problems without the limits of arbitrary, territorial boundaries imposed on them.[51]

With Philip Cerny, globalisation leads to 'increasing differentiation of both economic and political structures', the result of which is a transformation of the state into 'a complex mix of civil and enterprise associations.'[52] That complex is then projected unto the global level, where governance is not so much a matter of states but of depoliticised regulatory networks,[53] and private associations and organizations operating on transnational level.[54] Sectors of the economy are developing 'autonomous self-regulatory governance processes', leading to a kind of 'transnational oligopolistic neo-corporatism.'[55] The relentless capacity of the economy to break through the frames of political and legal borders puts the theory of corporations under pressure, as Durkheim himself already acknowledged. Most obviously, globalisation poses a problem for those who hold that neocorporatist arrangements can only function in the shadow of the state, or rather, under a credible threat of state intervention.[56]

More generally, private structures of governance cut loose from socially integrated societies and political systems cannot be legally constituted, and cannot hence be 'public institutions' in the sense of Durkheim. For Teubner, then, the consequence is a further intensification of heterarchy:

[51] Aman, 'The Limits of Globalization and the Future of Administrative Law: From Government to Governance' (2001) 8 *Ind J Glob L S* 379, 391.

[52] Cerny, 'Globalization, governance, and complexity' in Prakash and Hart (eds), *Globalization and Governance* (Routledge, London, 1999) 188, 206. See also Cerny, 'Globalization and the Changing Logic of Collective Action' (1995) 49 *IO* 595. Cf Knill and Lehmkuhl, 'Private Actors and the State: Internationalization and Changing Patterns of Governance' (2002) 15 *Governance* 41.

[53] See eg Picciotto, 'Networks in International Economic Integration: Fragmented States and the Dilemmas of Neo-Liberalism' (1997) 17 *Northwestern J Int L and Business* 1014; Raustiala, 'The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law' (2002) 43 *Virginia J Int L* 1; Slaughter, 'Governing the Global Economy through Government Networks' in Byers (ed), *The Role of Law in International Politics: Essays in International Relations and International Law* (OUP, Oxford, 2000) 177; Slaughter, 'Global Government Networks, Global Information Agencies, and Disaggregated Democracy' (2003) 24 *Mich J Int L* 1041.

[54] See eg Haufler, 'Crossing the Boundary between Public and Private: International Regimes and Non-State Actors' in Rittberger (ed), *Regime Theory and International Relations* (Clarendon Press, Oxford, 1993) 94; Ronit and Schneider, 'Global Governance through Private Organizations' (1999) 12 *Governance* 243. Cf Ottaway, 'Corporatism Goes Global: International Organizations, Nongovernmental Organization Networks, and Transnational Business' (2001) 7 *Global Governance* 265; Abbott and Snidal, 'International "Standards" and International Governance' (2001) 8 *JEPP* 345.

[55] Cerny, above n 52, 206.

[56] See Voelzkow, *Private Regierungen in der Techniksteuerung: Eine sozialwissenschaftliche Analyse der Technischen Normung* (Campus, Frankfurt, 1996) 215. Cf Streeck, 'Inclusion and Secession: Questions on the Boundaries of Associative Democracy' (1992) 20 *Politics & Society* 513; Mayntz, *Politikwissenschaft in einer Entgrenzten Welt*, MPIfG Discussion Paper 00/3 (Max-Planck-Institut für Gesellschaftsforschung, Köln, 2000).

> Under conditions of the nation-state, standard-setting, professional self-regulation, and intra-organizational legal regimes are strongly politically mediated when they are to be transformed into valid legal rules. Under conditions of globalisation, however, private governance regimes lose this organizational and legitimating mediation and can be institutionalised only as forms of a close contact between operationally closed systems, without mediation by institutionalised politics.[57]

3.3 Governance, Knowledge and Risk

In 1963, Habermas wrote a short article on the relationship between science and politics in which he argued against both 'decisionism'—or the subordination of science to politics, and technocracy—or the subordination of politics to science.[58] Instead of these models, which ultimately separate the two spheres, he offered a 'pragmatic model' of critical reciprocal exchange. For that model to work, however, he posited the requirement 'a general flow of communication between science and politics, free of domination and spread out over the public of citizens.'[59] Forty years on, it seems his worst fears have come true as the political system seems to have lost all claims to epistemic authority, while science is struggling to hold on to mere remnants of political authority.[60] Instead of through public communication, the two systems are tied together by the services of experts. What these transmit, however, is not authority but uncertainty. In Luhmann's analysis, then, they should be regarded not as politicians or as scientists, but as 'highways for reciprocal irritation, as mechanisms of structural coupling.'[61]

For a long time, the state's increased reliance on scientific expertise could be explained in fairly classic Weberian terms as a stage in the ongoing process of rationalisation. The epistemic authority of expert administration, however, depends crucially on the state's capacity to monopolise or at least control scientific and technical expertise, either in the hierarchical

[57] Teubner, above n 20, 780.

[58] Habermas, 'Verwissenschaftlichte Politik und öffentliche Meinung' in Id, *Technik und Wissenschaft als 'Ideologie'* (Suhrkamp, Frankfurt, 1968) 120.

[59] Above, 138. Translation mine. See also Habermas, above n 24, 351.

[60] From very (*very*) different perspectives, see eg Beck, *Risikogesellschaft—Auf dem Weg in eine andere Moderne* (Suhrkamp, Frankfurt, 1986); Luhmann, *Die Wissenschaft der Gesellschaft* (Suhrkamp, Frankfurt, 1990); Ezrahi, *The Descent of Icarus—Science and the Transformation of Contemporary Democracy* (Harvard University Press, Cambridge, 1990); Latour, *Politiques de la Nature—Comment Faire Entrer les Sciences en Démocratie* (La Découverte, Paris, 1999). For a bit of much needed historical relativism, see MacLeod, 'Science and Democracy: Historical Reflections on Present Discontents' (1997) 35 *Minerva* 369.

[61] Luhmann, above n 16, 786. Translation mine.

structures of public bureaucracies[62] or, perhaps even more importantly, in heavily regulated professions.[63] As Helga Nowotny argues, however, expertise has now been cut loose from 'the public realm and the centralised decision-making structures of modernity,' and has become 'disembedded.'[64] This, then, leads to a fragmentation of established links between scientific expertise and institutional structures, whether of government, industry or the professions.[65] The interaction between the different systems takes place more and more through 'hybrid forms of organisation.'[66]

Against the backdrop of privatisation and globalisation, this development is, in part, a logical corollary of the diminishing steering capacities of the state. With economic progress now so much dependent on knowledge, much of the expertise needed to regulate the risk society is located exactly where the risks are 'manufactured'—in industry. And with the economic system bursting out of the territorial bounds of political systems, national regulators have little choice but to tie on to transnational arrangements of negotiation where the boundaries between the economy, science and politics are constantly being reconfigured and reconstituted.[67] The rise of

[62] See eg Nelkin, 'The Political Impact of Technical Expertise' (1975) 5 *SSS* 35, 36 ('[T]he viability of bureaucracies depends so much on the control and monopoly of knowledge in a specific area, that this may become a dominant objective.') For renewed faith in rational government aided by a caste of expert policy advisors, see Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Harvard University Press, Cambridge, 1993). For mainstream critique, see Pildes and Sunstein, 'Reinventing the Regulatory State' (1995) 62 *U Chi L Rev* 1; Pollak, 'Regulating Risks' (1995) 33 *Journal of Economic Literature* 179.

[63] A good effort to (re-)integrate the role of the professions and other collegiate organisations into Weber's work on rationalisation is Waters, 'Collegiality, Bureaucratization and Professionalization: A Weberian analsyis' (1989) 94 *Am J Soc* 945. Abbott, *The System of Professions—An Essay on the Division of Expert Labor* (University of Chicago Press, Chicago, 1988) is not so much a sociology of the professions as such as it is an investigation into the ways societies structure expertise. Above, 323 ff. Cf Gieryn, 'Boundaries of Science' in Jasanoff, Markle and Petersen (eds), *Handbook of Science and Technology Studies* (Sage, Thousand Oaks, 1995) 393, 407 ff.

[64] Nowotny, 'Transgressive Competence—The Narrative of Expertise' (2000) 3 *EJST* 5, 13. This is related to what has become known in awful shorthand as 'Mode 2' production of knowledge. See Gibbons, *et al*, *The New Production of Knowledge—The Dynamics of Science and Research in Contemporary Societies* (Sage, London, 1994). For the diffusion of expertise as a (civic republican) political program, see Fuller, *The Governance of Science—Ideology and the Future of the Open Society* (Open University Press, Milton Keynes, 2000).

[65] In Nowotny, Scott and Gibbons, *Rethinking Science: Knowledge and the Public in an Age of Uncertainty* (Polity Press, Cambridge, 2001), this process is explicitly linked to a social theory of *de*-differentiation. That conceptualisation, however, could well be argued to stem from a failure to distinguish between the (increasing) relevance of knowledge in society and the (diminishing) social relevance of the scientific *system*. Cf Willke, *Dystopia—Studien zur Krisis des Wissens in der modernen Gesellschaft* (Suhrkamp, Frankfurt, 2002).

[66] Stehr, *Wissenspolitik—Die Überwachung des Wissens* (Suhrkamp, Frankfurt, 2003) 212.

[67] 'Risk society' is by its very nature a global risk society. Cf Beck, above n 61, 300 ff; Beck, *Weltrisikogesellschaft, Weltöffentlichkeit und Globale Subpolitik* (Picus, Wien, 1997). In her study on the globalisation of risk in the context of the BSE crisis, Veronika Tacke proposes to broaden the research on business associations from a political interest mediation perspective to a 'more sociological approach.' In that approach, 'business associations have become visible not only as 'structural coupling' of the nationally segmented political and economic

transnational 'epistemic communities' is an institutionalised acknowledgement not only of the loss of political authority on the part of single nation states, but of the loss of epistemic authority on the part of the political system generally.[68]

Science is, of course, a tremendously powerful candidate to take over from politics as the structuring force in global society. Indeed, there are those who see globalisation as an opportunity to move society on to the next stage in rationalisation, where 'local truths of custom and example' can be 'corrected and replaced' with 'universal, secular truths.'[69] After all, as Jarvie makes yet another play on Pascal's famous paradox,

> [t]he authority of science, unlike the authority of other institutions, is not bounded by national jurisdiction. What is truth on this side of the Pyrenees remains truth on the other side, whether or not those over there are ready to admit it.[70]

The problem with this stance is that even those 'over here' seem less and less ready to accept the authority of science,[71] its 'universal, secular truths' increasingly called into question the more social (and economic) life is seen to depend on them.[72] For present purposes, matters of the epistemological

realm, but moreover as a particular mechanism for removing uncertainty in globalization processes.' Tacke, 'BSE as an Organizational Construction: a Case Study on the Globalization of Risk' (2001) 52 *B J Soc* 293, 310. Cf Tacke, 'Das Risiko der Unsicherheitsabsorption—Ein Vergleich Konstruktivistischer Beobachtungsweisen des BSE–Risikos' (2000) 29 *Zeitschrift für Soziologie* 83.

[68] The obligatory reference is Haas, 'Introduction: Epistemic Communities and International Policy Coordination' (1992) 46 *IO* 1. More or less all there is said about technical standardisation in Braithwaite and Drahos, *Global Business Regulation* (CUP, Cambridge, 2000), is a casual remark that standards bodies are 'crucial sites of epistemic community building.' Above, 503. For a chilling example of how 'a few hundred scientists in transnational pharmaceutical companies and government drug regulatory agencies are determining the risks that new pharmaceutical products will pose to a potential patient population of at least half a billion', see Abraham and Reed, 'Trading Risks for Markets: The International Harmonisation of Pharmaceuticals Regulation' (2001) 3 *Health, Risk & Society* 113; Abraham and Reed, 'Progress, Innovation and Regulatory Science in Drug Development: The Politics of International Standard-Setting' (2002) 32 *SSS* 337.

[69] Jarvie, 'Science in a Democratic Republic' (2001) 68 *Philosophy of Science* 545, 562.

[70] Above. Cf Drori, *et al*, *Science in the Modern World Polity—Institutionalization and Globalization* (Stanford University Press, Stanford, 2003).

[71] Or, at least, of what Latour calls 'Science, with a capital S, the ideal of the transportation of information without discussion or deformation.' This he dismisses as an ideology 'that never had any other use, in the epistemologists' hands, than to offer a *substitute* for public discussion.' Latour, *Pandora's Hope—Essays on the Reality of Science Studies* (Harvard University Press, Cambridge, 1999) 258 (emphasis in original). Cf Latour, above n 61, 46 ('L'épistémologie et la politique sont une seule et même affaire conjointe dans l'épistémologie (politique) pour rendre incompréhensibles et la pratique des sciences et l'object même de la vie publique.')

[72] Its declining authority, in that sense, is of course a result of its extraordinary success rather than of its failure. See eg Gieryn, *Cultural Boundaries of Science—Credibility on the line* (University of Chicago Press, Chicago, 1999) 3 ('So secure is the epistemic authority of science these days, that even those who would dispute another's scientific understanding of nature must ordinarily rely on science to muster a persuasive challenge.'); Beck, above n 61, 266

validity and the social integrity of 'laboratory science' are perhaps best left aside.[73] The more pertinent questions arise not so much in the production of 'facts' as in their consumption, that is, in the conditions for the social and political acceptance of truth claims made by experts in the name of science.[74] And these surely have changed in recent times, as Giddens explains:

> Our relationship to science and technology today is different from that characteristic of early industrial society. In Western society, for some two centuries, science functioned as a sort of tradition. Scientific knowledge was supposed to overcome tradition but actually became a taken-for-granted authority in its own right. It was something that most people respected, but was external to their lives. Lay people 'took' opinions from the experts. The more science and technology intrude in our lives, the less this external perspective holds. Most of us—including government authorities and politicians—have, and have to have, a much more dialogic or engaged relationship with science and technology than used to be the case. We cannot simply 'accept' the findings which scientists produce, if only because scientists so frequently disagree with one another, particularly in situations of manufactured risk.[75]

('Man kann sogar sagen: je erfolgreicher die Wissenschaften in diesem Jahrhundert agiert haben, desto schneller und gründlicher sind ihre ursprünglichen Geltungsansprüchen relativiert worden.')

[73] This is hardly the place for more battlefield journalism on the science wars. Among the milestones of science studies, see eg Shapin and Schaffer, *Leviathan and the Air-Pump—Hobbes, Boyle and the Experimental Life* (Princeton University Press, Princeton, 1985); Barnes, Bloor and Henry, *Scientific Knowledge: A Sociological Analysis* (University of Chicago Press, Chicago, 1996); Fuller, *Science* (Open University Press, Milton Keynes, 1997); Latour, above n 72. Overviews in Shapin, 'Here and Everywhere: Sociology of Scientific Knowledge' (1995) 21 *Annual Review of Sociology* 289; Hess, *Science Studies—An Advanced Introduction* (New York University Press, New York, 1997), and, polemically, Fuller, 'Why Science Studies Has Never Been Critical of Science—Some Recent Lessons on How to be a Helpful Nuisance and a Harmless Radical' (2000) 30 *Philosophy of the Social Sciences* 5. 'Scientific' objections in eg Sokal and Bricmont, *Fashionable Nonsense: Postmodern Intellectuals' Abuse of Science* (Picador, New York, 1998); Koertge (ed), *A House Built on Sand: Exposing Postmodern Myths About Science* (OUP, Oxford, 1998); Weinberg, *Facing Up—Science and Its Cultural Adversaries* (Harvard University Press, Cambridge, 2001). In Merton's classic formulation, the 'ethos' of science comprises four sets of 'institutional imperatives': universalism, communism, disinterestedness, and organised skepticism. See RK Merton, 'The Normative Structure of Science' in Id, *The Sociology of Science* (University of Chicago Press, Chicago, 1973) 267 (originally published in 1942 as 'Science and Technology in a Democratic Order' (1942) 1 *Journal of Legal and Political Sociology* 115).

[74] See generally Gieryn, *Cultural Boundaries of Science—Credibility on the line* (University of Chicago Press, Chicago, 1999) ix (proposing a 'downstream' sociology of scientific knowledge, since 'upstream science substantially underdetermines the epistemic authority that marks its consumption downstream.') See also Gieryn, 'Boundary—Work and the Demarcation of Science from Non-Science: Strained Interests in Professional Ideologies of Scientists' (1983) 48 *Am Soc Rev* 781; Collins and Evans, 'The Third Wave of Science Studies: Studies of Expertise and Experience' (2002) 32 *SSS* 235. Cf Martin and Richards, 'Scientific Knowledge, Controversy and Public Decision-Making' in Jasanoff, Markle and Petersen (eds), above n 64, 506.

[75] Giddens, 'Risk and Responsibility' (1999) 62 *MLR* 1, 6. Compare Ezrahi, 'Technology and the Illusion of the Escape from Politics' in Ezrahi, *et al*, (eds), *Technology, Pessimism and Postmodernism* (University of Massachusetts Press, Amherst, 1995) 29 (arguing that the growing public distrust of science and technology is 'more a symptom of a transformation of the conception of politics than of changes in science and technology.')

He proceeds to argue that 'politics must give some institutional form to this dialogic engagement, because at the moment it concerns only special interest groups, who mostly struggle outside the main political domain.'[76] That suggestion, however, seems to go against the grain of recent efforts to restore faith in science by doing just the opposite—that is, to institutionalise the separation of science from politics, usually along the lines of the dichotomy between the purely scientific exercise in 'risk assessment' on the one hand, and the political job of 'risk management' on the other.[77] This nostalgia for decisionism is based, ultimately, on the view that technocracy has stretched science beyond its cognitive boundaries and limitations. 'Regulatory science', 'mandated science', and 'trans-science' are the concepts used to describe a state of affairs where science responds to the demands of policy by answering questions it simply does not have scientific answers to.[78] From this perspective, science has been losing authority because it has been passing off political decisions as 'scientific', and politics has been losing authority because it has been masquerading political preferences as scientific necessities. Standardisation, then, is intrinsically suspect. With Giandomenico Majone,

> Few aspects of regulation reveal, when closely examined, a more subtle blend of scientific, trans-scientific, and political elements than standard-setting. Far from being an almost mechanical process safely relegated to technicians, the setting of health, safety and environmental standards is in reality a microcosm in which conflicting epistemologies, regulatory philosophies, national traditions, social values, and professional attitudes are faithfully reflected.[79]

[76] Above. For some, of course, this institutionalised dialogue is exactly what takes place in administrative agencies. Compare Habermas, above n 59, 134 (describing US scientific agencies as 'Lenkungsbürokratien' instititutionalising continuous communication between science and politics) with Guston, *Between Politics and Science—Assuring the Productivity and Integrity of Research* (CUP, Cambridge, 1999).

[77] Prominently in recent European food safety regulation. See Commission, *White Paper on Food Safety*, COM (1999) 719, and Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety, (2002) OJ L 31/1. See further generally eg Vos, *Institutional Frameworks of Community Health & Safety Regulation—Committees, Agencies and Private Bodies* (Hart Publishing, Oxford, 1999); Fischer, 'Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration' (2000) 20 *OJLS* 109. Authoritative rejection of the risk assessment/risk management dichotomy in Jasanoff, *The Fifth Branch—Science Advisers as Policymakers* (Harvard University Press, Cambridge, 1990); Shrader-Frechette, *Risk and Rationality—Philosophical Foundations for Populist Reforms* (University of California Press, Berkeley, 1991). The problem for the political system, of course, is not so much how to act on knowledge, but how to deal competently with non-knowledge. See Willke, *Dystopia—Studien zur Krisis des Wissens* (Suhrkamp, Frankfurt, 2002) 18–19. Cf Japp, 'Distinguishing Non-Knowledge' (2000) 25 *Canadian Journal of Sociology* 225.

[78] See eg Weinberg, 'Science and Trans-Science' (1972) 10 *Minerva* 209; Salter, *Mandated Science: Science and Scientists in the Making of Standards* (Kluwer, Dordrecht, 1988).

[79] Majone, 'Science and Trans-Science in Standard Setting' (1984) 9 *ST & HV* 15. See further eg Salter, above n 79; Gusy, 'Wertungen und Interessen in der Technischen Normung' (1986) 6 *Umwelt—und Planungsrecht* 241; Mayntz, 'Entscheidungsprozesse bei der Entwicklung von Umweltstandards' (1990) 23 *Die Verwaltung* 137; Jacobsson, 'Standardization and Expert Knowledge' in Brunsson, *et al*, *A World of Standards* (OUP, Oxford, 2000) 40.

This conceptualisation, however, crucially depends on the assumption that there *is* such a thing as pure science, unencumbered by 'conflicting epistemologies, regulatory philosophies, national traditions, social values, and professional attitudes.' The dominant view in the sociology of science,[80] however, would see these latter attributes as intrinsic to the construction of scientific knowledge, and not necessarily as indicators of deviation from proper standards of scientific objectivity. Standards bodies should hence not be conceptualised so much as hybrids of science and policy, but rather as sites for the mutual construction of science and policy.[81] The importance of associational governance in globalised risk regulation lies not in its capacity of delivering 'universal, secular truths'; its importance lies in its capacity to internalise and renegotiate the boundaries between science and politics, and to tie expert knowledge to local professional judgments, institutional structures, social relationships and economic conditions.[82] Associational governance is perhaps as close as we can come to the *agora*, that mythical place, as elusive as necessary, neither state nor market, neither exclusively public nor exclusively private, where societal and scientific problems are framed and defined, and where what will be accepted as 'solution' is being negotiated.[83]

4. THE LEGAL REGULATION OF PRIVATE GOVERNANCE

4.1 Law and Governance

'Law' does not seem, at first sight, a very promising instrument for 'governance.' After all, law surely presupposes the centrality of the state in the activity of governing and does depend on a rather sharp distinction between the governing and the governed. And yet, these are exactly the qualities that the category of law seems to have shed over the last decades.[84] The crisis of law in the welfare state, if there ever was one,[85]

[80] See above.

[81] See Irwin, *et al*, 'Regulatory Science—Towards a Sociological Framework' (1997) 29 *Futures* 17; Rothstein, *et al*, 'Regulatory Science, Europeanization, and the Control of Agrochemicals' (1999) 24 *ST & HV* 241.

[82] Compare the notion of 'risk regulation regimes' in Hood, Rothstein and Baldwin, *The Government of Risk—Understanding Risk Regulation Regimes* (OUP, Oxford, 2001).

[83] Nowotny, 'Rethinking Science: From Reliable Knowledge to Socially Robust Knowledge' in Nowotny and Weiss (eds), *Jahrbuch 2000 des Collegium Helveticum* (Verlag der Fachvereine, Zürich, 2000) 221, 239. See also Pellizzoni, 'Knowledge, Uncertainty and the Transformation of the Public Sphere' (2003) 6 *EJST* 327. Cf Nowotny, Scott and Gibbons, *Rethinking Science: Knowledge and the Public in an Age of Uncertainty* (Polity Press, Cambridge, 2001).

[84] See eg Clam and Martin (eds), *Les Transformations de la Régulation Juridique* (LGDJ, Paris, 1998) 183; Morand, *Le Droit Néo-Moderne des Politiques Publiques* (LGDJ, Paris, 1999).

[85] Lonely but forceful, Rottleuthner, 'The Limits of Law—The Myth of a Regulatory Crisis' (1989) 17 *Int J Soc L* 273.

could be explained as a rather straightforward consequence of increased social complexity: as demands on the regulatory machinery of the state become ever greater, the capacity of the legal system to respond to these demands decreases more or less proportionally. This, in turn, leads to an erosion of the coherence, authority and effectiveness of law, on the one hand,[86] and to the social problems associated with dysfunctional regulation on the other: the 'juridification of social spheres' or the 'colonization of the lifeworld.'[87] Many of the normative solutions proposed for the problem consist, in one way or another, in attempts to bridge the 'gap' between law and society,[88] or between the regulator and the regulated.[89] Gunther Teubner's proposal, for 'reflexive' law,[90] sets out to accomplish exactly the opposite: it takes the social autonomy of both the legal system and other social subsystems seriously.[91] To strip a sophisticated argument from its theoretical richness: the operational closure of social systems renders them inaccessible for direct legal intervention. Law cannot, hence, directly accomplish, steer or change anything: law is but 'a system for the coordination of action within and between semi-autonomous social subsystems.'[92] The legal imperative is hence to find 'more indirect, abstract forms of social control;' no more regulation, but regulation of self-regulation:

> Thus, law must act at the subsystem-specific level to install, correct, and redefine democratic self-regulatory mechanisms. Law's role is to decide about decisions, regulate regulations, and establish structural premises for future decisions in terms of organisation, procedure, and competencies.[93]

[86] See eg Chevallier, 'La Régulation Juridique en Question' (2001) (49) *Droit et Société* 827.

[87] This can be taken as a very clumsy summary of Teubner, 'Juridification—Concepts, Aspects, Limits, Solutions' in Teubner (ed), *Juridification of Social Spheres* (de Gruyter, Berlin, 1987) 3.

[88] See Nonet and Selznick, *Law and Society in Transition: Toward Responsive Law* (Harper and Row, New York, 1978); Selznick, *The Moral Commonwealth—Social Theory and the Promise of Community* (University of California Press, Berkeley, 1992).

[89] See eg Stewart, 'Regulation and the Crisis of Legalisation in the United States' in Daintith (ed), *Law as an Instrument of Economic Policy—Comparative and Critical Approaches* (de Gruyter, Berlin, 1988) 97; Stewart, 'Madison's Nightmare' (1990) 57 *U Chi L R* 335; Ayres and Braithwaite, *Responsive Regulation—Transcending the Deregulation Debate* (OUP, Oxford, 1992); Freeman, 'Collaborative Governance in the Administrative State' (1997) 45 *UCLA L Rev* 1.

[90] See Teubner and Willke, 'Kontext und Autonomie: Gesellschaftliche Selbststeuerung durch reflexives Recht' (1984) 5 *ZfRsoz* 4; Teubner, 'Substantive and Reflexive Elements in Modern Law' (1983) 17 *Law & Soc Rev* 239.

[91] Though not seriously enough for the master. See Luhmann, 'Einige Probleme mit "Reflexivem Recht"' (1985) 6 *ZfRsoz* 1. Cf Maus, 'Perspektiven "Reflexiven Rechts" im Kontext gegenwärtiger Deregulierungstendenzen' (1986) 19 *Kritische Justiz* 390; Dimmel and Noll, 'Autopoiesis und Selbstreferentialität als "Postmoderne Rechtstheorie"—Die neue reine Rechtsleere' (1988) 16 *Demokratie und Recht* 379; Teubner, above n 18, 75 ff. Even Habermas accuses Teubner of straying from systems-theoretical correctness. See Habermas, above n 24, 53, especially on the basis of a statement in Teubner, above n 18, 88 ('[E]very specialized legal communication is always at the same time an act of general societal communication.')

[92] Teubner, above n 91, 242. Cf Willke, above n 23, 175 *et seq*.

[93] Above, 275.

How reflexive law relates to neocorporatist models of self-regulation is an ambiguous matter. On the one hand, Teubner is adamant that 'to think of functional subsystems in terms of large formal organisations with the capacity for action is a mistake.'[94] On the other hand, he does admit that 'one can think, to a certain extent, in terms of reflexive law' of what in neocorporatist literature passes for 'procedural regulation,' where the role of law is limited to providing, indeed, 'forms of organisation, procedures and competencies for relationships within and between organisations.'[95] Even as a solution to the cognitive problems arising from differentiation and social complexity, he approves of the 'delegation of epistemic authority' to 'various collective actors' with the law limiting itself to defining 'certain fundamental requirements relating to procedure and methods of cognition.'[96]

4.2 The Regulation of Self-Regulation

Where Teubner regards corporatist arrangements as a necessary strategy for coping with the cognitive problems caused by differentiation and social complexity, the traditional case for self-regulation rests almost exclusively on considerations of cost. As aptly summarised by Anthony Ogus:

> First, since self-regulatory agencies can normally command a higher degree of expertise and technical knowledge of practices and innovatory possibilities within the relevant area than independent agencies, information costs for the formulation and interpretation of standards are lower. Secondly, for the same reasons, monitoring and enforcement costs are also reduced, as are the costs to practitioners of dealing with regulators, given that such interaction is likely to be fostered by mutual trust. Thirdly, to the extent that the processes of, and rules issued by, self-regulatory agencies are less formalized than those of public regulatory regimes, there are savings in the costs (including those

[94] Teubner, above n 18, 83. 'Construing inter-system communication through inter-organisation communication,' hence 'merely compounds the problem.' The latter comment is directed especially at the fantastically complicated model of law production in Hutter, *Die Produktion von Recht* (Mohr, Tübingen, 1989), where inter-system communication is ensured by 'persons' who may constitute 'conversation circles' who may turn into social systems, achieve closure, and hence need new 'persons' and 'conversation circles' to ensure communication between them. And so on.

[95] Teubner, above n 18, 96. See Traxler and Voruba, 'Selbsteureung als Funktionales Äquivalent zum Recht? Zur Steuerungskapazität von Neokorporatistischen Arrangements und Reflexivem Recht' (1987) 16 *ZfSoz* 3; Macaulay, 'Private Government' in Lipson and Wheeler (eds), *Law and the Social Sciences* (Russell Sage, New York, 1986) 445, 492 ff. Cf Teubner, above n 45.

[96] Teubner, 'How the Law Thinks: Toward a Constructivist Epistemology of Law' (1989) 23 *Law & Soc Rev* 727, 751. On systemic epistemology, see further eg Willke, above n 22, 257 *et seq*. On reflexive law and risk regulation, see Paterson, 'Trans-Science, Trans-Law and Proceduralization' (2003) 12 *Soc & L S* 525.

> attributable to delay) of amending standards. Fourthly, the administrative costs of the regime are normally internalised in the trade or activity which is subject to regulation; in the case of independent, public agencies, they are typically borne by taxpayers.[97]

The underlying idea here seems to be one of comparative advantage. 'Regulation' is seen as an activity necessitating a number of mutually exclusive qualities – expertise and efficiency on the one hand, accountability and legitimacy on the other. The first set of qualities is then ascribed to private actors, the latter to the public sector, and the ultimate 'case' for or against self-regulation is a function of what is considered on balance to be the appropriate trade-off. Ultimately, then, the idea is one of functional equivalence: the choice is either public regulation or private regulation, each with its own advantages and drawbacks.[98] Concomitant with the shift from 'government' to 'governance,' this rigid understanding of the distinctions between public and private roles and values is now becoming altogether more fluid.[99] The corresponding process in law is one of 'decentring' regulation, which in itself involves, with Julia Black, a shift in the locus of the activity of 'regulating' from the state to other, multiple, locations.[100] Self-regulation, in this conception, is no longer necessarily seen as an alternative to state regulation; rather, the regulation of self-regulation is conceived of as regulation by other means.[101] The imperative for legal policy is, then, no longer either the submission of the market to the public interest or the liberation of market forces from the dysfunctional bureaucratic

[97] Ogus, 'Rethinking Self-Regulation' (1995) 15 *OJLS* 97, 97–98. Ogus immediately adds the caveat that it would be 'naïve' to assume that public interest justifications provide an exclusive explanation for the existence of self-regulatory regimes.

[98] See eg Baldwin and Cave, *Understanding Regulation—Theory, Strategy and Practice* (OUP, Oxford, 1999) 125 *et seq*. Cf Birkinshaw, Harden and Lewis, *Government by Moonlight—The Hybrid Parts of the State* (Unwin Hyman, London, 1990); Graham, 'Self-Regulation' in Richardson and Genn (eds), *Administrative Law and Government Action—The Courts and Alternative Mechanisms of Review* (Clarendon Press, Oxford, 1994) 189.

[99] See eg Braithwaite, *Restorative Justice and Responsive Regulation*, (OUP, Oxford, 2002) 29 ('Responsive regulation is not only something governments can do; private actors in civil society can also regulate responsively, indeed, even regulate governments responsively.') Cf Scott, 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance' (2002) 29 *J Law & Soc* 56. See also Freeman, 'Extending Public Law Norms Through Privatization' (2003) 116 *Harv L Rev* 1285.

[100] Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 *Current Legal Problems* 103, 112. See also Arnaud, 'De la Régulation par le Droit à l'heure de la Globalisation: Quelques Observations Critiques' (1997) 35 *Droit et Société* 11.

[101] See generally eg Gunningham and Sinclair, 'Regulatory Pluralism: Designing Policy Mixes for Environmental Protection' (1999) 21 *Law & Policy* 49; Freeman, 'The Private Role in Public Governance' (2000) 75 *NYU L Rev* 543. For much needed historical relativism, see Guttman, 'Public Purpose and Private Service: The Twentieth Century Culture of Contracting Out and the Evolving Law of Diffused Sovereignty' (2000) 52 *Admin L Rev* 859. Consider also the concepts of 'enforced' and 'audited' self-regulation in Ayres and Braithwaite, above n 90, ch 4; Michael, 'Federal Agency Use of Audited Self-Regulation as a Regulatory Technique' (1995) 47 *Admin L Rev* 171.

stranglehold of state regulation; rather, the imperative is to look for ways of co-ordinating public and private rulemaking in such a way as to preserve both social autonomy and the public interest.

The ascendance of private governance regimes poses enormous problems for lawyers. A growing body of work is concerned with the 'privatisation' of public law to ensure that private regulators are held to standards of good governance and made somehow accountable.[102] The obvious problem with this solution is that it has no way of dealing with transnational private governance regimes that are proliferating in a globalising economy.[103] Gunther Teubner's new project, hence, is to transform private law into the constitutional law of the diverse private governance regimes:

> The core function of private law is to juridify diverse processes of decentralized spontaneous norm-formation in civil society which are fundamentally different from processes of political regulation by the central authority of the State. Private law's job in this broader sense is to constitutionalize spaces of social autonomy, not only economic forms of action but in particular non-economic forms of contracting and other modes of consensual action, idiosyncratic private ordering, standardization, normalization, codes of practice, formal organization and loosely organized networks in different contextures of civil society.[104]

4.3 Legal Pluralism

If the modern world of political sociology looks a lot like Emile Durkheim's world, the modern world of legal theory looks a lot like the world inhabited by Eugen Ehrlich and Georges Gurvitch, the fathers of legal pluralism.[105] Rather than extending the limits of legal categories by

[102] See especially Black, 'Constitutionalising Self-Regulation' (1996) 59 *MLR* 24; Freeman, 'Private Parties, Public Functions and the New Administrative Law' (2000) 52 *Admin L Rev* 813.

[103] But see Aman, 'Proposals for Reforming the Administrative Procedure Act: Globalizaton, Democracy and the Furtherance of a Global Public Interest' (1999) 6 *Ind J Glob L S* 397; Aman, 'The Limits of Globalization and the Future of Administrative Law: From Government to Governance' (2001) 8 *Ind J Glob L S* 379; Aman, 'Globalization, Democracy, and the Need for a New Administrative Law' (2002) 49 *UCLA L Rev* 1687. Cf Engel, 'Hybrid Governance Across National Jurisdictions as a Challenge to Constitutional Law' (2001) 2 *European Business Organization Law Review* 569; Shapiro, 'Administrative Law Unbounded: Reflections on Government and Governance' (2001) 8 *Ind J Glob L* S 369. For a review of the, blissfully limited, impact of globalisation and privatisation on French administrative law, see Auby, 'La Bataille de San Romano: Réflexions sur les évolutions Récentes du Droit Administratif' (2001) 11 *AJDA* 912.

[104] Teubner, 'After Privatization? The Many Autonomies of Private Law' (1998) 51 *Current Legal Problems* 393, 399. Cf Teubner, 'Contracting Worlds: The The Many Autonomies of Private Law' [2000] *Soc & L S* 399.

[105] See Teubner, '"Global Bukowina": Legal Pluralism in the World Society' in Teubner (ed), *Global Law Without a State* (Dartmouth, Aldershot, 1997) 3. The classics are Ehrlich, *Fundamental Principles of the Sociology of Law* (Harvard University Press, Cambridge, 1913), and Gurvitch, *L'idée du Droit Social* (Sirey, Paris, 1932).

privatising public law or publicizing private law, the more relevant exercise under modern conditions seems to be to rethink the limits of the concept of law itself. Again with Gunther Teubner,

> The distinction law/nonlaw is based on law's hierarchy of rules where the higher rules legitimate the lower ones. Normative phenomena outside of this hierarchy of rules are not law, just facts. After the decline of natural law, the highest rules in our times is the constitution of the nation-state—whether written or unwritten—which in turn refers to democratic political legislation as the ultimate legitimation of legal validity.[106]

And thus:

> Contractual rulemaking as well as intra-organizational rule production is still seen as either nonlaw or as delegated lawmaking that must be recognized by the official legal order. Rulemaking by 'private governments' is thus subjugated under the hierarchical frame of the national constitution that represents the historical unity of law and state.[107]

Now, if globalisation has done anything, it has broken up this frame, it has depossessed the state of its monopoly in lawmaking. Private governance regimes produce 'law' exerting validity far beyond the borders of single nation-states, controlling and sanctioning behaviour in trans-national markets.[108] And that brings us back to Durkheim's problem: how can these regimes be constituted as 'legal institutions' if they leap over the territorial boundaries of 'the' law? The tradition of legal pluralism, with its respect for non-statal legal orders and 'private governments,' seems of obvious relevance here. With Philip Selznick,

> Law is endemic in all institutions that rely for social control on formal authority and rule-making. . . . Indeed, to equate law with the state impoverishes both sociological and legal analysis. When we fail to see the place of law in 'private' institutions, we withhold from that setting the experience of the political community in matters of governance.[109]

Legal pluralism finds its roots in colonial societies and its ethos in the rejection of the reduction to 'social custom' of indigenous law. Its main theoretical achievement has been to move away from the hierarchical frame of state law as the appropriate unit of analysis and hence from

[106] Teubner, above n 20, 768.

[107] Above. See also Teubner, 'Breaking Frames: The Global Interplay of Legal and Social Systems' (1997) 45 *Am J Comp L* 149. See also Gurvitch, above n 105, 73–74 ('[E]n combattant le pluralisme naissant d'une séries d'ordres equivalents, qui cherchent et réussissent peu à peu a dépossséder l'Etat de son prétendu monopole juridique, celui-ci recourt, là oú il en a la possibilité, à l'ultime moyen, qui est l'annexion de certains de ces orders concurrents pour les transformer et les faire servir à la cause étatiste.')

[108] See generally Teubner (ed), above n 106; Cutler, *Private Power and Global Authority—Transnational Merchant Law and the Global Political Economy* (CUP, Cambridge, 2003).

[109] Selznick, above n 89, 300–1.

questions of the impact of society on law or vice versa as the only possible queries. Instead, the focus is the interaction of different normative orders within social fields.[110] Still taking the state as the main 'social field', Boa de Sousa Santos has described the result of globalisation to be 'the coexistence within the nation-state of international or transnational legal orders articulated in different ways with the nation-state legality.'[111] In Francis Snyder's work on global economic governance, the state is but one, if an important one, of the sites that locate and produce the institutions, norms and dispute-resolution processes involved in global legal pluralism.[112] In Teubner's globalised version of legal pluralism, the State has no place at all in the definition of 'law.' Law as a fully differentiated closed system of communications defines its own boundaries. In that sense, Teubner is only coherent when he defines legal pluralism not as a set of conflicting social norms in a given social field, but as 'a multiplicity of communicative processes.'[113] From that viewpoint, his concern is not with the hierarchical process of the legal formalization of diffuse social norms, but with heterarchical processes of coupling and linkage, with 'the specialized institutions that bind law to a multitude of functional subsystems and formal organizations.'[114] Legal pluralism, in this view, makes law responsive to society by providing structural coupling between fragmented social discourses. Indeed, '"Standard setting" is the new paradigm supplanting "social customs"!'[115]

> The legal discourse no longer 'incorporates' results by misreading social norms as legal norms; today it 'incorporates' processes by misreading economic or technical production as law production.[116]

[110] See the overviews in Macaulay, above n 96; and Merry, 'Legal Pluralism' (1988) 22 *Law & Soc Rev* 869. See also Arnaud, *Entre Modernité et Mondialisation—Cinq Leçons de l'Histoire de la Philosophie du Droit et de l'Etat* (PUF, Paris, 1998). Cf Schepel, 'Legal Pluralism in the European Union' in Fitzpatrick and Bergeron (eds), *Europe's Other—European Law Between Modernity and Postmodernity* (Ashgate, Aldershot, 1998) 47. For protestations, see Tamanaha, 'The Folly of the 'Social Scientific' Concept of Legal Pluralism' (1993) 20 *J Law & Soc* 192; Tamanaha, 'A Non-Essentialist Version of Legal Pluralism' (2000) 27 *J Law & Soc* 296. 'Institutionalist' approaches to self-regulation come close to accepting legal pluralism. See Gunningham and Rees, 'Industry Self-Regulation: An Institutional Perspective' (1997) 19 *Law & Policy* 365. See also Encinas de Munagorri, 'La communauté Scientifique est-elle un Ordre Juridique?' (1998) *RTDC* 247. Cf Schwarcz, 'Private Ordering' (2002) 97 *Northwestern U L Rev* 319.

[111] De Sousa Santos, 'State, Law and Community in the World System: An Introduction' (1992) 1 *Soc & L S* 131, 134. Cf De Sousa Santos, *Toward a New Common Sense. Law, Science and Politics in the Paradigmatic Transition* (Routledge, London, 1995).

[112] Snyder, 'Governing Economic Globalisation: Global Legal Pluralism and EU Law' in Snyder (ed), *Regional and Global Regulation of International Trade* (Hart Publishing, Oxford, 2001) 1, 10.

[113] Teubner, 'The Two Faces of Janus: Rethinking Legal Pluralism' (1992) 13 *Cardozo L Rev* 1443, 1450. Cf Teubner, above n 105.

[114] Above, 1448.

[115] Above, 1457.

[116] Above, 1459.

5. CONCLUSION

There is nothing inevitable about the ascendance of private governance regimes; the point of this chapter has decidely not been to ascribe the rise of trasnational private standard setting to the forces of social evolution. Rather, the point has been to render it at least plausible that associational governance has a distinct contribution to make to social integration under conditions of globalisation and differentiation. Modern governance requires not the separation of the political, the scientific and the economic, nor the total collapse of these distinctions: modern governance requires ways of linking these spheres of life while maintaining their social autonomy. Standards bodies link the global marketplace to national politics, link scientific knowledge to industrial practice, and link social custom to law. They should at least be taken seriously as sites of modern governance.

2

The European Community: Market Integration and Private Transnationalism

1. INTRODUCTION

TWENTY YEARS AGO, Joseph Weiler famously modelled the early development of European law as the cyclical causal connection between the two extremes of an apparent paradox: where the supremacy and direct effect of EC law led to a deepening of normative supranationalism, assertions of veto power and other manifestations of intergovernmental bargaining by Member States steadily eroded decisional supranationalism. He understood Member States' taking control over the policy process not only as a reaction against the Court's 'constitutionalisation' of the Treaty, but as a precondition for it. Legal integration moulds the conditions for political disintegration and vice versa.[1] By the time he penned 'The Transformation of Europe' ten years later, he had the chance to test the theory and explain '1992' from his variables.[2] Where the Court had expanded the reach of Article 28 EC to include 'all trading rules which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade',[3] that provision exercised enormous deregulatory pressure on national legislative frameworks; national measures not only had to be defended in terms of public interest objectives, but also in terms of the necessity and proportionality of the measure for achieving those objectives.[4] The only way to escape this intrusive review of health protection measures by the Court was to agree unanimously with other Member States on a Community measure. That was intrinsically difficult, and was further complicated by the Court's pre-emption

[1] Weiler, 'The Community System: The Dual Character of Supranationalism' (1981) 1 *YEL* 257.

[2] First published in (1991) 100 *Yale L Rev* 2403; revised and supplemented in Weiler, *The Constitution of Europe* (CUP, Cambridge, 1999) 10–101.

[3] Case 8/74 *Procureur du Roi v Dassonville* [1974] ECR 837, para 5.

[4] See Case 120/78 *Rewe Zentrale v Bundesmonopolverwaltung für Branntwein ('Cassis de Dijon')* [1979] ECR 649.

caselaw; once a Community Directive is in place on a given subject-matter, all recourse to Article 30 EC is closed down.[5] In this framework, Weiler saw the Single European Act as reaching a new equilibrium between legal structure and political process.[6] On the one hand, Member States agreed to give up unilateral control over the legislative process concerning the internal market and acquiesced in qualified majority voting in Article 95 (1) EC; on the other, they obtained Article 95 (4) EC allowing them the derogation that the judicial pre-emption doctrine had denied them.[7] Roughly another decade later, Weiler could complete his story. With qualified majority voting, the relationship between Article 28 and 95 (1) EC put considerable stress on the new equilibrium: after all, anything the Court considered to fall within the scope of Article 28 EC automatically fell within the orbit of the Community's competences under Article 95 (1) EC. With *Keck*, the Court let go of Article 28 EC as a vehicle of wholesale deregulation and restored it to its function of regulating trade between Member States.[8] *Keck*, then, represents for Weiler the flip side of his theory; the deepening of decisional supranationalism leads to perhaps not an erosion, but certainly a narrowing down of the reach of normative supranationalism.[9]

The rise to prominence of standards in the process of European integration can best be explained in juxtaposition to this narrative: standards are caught by neither legal structure or political process. Their character as private, non-binding measures makes national standards immune to the reach of Article 28 EC; in a first phase, European standards were just considered if not the only, certainly the most effective way to deal with the

[5] See Case 5/77 *Tedeschi v Denkavit* [1977] ECR 1555. The pre-emption rule is limited to measures of full harmonisation which allow for monitoring compliance. See Case 247/84 *Motte* [1985] ECR 3887. See generally Weatherill, 'Pre-emption, Harmonisation and the Distribution of Competence to Regulate the Internal Market' in Barnard and Scott (eds), *The Law of the Single European Market—Unpacking the Premises* (Hart Publishing, Oxford, 2002) 41.

[6] See Weiler, above n 2, 66ff. For other authoritative accounts of the interplay of 'positive' and 'negative' integration from different perspectives, see Weatherill, *Law and Integration* (Clarendon Press, Oxford, 1995); Scharpf, *Governing in Europe—Effective and Democratic?* (OUP, Oxford, 1999).

[7] See Article 95 (1) and (4) EC, inserted by the Single European Act. Article 95 (3) EC is the 'soft' version of the trade-off, requiring the Commission to table proposals that take as their base a 'high level of protection'.

[8] Joined Cases C–267 and 268/91 *Keck and Mithouard* [1993] ECR I–6097. This is how Joliet, 'La Libre Circulation des Marchandises: L'arrêt *Keck et Mithouard* et les Nouvelles Orientations de la Jurisprudence' (1994) 2 *JTDE* 145, 151; Tesauro, 'The Community's Internal Market in the Light of the Recent Case-law of the Court of Justice' (1995) 15 *YEL* 1, 5, and Möschel, casenote, [1994] *NJW* 429, 431 all read the case. See generally Weatherill, 'After *Keck*: Some Thoughts on how to Clarify the Clarification' (1996) 33 *C M L Rev* 885; Poiares Maduro, *We the Court—The European Court of Justice and the European Economic Constitution* (Hart Publishing, Oxford, 1998).

[9] Weiler, 'The Constitution of the Common Market Place: Text and Context in the Evolution of the Free Movement of Goods' in Craig and Búrca (eds), *The Evolution of EU Law* (OUP, Oxford, 1999) 349, 371–72 (by implication at least; Weiler is now so *sui generis* an author of 'thinkpieces' that he even does without 'I told you so'-references to his own work).

technical barriers to trade represented by divergent national standards. In a second phase, this changed. European standards bodies offered a way of circumventing the intricacies of political decision-making in the Council and speed up the process of European harmonisation.[10] The Europeanisation of standardisation thus encouraged by the Community led to an increase of the autonomy and power of recognised private European and national standards bodies. This, in turn, produced the great dilemma private governance always poses for public authorities: to 'publicise' private arrangements or to 'privatise' the notion of governance itself. The Community first unsuccessfully tried the first and then embraced the second option.

2. MEMBER STATES, STANDARDS AND THE REACH OF NEGATIVE INTEGRATION

2.1 Integration, Deregulation and Article 28 EC

Community efforts to eliminate technical barriers to trade were put on a higher plain by the principle of mutual recognition established by the Court in *Cassis de Dijon*.[11] In *Neeltje Houtwipper*, the Court conveniently summed up its caselaw:

> It is established by the case-law beginning with 'Cassis de Dijon' that, in the absence of harmonisation of legislation, obstacles to the free movement of goods which are the consequence of applying, to goods coming from other Member States where they are lawfully manufactured and marketed, rules that lay down requirements to be met by such goods (such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging) constitute measures of equivalent effect prohibited by Article 28. This is so even if those rules apply without distinction to all products unless their application can be justified by a public-interest objective taking precedence over the free movement of goods.[12]

The Commission ably exploited *Cassis de Dijon* to launch the internal market programme. Part of that programme was a litigation strategy:

[10] Compare Armstrong and Bulmer, *The Governance of the Single European Market* (MUP, Manchester, 1998) 144 (explaining the development in three phases where the problems posed by national standards, bizarrely, only come to the fore in the last of these). The whole story is told well and exhaustively in Joerges, *et al*, *Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft* (Nomos, Baden-Baden, 1988). From a political sociology perspective, Voelzkow, *Private Regierungen in der Technik steuerung. Eine Sozialwissenschaftliche Analyse der Technischen Normung* (Campus, Frankfurt, 1996) 261 ff. From a political economy perspective, Egan, *Constructing a European Market—Standards, Regulation and Governance* (OUP, Oxford, 2001).

[11] Above n 4.

[12] Case C–293/93 *Neeltje Houtwipper* [1994] ECR I–4249, para 11. See further eg Case C–383/97 *Arnoldus van der Laan* [1999] ECR I–731, para 19.

> The Commission now has to tackle a whole body of commercial rules which lay down that products manufactured and marketed in one member state must fulfil technical or qualitative requirements in order to be admitted to the market of another and specifically in all cases where the trade barriers occasioned by such rules are inadmissible according to the very strict criteria set out by the Court. The Commission is referring in particular to rules covering the composition, designation, presentation and packaging of products as well as rules requiring compliance with certain technical standards.[13]

If 'to tackle' is 'bring infringement proceedings', the Commission only tackled two rules requiring compliance with technical standards. A successful action was brought against Ireland. In a call for tender, the city of Dundalk had inserted the condition that the cement pressure pipes involved 'shall be certified as complying with Irish Standard Specification 188: 1975'. There being only one, Irish, proud owner of such a certificate, the Court had no difficulty holding that the clause had the effect of restricting the supply of pipes to Irish manufacturers alone.[14] The Court held the clause to fall foul of Article 28 EC not because of the technical requirements imposed, but because of the refusal to verify compliance with those requirements for products that were not certified to the Irish standard. A simple addition of 'or equivalent' in the clause would have done the trick.[15]

The Commission brought an unsuccessful action against France in a case that brings the limits of the principle of mutual recognition to the fore. The Commission took issue with technical requirements imposed on woodworking machines; depending on the degree of danger they represented, the French authorities required either a mere declaration of conformity with French standards, or a certificate from a national testing laboratory, or ministerial approval.

The Court first delivered a ringing endorsement of the principle of mutual recognition:

> [A Member State] is not entitled to prevent the marketing of a product originating in another Member State which provides a level of protection of the health and life of humans equivalent to that which the national rules are intended to ensure or establish. It is therefore contrary to the principle of proportionality for national rules to require such imported products to comply strictly and exactly with the provisions or technical requirements laid down for products manufactured in the Member State in question when those imported products afford users the same level of protection.[16]

[13] Communication concerning the consequences of the judgment given by the Court of Justice in Case 120/78 ('*Cassis de Dijon*'), (1980) OJ C 256/2.

[14] Case 45/87 *Commission v Ireland* [1988] ECR 4929, para 20.

[15] Above. Ireland maintained that compliance with the international standard ISO 160: 1980 would not suffice to eliminate technical difficulties.

[16] Case 188/84 *Commission v France* [1986] ECR 419, para 16.

The crux of the matter is, of course, the 'same level of protection'. The whole principle of mutual recognition is based on a means/ends dichotomy. As the Commission has it in its White Paper:

> [T]he objectives of national legislation, such as the protection of human health and life and of the environment, are more often than not identical. It follows that the rules and controls developed to achieve those objectives, although they take different forms, essentially come down to the same thing, and so should normally be accorded recognition in all Member States.[17]

The Commission advanced the same argument in the woodworking machines case. Both French and German law seek to protect users from being hurt by dangerous machines. Whether they try to do so by making sure that the machine itself is less dangerous, as the French do, or by making sure that the user is properly trained and will not put himself in unnecessary danger, as the Germans do, it 'essentially comes down to the same thing.' The Court disagreed, unpersuaded by statistical evidence of accidents, and held that the fundamentally different approaches to controls precluded a finding that machines lawfully marketed in other Member States offered 'the same level of protection'.[18]

The Court's caselaw certainly has had the effect of making the protectionist use of standards more difficult for public authorities. This, for example, is how French standards law throws in Article 30 EC, *Cassis de Dijon* and *Dundalk* to describe the conditions under which French standards can be made obligatory:

> Si des raisons d'ordre public, de sécurité public, de protection de la santé et de vie des personnes et des animaux ou de préservation des végétaux, de protection de trésors nationaux ayant une valeur artistique, historique ou archéologique, ou des exigences impératives tenant à l'efficacité des contrôles fiscaux, à la loyauté des transactions commerciales et à la défense du consommateur rendent une telle mesure nécessaire, l'application d'une norme homologuée, ou d'une norme reconnue équivalente applicable en France en vertu d'accords internationaux peut être rendue obligatoire par arrêté.[19]

If, however, only those standards that are rendered obligatory by state measures are tackled, a vast array of national standards is left untouched. But the capacity of standards to effectively close off markets to those products which do not comply with them hardly depends on their being

[17] Commission White Paper, *Completing the Internal Market*, COM (1985) 310/final, para 58.

[18] *Commission v France*, above n 16, para 22.

[19] Article 12, Décret 84–74 of 26 January 1984 as amended by Décret 91–283 of 19 March 1991. The National Standards Authority of Ireland Act, SI 1996: 28, is less generous. Article 28 (1) allows Irish standards, 'or the standard of another Member State which is equivalent to the Irish Standard Specification declared under this Act' to be rendered obligatory 'for the purpose of promoting the safe use by the public of a commodity' and for 'promoting safe practices'.

obligatory. They can do so on mere market strength—consumer confidence in certain quality marks is strong enough on occasion to render it impossible for imported goods to compete with certified goods. Moreover, institutions other than the state can require compliance with standards—most notably through insurance policies or supplier contracts. The crucial question, then, is whether the reach of Article 28 EC can be extended to non-obligatory standards. A frustrated Alfonso Mattera, the Commission's free movement czar, opined in 1983:

> Les normes ou spécifications techniques nationales constituent l'instrument de protection le plus actuel et litigieux, car si d'une part, il n'est pas contestable que de telles normes comportent dans la pratique des effets restrictifs et parfois insurmontables dans les échanges, il est d'autre part difficile, voire impossible, de les appréhender au titre de l'article 28 CEE en raison de leur caractère de 'normes privées' ou prétendues telles.[20]

There are two aspects to the 'private' nature of standards. One is the fact that they are non-binding; the other that they emanate from 'private' institutions. In 1982, the Court of Justice held in the '*Buy Irish*' case that the first does not bar the application of Article 28 EC, since even non-binding measures 'may be capable of influencing the conduct of traders and consumers in that State and thus of frustrating the aims of the Community.'[21] It is the second aspect that causes the problems. The Court has consistently held that Article 28 concerns 'only public measures and not the conduct of undertakings'.[22] There are, nonetheless, three approaches discernible in the Court's caselaw that could lead to the free movement rules being applied to private parties.

2.2 Extending the Reach of Article 28

The first and most obvious solution is to substitute a Community definition of what is 'public' for national legal designations. The mirror image of its efforts in competition law to define 'undertakings' in functional terms,[23] the Court has shown some vigour in dispelling the notion that a public authority is only what a Member State says it is. Unlike its efforts in competition law, however, the Court has declined to fit the notion in a neat

[20] Mattera, 'Les Nouvelles Formes de Protectionnisme Economique et les Articles 30 et Suivants du Traité CEE' (1983) 26 *RMC* 252, 255.

[21] Case 249/81 *Commission v Ireland* [1982] ECR 4005. See also Case C–325/00 *Commission v Germany* [2002] ECR I–9977, para 24 (Holding incompatible with Article 28 EC the optional use of the quality label '*Markenqualität aus deutschen Landen*' because 'the use of that designation promotes or is likely to promote the marketing of the product concerned as compared with products which do not benefit from its use.')

[22] See eg Case 311/85 *Vlaamse Reisbureaus* [1987] ECR 3801, para 30.

[23] See below, Chapter 9.

definition. What it does instead is accumulate evidence of state involvement in the set-up, organisation and operation of the body concerned. In *Buy Irish*, the Court attributed a campaign for home grown food conducted by the Irish Goods Council, a private body, to the Irish Government since it (a) appointed the members of the management committee, (b) largely financed the operation, and (c) broadly defined the policy objectives of the organisation.[24] A year later, it attributed a similar campaign conducted by the 'Apple and Pear Development Council' to the United Kingdom since the body was (a) set up by the Government and (b) financed by a compulsory charge imposed on the Council's members by virtue of national regulations.[25] The tougher test came with two cases dealing with self-regulatory associations of pharmacists. The Royal Pharmaceutical Society stood accused of infringing Article 28 EC by prohibiting its members from selling medicinal products other than the brands prescribed by doctors, thus effectively closing down the market for parallel imports of therapeutically equivalent products. The Society was a private body, incorporated by Royal Charter, and the sole professional body for pharmacy. The Court regarded it as capable of taking measures of the kind prohibited by Article 28 EC especially by virtue of its disciplinary powers, recognised by legislation.[26] The *Landesapothekerkammer Baden-Württemberg* had no such powers, but was nonetheless considered capable of taking measures having equivalent effect to quantitative restrictions to trade since it was, in contrast to the Pharmaceutical Society, a public law body, and was regulated by the State.[27]

What the Court does is thus gather as many elements as possible of 'state involvement', without it being settled what kind of aspects count more than others. Formal criteria—legal recognition—appear side by side to factual criteria—financing, appointment of personnel, and other means of control, even if they do seem to carry more weight. In his extensive

[24] *Commission v Ireland*, above n 21, para 15. In the context of Article 29 EC, see Case C–302/88 *Hennen Olie* [1990] ECR I–4625, para 15 (private body capable of enacting measures having equivalent effect to quantitative export restrictions because of being 'controlled and directed by public authorities' who appointed the members of the Executive Council, and had the power to dissolve the body, approve the budget, and issue binding instructions').

[25] Case 222/82 *Apple and Pear Development Council* [1983] ECR 4083. Apart from a publicity campaign promoting home-grown fruits, the Council also made quality recommendations as regards the size of apples and pears. The Court held in para 23: 'it should be emphasised that the rules on the common organisation of the market in fruit and vegetables provide for an exhaustive system of quality standards applicable to the products in question. Unless these rules provide otherwise, Member States and, *a fortiori*, bodies such as the Development Council are therefore prevented from imposing unilateral provisions concerning the quality of the fruit marketed by growers.'

[26] Joined Cases 266 and 267/88 *Royal Pharmaceutical Society of Great Britain* [1989] ECR 1295, paras 14–15. The Court justified the measure under Article 30 EC as being part of the national health system.

[27] Case C–292/92 *Ruth Hünermund* [1993] ECR I–6787, para 14. See also Case C–325/00 *Commission v Germany* [2002] ECR I–9977, para 14 ff.

study on the subject of standards and Article 28 EC, Mohr concludes that States should have a 'dominant influence' over standards bodies in order for standards to be attributed to them, which he defines in three categories; either financially, or in control over the composition of the management board, or in terms of state delegating authority and controlling its exercise.[28] Under those formal conditions, the Irish, French and Greek standards bodies would be considered capable of taking measures contrary to Article 28 EC; DIN, BSI and DS would certainly not be. And yet, DS has been reported to have 'probably the biggest proportion of direct state involvement of any standards organisation in Europe'.[29] That is demonstrably false,[30] but it does bring out how far the Court stops short in its 'functional' interpretation.

The second approach is admittedly far-fetched, but nonetheless significant as a matter of principle. It consists in holding Member States responsible for measures taken by private parties. The Commission argued for such a construction as early as 1984;[31] the relevant caselaw, however, only starts in 1994 with the first stage of the Commission's efforts to crack down on Italian customs forwarding agents. Organised in a public law body, these agents charged for making customs declarations on the basis of tariffs they had set themselves, approved and made binding by the public authorities. The Commission brought an infringement case against Italy on the grounds that it imposed 'charges having equivalent effect to customs duties' prohibited by Articles 23 and 25 EC. The Court held as a matter of principle:

> [T]he justification for the prohibition of charges having equivalent effect to customs duties lies in the fact that pecuniary charges imposed on goods by reason of, or in connection with, the crossing of a frontier are an obstacle to the free movement of goods. Accordingly, any pecuniary charge, however small and whatever its designation and mode of application, which is

[28] Mohr, *Technische Normen und freier Warenverkehr in der EWG* (Carl Heymanns, Köln, 1990) 108. Mohr transplants the criteria of Commission Directive 80/723/EEC on the Transparency of Financial Relations between Member States and Public Undertakings, (1980) OJ L 195/35. That Directive demands 'dominant influence' of public authorities, which it presumes to exist when they hold the major part of the undertaking's subscribed capital, control the majority of votes attached to shares issued by the undertaking, or can appoint more than half of the members of the undertaking's supervisory, administrative or managerial body. The analogy seems misguided. The Directive is an instrument to enforce the application of Article 86 (1) EC, which seeks to curtail States' distorting competition. The Directive, issued under Article 86 (3) EC, was held up by the Court in Joined Cases 188 to 190/80 *France, Italy and UK v Commission* [1982] ECR 2545.

[29] Bundgaard-Pedersen, 'States and EU Technical Standardization: Denmark, the Netherlands and Norway Managing Polycentric Policy-Making 1985–95' (1997) 4 *JEPP* 206, 218.

[30] See Schepel and Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA, Vol 1: Comparative Report* (Opoce, Luxembourg, 2000) 68 ff.

[31] See the First report on Commission monitoring the application of Community law, COM (1984) 181 final, 11.

> imposed unilaterally on goods by reason of the fact that they cross a frontier, and which is not a customs duty in the strict sense, constitutes a charge having equivalent effect within the meaning of Articles 23 and 25 of the Treaty, even though it is not levied by the State.[32]

It dismissed the Commission's claim, however, on the grounds that importers had a 'genuine choice' to have their declarations drawn up by others than the forwarding agents.[33] Eventually, the Commission succeeded in condemning both the agents and Italy under the competition rules.[34]

In *Dubois*, a year later, the Court was confronted with a contract between the operator of a road station and forwarding agents which provided for a flat rate transit charge for every vehicle in international transit whose customs formalities were handled by the agents on the premises of the road station. The Court held:

> The nature of the measure requiring economic agents to bear part of the operating costs of customs services is immaterial. Whether the pecuniary charge is borne by the economic agent by virtue of a unilateral measure adopted by the authorities or, as in the present case, as a result of a series of private contracts, it arises in all cases, directly or indirectly, from the failure of the Member State concerned to fulfil its duties under Articles 23 and 25 of the Treaty.[35]

Blaming Member States for charges having equivalent effect to customs charges is relatively easy. The principle is well established that Member States are to bear all costs relating to controls and formalities goods have to go through by reason of their crossing borders;[36] *a contrario*, Member States are bound to prevent any costs being imposed on goods for that reason, even by private parties. Such a general duty cannot be presumed to exist in the wider area of the free movement of goods. The radical novelty in the next step the Court took was to use the principle of Community loyalty enshrined in Article 10 EC for that purpose. Frustrated with the passivity of French authorities in face of farmers' actions against lorries importing fruits and vegetables from other Member States, the Commission brought France to Court. The Court accepted the argument that Article 28 EC read together with Article 10 EC entailed not just a duty to abstain from erecting barriers to trade, but also a duty to prevent private parties from erecting these barriers. Specifically, States are under

[32] Case C–119/92 *Commission v Italy* [1994] ECR I–393, para 44.

[33] Above, para 46

[34] Commission Decision 93/438/EEC, IV/33.407–CNSD, (1993) OJ L 203/27, unsuccessfully appealed in Case T–513/93 *CNSD v Commission* [2000] ECR II–1807; and Case C–35/96 *Commission v Italy* [1998] ECR I–3851. See infra.

[35] Case C–16/94 *Edouard Dubois v Garonor* [1995] ECR I–2421, para 20.

[36] Case 87/75 *Bresciani v Amministrazione delle Finanze* [1976] ECR 129, para 10.

an obligation to 'take all necessary and appropriate measures' to ensure that the freedom of movement of goods is respected on their territory.[37]

Avant la lettre in 1985, Sabine Lecrenier wondered out loud whether the Commission should not instigate infringement proceedings against Member States who failed to intervene in such things as boycotts of goods not certified to national standards by consumer organisations and insurance companies.[38] It should be borne in mind, however, that the case under discussion dealt with the French authorities' declining to do what government is supposed to do under any conception of statehood: keep public order, prevent damage to life and limbs, prosecute criminal acts. To extend the principle of States' duty to prevent private parties to do anything that might, actually or potentially, directly or indirectly, prevent trade to activities that are not traditionally in the province of government, like standardisation, would be for Community law to require national public authorities to police private economic life to an extent that is, at least, at odds with the general ideas underlying the internal market.

The last, and most improbable, approach is based on bold principle. In an isolated *obiter dictum* in *Dansk Supermarked*, the Court held in 1981 that

> it is impossible in any circumstances for agreements between individuals to derogate from the mandatory provisions of the Treaty on the free movement of goods.[39]

Even if the Court has ignored the statement ever since like an unwanted child, there is quite some support for the general principle.[40] The Treaty operates on a rigid public/private distinction, where public measures are

[37] Case C–265/95 *Commission v France* [1997] ECR I–6959, paras 30–32. The decision came just weeks after the Commission tabled its ill-fated Proposal for a Council regulation creating a mechanism whereby the Commission can intervene in order to remove certain obstacles to trade, COM (1997) 619 final. Article 226 EC proceedings taking too long, the Commission wanted the power to take Decisions directed at recalcitrant Member States which would then be enforceable in national courts. The Council adopted a much-watered down version as Regulation 2679/98/EC on the functioning of the internal market in relation to the free movement of goods among the Member States, (1998) OJ L 337/8. The Commission tries to keep a brave face. See its answer to Question 3422/98 by MEP Amadeo, (1999) OJ C 182/82.

[38] Lecrenier, 'Les Articles 30 et Suivants CEE et les Procédures de Contrôle Prévues par la Directive 83/189/CEE' (1985) 283 *RMC* 20.

[39] Case 58/80 *Dansk Supermarked v Imerco* [1980] ECR 181, para 17.

[40] Earliest, Van Gerven, 'The Recent Case-Law of the Court of Justice concerning Articles 30 and 36 of the EEC Treaty' (1977) 14 *C M L Rev* 5, 22 ('at least as a matter of principle'); See also Steindorff, *EG-Vertrag und Privatrecht* (Nomos, Baden-Baden, 1996) 277 ff. *Contra*, Roth, 'Drittwirkung der Grundfreiheiten?' in Due, Lutter and Schwarze (eds), *Festschrift für Ulrich Everling* (Nomos, Baden-Baden, 1995) 1213; Kluth, 'Die Bindung privater Wirtschaftsteilnehmer an die Grundfreiheiten des EG-Vertrages' (1997) 122 *Archiv des öffentlichen Rechts* 557 (arguing that horizontal effect of fundamental freedoms leads to 'socialisation' of private law and would mean the end of the *Privatgesellschaft*). Cf Snell, 'Private Parties and the Free Movement of Goods and Services' in Andenas and Roth (eds), *Services and Free Movement in EU Law* (OUP, Oxford, 2002) 211.

caught by the free movement rules and private agreements are subjected to the principle of the competition rules. But just as state measures can restrict competition just as effectively as cartels can, private arrangements can hinder the free movement of goods just as effectively as state measures can.[41] The Court accepted this reasoning for the free movement of workers as early as 1974 in *Walrave*:

> The abolition as between Member States of obstacles to freedom of movement for persons and freedom to provide services, which are fundamental objectives of the Community contained in Article 3 (c) of the Treaty, would be compromised if the abolition of State barriers could be neutralised by obstacles resulting from the exercise of their legal autonomy by associations or organisations which do not come under public law.
>
> Since, moreover, working conditions in the various Member States are governed sometimes by means of provisions laid down by law or regulation and sometimes by agreements and other acts concluded or adopted by private persons, to limit the prohibitions in question would risk creating inequality in their application.[42]

Now, the free movement of goods is as much, if not more, a fundamental Community objective as the free movement of persons. Moreover, the reasoning behind *Walrave* applies with equal force to the regulation of product safety. And yet, the Court had relied on *Walrave* only in *Bosman* and other cases dealing with the free movement of athletes,[43] before

[41] For the application of the competition rules to state measures, see below. On the parallel, see eg Waelbroeck, 'Les Rapports Entre les Règles sur la Libre Circulation des Marchandises et les Règles de Concurrence Applicables aux Entreprises Dans la CEE' in F Capotorti, *et al* (eds), *Du Droit International au Droit de L'intégration* (Nomos, Baden-Baden, 1987) 781; VerLoren van Themaat, 'Gaat de Luxemburgse Rechtspraak over de Vier Vrijheden en die over het Mededingingsbeleid Uiteenlopen?' (1996) 44 *Sociaal Economische Wetgeving* 398; Mortelmans, 'Towards Convergence in the Application of the Rules on Free Movement and on Competition' (2001) 38 *C M L Rev* 613. Cf Baquero Cruz, *Between Competition and Free Movement—The Economic Constitutional Law of the European Community* (Hart Publishing, Oxford, 2002); Wernicke, *Die Privatwirkung im Europäischen Gemeinschaftsrecht* (Nomos, Baden-Baden, 2002).

[42] Case 36/74 *Walrave and Koch* [1974] ECR 1415, paras 18 and 19.

[43] See Case C–415/93 *Bosman* [1995] ECR I–4921, para 83; see also Joined Cases C–51/96 and C–191/97 *Christelle Deliège* [2000] ECR I–2549, para 47; Case C–176/96 *Jyri Lehtonen* [2000] ECR I–2681, para 35. Cf Case C–438/00 *Markus Kolpak* [2003] ECR I–4135, paras 32–37 (extending the principle to the provisions on free movement of workers in the Europe Agreements). In Case C–281/98 *Angonese v Cassa di Risparmio di Bolzano* [2000] ECR I–4139, the Court held that the prohibition of discrimination of Article 48 EC applies, *tout court*, to private persons. The Commission pulls together the threads of *Hünermund*, above n 27; and *Walrave and Koch*, above n 42, in its recent Proposal for a regulation concerning sales promotion in the Internal Market, COM (2001) 546. The proposal prohibits Member States and 'non-public regulatory bodies' from imposing certain restrictions on advertising. The latter concept is defined as 'an organisation or association not covered by public law, exercising its legal autonomy to regulate in a collective manner economic activities.' See also the amended Proposal, COM (2002) 585.

extending the principle to the Dutch Bar Association in *Wouters*.[44] The Court's backing off from *Dansk Supermarked* should probably be put in light of the relationship of Article 28 EC with the competition rules. The famous *Dassonville* formula, after all, was transplanted from the Court's holding in *Consten and Grundig* on when a private agreement may 'affect trade' for purposes of Article 81 (1).[45] In the *Leclerc* cases, the Court held both sets of provisions to further the same end:

> Articles 2 and 3 of the Treaty set out to establish a market characterised by the free movement of goods where the terms of competition are not disturbed. That objective is secured *inter alia* by Article 28 *et seq* prohibiting restrictions on intra-Community trade and by Article 81 *et seq* on the rules of competition.[46]

It then found it 'appropriate', *sic*, to consider the competition rules first; having found no infringement there, it went on to consider the free movement rules. In later cases, the Court seems to indicate that the competition rules form a *lex specialis* to the free movement of goods, it being a given that infringements of the former are automatically prohibited by the latter as well.[47] The mirror image of that argument does not apply, however. Contrary to the competition rules, the Court has explicitly refused a *de minimis* rule for the free movement of goods.[48] Moreover, the rigor of Article 28 EC is attenuated only by the judicial public interest justifications of Article 30 and the 'mandatory requirements' of *Cassis de Dijon* which are interpreted narrowly; no relief in administrative exemptions and discretion on grounds of economic benefits as in Article 81 (3) EC is available. If the Court were to follow through on *Dansk Supermarked*, it would have to scrutinise any number of private arrangements—insurance policies,

[44] Case C–309/99 *Wouters* [2002] ECR I–1577, para 120 ('Compliance with Articles 52 and 59 of the Treaty is also required in the case of rules which are not public in nature but which are designed to regulate, collectively, self-employment and the provisions of services.')

[45] Joined Cases 46 and 58/65 *Consten and Grundig v Commission* [1966] ECR 299, 341 ('In this respect, what is particularly important is whether the agreement is capable of constituting a threat, either direct or indirect, actual or potential, to freedom of trade between Member States in a manner which might harm the attainment of the objectives of a single market between States.')

[46] Case 231/83 *Cullet v Leclerc* [1985] ECR 305, para 11;Case 229/83 *Leclerc v Au blé vert* [1985] ECR 1, para 9.

[47] Case C–179/90 *Merci Convenzionali Porto di Genova* [1991] ECR I–5104, para 21. See also Case 13/77 *INNO v ATAB* [1977] ECR 2115, para 35. The same logic applies to the free movement of services. See eg Case C–55/96 *Job Centre* [1997] ECR I–7199, para 39 ('no need' to answer questions relating to Article 49 EC since the measure was already held to be contrary to Articles 82 and 86 (1) EC).

[48] Agreements must 'appreciably' affect trade for purposes of Article 81 (1) EC. See Case 5/69 *Völk v Vervaecke* [1969] ECR 295. On the other hand, Article 30 'does not distinguish according to the degree to which trade is affected.' See Joined Cases 177 and 178/82 *Van de Haar* [1984] ECR 1797, para 13. See eg Oliver, 'Some Further Reflections on the Scope of Articles 28–30 (ex 30–36) EC' (1999) 36 *C M L Rev* 783, 791 (arguing that the refusal to allow *de minimis* corresponds to the 'fundamental character' of the four freedoms and that 'the State bears a higher duty than private bodies').

supplier contracts—which, while not restricting competition, may well be liable to impede trade to some extent. To have Article 28 EC apply to private standards and not to supplier contracts would imply the necessity to make a distinction between economic private activity and regulatory private activity; and that distinction would invite a host of demarcation problems. But it could well be argued that this solution is a whole lot more rational than formal distinctions between 'public' and 'private' activity.

However much the definitions of 'undertaking' under the competition rules and 'public authority' under the free movement rules are stretched, and however one can 'attribute' to States or 'delegate' to private parties,[49] it is impossible to formulate a coherent regulatory framework under primary Community law for standards. Standards issued by public bodies or heavily regulated organisations will be caught by Article 28 EC, but by virtue of exactly the same characteristics they are immune to the competition rules. Private standards bodies with loose connections to the State can be subjected to Article 81 (1) EC, but escape the discipline imposed by the regime of the free movement of goods. Yet national standards, be they DIN standards or AFNOR standards, inevitably distort competition. And national standards, be they BSI or ELOT standards, inevitably affect trade directly or indirectly, actually or potentially. And standards may well contribute to economic or technological progress and qualify for an exemption under Article 81 (3) EC, be they drafted by NSAI or by NEN. They may also be necessary and proportional for the protection of health and safety, whether they are IBN standards or UNI standards.

The possible solutions are two. One would be to take the *Leclerc* formula to its logical conclusion and collapse the different objectives pursued by the two regimes into one *Schutznorm*. In that truly 'teleological' theory, the objective of 'establishing a market characterised by the free movement of goods where the terms of competition are not disturbed' is taken to be pursued by both Article 28 EC and Article 81 (1) EC, with one regime regulating public action and one regime regulating private conduct. Even if the Court has gone some way in inserting the *prima facie* objectives of the one into the other,[50] the problem with this theory lies not so much in the prohibitions as in the exceptions. To say that free trade and competition are congruent is one thing, to say that public interest considerations immunise from antitrust and that the promotion of 'technical and economic progress' justifies erecting barriers to trade is quite another.

The other solution would be to take the notion of 'functional' interpretation to its logical conclusion and focus not so much on the actor as on

[49] See below.

[50] In Case C–202/88 *France v Commission* [1991] ECR I–1223, para 41, the Court repeated the *Leclerc* formula and added that 'Article 28 EC must be interpreted in light of that principle, which means that the competition element of Article 3 (g) of the treaty has to be taken into account.'

the activity. In this theory, the notion that the two regimes pursue two different objectives is taken seriously. The free movement rules subject regulatory activity under a discipline of non-discrimination and proportionality; the competition rules subject economic activity to a prohibition of tinkering with the parameters of competition unless such would be justified by market failure. Whether the activity at issue is carried out by public authorities or private parties is immaterial. Private parties may, and do, engage in regulatory activity in the public interest; the State may, and does, participate in the market. Instead of distinguishing 'public' and 'private' actors, this theory would distinguish between 'public' and 'private' activities.

3. MEMBER STATES, STANDARDS AND THE REACH OF POSITIVE INTEGRATION

The Commission was faced with a big policy problem. In 1983 it held:

> It is only where, as a result of State action, products imported from other Member States have *de iure* or *de facto* to conform to German standards alone that such requirements or practices are to be assessed in the light of the treaty's provisions on the free movement of goods.
>
> [I]f agreements between firms or concerted practices were to hinder the marketing of products imported from other Member States on the ground that such products did not meet the standards applicable in the country of importation, including standards drawn up by private institutions, the Commission would have to assess the facts in the light of Article 81 of the Treaty.[51]

If, however, national standards cannot be presumed to be caught by Article 28 EC, they cannot be harmonised by Community legislation either.[52] Hence the full extent of Alfonso Mattera's frustration:

> Les effets restrictifs de telles normes techniques nationales sur la liberté des échanges sont néfastes à un double titre: si d'une part elles créent un véritable cloisonnement des marchés à l'intérieur de la Communauté, elles provoquent d'autre part une paralysie de toute action réglementaire en la matière au plan communautaire.[53]

The solution to this paralysis was found in the Information Directive; if the barriers crated by national standards could not be brought down by normative supranationalism nor by decisional supranationalism, the answer was, well, private transnationalism.

[51] The Commission's answer to Question 835/82, R–G Schwartzenberg, (1983) OJ C 93/1.

[52] Breulmann, *Normung und Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft* (Duncker & Humblot, Berlin, 1993).

[53] Mattera, above n 20, 255.

3.1 The Information Directive

Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical regulations and standards is one of the select success stories of internal market regulation.[54] It establishes two parallel systems of notification of technical specifications. In the public leg, Member States are to notify all draft technical regulations to the Commission, which immediately notifies all other Member States. The Commission and those Member States may then make comments, which the notifying Member States 'shall take into account'. If the Commission of those Member States object to the draft regulation, a stand still period starts. That period is doubled if the Commission announces plans to adopt a Directive on the same object as the draft regulation.

'Whereas, in practice, national technical standards may have the same effects on the free movement of goods as technical regulations', and 'whereas it would therefore appear necessary to inform the Commission of draft standards under similar circumstances to those which apply to technical regulations',[55] national standards bodies notify their standardisation programmes to the European standards bodies and the Commission; the Commission, after consulting the Standing Committee, may then request the European standards bodies to draw up a European standard. In that case, Member States 'shall take all appropriate measures' to ensure that their national standards bodies do not draw up or introduce new national standards covering the same subject. Eureka. The thinking is clear:

> Only European standards will bring about a common economic area. National standards on the contrary compartmentalise the common market. They cannot be the subject of mutual recognition, since, not laid down by the authorities, they are not obligatory.[56]

The Directive has been amended in 1988 and 1994 to expand its scope and sharpen its procedural obligations;[57] in June 1998 the Commission published a consolidated version which was unconsolidated less than a month later by a new amendment, extending the reach of the Directive to Information Society services.[58] Legislative activity, judicial attention, and

[54] Directive 83/189, (1983) OJ L 109/8.

[55] Above, Recitals 9 and 10.

[56] Commission Green Paper, *Action for faster technological integration in Europe*, COM (1990) 456 final, (1990) OJ C 20/1, 3.

[57] Directive 88/182/EEC, (1988) OJ L 81/75 and Directive 94/10/EC, (1994) OJ L 100/30.

[58] Directive 98/34/EC, (1998) OJ L 204/37; and Directive 98/48/EC, (1998) OJ L 217/18. The sorry spectacle probably has its roots in inter-service hostilities. The Information Directive is still administered by DG III (now: Enterprise), an anomaly and source of contention ever since DG XV (now: Internal Market) was created. The consolidation was a DG III project, the amendment a DG XV project.

scholarly commentary have all focused almost exclusively on the public leg of the system.[59]

The overarching concept of the Directive is 'technical specification', defined as

> A specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.[60]

A 'technical regulation' is then defined as

> technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, *de iure* or *de facto*, in the case of marketing or use in a member state or a major part thereof.[61]

'Standards' are defined by two distinguishing characteristics:

> A technical specification approved by a recognised standardisation body for repeated and continuous application, with which compliance is not compulsory and which is one of the following:
>
> —international standard: a standard adopted by an international standardisation organisation and made available to the public,
> —European standard: a standard adopted by a European standardisation body and made available to the public,
> —national standard: a standard adopted by a national standardisation body and made available to the public.[62]

3.1.1 Technical Regulations

The success of the Directive depends on two issues. First, the measure in which the Member States actually do notify their draft regulations; and second, what happens with those notifications.

[59] Exhaustively, Weatherill, 'Compulsory Notification of Draft Technical Regulations: the Contribution of Directive 83/189 to the Management of the Internal Market' (1996) 16 *YEL* 129. See also the official literature: Lecrenier, above n 38, 6; Mattera, *Il Mercato Unico Europeo* (UTET, Torino, 1990) 152ff; Fronia and Casella, 'La Procédure de Contrôle des Réglementations Techniques Prévue par la Nouvelle Directive 83/189/CEE' (1995) 2 *RMUE* 37; Fronia, 'Transparenz und Vermeidung von Handelshemmnissen bei Produktspezifikationen im Binnenmarkt' [1996] *EuZW* 101.

[60] Article 1 (2), Directive 98/34/EC, above n 58.

[61] Above, Article 1 (9). Ulrich Everling calls the definition of 'technical regulation' 'ein Musterbeispiel schlechter Rechtstechnik' and the definition of de facto regulation 'ein rechtstheoretisches Kuriosum'; see his note to Case C–194/94 *CIA Security v Securitel* [1996] ECR I–2201 in (1996) 23 *ZLR* 449.

[62] Above, Article 1 (4).

Until recently, the only way to convince a Member State to notify was to bring infringement proceedings for failure to do so. The Commission starts the Article 226 EC procedure a lot, usually to break it off in early stages after recalcitrant Member States promise to better their lives.[63] The few cases that do end up in Court are either the consequence of sheer lethargy of Member States,[64] or involve genuine disagreement on the scope of the obligation.[65] Infringement proceedings are, however, a notoriously slow and burdensome way of ensuring the effectiveness of Community law.[66] In good *Van Gend en Loos* fashion,[67] then, the Commission has argued since 1986 that failure to notify should render the regulation unenforceable against third parties in national legal systems.[68] After several targeted 'test cases' failed to produce the Court's confirmation of this theory,[69] the Commission finally had its way with the 1996

[63] Between 1995 and 1998, the Commission initiated 103 infringement proceedings. During the same period, the Court rendered judgment in only four such cases. See the Commission's Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, 29. This conforms to the overall path Article 226 EC proceedings. See Schepel and Blankenburg, 'Mobilising the European Court of Justice' in de Búrca and Weiler (eds), *The European Court of Justice* (OUP, Oxford, 2001) 9.

[64] See Case C–139/92 *Commission v Italy* [1993] ECR I–4707 (regulation laying down technical requirements on pleasure craft; the Italian government admitted its failure and notified after the fact); Case C–52/93 *Commission v Netherlands* [1994] ECR I–2039 (regulation on quality standards for flower bulbs; the Dutch government admitted failure no notify); Case C–61/93 *Commission v Netherlands* [1994] ECR I–3607 (regulations on strength requirements for soft-drinks bottles, on kilowatt hour meters, and on pesticides; the Dutch government acknowledged its failure); and Case C–145/97 *Commission v Belgium* [1998] ECR I–2643 (regulation of the Region of Brussels rendering compliance obligatory with a Belgian standard on gas installations in furnished accommodations; the Belgian government acknowledged it should have notified).

[65] See Case C–317/92 *Commission v Germany* [1994] ECR I–2039 (regulation extending requirements on medical devices to other products; the Court held this to be a new 'technical regulation'); Case C–273/94 *Commission v Netherlands* [1996] ECR I–31 (regulation granting a *derogation* from existing technical regulations for margarine, the Court defined this as well as a 'technical regulation'); Case C–289/94 *Commission v Italy* [1996] ECR I–4405 (regulation laying down requirements on water quality for the cultivation of shellfish; the Court held this to be a marketing requirement and thus a 'technical regulation'); and Case C–279/94 *Commission v Italy* [1997] ECR I–4743 (regulation on asbestos; the Italian government did not dispute that it was a 'technical regulation' but objected to having notify the whole law and not just the relevant provisions; the Court rejected that argument).

[66] See Snyder, 'The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques' (1993) 56 *MLR* 19; Schepel and Blankenburg, above n 63.

[67] Case 26/62 *Van Gend en Loos* [1963] ECR 10 (enunciating the principle of direct effect on the theory that 'the vigilance of individuals concerned to protect their rights amounts to an effective supervision in addition to the supervision entrusted by Articles 226 and 227 EC to the diligence of the Commission and the Member States').

[68] Commission Communication concerning the non-respect of certain provisions of Council Directive 83/189/EEC, (1986) OJ C 245/4.

[69] See Fronia, above n 59, 108. In Case C–139/92 *Commission v Italy* [1993] ECR I–4707, the Italian government notified the regulation when the case was still pending; in Case C–96/91 *Decoster* [1993] ECR I–5335, concerning approval of copiers, the questions were formulated such that the Court could easily avoid a ruling on principle.

ruling in *CIA Security v Securitel*.[70] At issue was a prize-winning alarm system marketed by CIA Security, which its competitors openly claimed not to fulfil the requirements laid down by Belgian legislation on security systems. That piece of legislation, however, had not been notified to the Commission. The Court adopted the Commission's theory wholesale and held that national courts 'must decline to apply a national technical regulation which has not been notified in accordance with the Directive'.[71] It grounded that ruling as follows:

> [T]he aim of the Directive is to protect freedom of movement of goods by means of preventive control and the obligation to notify is essential for achieving such Community control. The effectiveness of Community control will be that much greater if the Directive is interpreted as meaning that the breach of the obligation to notify constitutes a substantial procedural defect such as to render the technical regulations in question inapplicable to individuals.[72]

The judgment was met with predictable enthusiasm as a 'very useful contribution to the completion of the internal market'.[73] The enormous ramnifications of the ruling became soon apparent when the Dutch government 'discovered' more than 400 technical regulations in force which it had never notified. In the end, the Dutch government notified 227 regulations in a giant 'catch-up' operation.[74] In the meantime, however, the Dutch government had a problem. Forced to make the list public, the press and trial lawyers soon found out that it contained regulations on such things as devices for breath analysis and traffic speed measurement. Dutch politics and public opinion were haunted by the question whether, for example, criminal sanctions for drunken driving were now all invalid since the requirements imposed on breath analysers had never been

[70] *CIA Security v Securitel*, above n 61.

[71] Above, para 55.

[72] Above, para 48.

[73] Slot, casenote, (1996) 33 *C M L Rev* 1035, 1043. See further the notes by Everling, above n 61; Fronia, (1996) *EuZW* 379; Lecrenier, 'La Contrôle des Règles Techniques des Etats et la Sauvegarde des Droits des Particuliers' (1997) 5 (35) *JTDE* 1; and Candela Castillo, 'La Confirmation par la Cour du Principe de Non-Opposabalité aux tiers des Règles Techniques Non Notifiées dans le Cadre de la Directive 83/189/CEE: un Pas en Avant vers l'Intégration Structurelle des Ordres Juridiques Nationaux et Communautaire' (1997) 404 *RMCUE* 51. Less enthusiastic, Weatherill, 'Compulsory Notification of Draft Technical Regulations: the Contribution of Directive 83/189 to the Management of the Internal Market' (1996) 16 *YEL* 129, 172 ff (questioning its constitutional propriety); less enthusiastic still, López Escudero, 'Efectos del Incumplimiento del Procedimiento de Información Aplicable a las Reglamentaciones Técnicas (Directiva 83/189/CEE)' (1996) 23 *Revista de Instituciones Europeas* 839, 861 ('el efecto directo no debe ser empleado jurisprudencialmente para 'enmendar' las deficiencias surgidas en la aplicación de cualquier tipo de norma comunitaria.')

[74] See the Commission's Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, 35.

notified.[75] When that question came to the Court of Justice in 1997, it employed the same argument Dutch EC lawyers had used to tranquilise Dutch public opinion: only individuals who have an interest in the objectives that the Directive seeks to further, that is, the free movement of goods, can rely on the inapplicability against them of non-notified regulations.[76] In *Lemmens*, it held accordingly that failure to notify 'renders regulations inapplicable inasmuch as they hinder the use or marketing of a product which is not in conformity therewith,' but did not render any use of a product manufactured according to non-notified regulations unlawful:

> The use of the product by the public authorities, in a case such as this, is not liable to create an obstacle to trade which could have been avoided if the notification procedure had been followed.[77]

The narrow escape in *Lemmens* was never going to help the Court on the decisive question of horizontal direct effect. In *Uniliver*, the Court had to decide whether *Securitel* could be relied on in private contractual relations.[78] At issue was a company's refusal to pay for the delivery of a batch of olive oil which was not labelled according to the requirements of a regulation enacted in breach of Italy's obligations under the Directive. Consistent with *Securitel*, but with disastrous consequences for the legal security of commercial transactions in the internal market, the Court decided, this time explicitly,[79] that national legislation enacted in breach

[75] A selection of headlines of *NRC Handelsblad* in the summer of 1997: 6 June: '400 laws and regulations invalid'; 7 June: 'Criminal prosecutions to go ahead' and 'EC: Securitel problem can be solved in three months'; 9 June: 'Drunken drivers not off the hook thanks to Securitel'; 10 June: 'Confusion in courts over Securitel'; 11 June: 'Public prosecutors: stop staying alcohol cases', and the political finale of 12 June: 'Cabinet apologises to Parliament'. See Sevenster, 'Het Securitel-syndroom' (1997) 25 *Nederlands Juristenblad* 1126.

[76] See Steyger, 'Het Belangvereiste in Verband Met de Inroepbaarheid van Richtlijnen' (1997) *Regelmaat* 67; Barents, 'Het Securitel Arrest: een Gat in de Rechtsorde?' (1997) 9 *Jurisprudentie Bestuursrecht* 655. René Barents, legal secretary of ECJ judge Kapteyn, gave an interview to *NRC Handelsblad* on 9 June which led to the headline: 'European lawyer: no problem with alcohol checks.'

[77] Case C–226/97 *Lemmens* [1998] ECR I–3711, paras 34–36. It is submitted that *Lemmens* is incoherent with *Securitel*. The latter ruling separated ends from means, and was exclusively preoccupied with enforcing the notification obligation, not with the regulation's potential of hindering trade. In Case C–278/99 *Van der Burg* [2000] ECR I–2015, the Dutch *Hoge Raad* asked whether a regulation should be disapplied if 'it generally, and thus irrespective of the specific case, has or may have the effect of an obstacle to trade.' Having denied that the provision in question constituted a 'technical regulation', the Court declined to answer. Happy with *Lemmens*, Weatherill, 'A Case Study in Judicial Activism in the 1990s: the Status before National Courts of Measures Wrongfully Un-notified to the Commission' in O'Keeffe and Bassavo (eds), *Judicial Review in European Union Law—Liber Amicorum Lord Slynn of Hadley* (Kluwer, The Hague, 2000) 481, 498 (praising the Court for not strectching *CIA Security* 'beyond its proper scope' and rejecting the 'ingenious manipulation' of that case.)

[78] Case C–443/98 *Unilever v Central Food* [2000] ECR I–7535.

[79] In truth, the Court could have ducked the issue by introducing a distinction between the consequences of failure to notify and failure to honour the standstill obligation: the regulation at issue had been duly notified but was published in the *Gazzetta Ufficiale* a good six

of the obligations of the Information Directive are to be declared inapplicable in proceedings between private parties.[80]

Whatever the merits of *Securitel*, it would seem beyond doubt that the ruling strengthens the notification mechanism. Statistically, however, the increase in notifications since the ruling is insignificant if one does not calculate the Dutch catch-up operation: notifications are up from 362 in 1992 to 530 in 2001, with a peak of 900 in 1997.[81] The 1997 figure, however, includes 341 Dutch notifications, and the figures thereafter illustrate a remaining zeal on the part of the Netherlands.[82] The rest of the increase can largely be explained on the force of notifications from new Member States.[83]

What, then, to do with all these notifications? The Commission moulds the Directive in a classic *Cassis de Dijon* internal market scheme. It seeks to prevent Member States from enacting regulations that would be counter to Article 28 EC; for those regulations that would be justified under Article

months before the standstill introduced by the Commission lapsed. To its credit, the Court brushed off this point. Advocate General Jacobs clung on to it, even if rather tentatively, in case the Court would ignore his plea on the main issue. Above, paras 104 *et seq* of the Opinion.

[80] Above, para 49, confirmed in Case C–159/00 *Sapod Audic v Eco-Emballages* [2002] ECR I–5031, para 51. Similar, if more sophisticated, criticism in Weatherill, 'Breach of Directives and Breach of Contract' (2001) 26 *ELR* 177. Cf Voinot, 'Le Droit Communautaire *et* l'Inopposabilité aux Particuliers des Règles Techniques' (2003) 39 *RTDE* 91; and the casenote to *Sapod Audic by Dougan*, (2003) 40 *C M L Rev* 193. In para 51, the Court distinguishes this case from its refusal to give horizontal direct effect to non-transposed Directives in Case C–91/92 *Faccini Dori* [1994] ECR I–3325 by pointing out that the Information Directive 'does not in any way define the substantive scope of the legal rule on the basis of which the national court must decide the case before it.' On this point, see the casenote by Dougan, (2002) 38 *C M L Rev* 1503. Whatever the merits of that distinction, it is submitted that it is less than comforting for businesses who now have to bury themselves in the Commission's files to make sure every single regulation they conform their products to has been duly notified and has not been enacted before the lapse of standstill obligations. Advocate General Jacobs sensibly advised the Court *against* applying *Securitel*: only if said regulation is found to infringe Article 28 EC can that provision's direct effect help Unilever. See, however, Advocate General Elmer's Opinion in *CIA Security v Securitel*, above n 61, paras 69 *et seq*. When Commission official Fronia, above n 73, 383 considered this question not resolved by *Securitel*, he was scorned by Everling, above n 61, 452 ('Schreckt er jetzt vor den Folgen der von der Kommission in der im Urteil zitierten Mitteilung und vor dem Gerichtshof vertretenen Ansicht zurück? Wußte die Kommission nicht, was sie tat?').

[81] See the Commission's Report on the Operation of Directive 83/189/EEC in 1992, 1993 and 1994, COM (1996) 286 final, table VII, the Commission's Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, and the Commission's Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final.

[82] The Dutch notified well over 120 regulations in each of the years 1998–2000.This accounts for some 20% of all notifications against the average of below 10% in earlier years. In 2001, the figure was down to 98 out of 530, still making the Netherlands the most active notifier by some distance.

[83] In 1998, Sweden, Finland and Austria notified a total of 122 technical regulations against a combined total of 47 in 1995. In 2000, the figure was up to 190, due mainly to the 132 regulations Austria chose to notify. In 2001, the figure was down again to 137. See the Commission's Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final.

30 EC or under *Cassis*' 'mandatory requirements', it will initiate harmonisation measures.[84]

First, the Commission or another Member State may deliver 'a detailed opinion to the effect that that the measure envisaged may create obstacles to the free movement of goods within the internal market', in which case the Member State is to suspend adoption of the regulation in question for six months.[85] More often than not, the Commission will simply urge the Member State to include a mutual recognition clause. If, however, a Member State dutifully fulfils all procedural obligations but simply chooses to ignore all advice, the only thing the Commission can do is to bring infringement proceedings for breach of Article 28 EC or with secondary legislation.[86] The Commission has done so only once.[87] It is not clear, however, if the scope of the notification obligation coincides with the scope of Article 28 EC. On the one hand, even if the scope of Article 28 EC has been brought back closer to the reach of the Information Directive by *Keck*,[88] 'measures having equivalent effect' constitutes the wider category than 'technical regulations'.[89] The question is, however, whether all measures that require notification fall within the scope of Article 28 EC. At one point, the Court has said that 'technical regulations are capable of hindering, directly or indirectly, actually or potentially, intra-Community

[84] See Commission Communication concerning the non-respect of certain provisions of Council Directive 83/189/EEC, (1986) OJ C 245/4. The 'true' effectiveness of the Directive, of course, lies more in fostering co-operation between the Commission and national authorities than in legalistics; probably the best way to describe the actual working of the whole mechanism is as a giant workshop on the subject of drafting mutual recognition clauses. The Commission credits the Directive with making 'a tangible contribution to improving national law-making.' Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final, 9.

[85] Article 9 (2), Directive 98/34/EC, above n 58.

[86] The Commission has tried to shortcut the procedural requirements of the infringement procedure by alleging that the detailed opinion under Article 9 (2) of the Directive can double as a letter of formal notice as prescribed by Article 226 EC. The Court of Justice will have nothing of it. See Case C–341/97 *Commission v Netherlands* [2000] ECR I–6611; Case C–230/99 *Commission v France* [2001] ECR I–1169.

[87] See Case C–184/96 *Commission v France* [1998] ECR I–6197 (France held in breach for failure to incorporate a mutual recognition clause in a regulation concerning products made on the basis of *foie gras*).

[88] C–267 and 268/91 *Keck and Mithouard*, above n 8. Thus, in Case C–278/99 *Van der Burg*, above n 77, para 20, the Court distinguishes between 'characteristics required of a product' as opposed to 'marketing methods'; and in Case C–390/99 *Canal Satélite* [2002] ECR I–607, para 45, between product characteristics and 'specifications concerning operators'. The general rule now is that any measure requiring the modification of the product, its packaging or labelling can never be classified a 'selling arrangement.' See eg Case C–169/99 *Schwarzkopf* [2001] ECR I–5901, para 39. Cf *Sapod Audic*, above n 80.

[89] See eg Case C–33/97 *Colim v Bigg's* [1999] ECR I–3175 (requirement that goods are labelled in the language of the area where they are sold: the Court held the regulation not to be a 'technical regulation', but still a 'barrier to trade' even if, absent harmonisation, one justified as long as it applies without distinction and is proportionate.)

trade in goods.'[90] In other cases, however, the Court has avoided making a ruling of principle on the issue.[91]

Second, the Commission may find that the regulation concerned is covered by a legislative proposal already presented to the Council or may announce its intention to table such a proposal, in which case the Member State is to suspend adoption for 12 months, prolonged to 18 months if the Council manages to adopt a common position within the year.[92] The presupposition here is that national measures that have to be notified are also capable of being harmonised under Article 95 EC. On this issue, the Court has made a ruling of principle. In *BIC Benelux*, it held a regulation imposing an eco-tax label on disposable razor blades to be a 'technical regulation', against the opinion of the Commission. The Court found 'no basis' for an interpretation of the Directive limiting its application to national measures capable of harmonisation only on the basis of Article 95 EC.[93]

3.1.2 Standards

If the public leg of the Directive system aims at tearing down barriers to trade by the double mechanism of preventing unjustified measures and harmonising justified measures, the private leg seeks to eliminate obstacles created by divergent national standards only by encouraging the drafting and use 'European' standards. Properly understood, the Directive employs the notification system for two reasons: first, to promote 'spontaneous' harmonisation through co-operation of national standards bodies united in

[90] Case C–13/96 *BIC Benelux v Belgium* [1997] ECR I–1753, para 19. See also Case C–317/92 *Commission v Germany* [1994] ECR I–2039 (regulation on medical devices was deemed to be caught by both.)

[91] Denying complete overlap, AG Ruiz-Jarabo Colomer in *Van der Burg*, above n 77, para 23 of the Opinion. The most obviously doubtful case is the Dutch regulation allowing for derogations from requirements on margarine at issue in Case C–273/94 *Commission v Netherlands* [1996] ECR I–31, paras 14–15, where the Court dismissed the Dutch submission that the measure was compatible with the objective of free movement of goods on the grounds that the obligation to notify was 'not subject to the unilateral assessment by the Member State which drafted the regulation of the effects which it may have on trade between Member States.' Under the angle of pre-emption, the parallel is easily drawn. In two other Dutch criminal cases arising out of the *Securitel* mess, the Court had to deal with the prohibition to administrate the hormone clenbuterol to cattle. In Case C–425–427/97 *Albers* [1999] ECR I–2947, the regulation was held to be a 'technical regulation', but one that fell under Article 10 of the Directive which, at the time, exempted from notification measures where Member States 'honour their obligations' arising out of Community legislation; in Case C–256/98 *Berendse-Koenen*, [2000] ECR I–1777, para 24, the same regulation was held to be compatible with Article 28 EC since 'it was adopted in order to comply with a directive of the Council in the general interest of the Community', with reference to Case 46/76 *Bauhuis v Netherlands* [1977] ECR 5.

[92] Article 9 (3), (4) and (5), Directive 98/34/EC, above n 58. The automatic extension was introduced by the 1994 amendment. The time frame still seems tight: if in 1992–94 a Community measure was adopted before the end of the standstill only in 6 out of 30 cases, that figure was up, but not much, in 1995–98 to 10 out of 30.

[93] *BIC Benelux*, above n 90, para 19.

the European standards bodies and second, to monitor compliance of national standards bodies' obligations under the internal rules of CEN and CENELEC in case a mandate for a 'European' standard has been given.

The original version of the Directive provided for the Commission and the European standards bodies to be informed of national standards bodies' 'standardisation programmes', which it defined as 'document listing the subjects for which it is intended to draw up or alter a standard.'[94] These were to include an indication of whether the standards were transpositions of international or European standards or the result of purely national work.[95] In practice, this meant that the national standards bodies sent around documents containing endless lists of acronyms and titles the Commission couldn't make head or tail of, announcements of public enquiry for draft standards and numbers of adopted national standards.[96] The 1994 amendment streamlined the procedure. Standards fully transposing European or international standards no longer have to be notified at all. Only new national standardisation work now has to be notified, including international standards that are to be transposed with variations.[97] Even if it wanted to, the Commission still cannot even pretend to actually examine the notifications. It limits itself to helping to ensure that the information circulates in a transparent way among the organisations that do know what it means.[98] In practice, monitoring the whole information procedure is in the hands of CEN and CENELEC, as the Commission readily admits:

> Within the CEN Central Secretariat, notifications are periodically examined by technical experts. No statistics are available on the number of cases handled, but it could be useful to submit them to the Commission.

[94] Article 2 (1) and 1 (3), Directive 83/189/EEC, above n 54.

[95] Above, Article 2 (2).

[96] Nicolas, *Common Standards for Enterprises* (Opoce, Luxembourg, 1995) 78, called the system 'costly, difficult to manage, and unreliable'. The Commission complained in 1990 about receiving 'bulky registers' full of information 'which is unintelligible to a non-specialist and often out of date'. Green Paper, *Action for faster integration in Europe*, COM (1990) 456 final, para 75.

[97] Compare the new Article 2, Directive 98/34/EC, above n 58. The definition of 'standards programme' in Article 1 (5) now reads: 'a work programme of a recognised standardisation body listing the subjects on which standardisation work is being carried out'.

[98] The Commission has been complaining consistently about the quality of notifications; draft standards are often notified too late, in the public enquiry stage or beyond. In 2001, this still concerned 15% of all notifications. Another problem is that notifications often contain no more information than the title of the envisaged standard. In 1995, this was still true of more than half of all notifications. In 2000, the Commission reported a drop to 31% in 1998, and admitted this was still way too high. In 2003, the Commission had to report an 'average' of 36% over the period 1999–2001. See Commission Report on the Operation of Directive 83/189/EEC in 1992, 1993 and 1994, COM (1996) 286 final, 7; Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, 12; Commission's Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final, 14.

> The Commission departments continued to examine the notifications received, both to monitor the standstill in cases where mandates had been given to the European standardisation bodies and to examine whether it would be appropriate to transfer the notified activity to European level. The number of cases queried was cut from 16 in 1996 to 2 in 1997 because of lack of resources.[99]

The notification system, then, serves two purposes. On the one hand, it establishes a framework for 'spontaneous', horizontal harmonisation of standards. Referred to in the Directive's recitals as 'fundamental rights for the national standardisation bodies',[100] Member States are to take 'all necessary steps to ensure that their standardisation bodies': first, send all draft standards to all other standards bodies 'on request' and inform them of the action taken on any comments the other standards bodies may have made; second, grant other national standards bodies the right to be involved 'actively or passively (by sending an observer)' in their planned activities, and third, publish their draft standards in such a way for public review that foreign parties can make comments. Lastly, Member States are to ensure that their standards bodies 'do not object to a subject for standardisation in their work programme being discussed at European level in accordance with the rules laid down by the European standardisation bodies an undertake no action which may prejudice a decision in this regard'.[101] In practice, this 'horizontal' harmonisation has been an abysmal failure. In the ten years from 1992 to 2001, the standards bodies have exercised their 'fundamental rights' only scarcely: a grand total of 11 'spontaneous' requests for a European standard to be drawn up have been made by national standards bodies; comments on each other's draft standards average some 40 per year, and requests to participate in each other's work are made some 6 times per year.[102]

[99] Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, 13.

[100] Recital 25, Directive 98/34/EC, above n 58. The recital was introduced by Directive 94/10/EC, (1994) OJ L 100/30.

[101] Article 4, Directive 98/34/EC, (1998) OJ L 204/37.

[102] Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final; Commission Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final. In its latest report, the Commission notes that 'it can therefore be concluded once again that the mechanisms provided by Article 4 of the Directive in practice are not being used,' at 15, notes further than the information procedure is not 'directly efficient' and that 'reducing the legal framework' should be considered, at 19, even if it stresses that 'the very existence of the procedure has constrained national activities and to some extent changed the approach of the national standardisation bodies,' at 9. It should be noted that CENELEC operates its own notification procedure, known as the 'Villamour procedure', whereby national electrotechnical committees have to inform CENELEC at a very early stage of all their planned work. A request of one single national standards body then suffices to trigger the standstill; either the work then moves to European level, or the standstill is released by the Technical Board. Only in the latter case do national electrotechnical committees have to notify the subject under the Information Directive. In practice, then, 'spontaneous' harmonisation of electrotechnical standards is much more widespread than the statistics allow for.

The other variety of harmonisation of standards is the Commission's 'request' to the European standards bodies to draw up 'European' standard within a given time. The Commission may do so after compulsory consultation of the Standing Committee set up by the Directive.[103] This 'vertical' harmonisation by way of Commission mandates has been much more successful. From 1992 to 2001, some 230 mandates were given, 69 of which served to implement 'new approach' Directives.[104] The notification system then becomes an instrument for monitoring compliance with standstill obligations. The first version of the Directive phrased those obligations as follows:

> Member States shall take all appropriate measures to ensure that their standards institutions do not draw up or introduce standards in the field in question while the European standard referred to in the first indent of Article 6 (3) is being drawn up. This undertaking shall lapse unless a European standard has been introduced within six months following expiry of the time limit fixed in accordance with the said indent.[105]

The 1994 amendment of the Directive then changed the clause to bring it into line with CEN/Cenelec internal regulations.[106] The clause is now a direct copy of those internal regulations, and removes ambiguities about standards bodies' obligations *after* a European standard has been published:

> Member States shall take all appropriate measures to ensure that, during preparation of a European standard referred to in the first indent of Article 6 (3) or after its approval, their standardisation bodies do not take any action which could prejudice the harmonisation intended and, in particular, that they do not publish in the field in question a new or revised national standard which is not completely in line with an existing standard.[107]

Since standstill obligations arising out of the internal regulations do not end until the European standard has been cancelled or if the standstill is released by weighted majority vote of CEN/Cenelec members,[108] it must be assumed that the undertaking of the Member States does not 'lapse' either until such time. It must be noted, however, that the obligation on

[103] Article 6, Directive 98/34/EC, (1998) OJ L 204/37.

[104] Commission Report on the Operation of Directive 83/189/EEC in 1992, 1993 and 1994, COM (1996) 286 final, Table VI, Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, Table VI; Commission Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final, 17. It has to be noted that one mandate usually covers a whole series of standards.

[105] Article 7 (1), Directive 83/189/EEC, above n 54.

[106] Recital 8, Directive 94/10/EC, (1994) OJ L 100/30.

[107] Article 7 (1), Directive 98/34/EC, above n 58, and Section 6.1.1, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

[108] Sections 6.1.1 and 5.1.4, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

Member States takes effect only after CEN and/or Cenelec have accepted the mandate. They are not bound to take any steps, 'appropriate' or not, to ensure that their national standards body refrains from voting against acceptance of the mandate in the Technical Board.

Further, Member States are explicitly allowed to request their own standards bodies 'to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products'. In that case, the mandate itself is regarded as a 'technical regulation' and needs to be notified under the public leg of the Directive.[109]

The Directive imposes two restraints on regulatory use of national standards. First, Member States shall refrain from 'any act of recognition, approval or use by reference to a national standard' which has been adopted without fulfilling the procedural requirements of the Directive.[110] Second, not only regulations that make compliance with standards compulsory are to be notified as 'technical regulations', but also those that lend a presumption of conformity with technical regulations in case of compliance with standards.[111] The latter category is to be understood, it is submitted, as only covering direct references. A simple mutual recognition clause of the *Dundalk* 'or equivalent' variety would suffice here to put the Commission and the Court at ease.

The Information Directive provides for two sets of 'horizontal' procedural obligations and two sets of 'horizontal' harmonisation measures. Focusing on either ignores two important 'diagonal' issues at play. First, there is a clear bias in the whole system and in Commission practice to encourage national technical regulations to make more use of harmonised standards, or at least to mutually recognised national standards. As evidenced in the *Woodworking machines* case, mutual recognition of technical regulations can only go so far. Across the board 'rationalisation' of regulatory law by merely setting legislative objectives and 'essential requirements', and separating 'technical' matter from matters of policy makes technical regulations that much easier to justify.

On the other extreme of the diagonal spectrum, the Directive leaves a 'regulatory gap': there is nothing in it to prevent Member States from adopting national regulations in areas where a European standard is under preparation or even finished. In a recent report on the operation of the Directive the Commission noted:

> The Commission also made comments to inform the Member States about standardisation work being carried on by the European standardisation bodies in the field in question. In such cases the Commission's response has to be

[109] Article 7 (2), Directive 98/34/EC, above n 58.
[110] Article 4 (2), Directive 98/34/EC, above n 58.
[111] Above, Article 1 (9).

> limited to comments, as this type of 'European harmonisation' does not prevent the Member States from adopting technical rules on the same subject, even if such rules inevitably hamper the work of the European harmonisation bodies.[112]

To avoid such problems, but mainly to avoid others, the New Approach was invented, 'perhaps the most authoritative acknowledgement of the benefits of standardisation'.[113]

4. EMBEDDING STANDARDS IN EUROPEAN LAW

4.1 The New Approach

If the Information Directive is best conceived as an attempt to address the deficiencies of normative supranationalism, the New Approach is best understood as an attempt to overcome the inertia of decisional supranationalism. What is now, by historic revisionism, called the 'traditional approach' to technical harmonisation, consisted of a programmed patchwork of Directives establishing product-by-product and hazard-by-hazard regulation.[114] The drawbacks of this approach, stripped to the core, resulted from the perverse interaction of two factors. First, especially before the Single European Act but even after majority voting was introduced, it was hard to find consensus on sensitive issues of health and safety regulation. Second, the Directives required a high level of technical detail and sophistication. In the layered structure of Community decision-making, political bottlenecks were then 'kicked down' to the level of expert bureaucrats, and technical disagreements 'kicked up' to the level of 'political' decision-making. The result was the kind of legislative impotence that has given 'Brussels' a bad name: terribly complicated and detailed Directives on matters of questionable importance,[115] which, moreover, took so long to adopt that they were often outdated long before they actually came into force.[116]

[112] Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, 29.

[113] Majone, *Regulating Europe* (Routledge, London, 1996) 24.

[114] Under the 'General Programme for the elimination of technical barriers to trade that result from disparities between the provisions laid down by law, regulation or administrative action in the Member States' (1969) OJ C 76/1, some 100 Directives were envisaged.

[115] Possibly the all-time favourite example is Directive 87/402/EEC on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, (1987) OJ L 220/1, which runs for 43 pages.

[116] See eg Directive 84/438/EEC on the permissible sound power level of lawnmowers, (1984) OJ L 183/9, adopted six years after the Commission's proposal, (1979) OJ C 86/9; and Directive 84/526/EEC on seamless, unalloyed aluminium and aluminium alloy gas cylinders, (1984) OJ L 300/20, adopted a full ten years after the Commission's proposal, (1974) OJ C 104/75.

The 'New Approach' will most likely stay 'new' forever, but was not so 'new' even when it was launched. Harking back to the isolated experiment with the 1973 Low Voltage Directive,[117] the 1985 initiative introduced the reference to standards technique in Community legislation. Two major aspects of legislative technique were to be changed fundamentally. First, Directives were to limit themselves to laying down but the 'essential requirements' imposed on products. These represent, for Member States, the maximum requirements they may impose on products.[118] To enable assessment of products that are not manufactured in conformity with European standards, the Model Directive requires these requirements to be 'worded precisely enough in order to create legally binding obligations that can be enforced.'[119] Second, legislative activity is now to be focused in 'horizontal' Directives, covering a whole sector, or at least a wide range of products. Thus, it should be possible 'to settle at a stroke, with the adoption of a single Directive, all the problems concerning regulations for a very large number of products, without the need for frequent amendments or adaptations of that Directive.'[120]

Technical specifications are to be drawn up by the recognised European standards bodies on the basis of the procedure for 'requesting' the drawing up of European standards established by the Information Directive, which is now transformed into a general vehicle of technical harmonisation in place of Community law. In the 'Guidelines for Co-operation' signed by the Commission and CEN/Cenelec in 1984, the European standards bodies are granted a monopoly of drafting recognised European standards and financial assistance in exchange for the commitment to draw up standards that satisfy the essential requirements.[121]

Compliance with national standards implementing harmonised standards leads to a 'presumption of conformity' with the essential require-

[117] Directive 73/23/EEC, (1973) OJ L 77/29.

[118] Any doubts that may have existed in this regard are dispelled by Case C–112/97 *Commission v Italy* [1999] ECR I–1821. Cf Case C–14/02 *Atral v Belgium* [2003] ECR I–4431. Not that anyone seems to have noticed. For the most recent misunderstandings, see Craig, 'The Evolution of the Single Market' in Barnard and Scott (eds), above n 5, 1, and the House of Lords in *Regina v Bristol Magistrates Court ex parte Junttan Ony* (2003) 25 ICR 1475, para 89 (Lord Steyn on the Machine Directive: 'Member States are free to introduce safety measures which go further than the Directive, and to rely on pre-existing measures which impose additional or higher standards than the Directive.')

[119] Annex II (The 'Model Directive'), Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[120] Above.

[121] Signed 13 November 1984, the document is reproduced in Nicolas, above n 96, Appendix 4. It has now been replaced by a new set of Guidelines, this time decently published in the Official Journal. See (2003) OJ C 91/7. The Model Directive reinforces the monopoly; 'It is not ruled out that the harmonised standards will be prepared outside CEN and Cenelec by other bodies which may assume these functions in particular areas; in such cases adoption of the harmonised standards will be submitted for approval by CEN/Cenelec.' Model Directive, above n 119.

ments; certified products can thus circulate freely throughout the internal market. However; the standards remain of voluntary application: manufacturers are free to choose other means of satisfying the essential requirements. In that case, however, Member States may impose costly tests and certification procedures.

European standards are now not perceived negatively as the logical way to slay barriers to trade presented by national standards, but positively as a way of circumventing the arduous and cumbersome process of political decision-making.[122] As CEN's Secretary General commented with some satisfaction:

> En l'espace de dix ans, les responsables européens de la politique européenne économique et industrielle ont modifié radicalement l'image qu'ils ont de la normalisation technique: d'une activité génératrice par nature d'entraves techniques aux échanges, celle-ci est devenue un instrument privilégié de la politique d'intégration économique, au service de la réalisation du marché intérieur, et de la compétitivité des entreprises européennes.[123]

The basic structure of the New Approach follows the *Cassis*-scheme: the Council 'recognises that the objectives pursued by the Member States to protect the safety and health of their people as well as the consumer are equally valid in principle, even if different techniques are used to achieve them.'[124] The means/ends dichotomy is then recast as the difference between 'politics' and 'technology', and consequently as that between 'law' and 'standards':[125]

> If the basic characteristics of the new approach had to be summed up in a single sentence, it could be said that this method in fact makes it possible better to distinguish between those aspects of Community harmonisation activities which fall within the province of the law and those which fall within the province of technology, and to differentiate between matters which fall within the competence of public authorities and those which are the responsibility of manufacturers and importers.[126]

[122] See Reihlen, 'Technische Normung und Zertifizierung für den EG-Binnenmarkt' [1990] *EuZW* 444 (new approach to overcome bureaucracy and 'parliamentary paralysis'). Helmut Reihlen is the long standing Director of DIN and easily one of the most influential people in European standardisation.

[123] Repussard, 'Les Normes du Marché Européen: Enjeux et Challenges' (1994) (1) *Revue Economique Franco-Suisse* 5.

[124] Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[125] The Model Directive, above n 119, states that the new approach is appropriate only 'where it is genuinely possible to distinguish between "essential requirements" and "manufacturing specifications".'

[126] Nicolas, above n 96, 94. Cf Commission Report, Efficiency and Accountability in European Standardisation Under the New Approach, COM (1998) 291 final, 3 ('*the policy objective of the free movement of goods should not be delegated to the voluntary standardisation level*, as standardisation can only solve technical questions.')(emphasis in original).

As a strategy to accelerate Community legislation for the internal market, there is no denying the extraordinary success of the New Approach.[127] By 1992, the Council had already put in place regulatory frameworks for whole industrial sectors by adopting Directives on toys,[128] construction products,[129] electromagnetic compatibility,[130] machinery,[131] telecommunications terminal equipment,[132] and a range of other product groups.[133] Topped off for now by the 2000 adoption of the Directive on cableway installations,[134] the regime has been expanded to cover products from water boilers[135] to explosives,[136] from pressure equipment[137] to protective systems for us in explosive atmospheres,[138] from medical devices[139] to lifts,[140] and from satellite earth station equipment[141] to

[127] Often forgotten in New Approach euphoria is the lingering Commission proposal for a Directive on articles of precious metal, COM (1993) 322 final, amended by COM (1994) 267 final. In Case 220/81 *Robertson* [1982] ECR 2349, the Court held that a Member State may impose on imported precious metal a hallmark bearing equivalent information, intelligible to its consumers, to the one contained in the hallmark imposed on domestic metal; in *Neeltje Houtwipper*, above n 12, the Court held that an importing Member State may also impose such a hallmark to be stamped by an independent body if such a requirement exists in domestic law. Given the failure of its proposal, the Commission has become active in bringing infringement procedures for the use of *substantive* standards. In Case C–84/00 *Commission v France* [2001] ECR I–4553 and Case C–30/99 *Commission v Ireland* [2001] ECR I–4619, the Commission was successful in having Member States condemned for impeding the import of precious metal which are conform to standards of fineness of parts per thousand which are 'commonly used in commercial practice' and 'most frequently used in the Community', respectively.

[128] Directive 88/378/EEC, (1988) OJ L 187/1.

[129] Directive 89/106/EEC, (1989) OJ L 40/12.

[130] Directive 89/336/EEC, (1989) OJ L 139/19.

[131] Directive 89/392/EEC, (1989) OJ L 183/9, amended since; consolidated text in Directive 98/37/EC, (1998) OJ L 207/1. A new overhaul is announced in the Commission's Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC, COM (2000) 899 final.

[132] Directive 90/396/EEC, (1990) OJ L 196/15, amended by Directive 98/13/EC, (1998) OJ L 74/1.

[133] See Directive 87/404/EEC on simple pressure vessels, (1987) OJ L 220/48; Directive 89/686/EEC on personal protective equipment, (1989) OJ L 399/18; Directive 90/384/EEC on non-automatic weighing instruments, (1990) OJ L 189/1; Directive 90/385/EEC on implantable medical devices, (1990) OJ L 189/17; Directive 90/396/EEC on gasburners, (1990) OJ L 196/15. Overviews in eg Farr, *Harmonisation of Technical Standards in the EC* (Chancery, London, 1992); Kendall, *EC Consumer Law* (Wiley, London, 1994) 49 ff.

[134] Directive 2000/9/EC, (2000) OJ L 106/21. The Council has recently adopted Common Position 51/2003 on a Directive on measuring instruments, (2003) OJ C 252 E/1.

[135] Directive 92/42/EEC, (1992) OJ L 167/17.

[136] Directive 93/15/EEC, on explosives for civil uses, (1993) OJ L 121/20.

[137] Directive 97/23/EC, (1997) OJ L 181/1.

[138] Directive 94/9/EC, (1994) OJ L 100/1.

[139] Directive 93/42/EEC on medical devices, (1993) OJ L 169/1 and Directive 98/79/EC on in vitro diagnostic medical devices, (1997) OJ L 331/1.

[140] Directive 95/16/EC, (1995) OJ L 213/1.

[141] Directive 93/97/EEC, (1993) OJ L 290/1, amended by Directive 98/13/EC, (1998) OJ L 74/1.

recreational craft[142] to cover products representing 17% of intra-Community trade.[143]

The 'New Approach' has been widely perceived by academics as an exercise in 'deregulation' and 'privatisation' of Community regulation.[144] The issue conjures up a whole range of normative questions which shall be addressed later. For now, the point is that the Community entrusts the task of ensuring free movement of the products covered by the Directive to private transnationalism. Without the standards, the Directives can come into effect formally, but do not significantly ease free movement since importing states can still demand costly checks and tests to be carried out. But the nature of standardisation and the structure of CEN are such that the standards are slow in coming. CEN operates on the principles of consensus and national representation: in practice, the Community has resolved the problem of decisional supranationalism by handing over the task of hammering out agreement on technical details to private intergovernmentalism.

[142] Directive 94/25/EC, (1994) OJ L 164/15, amended by Directive 2003/44/EC, (2003) OJ L 214/18 to include provisions on exhaust and noise emissions from engines installed on personal watercraft. The proposal was prompted by several notifications of technical regulations under the Information Directive. See the Commission's Proposal, COM (2000) 639 final.

[143] Commission Report, *Efficiency and Accountability in European Standardisation Under the New Approach*, COM (1998) 291 final, 2. In its Communication, 'Enhancing the Implementation of the New Approach Directives', COM (2003) 240 final, 3, the Commission puts a figure 'largely exceeding' €1500 billion on annual trade in 'products covered only by the major sectors regulated by the New Approach Directives', whatever that may mean.

[144] Critical early commentary includes Bruha, 'Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft—Deregulierung durch "Neue Strategie"?' (1986) 46 *Zeitschrift für auslandisches öffentliches Recht* 1; Falke, 'Normungspolitik in der EG zum Schutz der Verbrauchern und Arbeitsnehmern' (1989) 3 *Jahrbuch für Staats und Verwaltungswissenschaft* 217. Positive assessments of the new approach as deregulation are Pelkmans, 'The New Approach to Technical Harmonization and Standardization' (1987) 25 *JCMS* 249; Waelbroeck, 'L'harmonisation des Règles et Normes Techniques dans la CEE' (1988) 36 *CDE* 243. Cf Ogus, *Regulation—Legal Form and Economic Theory* (Clarendon Press, Oxford, 1994) 174 ff. Critical assessments in the context of the overall internal market program are Dehousse, '1992 and Beyond: The Institutional Dimension of the Internal Market Programme' [1989] (1) *LIEI* 109 ('democracy v efficiency'); McGee and Weatherill, 'The Evolution of the Single Market—Harmonisation or Liberalisation' (1990) 53 *MLR* 578 ('deregulation at the cost of consumers'); in the context of overall product safety law, Joerges, 'The New Approach to Technical Harmonization and the Interests of Consumers: Reflections on the Requirements and Difficulties of a Europeanization of Product Safety Policy' in Bieber, *et al*, (eds), *1992: One European Market?—A Critical Analysis of the Commission's Internal Market Strategy* (Nomos, Baden-Baden, 1988) 175, 223 (new approach 'may in no way be regarded as an expression of a consistent deregulation strategy. . . . What is questionable is not the new regulatory system itself, but the neglect of the connections between internal market and product safety policy'); and Argiros, 'Consumer Safety and the Single European Market: Some Observations and Proposals' [1990] *LIEI* 139, 144 ('more a perocedure to unblock the harmonisation programme . . . than an instrument for consumer safety policy'). Cf. Burrows, 'Harmonisation of Technical Standards: Reculer pour mieux sauter?' (1990) 53 *MLR* 597; and Schreiber, 'The New Approach to Technical Harmonization and Standards' in Hurwitz and Lequesne (eds), *The State of the European Community* (Longman, Essex, 1991) 97. Officialdom in Anselmann, 'Die Rolle der europäischen Normung bei der Schaffung des Europäischen Binnenmarktes' (1986) 32 *Recht der internationalen Wirtschaft* 936.

4.2 The Green Paper

With the 1993 deadline approaching, the Commission grew increasingly nervous at the end of the 1980s that the European standards bodies would be unable to deliver the quantities of mandated standards needed to set the Directives in full operation. The Green Paper *Action for faster integration in Europe* it published in 1990 is accordingly full of wide ranging proposals to improve efficiency in the delivery of mandated standards.[145] In classic *divide et impere* fashion, the Commission sought to erode the monopoly and power of the European standards bodies and their national member organisations by introducing further distinctions between technical and political decision-making.

First, it objected to the committee system. 'Bringing together 18 national delegations to discuss conflicting technical solutions to a technical problem is costly, laborious and at times inefficient.'[146] The solution would be to use 'project teams', outside consultants and industry-based associated standards bodies to deliver a first technical summary draft of a standard. The 'intergovernmental' TC would then be relieved of much of the technical work. The next step is then to introduce majority voting not just as a principle but as practice on TC level to avoid any further blockages based on national interests.

Next, it objected to the role of national standards bodies after the drafting stage. To streamline the process, the time allowed for public inquiry at national level should be cut in half or more, and transposition as national standards should be abolished altogether. This loss of national input and control over standards was then to be compensated by further 'Europeanisation' of standardisation: direct interest representation at European level and increased industry commitment.

The further reaching proposals aimed to erode the monopoly of the European standards bodies by two complementary moves. On the one hand, the co-ordinating and policy making role of standards bodies would be lifted from the European standards bodies to a new *European Standardisation Council*, a body made up of representatives of industry, consumers, trade unions, the Commission, the EFTA secretariat and the European standards bodies themselves. A clear set of common rules for standardisation would then have to be defined and enforced at political level. Once that would be achieved, the reasons for a standards oligarchy of a few associations organised according to the principle of national delegations would cease to exist; standards developed by all sorts of sectoral European bodies would have the same claim to recognition and legitimacy

[145] COM (1990) 456 final.
[146] Above, para 38 (i).

as CEN and Cenelec standards: the field would hence be cleared for a whole range of sectoral standards bodies, competition between which should ensure strong pressure on efficiency and quality of standards work.

No one had anything to gain from the Commission's proposals.[147] The national standards bodies would see their position undermined; national authorities their venues of influence further narrowed, and European industry would have to invest vast quantities of time, expertise and money. Unsurprisingly then, the Green paper stands as one of the most widely and savagely trashed policy papers in the history of the Commission. 'Le livre vert ignore l'essence même de la normalisation' was AFNOR's reaction in *Le Monde*.[148] According to the Dutch public authorities,

> [T]he cure prescribed by the Commission seems, by and large, worse than the ailment; the measure proposed are indicative of an almost cavalier disregard for all interests other than the Community's and of incomplete grasp of history; they choose the wrong point of attack, they are complicated to implement and contestable in terms of Community law; they are damaging to the credibility and therefore the usefulness of the standardisation process.[149]

The Commission's Follow-up could not but withdraw most of the more radical proposals. Intended 'to assist and promote democratic self-management of standardisation', this Communication proposed, with equal lack of success, a merely consultative European Standardisation Forum.[150] Challenging the standards system to 'prove itself worthy of the responsibility now placed on it,' the Follow-up ended with a threat:

[147] Egan, above n 10, 212 ff.

[148] Le Monde, 27 February 1991, p 21. See also BSI, *The Future of European Standardisation—The BSI Response to the European Commission Green Paper* (On file with author). The wounds inflicted by the Greenbook are slow to heal. Ten years on, DIN still finds it necessary to point out that the principle of national delegations should be maintained, 'denn nur so ist eine effiziente Beteiligung aller interessierten Kreise möglich,' and qualifies its enthusiasm for an extension of the New Approach and other initiatives 'zur Deregulierung bzw. Koregulierung' with the condition that CEN's independence be guaranteed and 'kein Anspruch auf eine größere staatliche Enflussnahme erhoben wird.' DIN, Geschäfsbericht 2001. Similarly, the Commission was still complaining in 2003 that 'it takes far too long' to develop European Standards. See the Commission Communication, 'Internal Market Strategy: Priorities 2003–2006', COM (2003) 238 final.

[149] Position of the Interdepartmental Commission for Standardisation and Certification (ICN) on the Commission Green Paper on Standardisation, 1 May 1991, 7. The German authorities were not much kinder. Cf Communication of the Federal Republic of Germany to the EC Commission, 15 April 1991. Both documents on file with author. French official reaction is published in (1991) 114 *Enjeux* 23. See also Pelkmans and Egan, *Fixing European Standards: Moving beyond the Green Paper*, CEPS Working Document No 65 (Centre for European Policy Studies, Brussels, 1992), (arguing, in essence, that the green paper blamed the European standards bodies for failing to deliver in three years what the Commission itself had failed to do for over twenty years).

[150] Commission Communication, *Standardisation in the European Economy*, (1992) OJ C 96/2. See also Commission Report, *Efficiency and Accountability in European Standardisation under the New Approach*, (1998) COM 291 final.

> In the absence of an effectively managed European standardisation system the Community legislator will be forced to resort to technical regulation, with the inevitable risk of arbitrariness and loss of efficiency.[151]

5. EMBEDDING STANDARDISATION IN EUROPEAN GOVERNANCE

5.1 Subsidiarity and Governance

Just as the debate over the Green Paper was petering out, the Maastricht Treaty cast its shadow over Community policymaking. In light of the principle of subsidiarity, the Commission revamped its regulatory strategy. In 1992, it published a Communication on the subject where it expressly sought to link the ethos of decentralisation with an exercise in dejuridification. In functional terms, then, subsidiarity requires the Community 'to choose the form of action or measure which leaves the Member States, individuals or businesses the greatest degree of freedom.' The Commission even went so far as to claim that 'the main choice where subsidiarity is concerned is between binding and non-binding measures.'[152] As Fritz Scharpf concluded:

> Apparently, the intention is now to avoid, as far as possible, the detailed establishment of substantive norms in the Council of Ministers which would then have to be converted into national laws and administratively implemented in the Member States. Instead the aim is to take greatest possible advantage of corporatist, quasi-governmental, or subnational processes of norm formation, concretisation, and enforcement.[153]

In this new environment, the Commission was quick to recast standardisation in a new role as a shining example of the proper division of labour between the legislator and regulated industries. Its 1995 Communication on 'The Broader Use of Standardisation in Community Policy' is a ringing endorsement of the Community's increased reliance on standards.

> European standardisation as it has developed plays an enabling role in European integration, and European Union initiatives for the development of

[151] Above, para 78. Egan's assertion that the Commission has 'always maintained the *credible* threat of government intervention if this strategy fails to respond to the public interest' is, frankly, debatable at best. Egan, above n 10, 267 (emphasis added).

[152] Commission Communication on the principle of subsidiarity, SEC (1992) 1990 final, 13, 14.

[153] Scharpf, 'Community and Autonomy: Multi-level Policy Making in the European Union' [1994] 1 *JEPP* 219, 236. *Contra* Mestmäcker, 'Zur Anwendbarkeit der Wettbewerbsregeln auf die Mitgliedstaaten und die Europäischen Gemeinschaften' in Baur, Müller-Graff and Zuleeg (eds), *Europarecht, Energierecht Wirtschaftsrecht—Festschrift für Bodo Börner* (Carl Heymanns, Köln, 1992) 277, 287 (connecting the promotion of self-regulation with subsidiarity is 'wrong'). Cf Winter, 'Subsidiarität und Deregulierung im Gemeinschaftrecht' (1996) 31 *Europarecht* 247.

> European standardisation contribute to the European economy while avoiding the unnecessarily stifling of economic initiative due to excessive regulation.
>
> [Recourse to] standardisation could, in principle, replace regulatory action with voluntary standardisation action in sectors of Community activity. Since it is based on consensus, and relies on acceptance of the results by those who will use them, standardisation follows the principle of subsidiarity to a high degree.[154]

The Communication then sets out the possibilities to extend the use of standards to areas such as telecommunications, biotechnology, foodstuffs, energy and health and safety at the workplace. The Commission has now mandated standards on anything from the safety of bunk beds, lighters, babywalkers and amusement park equipment, on the safety of mobile phones in relation to thermal aspects of electromagnetic radiation, on the harmonisation of telephone tones generated by public networks, on traffic management systems, thermal solar systems and components, on the transport of dangerous goods, and for test methods for biodiesel; it has also mandated standards 'in the postal field', *sic*.[155]

The Commission's 'better lawmaking' initiative has continued the theme of light touch regulation and devolving regulatory responsibility.[156] Even if it's fair to say that the most striking result of the initiative seems to be the conspicuous lack of regulatory action over the last decade or so, the Commission has very recently published its proposal for a Directive on services very much in the spirit of 'cutting red tape.' Called upon by the Council to 'reflect on how European standards could contribute to a common high level of safety of services for consumers,'[157] the proposal contains a clause obliging Member States and the Commission

[154] Commission Communication, *On the Broader Use of Standardisation in Community Policy*, COM (1995) 412 final, 4. Cf Commission White Paper, *European Governance*, COM (2001) 428, 21 ('New Approach' an example of co-regulation), and the startling retroactivity in the *Consultation Document Prepared by the Directorate General for Enterprise on the Review of the New Approach*, 13 December 2001, 2 ('The New Approach and the Global Approach are heavily influenced by the principle of subsidiarity.')

[155] See Commission Report on the Operation of Directive 83/189/EEC in 1992, 1993 and 1994, COM (1996) 286 final, Commission Report on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final, and Commission Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final.

[156] See Commission Report, *Better Lawmaking 1998—A Shared Responsibility*, COM (1998) 715, 7 (encouraging alternatives to legislation that offer a suitable solution) and Commission Report, *Better Lawmaking 1999*, COM (1999) 562 final, 3 (discussing alternatives to regulation and self-regulation in light of subsidiarity). See also Commission Communication, Action plan 'Simplifying and improving the regulatory environment', COM (2002) 278 final, and the Council conclusions of 13 May 2003 on 'industrial competitiveness in Europe,' (2003) OJ C 149/1 (inviting the Commission to 'pursue its work on the action plan, integrating the concept 'think small first' and improving regulation affecting competitiveness, including the new approach to product policy and developing European standards, and to assess, where appropriate, the use of alternatives to legislation to avoid excessive administrative burdens.')

[157] Council Resolution of 1 December 2003 on safety of services for consumers, (2003) OJ C 299/1, para 13.

itself to 'encourage the development of European standards with the aim of facilitating compatibility between services supplied by providers in different Member States.'[158]

The final consecration of standardisation as a model for European governance came with the 2001 White Paper on Governance's call for a wider use of 'frameworks of co-regulation', drawing on the 'practical expertise' of the actors most concerned, which should result in 'wider ownership of the policies in question by involving those most affected.'[159] In the 2003 Guidelines for co-operation, it is noted that 'standardisation has acquired a high political profile,' which 'creates a correspondingly enhanced obligation to observe the principles of transparency, openness, consensus, independence, efficiency and coherence.'[160] The theme of extra-constitutional politics is then fleshed out where the European standards bodies are under an expectation

> [t]o provide a mechanism for economic and social partners in Europe and other relevant interest groups, namely NGOs, that might not otherwise be involved but who have a legitimate interest in the outcome, to be involved in the process of standardisation. This constitutes a means for them to play an active role in relation to public interests such as protection of the environment, workers, and consumers. It allows them to contribute to sustainable development and to safeguard the public interest in areas where co-regulation or self-regulation is considered preferable to outright regulation.[161]

In this climate, standardisation takes on a new significance. Instead of either the obvious way of removing barriers to trade represented by national standards or replacing political supranationalism with technical private transnationalism, European standards now take on an autonomous value in the project of European integration.[162] In the bitter

[158] Article 31 (5), Commission Proposal for a Directive on services in the Internal Market, COM (2004) 2 final. The Commission has issued an astonishing 'programming mandate' to the European standards bodies asking them to develop 'a standardisation work programme to support the internal market for the service sectors'. See Mandate 340-EN of 8 October 2003.

[159] Commission White Paper, *European Governance*, COM (2001) 428, 21. Cf Commission Report On Actions taken Following the Resolutions on European Standardisation Adopted by the Council and the European Parliament in 1999, COM (2001) 527, 3 (the New Approach is 'a well-implemented co-regulatory model.'). Compare Allott, 'European Governance and the Re-branding of Democracy' (2002) 27 *ELR* 60, 68 ('Self-governance by industrial and commercial corporations in the name of what they suppose to be ethics is a contradiction of capitalism. Governance by governments in collusion with something which they call civil society is a death-wish of democracy.') On the wider implications of 'new governance' in the EU legal order, see further eg Scott and Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 *ELJ* 1; De Búrca, 'The Constitutional Challenge of New Governance in the European Union' (2003) 28 *ELR* 814.

[160] Section 1, *General Guidelines for the Co-operation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association*, (2003) OJ C 91/7.

[161] Above, section 2.

[162] The Commission ends its recent 'reflection paper', *The New Approach: Quo Vadis?*, presented at the Commission seminar on the future of the New Approach, February 2003, with the rather tiresome pun: 'The New Approach can go anywhere.'

debates of Community competences versus Member States' sovereignty, the idea of European-wide industry self-regulation disarms both sides by introducing the notion that bottom-up integration generates its own normative frameworks. European standardisation dissolves the tension between negative and positive integration.

5.2 General Product Safety

The new status of European standards in Community law is dramatically brought to the fore in the recently amended General Product Safety Directive. The original Directive, adopted after great controversy in 1992,[163] contained the general requirement to put only 'safe' products on the market, defined as

> any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only minimum risk compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons.[164]

That requirement was presumed to be fulfilled by any product which conformed to applicable Community law where it existed, or else if it complied with specific rules of national law.[165] Absent any legislative provision, conformity was to be assessed

> having regard to voluntary national standards giving effect to a European standard or, where they exist, to Community technical specifications or, failing these, to standards drawn up in the Member State in which the product is in circulation, or to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.[166]

[163] Directive 92/59/EEC on general product safety, (1992) OJ L 228/24. For discussion of he controversy surrounding the adoption of the Directive, see eg Argiros, 'The EEC Directive on General Product Safety' [1994] *LIEI* 125; Weatherill, *EC Consumer Law and Policy* (Longman, London, 1997) 123 ff.

[164] Article 2 (b). The following points are to be taken into account: (a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance; (b) the effect on other products, where it is reasonably foreseeable that it will be used with other products; (c) the presentation of the product, the labelling, any instructions for its use and disposal and any other indication or information provided by the producer, and (d) the categories of consumers at serious risk when using the product, in particular children. For a discussion of the Product Safety Directive's 'risk/utility' test in comparison with the Product Liability Directive's 'consumer expectations' test, see Howells and Wilhelmsson, *EC Consumer Law* (Ashgate, Aldershot, 1997) 68 ff.

[165] Article 4 (1).

[166] Article 4 (2). The presumption of conformity is rebuttable, in that Member States can withdraw such products from the market 'where there is evidence' that they are 'dangerous to the health and safety of consumers'.

Even if Commission folklore has it that the reference to European standards was inserted more by chance than by conscious policy design, the Commission has attributed much of the Directive's lack of effectiveness to the standards' lack of a clear legal status.[167] In the amended 2001 Directive, European standards are hence lifted from the rest category and placed on the same footing as Community law and provisions of national law: products manufactured according to national standards transposing European standards are now presumed to be in conformity with the general safety requirement.[168]

Reliance upon standards is put forward not as a means of avoiding the need for political agreement on technical details within legislation, but as a means to do avoid the need for legislation altogether. As the Commission explains:

> On the side of both industry and consumers, the need for additional sectoral legislation is often felt as the Directive is not always considered sufficient for the objectives of consumer protection and the internal market. It would clearly not be possible to introduce into the Directive itself detailed safety requirements covering in a sufficient manner all the products falling within its wider scope. Therefore, it is essential to strengthen the role of European standards in establishing the conformity of products to the general safety requirement. In this way, the GPSD could provide a framework for ensuring a sufficient degree of harmonisation in consumer safety requirements, for the product groups most relevant for consumer safety, and the functioning of the internal market, with a flexible approach while avoiding the need for a proliferation of sectoral legislation.[169]

[167] Commission Proposal for a European Parliament and Council Directive on General Product Safety, COM (2000) 139/final, 10.

[168] Article 3 (2), Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, (2002) OJ L 11/4. In its Communication, 'Internal Market Strategy: Priorities 2003–6', COM (2003) 238 final, 8, the Commission announces that will seek to ensure compliance with the requirements of the Directive 'through the development and revision of European standards'. The European Parliament is slow to catch on with the times. In its Opinion on the Commission's proposal, it demanded publication of the full text of harmonised standards in the Official Journal. See Opinion of the European Parliament of 15 November 2000, (2001) OJ C 223/154. The Commission rejected that amendment, explaining: 'The standardisation organisations are the owners of the standards and they finance a large proportion of their activities selling standards. The EP's demand for publication in the Official Journal of the full text of the European standards would involve a major shift in the relations between the Commission and the standardisation organisations and would impose an additional financial burden on the Community.' Commission, Amended proposal for a Directive of the European Parliament and of the Council on general product safety, COM (2001) 63, section B 12.

[169] Commission Proposal for a European Parliament and Council Directive on General Product Safety, COM (2000) 139/final, 10. See also Commission Report to the European Parliament and the Council on the experience Acquired in the Application of Directive 92/59/EEC on General Product Safety, COM (2000) 140 final, 18–19. See further Council Resolution of 28 June 1999 on Community consumer policy from 1999 to 2001, (1999) OJ C 206/1, recital 10 ('The development of European standards can be of great benefit for consumers, in particular with regard to their health and safety').

6. CONCLUSION

Community reliance on standards has, then, come full circle. National self-regulatory frameworks are a problem for Community law in that they escape the reach of negative integration. The first move on the part of the Community legislator was, then, to promote the Europeanisation of standardisation as a means to remove the obstacles to trade represented by divergent national standards. The second move was in itself a radical departure from this first negative posturing. European standards were now regarded as way of relieving political decision-making from technical detail. In this phase, standards were seen as mere accessory instruments for the implementation of Community law. The problem here was that the deficits of decisional supranationalism were thought to be remedied by a species of transnational intergovernmentalism. The political timetables of the Commission and the consensus seeking of the standards bodies collided. The Commission then tried to disperse private power by asserting public authority over the standardisation bodies' governance functions and subjecting the technical work to the pressures of competition. After the failure of that initiative, standardisation is now established as a legitimate alternative to Community legislation.

3

The United States: Deregulation and Legalisation

1. INTRODUCTION

LAWRENCE FRIEDMAN HAS famously analysed America's 'legalisation' as a response to social change. As social distance grows and traditional sources of authority fade, as communal ties give way to a culture committed to individualism, social demands on the legal system increase dramatically, demands to which the legal system cannot but react.[1] Increased expectations of total justice, however, coincide with a waning trust in public authority. The 'due process revolution', in fact, 'consists essentially of attacks on authority.'[2] Robert Kagan's equally famous analysis of the roots of American 'adversarial legalism' points out a similar pattern:

> (1) heightened political demands for government to wield *more* power—to control risk, to protect the environment, to combat discrimination, and to prevent injustice; and (2) a fragmented governmental structure and a political culture that *distrusts governmental power*, and hence seeks to make any increases in governmental power legally controllable. The result is a more activist government, armed with tough regulatory powers, but within which administrative discretion is subjected to tight legal constraints exerted by other governmental units, by courts, and by lawsuits brought by a broad range of political and economic interests.[3]

From a review of comparative literature on social regulation, Kagan concludes that the US system for implementing public policies and resolving related disputes is characterised by: (1) more complex, prescriptive legal rules; (2) more formal, adversarial procedures for resolving policy or scientific disputes; (3) more costly forms of legal contestation; (4) stronger, more punitive legal sanctions; (5) more frequent judicial review of, and

[1] Friedman, *Total Justice* (Russell Sage, New York, 1985).

[2] Above, 89.

[3] Kagan, 'Adversarial Legalism and American Government' (1991) 10 *J Pol An & Man* 369, 394–98. Cf Kagan, *Adversarial Legalism—The American Way of Law* (Harvard University Press, Cambridge, 2001) 181 ff.

intervention in, administrative decisions and processes; (7) more politically fragmented, less closely co-ordinated decision-making systems; and (8) more legal uncertainty and malleability.[4] Whether the legalisation of regulatory policy is *per se* a bad thing is widely discussed, rule of law virtues contrasting with cost, delay, gridlock and social antagonism.[5] Kagan himself flirts with the idea of corporatist modes of regulation but is the first to point out the virtues of adversarial legalism.[6] The point for now is that it is widely perceived to be a problem—stifling innovation and economic growth as well as undermining social justice by putting a premium on costly access to the legal system. The spread of ADR, arbitration, and other consensual mechanisms in civil litigation has its corollary in regulatory matters. The objections critics of informal justice have to these forms of out-of-court settlement apply with equal force to the various forms of consensual regulation—they presuppose equal bargaining power in a framework of broad consensus over substantive issues.[7] Absent these conditions, Richard Abel argues that informal institutions invariably suffer one of two fates: either they remain powerless in which case they will have responded to demands of increased access by creating a right to invoke a useless institution. In the alternative, they may regain power, in which case they can only claim legitimacy by introducing all the technicalities of due process.[8]

This chapter presents an account of American regulatory law as a continuous search for more flexible and informal ways of rulemaking followed by the legalisation of the institutions thus created followed by another round of seeking more informal regulatory mechanisms, and so on. The spiral starts with the APA itself—originally designed to provide procedures of 'informal rulemaking'. Intrusive judicial review seeking to

[4] Above, 372–74. Cf Jasanoff, 'American Exceptionalism and the Political Acknowledgement of Risk' (1990) 119 *Daedalus* 61, 63 (describing the US system as 'costly, confrontational, litigious, formal and open to the public' as opposed to European 'consensual, co-operative and cost conscious' systems which are 'closed to the public.') See, however, Vogel, *The New Politics of Risk Regulation in Europe*, CARR Discussion Paper 3, (London School of Economics, London, 2001) arguing that the 'American style of regulation' has travelled to Europe.

[5] Contrast eg Howard, *The Death of Common Sense—How Law is Suffocating America* (Warner Books, New York, 1996), and Galanter, 'Law Abounding: Legislation Around the North Atlantic' (1992) 55 *MLR* 1.

[6] Kagan, above n 3. Cf Stewart, 'Regulation and the Crisis of Legalisation in the United States' in Daintith (ed), *Law as an Instrument of Economic Policy—Comparative and Critical Approaches* (de Gruyter, Berlin, 1988) 97; Kelman, 'Adversary and Cooperationalist Institutions for Conflict Resolution in Public Policy Making' (1992) 11 *J Pol An & Man* 178; Kagan, 'Adversarial Legalism: Tamed or Still Wild?' (1999) 2 *NYU J Leg & Pub Pol* 217.

[7] Cf Abel (ed), *The Politics of Informal Justice* (Free Press, New York, 1982); Harrington, *Shadow Justice—The Ideology and Institutionalization of Alternatives to Court* (Greenwood, Westport, 1985).

[8] Abel, 'Delegalization—A Critical Review of Its Ideology, Manifestations, and Social Consequences' (1980) 6 *JfRsozRth* 27, 42.

constrain the discretion of regulators then clogged up these procedures and transformed informal rulemaking into a system of regulation by litigation. The next step is 'negotiated rulemaking', still caught in Abel's basic dilemma of being either a useless institution or awaiting the infusion of due process rules. Increased recourse to standards bodies constitutes the next stage. Under the influence of, notably, competition law as well as federal regulatory policy, consensual standards–setting is now, however, endowed with an impressively elaborate set of internal para-legal procedures which may induce the search for yet a further step down the spiral—to *de facto* industry standards. The section first describes the general features of the development and then follows the spiral in specific regulatory agencies.

2. INFORMAL RULEMAKING

A 'fierce compromise' between expertocratic New Deal optimism and fear of encroachment upon private rights by unelected bureaucrats, the Administrative Procedure Act (APA) was passed by Congress in 1946.[9] It provides for a basic informal rulemaking procedure for administrative agencies. The latter are to publish a notice including either the terms or the substance of the proposed rule or a description of the subjects and issues involved. The agency shall then give 'interested persons' the opportunity to participate in the process by submitting 'written data, views, or arguments.' The agency is then to 'consider' the relevant matter presented and incorporate in the final rules 'a concise statement of their basis and purpose.'[10] Courts are to set aside any agency action it finds to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' and 'contrary to constitutional right.'[11]

The whole of American administrative law, in a very real sense, revolves around the judicial interpretation of these formula. One could, as some do, describe its history as one long effort to come to terms with the

[9] For a political history of the enactment of the APA, see Shepherd, 'Fierce Compromise: The Administrative Procedure Act Emerges From New Deal Politics' (1996) 90 *Northwestern U L Rev* 1557. Cf McCubbins, Noll, and Weingast, 'The Political Origins of the Administrative Procedure Act' (1999) 15 *J L Econ & Org* 180. The Supreme Court has credited the APA with settling 'long-continued and hard-fought contentions' and enacting 'a formula upon which opposing social and political forces have come to rest'. See *Wong Yang Sung v McGrath*, 339 US 33, 40 (1950). According to Edward Rubin, the Act was out of date even when it was first enacted. See Rubin, 'It's Time to Make the Administrative Procedure Act Administrative' (2003) 89 *Cornell L Rev* 95, 96. For a history of the early years of administrative rulemaking and judicial review, see Schiller, 'Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s' (2001) 53 *Admin L Rev* 1139.

[10] 5 USC 553.

[11] 5 USC 706.

'trichotomy' of politics, science and adjudicatory fairness.[12] The now standard view of its historical development is 'from expertise to politics'.[13] 'Economic' regulation, often focusing on single industries or sectors, gave way to 'social'—environmental, consumer, health and safety—regulation, spanning the whole economy. Regulatory action was more and more perceived as policy choices rather than apolitical rational administration. In response, judicial review began to emphasise interest representation, inserting a host of hyperpluralist, access-equalising and anti-capture devices that turned administrative law into a sort of surrogate political process.[14] This development caused two interrelated sets of worries. One is concern over the equation of the 'public interest' with the mere aggregation of private interests, the other with scepticism concerning the capability of such a political process to come up with scientifically sufficiently sophisticated solutions. In short, the victory of procedure over substance.[15] The way back to expertise was found through 'synoptic review', a judicialised version of truth-finding.[16] Even if the Supreme Court struck down excessively 'hard looks' in *Vermont Yankee* by prohibiting courts to impose more stringent procedural requirements than those the APA guaranteed,[17] courts are still to demand of the agency that its fact finding be supported by 'substantial evidence',[18] and that it 'examine the relevant

[12] Edley, *Administrative Law—Rethinking Judicial Control of Bureaucracy* (Yale University Press, New Haven, 1990) (arguing that judicial reification of the three decisionmaking paradigms reflects a pathological separation of powers doctrine). Cf Schuck, 'Multi-Culturalism Redux: Science, Law and Politics' [1992] *Yale L & Pol Rev* 1.

[13] Strauss, 'From Expertise to Politics: The Transformation of American Rulemaking' (1996) 31 *Wake Forest L Rev* 745. For a sense of the intellectual climate in 1946, see Butler, 'The Rising Tide of Expertise' (1946) 24 *Fordham L Rev* 19.

[14] The *locus classicus* is Stewart, 'The Reformation of American Administrative Law' (1975) 88 *Harvard L Rev* 1669.

[15] Sunstein, 'Interest Groups in American Public Law' (1985) 38 *Stanford L Rev* 29, 63. Cf Rose-Ackerman, *Rethinking the Progressive Agenda—The Reform of the American Regulatory State* (Free Press, New York, 1992); Sunstein, *After the Rights Revolution—Reconceiving the Regulatory State* (Harvard University Press, Cambridge, 1990) (using 'progressive' law and economics to argue for 'substantive' as opposed to 'proceduralized' administrative law).

[16] Shapiro, *Who Guards the Guardians? Judicial Control of Administration* (University of Georgia Press, Athens, 1988) 110 ('In the United States judges think they are such truly wonderful people, and courts such truly wonderful places, and litigation such a truly wonderful way of getting at truth and resolving conflict, that their almost instinctive reaction whenever they try to seek to improve some other part of government's behaviour is to require it to act like a court'). On the evolution from expertise to politics back to expertise, see also Horwitz, 'Judicial Review of Regulatory Decisions: The Changing Criteria' (1994) 109 *Political Science Quarterly* 133.

[17] *Vermont Yankee Nuclear Power Corp v NRDC* 435 US 519 (1978). The angry plurality opinion directed its wrath to the notoriously hard looking DC Circuit Court, which it accused of 'Monday morning quarterbacking'. 435 US 547. In *Pension Benefit Guaranty Corp v The LTV Corp* 496 US 633, 655 (1990), the Court held that reviewing courts may not add their own procedural notions of 'fundamental fairness' to the APA's rules on agency adjudication.

[18] 'Substantial' evidence is 'less than a preponderance but more than a scintilla', *Cellular Telephone Co v Town of Oyster Bay* 166 F 3d 490, 494 (2nd Cir 1999).

data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made'.[19] That explanation then is to be reviewed by Courts in a 'careful and searching' inquiry to ensure that the agency considered the 'relevant factors' and did not make a 'clear error of judgment'.[20] In practice, the 'hard look' comes very close to demanding of the agency that it convince the court that it was absolutely right.[21] As the Supreme Court held in 1986:

> The mere fact that there is *some* rational basis within the knowledge and experience of the regulators under which they *might* have concluded that the regulation was necessary to discharge their statutorily authorized mission will not suffice to validate agency decisionmaking.[22]

Agencies can count on their rules being challenged and intensely scrutinised in court in 'a costly and clumsy system of "central planning through litigation."'[23] To make their rules legally defensible, agencies must open up their policymaking procedures to all sorts of adversarial interest groups; they have to provide exhaustive records of scientific data and cost-benefit analyses, have to prove that they took all comments and suggestions into due consideration and explored all possible alternatives to the final choice made. A number of consequences arise. Most perversely, Shapiro argues forcefully that synoptic review leads to a vicious cycle as 'judges must yield to the technocratic defence that they have forced the agencies to create'.[24] In the process, values of deliberation are subverted as synoptic review provides parties to litigation with strong incentives to falsify their contribution, and lie sophistically.[25] Most obviously, the cost and time needed for rulemaking increases at frightening

[19] *Motor Vehicle Manufacturers Association v State Farm Mutual Automobile Insurance Co* 463 US 29 (1983); *Burlington Truck Lines, Inc v United States*, 371 US 156 (1962).

[20] *Citizens to Preserve Overton Park, Inc v Volpe* 401 US 402 (1971).

[21] Cf Shapiro, 'Codification of Administrative Law: The US and the Union' (1996) 2 *ELJ* 26; Mashaw, 'Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State' (2001) 70 *Fordham L Rev* 17, 26 ('"Expertise" is no longer a protective shield to be worn like a sacred vestment. It is a competence to de demonstrated by cogent reason-giving.')

[22] *Bowen v American Hospital Association* 476 US 610, 627 (1986), (citations omitted, emphasis added).

[23] Stewart, 'The Discontents of Legalism: Interest Group Relations in Administrative Regulation' [1985] *Wisconsin L Rev* 655. Cf Freeman, 'Collaborative Governance in the Administrative State' (1997) 45 *UCLA L Rev* 1, n 28 ('In the context of environmental and health and safety regulation, parties have increasingly treated the rulemaking process as a time to prepare for litigation.')

[24] Shapiro, above n 16, 155.

[25] Above, 141 ('The "deliberation" of synopticists might be imagined as a philosophy seminar in ethics and public values followed by a series of laboratory experiments and computer runs.') 152 *et seq*.

rates.[26] Moreover, agencies inevitably 'internalise' the threat of judicial review and introduce elaborate procedural mechanisms inside the agency—staffing their offices with experts in record keeping and procedure—lawyers—rather than engineers.[27] Agencies are, furthermore, so discouraged that they may give up on rulemaking altogether and opt for non-regulation:

> Because the courts are relatively uninformed about what is important among the many issues thrown up by the parties seeking review of a rule, and because they are technically and scientifically unsophisticated in analyzing the issues that they perceive to be critical to a rule's 'reasonableness', the perception in the agencies is that anything can happen. This produces defensive rulemaking, if not abandonment of the rulemaking process.[28]

As Jerry Mashaw has documented in great detail for the National Highway Traffic Safety Administration, the practical effect of judicial review has been to force agencies away from rule-based technology-forcing into retrospective case by case adjudication.[29] Imposing ever stricter procedural requirements on agencies subject to judicial review is so effective an instrument of deregulation that it has now become the main policy tool for neoliberal politics.[30]

[26] The phenomenon is now generally known as the 'ossification' of the rulemaking process, after McGarity coined that term to describe the effect of judicial review on agency regulation. See McGarity, 'Some Thoughts on "Deossifying" the Rulemaking Process' (1992) 41 *Duke L J* 1385; Pierce, 'Seven Ways to Deossify Agency Rulemaking' (1995) 47 *Admin L Rev* 59, and the debate between Seidenfeld, 'Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking' (1997) 75 *Texas L Rev* 483, and McGarity, 'The Courts and the Ossification of Rulemaking: A Response To Professor Seidenfeld' (1997) 75 *Texas L Rev* 525.

[27] See eg Mashaw, *Greed, Chaos and Governance* (Yale University Press, New Haven, 1997) 146.

[28] Above, 165. See also Strauss, above n 13, 775 (arguing that current requirements produce 'a procedural matrix so clogged and expensive that agencies are driven to evade, to seek out alternatives'). *Contra*, Jordan, 'Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?' (2000) 94 *Northwestern U L Rev* 393, 445 (concluding that the paralysing effects of hard look review are far less than assumed in the ossification thesis).

[29] Mashaw and Harfst, 'Regulation and Legal Culture: The Case of Motor Vehicle Safety' (1987) 4 *Yale J Reg* 257; Mashaw and Harfst, *The Struggle for Auto Safety* (Harvard University Press, Cambridge, 1990). For a 'counter-narrative' of how easily the NHTSA could have succeeded in 'experimental' regulation, see Dorf and Sabel, 'A Constitution of Democratic Experimentalism' (1998) 98 *Colum L Rev* 267, 357 *et seq*. The NHTSA recently promulgated a standard for the securement of wheelchairs on school buses which fell short of requiring 'dynamic testing'—that is, a simulated crash test. ISO, Australian and Canadian private standards do require dynamic testing. The sixth circuit was delighted to hold up the conservative standard. See *Debra Simms and Lyle Stephens v NHTSA*, 45 F 3d 999 (6th Cir 1995).

[30] Cf the Unfunded Mandates Reform Act of 1995 2 USC 1535, obliging all agencies to choose 'the least costly, most cost-effective or least burdensome alternative') and the Contract with America Advancement Act of 1996, Pub Law No 104–121, § 242, 110 Stat 864 (putting in place a formal system of Congressional review of all agency rules). See Mashaw, 'Reinventing Government and Regulatory Reform: Studies in the Neglect and Abuse of Administrative Law' (1996) 57 *U Pittsburgh L Rev* 405 (discussing 'Contract With America' regulatory reform proposals, self-styled to promote 'procedural fairness' as 'ensuring

3. NEGOTIATED RULEMAKING

Another consequence of litigation and intrusive judicial review is that agencies measure regulatory effectiveness not so much in winning as in avoiding litigation altogether. Agencies have turned their attention more and more to ensuring that the final proposed rule was acceptable to major parties before the formal notice-and-comment even begun. Practiced especially by the Environment Protection Agency from the late 1970s on, 'negotiated regulation' caught on quickly as an attractive way of ensuring regulatory efficiency.[31] Either as a sign of political support for flexible rulemaking or as a measure to clog up even the pre-notice period with procedural requirements, Congress passed the Negotiated Rulemaking Act as a supplement to the APA's normal rulemaking procedures in 1990.[32] President Clinton followed up with an Executive Order directing all agencies 'to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking'.[33] Before issuing a proposed rule, the agency convenes a committee consisting of all interested parties. The committee meets publicly to negotiate the rule. Once 'consensus', defined as unanimity,[34] is reached, the agency can adopt the rule as its own and proceed to the normal notice-and-comment procedures. Congressional findings on the Act are worth quoting in light of the relative merits of adversarial legalism, regulations and standards:

(1) Government regulation has increased substantially since the enactment of the APA.

regulatory rigor mortis'); Dorf and Sabel, above n 29, 443 ('The clash between procedural safeguards and administrative adaptability is so great and manifest that open enemies of government regulation can think of no more expeditious way to frustrate the agencies than to impose on them additional requirements of due process'). See also Asimow, 'Nonlegislative Rulemaking and Regulatory Reform' (1985) *Duke L J* 381, 424–25 (describing earlier procedural proposals to introduce notice-and-comment procedures for the adoption of non-legislative rules as 'a surrogate for substantive deregulation'). For an overview of the stress put on agencies, see Seidenfeld, 'A Table of Requirements for Federal Administrative Rulemaking' (2000) 27 *Florida State U L Rev* 533.

[31] For contrasting early views on the merits of negotiated rulemaking, see Harter, 'Negotiated Regulations: A Cure for Malaise' (1982) 71 *Georgetown L J* 42; Funk, 'When Smoke Gets In Your Eyes: Regulatory Negotiation and the Public Interest—EPA's Woodstove Standards' (1987) 17 *Environmental L J* 55. For later debate, see Freeman, above n 23; Seidenfeld, 'Empowering Stakeholders: Limits on Collaboration as the Basis for Flexible Regulation' (2000) 41 *William & Mary L Rev* 411.

[32] 5 USC 561–70. The Act was permanently re-authorised by the Administrative Dispute Resolution Act of 1996, Pub. L No 104–320, § 11 (a), 110 Stat 3870, 3873.

[33] Executive Order 12866, Regulatory Planning and Review (1993) 58 FR 51735, reprinted in 5 USC 601, Section 6 (a) (1).

[34] 5 USC 562 (2): 'consensus means unanimous concurrence among the interests represented on a negotiated rulemaking committee established under this subchapter, unless such committee (a) agrees to define such term to mean a general but not unanimous concurrence, or (b) agrees upon another specified definition.'

(2) Agencies currently use rulemaking procedures that may discourage the affected parties from meeting and communicating with each other, and may cause parties with different interests to assume conflicting and antagonistic positions and to engage in expensive and time-consuming litigation over agency rules.
(3) Adversarial rulemaking deprives the affected parties and the public of the benefits of face-to-face negotiations and cooperation in developing and reaching agreement on a rule. It also deprives them of the benefits of shared information, knowledge, expertise, and technical abilities possessed by the affected parties.
(4) Negotiated rulemaking, in which the parties who will be significantly affected by a rule participate in the development of the rule, can provide significant advantages over adversarial rulemaking.
(5) Negotiated rulemaking can increase the acceptability and improve the substance of rules, making it less likely that the affected parties will resist enforcement or challenge such rules in court. It may also shorten the amount of time needed to issue final rules.[35]

After a decade, however, the mechanism is still used very infrequently. Moreover, both in terms of delays and in terms of litigation, negotiated rulemaking seems to have failed miserably.[36] Especially the lack of a significant decrease in litigation seems startling. Consensus among all affected parties, one would think, should eliminate all incentives for judicial challenge. Coglianese offers two explanations. First, formalised negotiations merely add a preliminary phase to the rulemaking process, without eliminating any of the procedural and judicial devices of the notice-and-comment procedure. Rather than eliminating conflict, the selection of committee members, the handling of the negotiations themselves, and the difficulty for the agency to secure and maintain consensus in a long process add potential sources of conflict. Once promulgated, 'reg neg' rules seem to be challenged in court as much as normal ones. Moreover, he challenges the accepted law and society wisdom that litigation either fatally disrupts ongoing relationships between regulators and the regulated, or is a sure sign that these relations were sour from the outset. Instead, he posits that judicial challenges of agency rules are merely a slight 'disturbance' in that relationship, and that litigation has become

[35] 5 USC 561.

[36] Coglianese, 'Assessing Consensus: The Promise and Performance of Negotiated Rulemaking' (1997) 46 *Duke L J* 1255, 1321 ('an oversold solution to an overstated problem'). See also the bitter debate between Harter, 'Assessing the Assessors: The Actual Performance of Negotiated Rulemaking' (2001) 9 *NYU Env L J* 32, and Coglianese, 'Assessing the Advocacy of Negotiated Rulemaking: A Response to Philip Harter' (2001) 9 *NYU Env L J* 386.

part and parcel of the legal and political environment in which these relationships evolve.[37]

The big issue, obviously, is the definition of the scope and standard of judicial review of 'neg reg' rules. Two interrelated questions are logically at stake: whether to afford greater leeway to negotiated rules than to normal rules, and the extent to which courts should scrutinise the negotiation process itself. The Act settled the issue as follows:

> Any agency action relating to the establishing, assisting, or terminating a negotiated rulemaking committee under this subchapter shall not be subject to judicial review. Nothing in this section shall bar judicial review of a rule if such judicial review is otherwise provided by law. A rule which is the product of negotiated rulemaking and is subject to judicial review shall not be accorded any greater deference by a court than a rule which is the product of other rulemaking procedures.[38]

On one theory, the agreement of all the affected parties should ensure a rule's substantial 'reasonableness' and should hence induce courts to defer. In that case, courts' attention should focus on issues of sufficient interest representation, the fairness and openness of the process and whether the final rule actually reflects the consensus reached. The theory espoused by the Act relegates the negotiations to a merely preliminary tactical device and refuses to look any less hard at the final rule. The corollary is, logically, that courts should leave the negotiation process itself alone. Richard Posner on the Seventh Circuit in *USA Group* espouses this view:

> The Act's purpose—to reduce judicial challenges to regulations by encouraging the parties to narrow their differences in advance of the formal rulemaking proceeding—would be poorly served if the negotiations became a source and focus of litigation.[39]

His concern here was not with the integrity of the process that would inevitably be at risk by allowing judicial review to introduce adversarial legalism and confrontational stances into the negotiations. Rather, it was his complete contempt for the whole notion of regulatory negotiation that led him to refuse to bestow any value on it. Discussing an official's promise during the negotiations to abide by any consensus rule reached, he stated:

[37] Coglianese, 'Litigating Within Relationships: Disputes and Disturbance in the Regulatory Process, (1997) 30 *Law & Soc Rev* 735, 763 (regulatory litigation is seen as a 'legitimate institutional process for carrying on business as usual'). Compare Stewart, above n 23.

[38] 5 USC 570. For pre-enactment debate, see Harter, 'The Political Legitimacy and Judicial Review of Consensual Rules' (1983) 32 *Am U L Rev* 471; Wald, 'Negotiation of Environmental Disputes: A New Role for the Courts?' (1985) 10 *Colum J Env L* 1; Harter, 'The Role of Courts in Regulatory Negotiation—A Response to Judge Wald' (1986) 11 *Colum J Env L* 51.

[39] *USA Group Loan Services v Riley* 82 F 3rd 708, 715 (7th Cir 1996).

> The propriety of such a promise may be questioned. It sounds like an abdication of regulatory authority to the regulated, the full burgeoning of the interest-group state, and the final confirmation of the 'capture' theory of administrative regulation.[40]

Such a promise could in any event not be enforced since the whole notice-and-comment procedure would be rendered irrelevant if the agency is already bound to its promises. The Act

> does not envisage that the negotiations will end in a binding contract. The Act simply creates a consultative process in advance of the more formal arms' length procedure of notice and comment rulemaking.[41]

Agency discretion over the final rule is vital to keep the scheme from falling foul of the non-delegation doctrine.[42] This, however, is hardly the end of it. As the late Judge Wald argued, if agencies are to expect business-as-usual judicial challenges anyway, they will still have the burden of compiling a record sufficient to meet APA standards 'at the expense of forfeiting any cost and resource gains that are supposed to come from hammering out a consensus regulation'.[43] She thus argued that a court might tolerate 'something less than the 'hard look' rationale' on the theory that the negotiation process itself should reassure the court that reasonable alternatives have been seriously considered. But then,

> The agency must take the bitter with the sweet. If a court is allowed to give credence to the preliminary process to support an agency's decision, it follows that interested parties must be able to challenge the validity of the process with information regarding its deficiencies.[44]

The same dilemma, then, is played out again. Critics of negotiated rulemaking fear the 'final confirmation of the 'capture' theory of administrative regulation', the public interest defined as the outcome of a clash between private interests. As Funk summarises:

> The rulemaking has 'parties' who make the agreement. They make the agreement among and for themselves. They bargain and deal to achieve their own interests. There is no mention of the 'public'. The wisdom and fairness of the

[40] Above, 714. His depreciation of the mechanism is further expressed in his calling negotiated rulemaking 'a novelty in the administrative process' and his constant refusal to acknowledge the balanced composition of the committee, treating the whole process as hardly disguised rent-seeking by industry.

[41] Above.

[42] Funk, 'Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest' (1997) 46 *Duke L J* 1351, 1373.

[43] Wald, 'ADR and The Courts: An Update' (1997) 46 *Duke L J* 1445, 1466.

[44] Above, 1468. She concluded that courts should be able to take account of 'consensus as 'a factor suggesting the reasonableness of the rule' but insists on the APA's 'baseline standards of rationality'. Cf Choo, 'Judicial Review of Negotiated Rulemaking: Should *Chevron* Deference Apply?' (2000) 52 *Rutgers L Rev* 1069 (arguing for *stricter* judicial review of negotiated rulemaking).

> rule is equated with the satisfaction of the parties. Public law has been subtly transformed into private law relationships.[45]

Negotiated rulemaking is, then, in a classic informal justice-dilemma. Either courts will formalise the procedure and clog it up with procedural requirements in exchange for a 'softer' look at the final rule, or it will remain an informal, merely 'consultative', process with no bearing on judicial treatment of the final rule. In both scenarios, it will prove unable to address the problems it was invented to resolve. The next stage, then, is reliance on voluntary standards.

4. RULEMAKING BY RELIANCE ON PRIVATE STANDARDS

4.1 General Federal Standards Policy

In exquisite analogy with the Commission's aborted plans in the Green paper, unsuccessful steps toward a national standards policy were taken in the late 70s. A 'Voluntary Standards and Accreditation Act' was proposed in 1977. Its sponsor expressed concern about the 'vast power' in the hands of 'giant private bureaucracies' and was determined to 'bring some accountability' to the process by creating a 'partnership' between Government, industry and affected parties. The Act would have created a new agency, the National Standards Management Board, charged with management and co-ordination of voluntary standardisation, with the accreditation of standards bodies, and with the listing and approval of National Standards.[46] The proposal was abandoned soon in the face of fierce opposition.

In Samuel Krislov's summary, what is left is a system at 'cross purpose with itself', which 'minimizes government interference in the formative stages and casts a legal shadow over everything else'.[47]

The Office of Management and Budget has a circular in place since 1982 that encourages the use of voluntary standards by federal agencies, born out of much the same deregulatory sentiment as the negotiated rulemaking movement.[48] The policy seems to have failed miserably, with most agencies ignoring the circular and the interagency committee

[45] Funk, above n 42, 1386.

[46] S 825, 95th Cong, 1st sess, 123 Cong Rec 3156, 3170 (1977). See Hamilton, 'The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety and Health' (1978) 56 *Texas L Rev* 1329, 1437 *et seq*.

[47] Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, Pittsburgh, 1997) 133.

[48] See Hamilton, 'Prospects for the Nongovernmental Development of Regulatory Standards' (1983) 33 *American U L Rev* 455. Less enthusiastic, Baram, *Alternatives to Regulation: Managing Risks to Health, Safety and the Environment* (Lexington Books, Lexington, 1982).

charged with implementing it disbanding in 1987 for lack of interest.[49] The issue was rekindled with the passing of the National Technology Transfer and Advancement Act of 1995.[50] The Act entrusted standards policy to the National Institute of Standards and Technology, a government agency attached to the Department of Commerce,[51] which is directed to 'coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations.'[52] Accompanying the policy change, a number of agency statutes were modified in order to encourage or even oblige regulators to take account of standards.[53] Moreover, the OMB revised the Circular in 1998. It instructs all federal agencies to use 'voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.'[54] In that case, the agency must submit a reasoned statement

[49] Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990) 224. He blames vague language and lack of guidance. Cf Jim Turner, Chief Democratic Counsel, US House of Representatives' Committee on Science, 'Government Use of Voluntary Private Sector Standards—Still a Work in Progress', Speech delivered at the 2000 Annual Conference of the SAE, 15 August 2000 ('A–119 sat on the books, largely unenforced, for the next 15 years. It takes a long time to break old habits.')

[50] Pub Law 104–13.

[51] Formerly the National Bureau of Standards, the outfit changed its name in 1989. Established in mid industrial Revolution, 1901, the Bureau has long been associated with Fordist standardisation, then was turned into an agency for 'science policy' for the nuclear age, and was threatened with abolition by the cost cutting Republican Congress as late as 1995. It now limits itself to a coordinating role. Samuel Krislov calls it a 'strange operation'. Krislov, above n 47, 100.

[52] 15 USC 272 (b) (3). See Meidinger, 'Environmental Certification Programs and US Environmental Law: Closer Than You May Think' (2001) 31 *Env L Rep* 10162, 10169 ('The exact reach of the statute remains open to interpretation, particularly because it does not define key terms such as "technical standard" and "voluntary consensus body." Nonetheless, it seems likely to exert a steady pull on agency practice over time.')

[53] See eg The Food and Drug Administration Modernization Act of 1997, Public Law 105–15, Section 204, amending 21USC 360d. The FDA is to establish a list of 'recognised standards' for devices in addition to its own performance standards. See (1999) 64 FR 37546. ASTM standards dominate together with those adopted by the National Committee for Clinical Laboratory Standards, with a fair share of ISO and IEC standards. EN 1441 (1997)—Risk analysis for medical devices—is the only European standard recognised. The FDA will recognise 'standards developed by any organisation where the standard development process is transparent (ie, open to public scrutiny), where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope'. See the 'Guidance for the Recognition and Use of Consensus Standards' (1998) 63 FR 9561.

[54] OMB Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities, 2 October 1998, Article 6. See 15 USC 272 note (Supp IV 1998), (Utilisation of Consensus Technical Standards by Federal Agencies). In 1995, the National Research Council's Board on Science, Technology and Economic Policy urged Congress to replace the Circular with legislation. See National Research Council, *Standards, Conformity Assessment, and Trade: Into the 21st Century* (National Academic Press, Washington, 1995), Recommendation 3 (on the basis that 'current efforts by the US government to leverage the strengths of the private US standards development system are inadequate' and that 'effective, long-term public-private cooperation in developing and using standards requires a clear division of responsibilities.')

to the OMB explaining the reasons why it refuses to defer to voluntary standards. Moreover, all federal agencies are required to consult with and participate in voluntary consensus standards bodies in order to eliminate the necessity for the development of Government-unique standards.[55] Despite all the effort, it seems the policy is off to a shaky start. On the one hand, the number of standards used by federal agencies is up from 187 in 1997 to 5453 in 2000.[56] On the other hand, outside the military and space industries, the numbers of government standards displaced by voluntary consensus standards are negligible.[57] The development of the numbers of government standards used in place of voluntary standards is erratic, starting from 7 in 1997 rising to 88 in 1999 and coming back again to 16 in 2000.[58] Paradoxically, increased reliance on private standards is accompanied by a sharp decrease in agency staff participation in technical committees—from 1997 to 2000, the number of participants fell by half to under 3000.[59] The Circular is not a shining example of a clear policy document. It instructs agencies to recognise the positive contribution of standards development:

[55] Above, Article 7.

[56] See NIST, Annual Report on the Implementation of OMB Circular and PL 104–13, Fiscal Year 1997, October 1999; Fourth Annual Report on Federal Agency Use of Voluntary Consensus Standards, Fiscal Year 2000, March 2002.

[57] Over 1997, the EPA managed to substitute 4 standards, as compared to 58 of the Department of Defence and 92 of NASA. See NIST, Annual Report on the Implementation of OMB Circular and PL 104–13, Fiscal year 1997, October 1999. Over 2000, a total of 537 government standards were substituted for by private standards: of these, the DOD is responsible for 509, while NASA and the EPA managed none; otherwise, only the Department of Transport puts up numbers of any significance (11). See NIST, Fourth Annual Report on Federal Agency Use of Voluntary Consensus Standards, Fiscal Year 2000, March 2002.

[58] See NIST, Annual Report on the Implementation of OMB Circular and PL 104–13, Fiscal Year 1997, October 1999; Annual Report on the Implementation of OMB Circular and PL 104–13, Fiscal Year 1999, October 2001; Fourth Annual Report on Federal Agency Use of Voluntary Consensus Standards, Fiscal Year 2000, March 2002.

[59] NIST, Fourth Annual Report on Federal Agency Use of Voluntary Consensus Standards, Fiscal Year 2000, March 2002. Even from 1999 to 2000 the numbers fell by 110 to 2723. Though hardly the cause for this state of affairs, public officials' participation in private standards setting bodies is dogged by two legal provisions from before the public private partnership age. First, under 18 USC 208, the financial interests of any 'organisation in which he is serving as officer, director, trustee, general partner or employee' are imputed to public officials, which renders their fulfilling such functions illegal. Authoritative opinion considers that the NTTAA and the OMB Circular override the prohibition as regards actual involvement in standard setting, but not for any administrative or managerial functions. See *Memorandum* for Marilyn L Glynn, General Counsel, Office of Government Ethics, from Beth Nolan, Deputy Assistant Attorney General, Office of Legal Counsel, Department of Justice, 24 August 1998. Second, there is a 'recently discovered' law from 1912, on the books in 5 USC 5946, which prohibits federal funds to be used for payment of 'expenses of attendance of an individual at meetings or conventions of a society or association' unless such is authorised by a specific appropriation. The issue was raised in a statement by Oliver R Smoot, ANSI, before the Science Committee Subcomittee on Technology, Environment and Standards, House of Representatives, 28 June 1998. The problem is about to be solved, as Section 1124 of Senate Bill 1438, approved on 2 October 2001, disapplies 5 USC 5946 for purposes of the National Technology Transfer and Advancement Act.

> When properly conducted, standards development can increase productivity and efficiency in Government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment.

Yet, agencies should also recognise that use of standards, 'if improperly conducted' can accomplish exactly the opposite. Participation in standardisation is limited to the 'public interest' and a determination of compatibility with agency 'missions, authorities, priorities, and budget resources'.

NIST signed a Memorandum of Understanding with the American National Standards Institute in 1998. In it, ANSI pledges to develop and publish American National Standards in accordance with the principles of openness, due process, balance of interests and consensus, and to meet the obligations of the WTO Code of Good Practice. NIST takes it upon itself to co-ordinate standards activities with responsible government agencies to use voluntary standards to the extent practicable, to participate appropriately in their development, and to ensure that they meet federal agency needs.[60] Most conspicuous is the absence of any clear commitment to strengthen the regulatory role of the voluntary standards system. There is an explicit policy statement of not establishing any preference between consensus and non-consensus standards. Within the category of consensus standards, the Circular refuses to make any reference to the ANSI accreditation system,[61] relying instead on rehearsing the general hallmarks of openness, balance of interest, consensus, and an appeals mechanism.

4.2 Manufactured Housing Standards

The state-of-the-art of the new regulatory policy is probably best illustrated by the recent overhaul of the Manufactured Housing Construction and Safety Standards Act.[62] The 1974 Act was a fairly traditional piece of legislation, instructing the Secretary of Housing and Urban Development (HUD) to establish standards under traditional APA rulemaking procedures.[63]

[60] MOU between ANSI and NIST, signed 24 September 1998.

[61] Much to the chagrin of ANSI. See ANSI, *National Standards Strategy for the United States*, 2000, 8 ('US Government should encourage more use of the principles embodied in accreditation by recognising the ANSI process as providing sufficient evidence that American National Standards (ANS) meet federal criteria for voluntary consensus standards').

[62] 42 USC 5401 *et seq.*

[63] Section 604 (b), Public Law 93–383, 22 August 1974, 88 Stat 700. These standards are to be 'reasonable' and 'meet the highest level of protection', and to be issued after considering 'relevant safety data' as well the probable effect on the cost to the public. Above, Sections 604 (a) and (f). Review is under the 'arbitrary and capricious' standard, not under the 'substantial evidence' standard. See *Florida Manufactured Housing Association v Cisneros* 53 F 3d 1565, 1573 (11th Cir 1995), distinguishing from *Motor Vehicle Manufacturers*, above n 19, on grounds of legislative history.

Additionally, before establishing, amending or revoking these FMHCSS, the agency was to consult, 'to the extent feasible,' an Advisory Council made up of consumers, industry and public authorities.[64] Moreover, in the development of the standards, HUD was 'authorised' to 'advise, assist and co-operate with' interested public and private agencies.[65]

In practice, of course, the standards inevitably incorporate a large number of private standards.[66] Upon publication of the OMB Circular in 1982, HUD announced its intention to select a private standards body to assist in the development of standards, adding that such an approach would 'not be difficult', given how a large part of the federal standards were adopted from standards developed through the voluntary consensus process anyway.[67] Nothing was heard of the policy until 1987, when HUD published a call for tender for the job,[68] and announced a year later that it had selected CABO.[69] The exercise was repeated in 1997,[70] and in a further bitter instalment of the battle of the codes,[71] CABO was ditched in favour of the NFPA.[72]

Legally, the role of the 'designated' standards body is one of pure pre-rulemaking consultation. HUD emphasised on both occasions that the arrangement did not include an obligation for it to use or pay for the standards developed by the selected body, nor an obligation on that body to develop recommended standards. If it announced in the 1987 notice that only the standards adopted by the selected body would be incorporated into the federal standards,[73] that monopoly was abolished before it was granted:

[64] Above, Section 605.

[65] Above, Section 609.

[66] 24 CFR 3280.4 lists 26 associations the specifications, standards and codes of which are incorporated by reference. 24 CFR 3280.703 requires heating, cooling and fuel burning appliances to be 'free of defects' and to be conform to a long list of ANSI, ASME, ASTM, NFPA, IAPMO, SAE and UL standards, with the laconic proviso that where more than one applicable standard is referenced, compliance with any one them meets the requirements of the federal standard.

[67] HUD, Notice, Manufactured Home Construction and Safety Standards, (1982) 47 FR 29605.

[68] HUD, Notice requesting a Private Organization to Develop and Maintain the Federal Manufactured Home Construction and Safety Standards, (1987) 52 FR 4663.

[69] HUD, Notice Announcing the Selection of a Private Organization to Develop Model Federal Manufactured Home Construction and Safety Standards, (1988) 53 FR 4463. CABO was preferred to ASTM, UL and a joint proposal from the NFPA and the National Conference of States on Building Codes and Standards (NCSBCS).

[70] HUD, Notice Requesting Statements of Interest From Private Organizations to Administer a Voluntary Process for the Development of Suggested Manufactured Housing Standards, (1997) 62 FR 42382.

[71] See below.

[72] HUD, Notice Announcing the Selection of a Private Consensus Standards Development Organization, (1998) 63 FR 30509. CABO found it 'curious' that HUD would have found it necessary to solicit new proposals, never having had 'any negative feedback'. See 'Federal Register Solicits Interested Organizations', *CABO Newsletter*, August 1997.

[73] HUD, Notice requesting a Private Organization to Develop and Maintain the Federal Manufactured Home Construction and Safety Standards, (1987) 52 FR 4663.

> Although CABO was selected under the notice of February 13, 1987 to develop standards, the Department will consider standards developed by other organizations on an equal basis with standards developed by CABO for incorporation into FMHCCS. The Department does not consider CABO as an exclusive or preferred source of model standards. Interested organizations may submit model standards for consideration to HUD at any time.[74]

HUD itself made it clear that it would not 'relinquish its responsibility and its authority under the Act to establish and enforce the FMHCSS' even if it 'hoped' and 'intended' to be able to accept as a proposed rule the standards developed by the designated body.[75] Most importantly, the arrangement left the APA rulemaking procedures and the Act's own consultation mechanisms completely untouched. The 'designated' standards body in no way replaced the Advisory Council, and the origin of model standards in no way detracted from HUD's notice-and-comment obligations under the APA, not from its obligations to provide cost/benefit analyses and statements of reasons.

The whole complicated system led to an enormous backlog of standards in HUD.[76] The 2000 amendments, in a move to address both efficiency and accountability, simultaneously give greater weight to private standards and tighten the public hold over the standard-setting process itself.[77] The distinction between public rulemaking, balanced consultation and private standardisation is collapsed and a hybrid process is established.[78] The Advisory Council is abrogated and HUD is to establish a 'consensus committee' itself in accordance with ANSI procedures and criteria but with adapted interest categories.[79] Once appointed by HUD, however, the committee is to be run by an 'administering organisation', defined as a 'recognised, voluntary, private sector, consensus standards body,'[80] under a competitively awarded contract.[81] The committee is to operate in con-

[74] HUD, Notice Announcing the Selection of a Private Organization to Develop Model Federal Manufactured Home Construction and Safety Standards, (1988) 53 FR 4463.

[75] HUD, Notice Requesting Statements of Interest From Private Organizations to Administer a Voluntary Process for the Development of Suggested Manufactured Housing Standards, (1997) 62 FR 42382.

[76] From the floor: 'There are more than 150 proposed changes to construction and safety standards currently pending at HUD. Some of these are more than five years old.' Mr LaFalce, 146 Cong Rec H10687 (2000).

[77] The Manufactured Housing Improvement Act 2000, Title VI of the American Homeownership and Economic Opportunity Act 2000, Public Law 105–569, 27 December 2000, 114 Stat 2944.

[78] To the anger of the standardisation community. See eg Milder, 'Blurring the Boundaries—New Manufactured Housing Bill Challenges the Independence of Standards Development and Regulation', *ASTM Standardization News*, January 2000, 26.

[79] 42 USC 5403 (a) (2) (D).

[80] 42 USC 5402 (14). Committee members are reimbursed by HUD 'for actual expenses.' 42 USC 5403 (a) (3) (G).

[81] 42 USC 5403 (a) (2) (B).

formance with ANSI procedures and the 'administering organisation' is to seek ANSI accreditation.[82] The committee is bound to operate on two-year development cycles.[83] When it adopts a draft standard, it is published for notice and comment in the Federal Register in accordance with the APA.[84] That exercise, however, also doubles as a public review process in accordance with ANSI procedures.[85] Only after publishing notice of the committee's revisions,[86] can HUD decide whether or not to adopt the committee's standard. If it does, it is allowed to issue a final order 'without further rulemaking'.[87] If the standard is rejected, the agency is to publish notice to that effect accompanied by a statement of reasons.[88] Finally, when HUD decides that the committee standard is to be modified, the whole exercise will have been for naught. In that case it is to publish the modified standard for notice and comment, explain its reasons, and start APA rulemaking from scratch.[89] Conspicuously, practically the only part of the Act to remain intact is the provision for judicial review.[90] It seems, then, that the legalisation dilemma is solved in case HUD decides to adopt the standard. In that case, it is excused from 'further rulemaking' and the implication must be that courts are to accept the committee's adherence to ANSI procedures to pass 'arbitrary and capricious' muster.[91] In case the standard is rejected or modified, however, the dilemma is still there.

4.3 The Occupational Safety and Health Administration

When the Occupational Safety and Health Administration was established in 1970, part of the plan was for it to replace private organisations such as the American Conference of Governmental Industrial Hygienists (ACGIH) as the main standards body for occupational hazards. For the first two years of its operation, the statute allowed OSHA to adopt 'national consensus standards' as mandatory standards without the

[82] 42 USC 5403 (a) (2) (H). The Act does specify a two-thirds majority on the committee for approval of standards, and obliges the committee to engage in economic analysis. 42 USC (a) (4) (A) (ii).

[83] 42 USC 5403 (a) (4).

[84] 42 USC 5403 (a) (4) (B) (i).

[85] 42 USC 5403 (a) (4) (C) (i).

[86] 42 USC 5403 (a) (4) (C) (ii).

[87] 42 USC 5403 (a) (5) (C) (i).

[88] 42 USC 5403 (a) (5) (C) (ii).

[89] 42 USC 5403 (a) (5) (C) (iii).

[90] 42 USC 5404.

[91] In *Florida Manufactured Housing Association*, above n 63, the adoption of ASCE wind resistance standards after hurricane Andrew was subjected to extensive review, especially as regards the Secretary's cost/benefit analysis.

formalities of administrative rulemaking.[92] The importance of by-passing these became apparent as soon as OSHA attempted to modify these standards through notice-and-comment rulemaking. At issue in *Associated Industries of New York* was an adopted ANSI sanitation standard which required one lavatory for every ten workers in all places of employment. OSHA gave in to industry pressure and issued a new rule relaxing the rule for non-industrial offices but retaining the standard for industrial factories. The Second Circuit struck down the rule as 'arbitrary and capricious' and demanded from OSHA what could not have been demanded from ANSI: to 'present some justification for selecting what apparently is the highest numerical requirement in any state code.'[93] In 2000, the NFPA complained that OSHA's protracted rulemaking process translates into OSHA maintaining references to standards that date back as far as the 1950s.[94]

For the purpose of regulating health and safety at work, OSHA has been granted policing powers over the 'general duty' of employers to provide employment 'free from recognized hazards that are causing or are likely to cause death or serious physical harm'.[95] It also has the rulemaking authority to promulgate mandatory 'occupational health and safety standards' which are to be 'reasonably necessary or appropriate' to provide safe or healthful employment.[96] 'Any person adversely affected' by such a standard may seek judicial review. The statute itself instructs judges to look at 'substantial evidence in the record taken as a whole', a standard of review which has been interpreted as a harder look than the 'arbitrary and capricious' standard of the APA.[97] The Supreme Court has defined as substantial such evidence 'as a reasonable mind might accept as adequate to support a conclusion.'[98] In the landmark *Benzene* case, the Court deduced from the Statute's demand for 'reasonably necessary or appropriate' standards the requirement 'to make a threshold finding that a place of

[92] Occupational Health and Safety Act (1970), last amended by Public Law 105–241, 29 September 1998, 29 USC 651–78, 655 (a). McGarity and Shapiro, *Workers at Risk: The Failed Promise of the Occupational Safety and Health Administration* (Praeger, Westport, 1993) 42, note that '[t]he agency's early enforcement actions focused on violations of the national consensus standards, many of which were hopelessly vague or 'needlessly detailed' and some of which were plainly ridiculous.'

[93] *Associated Industries of New York State v US Department of Labor* 487 F 2d 342, 351 (2nd Cir 1973).

[94] John Biechman, Vice President for Government Affairs, NFPA, 'The Role of Consensus Standard Setting Organizations with OSHA', Testimony before the Subcommittee on the Workforce Protection Committee on Education and the Workforce, US House of Representatives, 1 November 2000.

[95] 29 USC 655 (a) (1) jo (8) and (9).

[96] Above, Section 6 (a).

[97] Above, Section 6 (f). Cf *AFL–CIO v OSHA* 965 F 2d 962 (11th Cir 1992).

[98] *American Textile Manufacturers Institute v Donovan* 452 US 490, 521 (1981), applying to the OSH Act a formula first pronounced in *Universal Camera Corporation v NLRB* 340 US 474, 477 (1951).

employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices'.[99] Judicial review of OSHA standards, then, has led to a 'race to the courthouse'[100]

Even if Judge Posner on the Seventh Circuit, in a generous mood, described the duty of reviewing courts as merely 'to patrol the boundaries of reasonableness',[101] OSHA does find itself in the sometimes unreasonable position of having to convince courts it has made the correct decision by presenting scientific studies, risk assessments, both supportive and countervailing evidence and then explaining in great detail and with stated reasons every step of the way why it has done what it has done.[102] This is burdensome and costly, creates insecurity as to what will hold up and what will not, and places a premium on non regulation.[103] Intrusive judicial review, and the conservative rulemaking it produced, then, has been identified as one of the major reasons for OSHA's 'failed promise'.[104]

Litigation against OSHA is instigated either by trade unions or, more frequently, by trade associations. Significantly, the American Petroleum Institute, the American Dental Association, the American Textile Manufacturers Association and the American Iron and Steel Institute, all involved in litigation against OSHA standards, are all ANSI-accredited standards developers.[105] In line with general regulatory policy, the OSH Act itself gives preferential treatment to the adoption of private standards by OSHA. Section 6 (b)8 provides:

> Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time,

[99] *Industrial Union Department, AFL–CIO v American Petroleum Institute et al* 448 US 607, 642 (1980).

[100] Cherrington, 'The Race to the Courthouse: Conflicting Views Toward the Judicial Review of OSHA Standards' [1994] *Brigham Young U L Rev* 95. Cherrington argues for even stricter review.

[101] *American Dental Association v Martin* 984 F 2d 823, 831 (7th Cir 1991).

[102] Most litigation stems from standards on toxic substances where Section 6 b (5) requires OSHA to set the standard 'which most adequately assures, to the extent feasible, on the basis of the best available evidence' that no employee will suffer damage to his health. Justice Rehnquist considers 'to the extent feasible' unconstitutional delegation by Congress. Cf Rehnquist, concurring in *Industrial Union Department, AFL–CIO v American Petroleum Institute et al* 448 US 607, 671 (1980) and dissenting in *American Textile Manufacturers Institute v Donovan* 452 US 490, 543 (1981).

[103] The Third Circuit has, however, compelled OSHA into 'unreasonably delayed' action after the agency failed to update the consensus standard for exposure to hexavalent chromium for over thirty years. See *Public Citizen Health Research Group v Elaine Chao* 314 F 3d 143 (3rd Cir 2002). Four years earlier, it had found the delay still 'reasonable'. See *Oil Workers Union v OSHA* 145 F 3d 120 (3rd Cir 1998).

[104] McGarity and Shapiro, above n 92. Cf Mendeloff, *The Dilemmas of Toxic Substance Regulation: How Over-regulation Causes Under-regulation at OSHA* (MIT Press, Cambridge, 1988).

[105] For the API, the ADA and ATMA, see above. Cf *American Iron and Steel Institute v OSHA* 182 F 3d 1261(11th Cir 1999). The equivalent would be for, say, CEN to challenge the EMAS Regulation before the ECJ.

> publish in the federal register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.[106]

A 'national consensus standard' is then defined as one

> adopted and promulgated by a nationally recognised standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope of provisions of the standard have reached substantial agreement on its adoption, [and] was formulated in a manner which afforded an opportunity for diverse views to be considered.[107]

Adopting private standards as mandatory OSHA standards thus functions as the equivalent of negotiated rulemaking. Three differences do exist, however. First, negotiated rulemaking involves the active participation of the agency. Second, 'consensus' under negotiated rulemaking means unanimity. Third, private standards referenced in OSHA regulations are mandatory only in those provisions where the standard itself uses mandatory language.[108]

Lack of updated standards is an obviously good reason not to use private standards. In 1988, OSHA stated that because of the problem of outdated ANSI standards, it 'has avoided the use of incorporation by reference whenever possible in recent years, and has attempted to include all relevant provisions within the regulatory text.'[109] In case a private standard addresses a hazard the OSHA standard does not, it is stated policy to use the standard under the 'general duty' clause. A standard is evidence

[106] In *AFL–CIO v Brennan* 530 F 2d 109, 115–16 (3rd Cir 1975), the Court held that this does not impose a higher burden of proof that would otherwise apply to a safety standard: 'Saddling the Secretary with the burden of proving to our satisfaction the scientific superiority of every departure from a national consensus standard—a burden which in many instances he cannot meet—might well in the long run compromise the cause of safety in the workshop.' This did not stop the Court from striking down OSHA's attempt to revoke a—strict—ANSI standard adopted under Section 655 (a) in favour of a more relaxed standard, notwithstanding readily acknowledging that ANSI had never meant the standard to be more than a 'guideline' and that the ANSI Committee concerned was in a position 'where it can neither obtain consensus on a revision nor reaffirm the standard'. 530 F 2d 109, 122, n 5.

[107] 29 USC 652 (9). While OSHA maintained that '[t]he relevant legislative history of the Act indicates congressional recognition of the American National Standards Institute and the National Fire Protection Association as the major sources of national consensus standards' it did invite 'any organization which deems itself a producer of national consensus standards' to make its case. 29 CFR 1910.3.

[108] OSHA regulations generally provide: 'The standards of agencies of the US Government, and organizations which are not agencies of the US Government, have the same force and effect as other standards in this part. Only the mandatory provisions (ie, provisions containing the word "shall" or other mandatory language) of standards are adopted as standards under the OSH Act.' Cf for example 29 CFR 1910.

[109] (1988) 53 FR 116, 117.

of both the fact that the hazard is 'recognised' and of a 'feasible and accepted method of abating the hazard'.[110]

This is the official version of OSHA's journey:

> Several years ago, OSHA recognised the need for to find a better way to carry out its mission—to save the lives and improve the safety and health of America's men and women. In the regulatory arena, this meant that OSHA had to change its regulatory approach to establish clear and sensible priorities and emphasise consensus-based approaches to rulemaking.'[111]

This new approach culminated in 2001 with the signing of a Memorandum of Understanding between OSHA and ANSI.[112] Intended 'to enhance and strengthen the national voluntary consensus standards system of the United States and to support continued US competitiveness, economic growth, safety, and health,' the document provides for various mechanisms of mutual technical assistance, information sharing and 'consultation in the planning of occupational safety and health standards development activities.' OSHA will participate on 'selected ANSI accredited standards committees.' ANSI will 'continue to encourage the development of national consensus standards for occupational safety and health issues for the use of OSHA and others.'

4.4 The Consumer Product Safety Commission

The Consumer Product Safety Commission, established in 1972, provides, according to Cheit, 'close to the "worst case" example of government regulation', its history marked by 'poor judgment and failure',[113] the few standards it manages to issue overturned in court.[114] The saga of the Commission's Safety Standard for Architectural Glazing Materials is a horror story of the perverse impact of judicial review on rulemaking. The Standard was first promulgated in 1977 to reduce the risk of injury of broken glass doors, shower enclosures and the like.[115] The standard covered wired glass, a material imposed by several local fire codes for fire doors. Yet, at the time, no wired glass existed that could satisfy the standard. Accordingly, the Commission granted a two-year exemption for wired

[110] See eg *Nelson Tree Services v OSHA* 60 F 3d 1207 (6th Cir 1995). See generally on the role of private standards in ensuring compliance with the OSH Act, Shapiro and Rabinowitz, 'Voluntary Regulatory Compliance in Theory and Practice: The Case of OSHA' (2000) 52 *Admin L Rev* 97, 133 ff.

[111] Department of Labor, Regulatory Plan, (2000) 65 FR 73408.

[112] Memorandum of Understanding between the Occupational Safety and Health Administration and the American National Standards Institute, signed 21 January 2001.

[113] Cheit, above n 49, 34.

[114] See eg *Aqua Slide–In Dive Corporation v CPSC* 569 F 2d 831 (5th Cir 1978).

[115] 16 CFR 1201.

glass to allow for technological advance. The DC Circuit remanded to the Commission, noting a general 'absence of a process of reasoned decision making' and finding no factual basis for limiting the exemption to two years.[116] The Commission then completely abandoned any effort to set standards for wired glass and simply struck the two year limitation from the regulations, effectively liberating wired glass manufacturers from any safety obligations indefinitely. The Commission was petitioned to include wired glass in the standard in 1992, in the light of the technological advances that were made meanwhile. The Commission, burnt once, refused, a decision held up in the Ninth Circuit under 'arbitrary and capricious' criteria.[117] Mashaw and Harfst draw the analogy with the experience of NHTSA, and find that 'CPSC's rulemaking power has atrophied while its primary regulatory activity has become product recalls.'[118] Cheit paints an analogous picture of the CPSC relying on labelling requirements rather than writing a standard which would prove hard to support in court.[119]

The original statute provided for two innovative procedures of participation in its rulemaking process. One was a 'petition' mechanism, whereby any party could request the Commission to initiate drafting a standard. Reasons for a decision to deny the petition were to be published in the *Federal Register*—subject to review in a district court by a trial *de novo*.[120] The 'offeror' procedure obliged the CPSC to 'invite' competent outside groups to develop the mandatory standard. Standards thus produced could not be modified by the Commission except through a full rulemaking process, including another 'offeror' procedure.[121] In Mashaw's phraseology, the progressive logic of participation soon turned into a progressive logic of disaster, causing not only debilitating delays but industry capture.[122] Congress repealed the two procedures in the 1981 overhaul of the Act.

This deregulatory amendment practically forces the Commission to abstain from rulemaking and rely on voluntary standards.[123] The CPSC is authorised to promulgate mandatory standards which are 'reasonably

[116] *ASG Industries v CPSC* 593 F 2d 1323 (DC Cir 1979).

[117] *O'Keeffe's v CPSC*, No 94–70580, decided 13 August 1996 (9th Cir).

[118] Mashaw and Harfst, above n 29, 310.

[119] Cheit, above n 49, 119.

[120] 15 USC § 2059, repealed 1981. Under the APA, agencies are merely to give 'prompt notice' of a petition's denial, and a 'brief statement of the grounds for denial'. Review is under the 'arbitrary and capricious' standard. See 5 USC §555 (e), 706 (2).

[121] 15 USC § 2056, repealed 1981.

[122] Mashaw, *Due Process in the Administrative State* (Yale University Press, New Haven, 1985) 262. Cf Schwartz, 'The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade' (1982) 51 *G Wash L Rev* 32; Rossi, 'Participation Run Amok: The Costs of Mass Participation for Deliberative Decisionmaking' (1997) 92 *Northwestern U L Rev* 173.

[123] See Klayman, 'Standard Setting Under the Consumer Product Safety Amendments of 1981—A Shift in Regulatory Philosophy' (1982) 51 *G Wash L Rev* 96, 112 (speaking of the 'elimination of public initiative in the promulgation of standards' and a government that 'is shifting its philosophy towards the self-regulation model of the pre-CPSA era'). Cf Howells, *Consumer Product Safety* (Ashgate, Aldershot, 1998) 210.

necessary to prevent or reduce an unreasonable risk of injury', but is to restrict itself to performance standards and labelling requirements.[124] It is required to rely on voluntary standards rather than issue mandatory standards of its own 'whenever compliance with such standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards.'[125] If compliance is deemed unlikely, the Commission may adopt a private standard as a mandatory standard.[126] The CPSC is required, upon notice of proposed rulemaking, to invite statements of intention to modify and develop a voluntary consumer product standard to address the risk of injury' and to provide standards bodies with technical and administrative assistance.[127] If it still pushes through with a mandatory standard, it is to provide 'a discussion of the reasons' for its finding that all these efforts would not be likely to result in the development, within a reasonable period of time, of an adequate voluntary standard.[128]

In 1985, the Commission voted down a policy proposal that would have allowed for the 'recognition' or 'endorsement' of voluntary standards because of lack of resources and fear of liability suits.[129] As it stands then, the Commission has a choice between all or nothing: wholesale administrative adoption of a private standard as a mandatory standard, or leaving the regulation of product safety up to private standardisation bodies. A 1995 CPSC policy paper comes up with the slogan 'negotiate, don't dictate' to describe the resulting regulatory style:

> The Commission has found that with the products it regulates, negotiating such standards can be far more efficient than rulemaking or even negotiated rulemaking. CPSC always attempts to work cooperatively with industry to address safety hazards. It is far more effective for CPSC and industry to work together than for the agency to dictate mandatory standards. Industry knows its own products best and obviously has considerable technical expertise. Accordingly, the Commission uses mandatory standards only as a last resort when negotiated voluntary standards and the marketplace prove ineffective.[130]

[124] 15 USC §§ 2051–84, 2056 (a).

[125] Above, (b), 2058 (a) 3 (D). Compare CPSC, Commission involvement in the development of voluntary standards, (1978) 3 FR 19216 ('While there might be circumstances in which a particular voluntary standard can substitute for a mandatory standard, the Commission generally views voluntary standards as complementary to and not a substitute for mandatory standards.'); CPSC, Commission Participation and Commission Employee Involvement Participation in Voluntary Standards (1989) 54 FR 6646.

[126] Above, 2058 (b) (1).

[127] Above, 2045 (a) 3, 2058 (a) 6,

[128] Above, 2058 (c) 3.

[129] See CPSC, 'Recognition and Endorsement of Voluntary Safety Standards Turned Down by CPSC', Press Release, 18 January 1985 (www.cpsc.gov).

[130] *US Consumer Product Safety Commission Regulatory Reform Initiative, Report*, June 1995, at 21. See also CPSC, Statement of Regulatory Priorities, (2000) 65 FR 73522. The one recent show of strength of the CPSC is its proposed rulemaking on metal-cored candle wicks

5. CONCLUSION

Explaining the increased reliance of American regulatory law on private standards in terms of judicially induced and politically celebrated emasculation of agency rulemaking is, perhaps, fanciful. Concerted efforts on the part of industry to litigate federal agencies to death with the ready help of courts and then to impose a system of self-regulation is only part of the story—if an important part. The phenomenon is certainly not only due to reasons endogenous to the American legal system and legal culture. But there is no denying of the strong explanatory power of the 'legalisation dilemma' and the spiral it produces. At every stage, increased regulatory power has been compensated for by increased procedural demands of rationality and due process. And in that sense, it may well be that private standards-setting in the United States will soon be caught squirming under 'hard looks' and all the paraphernalia of administrative due process. And in that case, it may well be that the 'official' voluntary consensus standards system will be undermined by the very same forces that undermined agency rulemaking—in which case the temptation will surely arise to rely more on 'unofficial' *de facto* standards. And so on.

containing lead, (2002) 67 FR 20062 (considering a standard of *Voices of Safety International* (VOSI) 'technically unsound' and adding: 'Even if a technically valid voluntary standard were developed, the Commission maintains that a mandatory standard is necessary to adequately protect public health.')

4

Standards in the European Union

1. INTRODUCTION

IF IT HAS been relatively easy for the European Community to work out a productive relationship with the European standards bodies, this is mostly due to the collective experience of close relations between standards bodies and public authorities on the national level. To be sure, the differences between the national standards systems of EC Member States are enormous. Some standards bodies are government agencies, some are completely private; in some countries all standardisation activity is concentrated in one institution, in others there are several sectoral bodies. By and large, however, European standardisation is relatively centralised, relatively closely tied to the public authorities, and relatively well endowed with resources. What is more, standards systems are converging towards what could be termed a 'European model' featuring centralised private associations enjoying public recognition and monopoly power, elaborating and promulgating standards according to a rather homogenous set of procedures built on the core principles of consensus, openness, and transparency. This chapter starts with an institutional and procedural discussion of the European Standardisation Committee. The bulk of the chapter is concerned with national standards systems and the influence exercised upon them by the Europeanisation of standardisation.

2. 'EUROPEAN' STANDARDS

2.1 The European Standardisation Committee (CEN)

The *Comité Européen de Normalisation* (CEN) was established in 1961 in Paris by several national standards bodies under the aegis of AFNOR.[1] In

[1] See generally eg Vos, *Institutional Frameworks of Community Health & Safety Regulation—Committees, Agencies and Private Bodies* (Hart Publishing, Oxford, 1999) 255 ff; Zubke von Thünen, *Technische Normung in Europa* (Duncker & Humblot, Berlin, 1999); Egan, *Constructing a European Market—Standards, Regulation and Governance* (OUP, Oxford, 2001) 133 ff. As throughout, electro-technical standardisation is not discussed. For a discussion of Cenelec, see eg Winckler, *Electrotechnical Standardization in Europe: A Tool for the Internal Market* (Cenelec, Brussels, 1994).

1975, the operation moved to Brussels and acquired the status of a private non-profit association under Belgian law by publication of its statutes in the *Moniteur Belge* on 29 January 1976. The association's statutory aim is 'the implementation of standardisation throughout Europe to facilitate the development of the exchange of goods and services, by the elimination of the barriers set by provisions of a technical nature.'[2] In 1975, it had a catalogue of 20 European standards; in 1985, that number had increased to a mere 250. Currently it has a catalogue of more than 7500 standards.[3] Even if it is often assumed, implicitly or explicitly, that CEN standards are drafted exclusively in support of Community policies,[4] particularly in the framework of the 'New Approach', these actually merely account for around a third of total standards production.[5]

The association has more than 250 active technical committees and an annual expenditure of 23 million Euro.[6] The EU and EFTA put up some 15 million Euro through subsidies and project financing;[7] almost 5 million Euro comes from Membership contributions.

CEN functions as an umbrella organisation; its members are the 28 national standards bodies (NSBs) of the 25 EU Member States, and of EFTA countries Iceland, Norway, and Switzerland.[8] A number of standards bodies from predominantly Eastern European countries have the status of 'Affiliated member'.[9] The European Commission and the EFTA Secretariat have the mysterious status of 'Counsellors', which enables them to participate in the General Assembly and in those meetings of the Administrative Board where policy issues are

[2] Article 4, CEN Statutes, as published in the *Moniteur Belge* on 18 March 1993.

[3] In 2002, CEN published 990 new standards. See DIN, *Geschäftsbericht* 2002.

[4] Cf Egan, 'Regulatory Strategies, Delegation and Market Integration' (1998) 5 *JEPP* 485, 493 (noting that 'the bulk of activity' in recent years has come from specific mandates under the New Approach).

[5] CEN reports 1950 ratified mandated standards in June 2001 and a total work programme of roughly 3500. See CEN, Annual Report 2000–1.

[6] CEN, Annual Report 2000–1. CEN's president puts the total real cost of its standardisation activities at 700 million Euro and the equivalent of 5000 person years.

[7] The Commission's assertion is hence easily, and disingenuously, made that 'only' 2% of 700 million Euro represents 'good value for money compared to the relatively strong influence that EC and EFTA have in promoting their policies through this system.' Commission Report on Actions Following the Resolutions on European Standardisation Adopted by the Council and the European Parliament in 1999, COM (2001) 527 final, 16.

[8] CEN's Statutes limit national membership to member states of the EC and EFTA or 'countries likely to become member states of EC or EFTA' Article 6.2. As of 1 January 2004, CYS–Cyprus, EVS–Estonia, LVS–Latvia, LST–Lithuania, SUTN–Slovakia, and SIST–Slovenia are full national members, a status already held by CSNI from the Czech Republic, the Malta Standards Authority, MSZT from Hungary and PKN from Poland.

[9] Current affiliated members are DPS–Albania, SASM–Bulgaria, DZNM–Croatia, ASRO–Romania, and TSE–Turkey. There are further a number of 'corresponding organisations' that, for a fee, receive all draft standards and ratified texts of adopted European standards. Currently, these are EOS of Egypt, DSTU of the Ukraine, SZS of Serbia and Montenegro, and SABS of South Africa.

discussed. They are also allowed to send observers to technical committee meetings.[10]

In organisation, ethos and methodology, CEN is a private 'intergovernmental' association of national delegations. It wasn't until 1992, and then under considerable pressure from the European Commission, that a category of 'Associated members' was introduced for 'organisations representative, at European level, of social and economic interests' with a 'legitimate interest' in European standardisation, the capability to contribute effectively and representatively to it, and the commitment to bring forward CEN's objectives.[11] Current associates are the European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC), the European Trade Union Technical Bureau for Health and Safety (TUTB), the European Environmental Citizens Organisation for Standardisation (ECOS), the European Office of Crafts, Small and Medium-sized Enterprises for Standardisation (NORMAPME), and four major trade federations: the European Chemical Industry Council (CEFIC), the European Committee for Co-operation of the Machine Tool Industries (CECIMO), the European Federation of Medical Devices Associations (EUCOMED), and the European Construction Industry Federation (FIEC).

Delegates from the national members and the associates form the General Assembly, the association's supreme body; only national members, however, have the right to vote. The Assembly decides by simple majority. The association is managed by the Administrative Board, acting as the Assembly's 'agent'. The Administrative Board consists of representatives of the national members; its decisions are open to review by the Assembly on the request of at least two of its members.[12] The Assembly elects a President and one or more Vice-Presidents; the President chairs both the Assembly and the Administrative Board with the right to vote only in case his would be the casting vote. The Assembly appoints, on proposal of the Administrative Board, a Secretary-General, who is to take care of the 'current and daily business of the association'. To that purpose, he is assisted by a Central Secretariat.[13]

[10] See the 1984 General Guidelines for Co-operation between the European Commission and CEN/Cenelec, doubling as CEN/Cenelec Memorandum 4, *juncto* Article 3.4.5, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

[11] Article 6.3, CEN Statutes. The Commission urged the development in its Green paper, *Action for faster technological integration in Europe*, COM (1990) 456 final, 19.

[12] Article 25, CEN Statutes, is silent on the composition of the Board apart from the one Belgian national who is always to be included. Composition and functions are described in Article 4, CEN/Cenelec Internal regulations Part 1A: Organisation and Administration.

[13] Article 33, CEN Statutes. CEN's annual accounts show the Secretariat to be financed for 47% from membership fees, and 48% from EC and EFTA support. The money is used for 56% for technical standardization activities, general administration takes up 19%, and IT work another 17%. CEN, Annual Report 2000–1.

The technical work is co-ordinated by the Technical Board, chaired by the President or a Vice-President and consisting of permanent delegates from national members who are to 'establish the necessary contacts at national level so as to be able to represent the member effectively.'[14] The Technical Board takes all major decisions concerning the technical standards work, including the creation of technical committees (TCs), the allocation of secretariats of TCs to NSBs,[15] the acceptance of Commission mandates, the imposition and release of standstill obligations, and the ratification of European standards.[16] The TB also hears appeals against decisions taken at TC level; the TB's decisions, in turn, can be appealed at the General Assembly.[17] The actual technical work is undertaken in Technical Committees, constituted by the CEN members who can send up to three properly briefed delegates. Members are to ensure that the delegation 'will convey a national point of view which takes account of all interests affected by the work.'[18] Normally, TCs are to work through 'working groups' to undertake 'specific short term tasks'; in case different expertise is needed for different parts of the work and the range of activities needs coordination over long periods of time, however, TCs can establish Subcommittees.[19]

2.2 Procedures for Standardisation

Standards work at European level starts with requests or proposals which may arrive from or through national members, from CEN technical bodies, from 'international organisations or by European trade, professional, technical or scientific organisations.'[20] Proposals are reviewed by the TB, which decides whether or not to pursue the project. Notably, Commission mandates are treated as just any other proposal and can be rejected by the TB at its discretion.

As soon as the TB establishes the need for a new work item, CEN is bound by the so-called Vienna agreement of 1991 with ISO to consider existing ISO standards or working drafts or, if no such document is avail-

[14] Article 2.1.2, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

[15] Secretariats of TCs can only be provided by National Standards Bodies. As part of its effort to break up NSB monopoly in CEN, the Commission has called on the European standards bodies to 'consider' allocating secretariats to 'European level sectoral associations (such as industrial federations.)' Commission Report, *Efficiency and Accountability in European Standardisation Under the New Approach*, COM (1998) 291, 5.

[16] Article 2.1.1, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

[17] Above, Annex A.

[18] Above, Article 2.3.2.

[19] Above, Articles 2.3, 2.4 and 2.5.

[20] Above, Articles 4.1.2 and 4.1.3.

able, to offer the work to ISO to develop, within a given time, a standard that is mutually acceptable.[21] Generally, standards development in CEN can follow two main tracks or some combination thereof. If there is some reference document, that document will be put through a 'Questionnaire procedure'—for all practical purposes, a public review process lasting three months. The replies are then considered by the relevant TC or by the TB who may decide, on the basis of response, to proceed to a formal vote on the adoption of the document as a European standard. The reference document will normally and usually be an ISO standard; however, the TB may, at its discretion, take any other 'appropriate' document as the basis for work leading towards a European standard, and consider documents prepared 'by an organisation other than ISO' for adoption as an European standard. The Technical Board may also 'subcontract' the preparatory work on such a reference document to so-called Associated Bodies. To that end, the President will have to sign a written agreement with that body upon approval of the General Assembly. That agreement should, at a minimum, provide for rights of participation by CEN members, the definition of the stage where the document will be fed into 'normal' CEN procedures, and the recognition that CEN will be solely responsible for at least formal voting and national implementation procedures.[22] CEN makes sparing use of the procedure, giving Associated Body status currently only to AECMA—the *Association europénne des constructeurs de matériel aerospatial*, and ECISS, the European Board for Iron and Steel Standardisation.

In the absence of a reference document, the drafting of one will be entrusted to a Technical Committee. Work is overseen by a chairman appointed by the TB who shall maintain 'strict impartiality and divest himself of a national point of view.' He shall do 'everything possible' to obtain unanimity in the TC; if such is not possible, he should 'try to seek consensus rather than simply rely on a majority decision.'[23] CEN adheres to the ISO definition of consensus as

> General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.[24]

[21] Above, Article 4.1.4. The Vienna agreement is reproduced in Nicolas, *Common Standards for Enterprises* (Opoce, Luxembourg, 1995) 249 ff. According to Article 3.3.1 of that agreement, at least five CEN members must commit themselves to participate in the ISO technical work.

[22] Above, Article 8.

[23] Above, Article 2.3.3. Political correctness is not a strong point of CEN.

[24] Article 1.7, EN 45020 (1993)—General Terms and their Definitions Concerning Standardization and Related Activities (ISO/IEC Guide 2:1991).

Once a draft is produced, this is subjected to the 'CEN enquiry' process consisting of a six-month public review procedure conducted at national level by the NSBs. If the results of that process show 'sufficient agreement, preferably unanimity', the TC prepares a final text subject to review of any technical comments received. That document is then submitted to the formal vote of CEN members. For approval as a European standard, a document needs a simple majority of national members and a qualified majority of 71% of the votes weighted in the same way as EU Member State votes in the Council are according to Article 205 EC.[25] On a positive vote and absent appeals, the TB ratifies the standard, sets a 'date of availability' and fixes the dates for national implementation.[26]

There is, strictly speaking, no such thing as a 'European standard': there are only national standards implementing CEN standards. The importance attached to unanimity, or at least consensus, rather than recourse to majority voting, becomes all the more apparent when one considers the obligations imposed on NSBs as regards European standards. As soon as work on a European standard starts, NSBs are subject to the standstill agreement and are bound not to take any action, either during the preparation of a European standard or after its approval, which could prejudice the intended harmonisation, and in particular not to publish a new or revised national standard which is not completely in line with an existing European standard. In case of mandated work, standstill starts 'no later' than the TB's decision to accept the mandate 'in principle'.[27] Standstill doesn't lapse until the standard is annulled.[28]

Once a European standard is adopted, CEN members are bound to implement it, regardless of their vote,[29] by (a) giving it the status of a national standard, either by publication of an identical text or by endorsement, and (b) by withdrawing any conflicting national standards.[30]

[25] Article 5.1.5.1, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work. This includes the contested amendments made by the Nice Treaty in view of enlargement, and thus gives DIN 29 votes, PKN 27, SIS 10, and MSA 3.

[26] Above, Article 4.5.5.

[27] Above, Article 6.3.

[28] Above, Article 6.1.

[29] For standards bodies from neither EU Member States nor Norway and Iceland (the EEA), the arrangement is a little more complicated. A standard adopted with a 71% majority from *all* CEN members is to be implemented by *all* CEN members. A standard adopted by a 71% majority from EEA members with the exclusion of the votes of non-EEA members is only to be implemented by non-EEA members if they have voted affirmatively. Above, Article 5.2 and Article 6.1.

[30] Above, Article 5.2.2.1, Article 6.1. CEN produces two main types of documents, EN (European standards) and HD (Harmonised Documents). HDs are less 'binding' than ENs, in that they are to be implemented by mere 'public announcement' of HD number and title and by withdrawal of conflicting national standards. Given the importance of publishing identical national standards, CEN has an official policy of preference for ENs. Article 4.1.9, Article 6.1, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

Talk of consensus should not obscure the fact that some NSBs have more influence in CEN than others. A crude but effective measure of this is the number of secretariats held by the different standards bodies: holding a secretariat in CEN is evidence of financial strength and proactive interest in a new project; it also ensures considerable clout over the process.[31]

Table 1: Repartition of the 378 CEN TC and SC Secretariats among National Standards Bodies, 2000.

DIN	BSI	AFNOR	UNI	NEN	IBN	SIS	DS
104	85	74	28	20	17	13	10
AENOR	NSF	SFS	SNV	NSAI	ELOT	STRI	IPQ
8	5	4	4	2	1	1	1

Source: CEN.

In terms of industrial support, sheer size of national standards catalogues as well as clout within European standardisation, DIN, BSI and AFNOR are in a class of their own. Tri-partite meetings between them, often including representatives of the Commission, are as important a platform for standards policy in Europe as anything taking place under the aegis of CEN.[32]

3. THE EUROPEANISATION OF STANDARDISATION

The most obvious consequence of the rapid development of European standardisation over the last two decades is the decrease in importance of purely national standardisation. Table 2 shows the share of European standards in CEN members' national catalogues in 1999.

[31] See CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work, Annex B: Guidelines for the allocation of technical secretariats. First, a member wishing to undertake a secretariat should 'consult nationally' to satisfy itself that adequate resources exist to carry out the work. Second, preference should be given to the originator of the proposal that sparked off the TB's decision to start the project. Otherwise, preference is to be given to the candidate holding proportionally fewer secretariats.

[32] Even if Elias, *UNI 1921–1991. Settant'anni al Servizio dell'Azienda Italia* (Hoepli, Milano, 1991) 146, includes UNI in this company ('L'Italia si affianca a Francia, Germania e Inghilterra nel determinare la politica di normazione europea').

Table 2: National members of CEN and national standards published at the end of 1997 in total and national standards transposing European standards adopted by CEN.

NSB	National Standards	National Standards Implementing ENs adopted by CEN
ON	8806	3627
IBN	7951	3912
DS	8800	3048
SFS	9759	3152
AFNOR	21128	3768
DIN	24886	2879
STRI	5950	3194
UNI	16185	2165
NEN	13002	4417
NSF	6520	2808
AENOR	13798	3175
SIS	13564	2939
SNV	7750	3100
BSI	16955	3316

Note: Dutch figures for implemented ENs include EN-ISO standards. Comparable data from Greece (ELOT), Ireland (NSAI) and Portugal (IPQ) are not available.

Source: H. Schepel and J. Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA, Volume 1: Comparative report*, Luxembourg: Opoce, 2000, 44, based on information provided by CEN on 17 February 1999.

To the degree that national standards impede trade, the main problems then seem to lie in but a few countries. Table 3 serves to illustrate, showing on the one hand a steady if not spectacular fall in the total amount of national standards notified over the last decade, and on the other hand the relative share of those notifications of the different national standards bodies.

As new work is increasingly shifted to the European level, the share of European standards is bound to rise further over time. Table 4 illustrates this development for the 'big' European standards bodies.[33] The relevant

[33] Some caution is called for with these figures. Pernollet, 'Le Processus délaboration des Normes Techniques au Plans National, Communautaire et International' [1998] *Petites Affiches* 12, 13, puts the proportion of franco-français standards at 10%, rather than 3%. UNI's low rate of adoption of ISO standards in 1997 was rather exceptional. See below.

figures for standards bodies from smaller Member States show a much smaller proportion of national standards work.[34]

Table 3: Purely National Standards projects notified under the Information Directive, non-electrotechnical sector.

	1988	1990	1992	1994	1996	1998	2000
Germany	27.4	19.6	13.9	23	29.1	32.7	28,9
France	21.9	35	29.9	27.5	13.3	11	14,7
UK	8.1	13.3	7	12.5	10.4	10.1	10,2
Italy	11.5	12.3	12.5	18	14.8	10.2	8,5
Spain		9.9	30.7	8.9	10.5	10.6	11,2
Other EC Countries	11.6	2.9	1.5	6.7	20.4	22.4	22,8
EFTA Countries	19.5	7	4.4	11.6	1.5	3	3,7
Total (absolute)	**2261**	**1838**	**2311**	**2401**	**1600**	**1583**	**1406**

Source: Commission Reports on the Operation of the Information Directive, COM (91) 108; COM (92) 565; COM (96) 286, COM (2000) 429, and COM (2003) 200. Note that the 'other EC countries' entry for 2000 includes 171 standards (or 12,1 %) notified by ON alone.

Table 4: Annual production of purely national, European-based and internationally based standards by AFNOR, BSI, DIN and UNI in 1993 and 1997 (in %).

NSB	Year	Purely national	European based	Internationally based
AFNOR	1993	26	60	14
	1997	3	83	14
BSI	1993	24	44	32
	1997	9	71	20
DIN	1993	20	71	9
	1997	7	87	6
UNI	1993	37	43	20
	1997	14	84	2

Source: Commission Report on Economic Reforms of Product and Capital Markets, COM (1999) 10, B 5.

[34] See Schepel and Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA, Vol 1: Comparative Report* (Opoce, Luxembourg, 2000) 53.

Harmonisation of technical requirements depends on a horizontal obligation arising out of membership to CEN. The association's statutes declare that status as national member implies 'total adhesion' to 'all decisions and prescriptions' taken by CEN.[35] The Internal Regulations, however, qualify that obligation by stating that members are bound by decisions taken by the association 'within the limits of their legal competence as national standards bodies.' In that case, all that can be asked is this:

> If a member is prevented from implementing a decision by regulations or conditions outside its competence to alter, it shall nevertheless do everything in its power to bring about the necessary changes.[36]

Member States are, of course, in no way bound by these obligations incumbent on national standards bodies. By the same token, standards bodies are not bound by obligations undertaken by Member States under Community law. In case of a Commission mandate to CEN, all the Information Directive can ask of Member States is to take 'all appropriate measures' to ensure that their national standards bodies 'do not take any action which could prejudice the harmonisation intended and, in particular, that they do not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard.'[37]

The success of European standardisation thus depends on two sets of diagonal relationships. On the one hand, national standards bodies could frustrate political initiatives of harmonisation either by exercising their power in the Technical Board to push for rejection of a mandate or by block voting in the ratification stage. On the other, Member States could frustrate European self-regulation by exercising their vertical powers, if any, over their national standards bodies. To the extent that self-regulation is used as an alternative to European legislation, Member States lose the power to impose their views in the process. The temptation could then be to tighten their control over their standards bodies. In its 1999 Resolution, the Council

> Highlights the legitimate interest of public authorities in European standardisation given its wide impact on society and the new dimension it has taken as a result of the wide recourse made to it by Community policies, especially in support of legislation under the new approach;

yet also

> Requests public authorities to acknowledge the strategic importance of standardisation, in particular by maintaining a stable and transparent legal,

[35] Article 13, CEN Statutes.

[36] Articles 5.1.1 and 5.1.2, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work.

[37] Article 7 (1), Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, (1998) OJ L 204/37.

> political and financial framework at the European, international and national levels, in which standardisation can further evolve, in ensuring compliance with the principles governing standardisation, and, where appropriate, in contributing to the standardisation process.[38]

4. 'NATIONAL' STANDARDS

The Europeanisation of standardisation has had profound consequences for national standards bodies themselves and for the way in which national governments define their relations with them. The new approach not only strengthens the position of CEN in Community policymaking, but also adds considerably to the weight CEN's national members carry on national level. As the Director of AFNOR states confidently,

> [Le conseil] a propulsé la normalisation au premier plan de l'actualité et fait sortir cette austère discipline des cercles restreints où, en France tout au moins, elle était confinée.[39]

If the New Approach effectively gives CEN a monopoly in European standards work, it also gives the national standards bodies a monopoly in the mobilisation and co-ordination of national interests. For economic operators and other interested parties, having a stake in the national standards body is the only way to get involved in European standardisation. In the measure that Community law leaves tasks to the European standardisation bodies, national public authorities see their role in European policymaking taken over by their national standards bodies.[40]

Public authorities almost everywhere have reacted to this situation with two complementary moves towards a 'European model of standards body' in order to meet the exigencies of European standardisation. First, in light of the notification duties and information gathering under the Information Directive as well as the duty to transpose European standards as national standards, Member States have been induced to centralise standards activities and establish closer relations with their standards

[38] Considerations 18 and 19, Council Resolution of 28 October 1999 on the role of standardisation in Europe, (2000) OJ C 141/1. See also the Council's Conclusions on Standardisation, (2002) OJ C 66/1.

[39] Boulin, 'La Normalisation dans la Construction Européenne' (1991) 4 *Revue des Affaires Européennes* 49. He continues even more confidently: 'C'est l'inverse qu'il faut dire: la normalisation a acquis au cours des dernières décennies une telle importance qu'on pouvait difficilement imaginer une autre solution au problème du Marché Unique que celle qui a été adoptée.' More enthusiasm in Repussard, 'Les Normes Techniques au Service de la Construction Européenne' (1996) 396 *RMCUE* 222.

[40] See eg Scharpf, 'Community and Autonomy: Multi-level Policy Making in the European Union' (1994) 1 *JEPP* 219, 237 (noting how, for countries with no tradition of corporatist self-regulation, the New Approach implies 'an abdication of political responsibility, a loss of national influence and, possibly, even a loss of political legitimacy.')

bodies, be it by regulation or by contract. On the other hand, the need to mobilise the economic support and the expertise needed to participate effectively in European standards work has led standards bodies to be 'privatised' or at least to be given greater degrees of autonomy. This section describes standards systems in various Member States and discusses these developments.[41]

5. GERMANY

5.1 The *Deutsche Institut für Normung*

Founded in 1917 for obvious reasons, the *Normen-Ausschuß der deutschen Industrie* (NDI) had published 3000 standards by 1927.[42] It changed its name to *Deutsche Institut für Normung* (DIN) in 1975, the same year the *Normenvertrag* with the German government institutionalised relations with the state. DIN is a non-profit association which publishes a regular stream of more than 2000 standards a year, pushing its total number of standards up to 27000 in 2003. The DIN Group's budget of 66 million Euro is financed largely from fees, sales, and other income, with a 10 million Euro contribution of the State.[43] A sizeable chunk is generated by *Beuth Verlag*, the publishing house which specialises in standards and is fully owned by DIN with the participation of the *Verein Deutscher Ingenieure* (VDI), the Austrian standards body ON and the Swiss SNV.[44] Other income is derived from a host of subsidiaries and joint ventures in the certification, accreditation and conformity assessment business.[45]

DIN has a rather overt policy to get its standards exported. It strives towards publishing all its new standards in English as well as in

[41] For comparative work, see generally Schepel and Falke, above n 32; Falke and Schepel (eds), *Legal Aspects of Standardisation in the Member States of the EC and EFTA—Vol 2: Country Reports* (Opoce, Luxembourg, 2000). Cf Zubke von Thünen, above n 1. De Vries, *Standardization—A Business Approach to the Role of National Standardization Organizations* (Kluwer, Amsterdam, 1999), occupies itself with the business aspects of national standards bodies in terms of organisation and services. For specific countries not dealt with here, see eg Bundgaard-Pedersen, 'States and EU Technical Standardization: Denmark, the Netherlands and Norway Managing Polycentric Policy-Making 1985–95' (1997) 4 *JEPP* 206; Brunner, *Technische Normen in Rechtsetzung und Rechtsanwendung* (Helbing & Lichtenhahn, Basel, 1991).

[42] Perhaps the most famous of all German standards, the A4 format for paper, was published in 1922. In 1926 the organisation changed its name to *Deutscher Normenausschuß* (DNA).

[43] Own income amounts to nearly 38 million, membership fees and other contributions by industry to 17 million Euro. DIN, *Geschäftsbericht* 2002.

[44] *Beuth* reported a turnover of 53 million Euro in 2001. DIN, *Geschäftsbericht* 2001.

[45] Thus, DIN owns or participates in DIN CERTCO, conformity assessment; DACH, accreditation in the chemical sector; DQS, certification of management systems; DIN VSB ZERT, certification for traffic systems; DIN GOST TÜV, the 'Berlin-Brandenburg Gesellschaft für Zertifizierung in Europa'; DIN Software; DIN IT Service, and DIN Bauportal.

German.[46] Moreover, it has a longstanding and effective *Ostpolitik*: DIN had negotiated its way into what could euphemistically be called a Standards Union with the government of the German Democratic Republic even before German political re-unification took place.[47] Further eastward, it has a co-operation agreement in place with the Chinese standards institute since 1979 and with Russian GOST since 1989.

The association's statutory aim is to produce German standards in the public interest, through the labours of the community of interested circles, in order to contribute to rationalisation, quality control, the protection of the environment and general safety, and compatibility.[48] Membership in DIN is restricted to undertakings and legal persons, currently numbering some 1650.[49] They form the general assembly, whose main function is to elect the *Präsidium*, or Management Board, of 40 to 45 members in which all interested parties are to be represented.[50] The association's President, Vice-Presidents and the Director sit on the Board as well, as do the presidents of ON and SNV.[51]

The actual standards work is co-ordinated by the *Normenprüfstelle* or Standards Board, a standing committee of the *Präsidium*.[52] It consists of a *Beirat* or Council, composed of a maximum of 21 honorary members representative of all interested circles and 7 DIN employees, and a much smaller *Geschäftsstelle* to which it delegates all routine matters.

[46] There are now a total of some 13 800 standards available in English. DIN, *Geschäftsbericht* 2002.

[47] *Vereinbarung über die Schaffung einer Normenunion zwischen der Deutschen Demokratischen Republik und dem DIN Deutsches Institut für Normung*, signed by DIN and the *Amt für Standardisierung, Maßwesen und Warenprüfung* on 4 July 1990 (on file with author). DIN had concluded an agreement on standards co-operation even before the Berlin wall fell. See Falke, *Rechtliche Aspekte der Normung in den EG-Mitgliedstaaten und der EFTA– Band 3: Deutschland* (Opoce, Luxembourg, 2000) 70 ff.

[48] Article 1(2), *DIN Satzung*. According to Article 5.7, DIN 802–Teil I, standards should promote the development and 'humanisation' of technology.

[49] DIN is rather heavy-handed in is approach to membership. Rather than accepting the usual and rather mundane motivations for membership (say, discounts on notoriously overpriced standards), it states: 'Mitgliedschaft im DIN ist eine ordnungspolitische Entscheidung für die Selbstverwaltung im Normungsbereich und sichert die Möglichkeit zur Einflussnahme auf normungspolitische Entscheidungen.' DIN, *Geschäftsbericht* 2001. Membership is 'desirable, but not a condition,' for participation in the organisation's standards work. Article 3.5, DIN 820–I.

[50] Article 5, DIN *Satzung*; Article 2.5, *Geschäftsordung des Präsidiums des DIN*. The current Board numbers 8 representatives of the Federal Government, and further features representatives of, *inter alia*, Airbus, ARAL, Thyssen, Daimler–Chrysler, Deutsche Bahn, Deutsche Bank, and IBM.

[51] From the large-scale survey of German undertakings conducted for DIN, *Gesamtwirtschaftliche Nutzen der Normung* (Beuth, Berlin, 2000) 21, 22, the prevalent opinion seems to be that DIN is both 'too bureaucratic' and 'too expensive'.

[52] The Standards Board, Conformity Assessment Committee and Consumer Committee are permanent; the Finance Committee and the Election Committee are established for the duration of the tenure of the Board. See Articles 4.2 and 4.3, *Geschäftsordung des Präsidiums des DIN*.

Responsibility for standards work is devolved to *Normenausschüsse*, or Sector Boards, which again are headed by a *Beirat* or Council of 21 members, one of whom should be a member of the *Präsidium*.[53] Each Sector Board, in turn, sets up *Arbeitsausschüsse*, or Working Groups, where the technical work is carried out.[54] DIN currently has 83 Sector Boards and a staggering 3672 Working Groups populated by some 25000 experts from 'interested circles.'[55]

5.2 Procedures for Standardisation

Procedural aspects of standardisation are prescribed in great detail in DIN 820, the 'standardisation standard,' strict observance of which on all levels of the standards work is to be controlled by the Chairman of the *Beirat* of the relevant Sector Board and by the *Geschäftstelle* of the Standards Board.[56] Anyone can send a request for standards work to be undertaken on any given item to either the Standards Board or a Working Group. The Standards Board decides whether to proceed, and gives notice of its decision.[57] If the request is accompanied by a draft technical document, this should be taken as the basis of discussion. In any event, the undertaking making the request is to be invited as 'guest' to the Working Group to present his case.[58]

Working Groups are constituted as balanced interest committees, and disputes about their composition can be brought before the Standards Board, then before DIN Management and lastly before the *Präsidium*.[59] DIN regulations further emphasise the need to involve experts able to bring in 'the newest developments in science' and the current state of the art.[60] Free-riders are not permitted: Working Groups maintain a strict three-strikes-you're-out rule.[61] Deliberations are explicitly not public, and drafts and other working documents are to be treated as strictly confidential, even if members are allowed to consult 'internally' with their constituents.[62]

[53] Article 7, *Richtlinie für Normenausschüsse im DIN.* Responsibility for setting up and disbanding Sector Boards is a matter of the *Präsidium*.

[54] Articles 7.7 and 10, *Richtlinie für Normenausschüsse im DIN*.

[55] DIN, *Geschäftsbericht* 2002.

[56] Article 4.2.1, *Geschäftsordung des Präsidiums des DIN*;Article 8.5, *Richtlinie für Normenausschüsse im DIN*.

[57] Article 2.1, DIN 820– IV Appeal against a rejection of a request is open all the way up to the *Präsidium.* Article 2.1.3. The *Präsidium* also has the last word in case two different Sector Boards declare themselves competent to carry out the work. Article 2.1.1.

[58] Article 2.2, DIN 820– IV The Working Group may decide to invite the undertaking to form part of the Group.

[59] Article 3.4, DIN 820–I.

[60] Article 10.4 (a), *Richtlinie für Normenausschüsse im DIN.*

[61] Article 10.4 (c), *Richtlinie für Normenausschüsse im DIN.* The rule applies even if members have sent replacements.

[62] Article 6, DIN 820–IV.

Decisions are to be taken by consensus, and formal voting should be avoided 'if possible':[63] should this not be possible, a simple majority suffices.[64]

Once a draft standard has been agreed upon within the Working Group, notice is given widely and a public review period of four months starts.[65] The draft is simultaneously reviewed by the Standards Board and the *Präsidium*.[66] Comments are to be dealt with by the Working Group within three months; objectors have to be invited to these sessions to present their case.[67] An appeal mechanism is provided for in case objections are not resolved, which ends before a appeals committee in the *Präsidium*, composed of a Board-appointed chairman and two members each appointed by the parties. The standard, however, can be adopted before the appeal process is finished.[68] Comments made on the draft by the Standards Board and the *Präsidium* are not binding on the Working Group; however, should they choose to ignore them, they have to provide a written statement of reasons for doing so.[69] The Sector Board formally adopts the standard.[70]

In DIN, European and international standardisation is given priority over national work,[71] and is absorbed as much as possible into the normal framework. The working group responsible for national standards work in a particular field is automatically made responsible for European and international work in the same area.[72]

Regional or international standards (eg ISO or EN standards) shall be adopted without amendments in German translation as German standards. This presupposes that the German public sphere has been kept informed of and been invited to comment on their drafting and that these comments have been taken into account.

[63] Article 6, DIN 820–IV.

[64] Article 13.1, Richtlinie für Normenausschüsse im DIN. Voelzkow, *Private Regierungen in der Techniksteuerung: Eine sozialwissenschaftliche Analyse der technischen Normung* (Campus, Frankfurt, 1996) 104, claims that votes are in fact often taken at all levels. A majority of interested parties people surveyed in DIN, *Gesamtwirtschaftliche Nutzen der Normung* (Beuth, Berlin, 2000) 21, however, object to voting over the consensus rule on the grounds that standardisation needs 'professional discussion' rather than 'political dealing.'

[65] Article 2.4, DIN 820–IV.

[66] Article 2.4.4, DIN 820–IV.

[67] Article 2.4.5, DIN 820–IV.

[68] Article 2.4.7, DIN 820–IV.

[69] Article 2.5.1, DIN 820–IV.

[70] Article 2.6.1, DIN 820–IV.

[71] Article 7.7, *Richtlinie für Normenausschüsse im DIN* (instructing Sector Board Councils to give priority to European and international standards work);Article 5.2, DIN 820–I (instructing Sector Boards and working groups to make sure no corresponding international work is being undertaken before accepting to start work on national level.)

[72] Article 3.3, DIN 820–I. Chairmen of working groups are instructed to adhere to CEN/Cenelec internal regulations. Article 10.6, *Richtlinie für Normenausschüsse im DIN*.

It is hence necessary that the responsible Sector Board and its Working Groups follow European and international standards work in their areas, actively participate in that work, and ensure that national standards work is co-ordinated with regional and international standardisation both in terms of subject area and in terms of time, especially when EN standards have to be adopted as German standards. Standstill obligations on regional level should be observed.

German representatives in European or international committees have to adhere to the guidelines of the responsible German body.[73]

For all the procedural safeguards and consensus building, standardisation in DIN has been accused of favouring private interests over public interests, the interests of large companies over those of SMEs, and industrial interests over all others.[74] Under impetus of the Government, diffuse interest representation in standardisation has been organised in thoroughly Teutonic fashion.[75] Environmental concerns are addressed through the *Koordinierungsstelle Umweltschutz*, set up within DIN in 1983. Financed for 75% by the federal ministry for the environment and for the rest by DIN itself, the KU brings together environmental experts who dispense comments on standard drafts. Its effectiveness is limited, partly because it does not have any privileged position. The de facto veto power that the principle of consensus in practice bestows on committee members does not extend to outside comments. Consumer representation is more effective in that regard. The Consumer Committee, constituted within DIN as a standing committee of *Präsidium*, consists of 5 members appointed by DIN's President with the consent of both a national consumer organisation and the federal ministry of economic affairs. Financed by the state, the consumer committee organises consumer representation and participation in all standards work. The actual work involved is carried out by DIN employees under instructions of the Committee. Again, their work is not privileged in any sense; the arrangement is explicitly set up as a method of mustering resources to take full advantage of the rights of participation and influence accorded generally by DIN 820.[76] The *Kommission Arbeitsschutz und Normung* (KAN), dealing with health and safety at work, is a different outfit altogether. Probably the best way to describe it is as a corporatist hijack of the standardisation process. The organisation was set up in 1994 and is financed in near equal parts by the trade unions and the federal ministry for social affairs. It is organised along classic tripartite lines of government, employers and trade unions.[77] Emphatically not a

[73] Article 3.4, DIN 820–IV.

[74] See Gusy, 'Wertungen und Interessen in der Technischen Normung' (1986) 6 *Umwelt und Planungsrecht* 241. Cf Voelzkow, above n 64, 230 ff.

[75] See the overview in Falke, above 46, 157 ff.

[76] Article 4.2.2, *Geschäftsordung des Präsidiums des DIN*.

[77] They each have five seats on the 17-member commission. DIN has one, the other being reserved to the insurance-industry.

standards body itself, the basic idea is for workers' organisations to go 'one on one' with employers—rather than be mightily outnumbered within the standards institutions—and feed a prefabricated, overwhelming and near-irrepressible common position of the social partners into the 'normal' channels of the standardisation process. As compensation for the dilution of their already tenuous influence in standards work brought about by the Europeanisation of standards work, the arrangement seems to make sense. On the other hand, it constitutes an indictment of traditional methods of interest representation within standardisation.

5.3 Public Recognition of Standardisation

Relations between DIN and the Government were left unregulated until 1975 when it was decided that, given the increasing importance of technical standards, collaboration between the standards body and the government were to be intensified.[78] This was achieved by a contract signed in 1975, the so-called *Normenvertrag*.[79] The government recognises DIN as the 'competent standards body' for Germany and as 'the national standards body in international private standards bodies'.[80] DIN, for its part, takes on the obligation to take the general interest into account in its standards work, and to ensure that standards can be used as descriptions of technical requirements in legislation, public administration and private law instruments.[81] DIN will treat requests from the government for standards work with priority; the Government, in turn, undertakes a standstill on all regulatory activity during an agreed term.[82] DIN will further involve representatives of the public authorities in its work, and will do 'everything in its power' to prevent its standards from obstructing the government's international commitments concerning trade liberalisation and the removal of technical barriers to trade.[83] DIN 820 is recognised and endorsed, and DIN undertakes not to amend it in any way that would

[78] *Erläuterungen zum Vertrag zwischen der Bundesrepublik Deutschland und dem DIN Deutsches Institut für Normung e.V*, reproduced in *DIN–Normenheft 10*, 6th edn, (Beuth, Berlin, 1995) pp 48–51.

[79] *Normenvertrag*, signed on 5 June 1975, reproduced in *DIN–Normenheft 10*, 6th edn (Beuth, Berlin, 1995) pp 43–45. For a description of the developments leading up to the signing of the contract, see Falke, above n 46, 57–60. As he emphasises, the contract did scarcely more than to codify the hitherto unwritten principles of co-operation between DIN and the Government. Above, 63.

[80] On the basis of the contract, DIN was charged with the notification duties concerning standards arising from the Information Directive in 1984. Exchange of letters between DIN and the Federal Minister of Economic Affairs, reproduced in (1984) 63 *DIN–Mitteilungen* 254.

[81] Article 1, Normenvertrag.

[82] Above, Article 4. This undertaking is qualified for reasons of the public interest or for needs of implementation of legislation.

[83] Above, Articles 2, 4 and 6.

prejudice the achievement of the objectives of the *Normenvertrag*.[84] The government undertakes to use DIN standards in public administration and public procurement, and to publish references to standards drafts, new standards and modifications thereof in the official journal.[85]

5.4 Legal Recognition of Standardisation

In terms of sheer numbers and their pervasiveness in socio-economic life, German standards have been described as a parallel universe to law:

> Neben und außerhalb der politischen Ordnung und des positiven Rechts hat sich ein zweiter Kosmos von Normen entfaltet, der im sozialen leben Recht bei weitem übertrefft.[86]

Given the widespread impression that German society is one of the most juridified societies in the world, and the German economy one of the world's most regulated economies, the idea of a second, even more pervasive, web of norms and standards seems counterintuitive. That perception, however, is largely based on the idea that private standards necessarily function as an alternative to public law. Christel Lane's analysis of inter-firm relations in Germany and Britain turns this around and emphasises the complementary functions of public law, state action, technical standards, associative organisation, and wider cultural processes. As she summarises her argument:

> The stronger endorsement of technical standards by German than by British industrialists has been explained by reference to the greater participation of firms in associative action, and once a certain level of compliance has been reached they become an unquestioningly accepted part of production and exchange relations. The emphasis in the wider culture on quality, safety and technical ingenuity of products further reinforces the taken-for-granted character of technical norms. In addition, the greater saliency of technical norms in Germany is crucially linked to the more marked and more consistent legitimation of standards by the state's legal and administrative practices. More state backing for, and use of, norms in Germany, as compared with British technical norms, is reflected in and reinforced by the material

[84] Above, Article 3.
[85] Above, Articles 8 and 9.
[86] Wolf, 'Zur Antiquiertheit des Rechts in der Risikogesellschaft' [1987] *Leviathan* 357, 367. Contrast the laconic Gusy, 'Probleme der Verrechtlichung Technischer Standards' (1995) 14 *Neue Zeitschrift für Verwaltungsrecht* 105, 107 ('Das bunte Nebeneinander unterschiedlichster Handlungs—und Rechtsformen scheint eher ein Problem der Theorie als ein solches der Praxis zu sein.')

> and organisational capacities of the two main, national norm-setting institutions.[87]

The embeddedness of German standards, both 'upward' in legal and regulatory frameworks and 'downward' in social and economic life, is vital in understanding the way the German legal system recognises standards, and in understanding the strain that the Europeanisation of standardisation puts on this mechanism.

Direct undated references to standards, or *normergänzende gleitende Verweisung*, are widely considered to constitute unconstitutional delegation of powers to private parties in German legal doctrine.[88] In this case, the requirements of the standard *add* to the legal requirement, leaving private organisations to impose substantive obligations on citizens. The solution has been found in the widespread use of the *normkonkretisierende gleitende Verweisung*, or indirect undated reference. This 'hinge-clause' method makes the *legal* requirement, however vague, the only legally relevant provision.[89] The problem with this solution is, of course, that it is hard to see how the use of a requirement such as to comply with the 'acknowledged rules of technology' is, in principle, less objectionable that the obligation to comply with 'DIN 1320'. It might solve the formal issue of the *author* of the requirement, but it would seem to add worries of legal certainty. The mechanism has, however, found wide currency. The explanatory note to the *Normenvertrag* explicitly states that standardisation is a matter of self-regulation of industry, and that DIN is given the task to 'support' and 'unburden' the government by creating 'acknowledged rules of technology' which enable the reference to standards in legislation, saving the Government the trouble of having to write technical

[87] Lane, 'The Social Regulation of Inter-Firm Relations in Britain and Germany: Market Rules, Legal Norms and Technical Standards' (1997) 21 *Cam J Econ* 197, 212. Without casting doubt on the quality of her research among firms, it does seem that her conclusions on German and British standardisation are skewed by having at her disposal Voelzkow, above n 64, and nothing comparable on British standards. And in as far as she seems to indicate that her analysis throws doubt on Stewart Macaulay's classic study on the use of contract law in business relations, she imputes on his theory a rather stronger contraposition between social norms and law than is warranted. See Macaulay, 'Non-Contractual Relations in Business: A Preliminary Study' (1963) 45 *Am Soc Rev* 55. Cf Macaulay, 'Private Government' in Lipson and Wheeler (eds), *Law and the Social Sciences* (Russell Sage, New York, 1986) 445.

[88] For authoritative early objections, see Breuer, 'Direkte und Indirekte Rezeption Technischer Regeln durch die Rechtsordnung' (1976) 101 *AöR* 46; Marburger, *Die Regeln der Technik im Recht* (Carl Heymanns, Köln, 1979).

[89] See eg Schmidt-Preuß, 'Normierung und Selbstnormierung aus der Sicht des öffentlichen Rechts' [1997] *ZLR* 249; Ladeur, 'The Integration of Scientific and Technological Expertise into the Process of Standard-Setting According to German Law' in Joerges, Ladeur and Vos (eds), *Integrating Scientific Expertise into Regulatory Decisionmaking—National Traditions and European Innovations* (Nomos, Baden-Baden, 1997) 77.

specifications itself.[90] The method has also been sanctioned repeatedly by the Courts. In a 1996 decision, the federal administrative court held:

> It is true that the federal legislator refers to 'acknowledged rules of technology.' These rules, however, do not constitute legal norms. The *Deutsche Institut für Normung* has no legislative powers. It is an association that has made it its statutory objective to produce standards in the general interest through the collective effort of interested circles with a view to rationalisation, quality assurance, safety and compatibility. Whether it reaches that objective in specific cases is not a legal matter, but a question of the practical usefulness of the standard for its stated purpose. Standards published by DIN obtain legal relevance not because of their autonomous normative strength ('*eigenständige Geltungskraft*'), but only because and in so far as they fulfil the constitutive conditions ('*Tatbestandsmerkmale*') of acknowledged rules of technology which the legislator incorporates as such in its regulatory will. When the legislator refers to standards, they have a normative function in the sense that they substantiate the material legal norm ('*daß die materielle Rechtsvorschrift durch sie näher konkretisiert wird*.').[91]

A first consequence of the technique is immediately apparent. Rather than delegating regulatory choices away from the legal sphere to a private association, it shifts these choices within the legal sphere from the legislature to the courts that now have to decide whether or not a standard is an adequate statement of the 'acknowledged rules of technology.'[92] And however appealing the idea of judicial control of the adequacy of standards might seem, a court is not at first sight the most suited institution to make technical judgments.

In its 1978 *Kalkar* decision, the federal constitutional Court addressed the problems posed to courts by hinge-clauses.[93] The Court made a clear correlation between different legal requirements and different stages of technical development. Accordingly, the '*Stand der Wissenschaft und Technik*', or 'state of scientific and technical knowledge' refers to the latest developments in science; the '*Stand der Technik*', or roughly, the 'state of

[90] *Erläuterungen zum Vertrag zwischen der Bundesrepublik Deutschland und dem DIN Deutsches Institut für Normung e.V*, reproduced in *DIN–Normenheft 10*, 6th edn, (Beuth, Berlin, 1995) pp 48–51. Variations on the theme in eg Bolenz, *Technische Normen zwischen 'Markt' und 'Staat'* (Kleine, Bielefeld, 1987); Eichener, Heinze, and Voelzkow, 'Techniksteuerung im Spannungsfeld Zwischen Staatlicher Intervention und Verbandlicher Selbstregulierung' in Voigt (ed), *Abschied vom Staat– Rückkehr zum Staat?* (Nomos, Baden-Baden, 1993) 393; Brennecke, *Normsetzung durch Private Verbände—Zur Verschränkung von Staatlicher Steuerung und Gesellschaftlicher Selbstregulierung im Umweltschutz* (Werner, Düsseldorf, 1996).

[91] *Bundesverwaltungsgericht*, judgment of 30 September 1996, (1997) *Neue Zeitschrift für Verwaltungsrecht—Rechtsprechungs Report* 214. My translation.

[92] Optimistic, Breuer, 'Gerichtliche Kontrolle der Technik als Gegenpol zu Privater Option und Administrativer Standardisierung' (1987) 4 *UTR* 91. Rather less so, Gusy, 'Leistungen und Grenzen Technischer Regeln—am Beispiel der Technischen Baunormen' (1988) 79 *Verwaltungsarchiv* 68, 84.

[93] *Bundesverfassungsgericht*, judgment of 8 August 1978, BverfGE 49, 80.

the art' imposes to do what is 'technically feasible'. The difficulty here, admits the Court, is that regulators and courts 'have to engage with experts' disagreements' in order to decide what is 'technically necessary, appropriate and avoidable.' The 'acknowledged rules of technology' avoid these problems: this requirement lies 'one step behind technological developments' and refers to mere 'dominant views among technical practitioners.'[94]

As the phrase itself already makes clear, the 'acknowledged rules of technology' bring together normative requirements, professional common sense and social acceptability. This democratisation of good engineering practice is taken a step further by the more elaborate definition given by a study published by the Ministry of Economic Affairs, according to which the *'anerkannte Regeln der Technik'* should be understood as:

> Technical stipulations for procedures, installations and processes that, according to the prevailing views of concerned circles (experts, users, consumers and public authorities),
>
> —are appropriate for the accomplishment of the statutory objectives;
> —take into account, within the framework of those objectives, economic points of view as part of proportionality considerations, and
> —have proven their worth in practice or will do so in the foreseeable future according to the prevailing view.[95]

The important thing to realise, then, is that standards derive their legitimacy not from being the results of objective expertise, nor as the results of a procedurally legitimate para-statal political process of interest balancing.[96] As the *Bundesverwaltungsgericht* held in 1987:

> The Technical Committees of DIN are composed in such a way that the necessary technical expertise is at their disposal. Their members, however, additionally include persons representing the interests of certain branches and undertakings. One cannot, therefore, understand the results of their deliberations uncritically as solidified expertise ('*geronnerer Sachverstand*') or as pure scientific results. On the one hand, one cannot deny that DIN standards are drafted with expertise and a sense of public responsibility. On the other hand, one must not overlook the fact that DIN standards are agreements between interested parties that have the aim to influence the market mechanism. Therefore, the Technical Committees of DIN do not meet the requirements one

[94] Above, 80, 135 *et seq.*

[95] Bundesministerium für Wirtschaft (ed), *Bericht der Arbeitsgruppe 'Rechtsetzung und Technische Normen'* Studienreihe vol 71, (Bonn, 1990) 12. Translation mine.

[96] See however eg Denninger, *Verfassungsrechtliche Anforderungen an die Normsetzung im Umwelt—und Technikrecht* (Nomos, Baden-Baden, 1990); Führ, 'Technische Normen in Demokratischer Gesellschaft' [1993] (2) *ZUR* 99; Lübbe-Wolff, 'Verfassungsrechtliche Fragen der Normsetzung und Normkonkretisierung im Umweltrecht' (1991) 6 *Zeitschrift für Gesetzgebung* 219; Roßnagel, 'Rechtspolitische Anforderungen an die verbandliche Techniksteuerung' in Kubicek and Seegers (eds), *Perspektive Technikssteuerung* (Sigma, Berlin, 1993) 169.

> must set as regards neutrality and objectivity of expert witnesses. Special caution with technical standards is warranted where their contents cannot be classified as extra-legal technical matters ('*außerrrechtliche Fachfragen*') but, rather, entail the balancing of opposing interests, which would need a democratically legitimised political decision in the form of a formal law or regulation.[97]

Legal recognition, instead, is conditional upon a) the ability of the legal system to differentiate between 'technical' and legally autonomous 'normative' requirements, and b) the ability of standards bodies to build a consensus among all interested circles as regards technically, politically, socially and economically acceptable solutions to technical problems, that is, to produce 'common sense.'[98] Both these conditions can only be fulfilled within a framework of shared cultural understandings and institutions which, in turn, are largely constituted by flanking legal and social frameworks, from the recognised and nurtured public calling of the engineering profession to the institutions of the social market democracy. It is in this sense that Breuer fears the disintegrative effects of the Europeanisation of standardisation. For him,

> [t]he normative reference to the acknowledged rules of technology presupposes the condition, immanent to the system, that the societal process of state-unburdening consensus-building be embedded in the national legal order.[99]

6. UNITED KINGDOM

6.1 The British Standards Institute

The British Standards Institute is a non-profit distributing organisation incorporated by Royal Charter. It considers itself 'the oldest and most respected National Standards Body in the world.'[100] A bit of corporate satisfaction is understandable: turnover has soared to over £ 230 million in 2002, from under £ 90 million in 1996.[101] Much of that revenue finds its source in activities that the founding members of the Engineering Standards Committee could hardly have understood to be their mission in 1901. The 'BSI Group' is a global operation involving consultancy,

[97] *Bundesverwaltungsgericht*, judgment of 22 May 1987, BverwGE 77, 285, 291. My translation.

[98] See eg Gusy, above n 92, 79 (arguing that the law demands the construction, rather than the mere codification, of consensus; Voelzkow, above n 64, 186 ff (dismissing legal systematics as '*rechtsdogmatische Bauchschmerzen*' and seeing the tension between expertise and interest representation dissolved by committee members' self-identification as '*Sachverständige.*')

[99] Breuer, above n 87, 71. Translation mine.

[100] BSI, Annual Review & Summary Financial Statements, 2000, Chairman's statement, on the occasion of the Association's centenary.

[101] BSI, Annual Review & Summary Financial Statements, 2002.

certification and inspection services, with offices and joint ventures from Peru to Iran.[102] All the expansion and diversification has led to the predictable signs of corporate confusion: interim management,[103] and a new logo to reinforce the identity of the group throughout its companies and divisions.[104] BSI's standards division, meanwhile, bravely marches on in what consultants presumably no longer refer to as BSI's 'core business'. Some 3000 technical committees published over 2000 new and revised standards in 2002.[105] The number of current British Standards has passed the 20.000 mark.

The organisation's 23.000 committee members make up the Annual General Meeting together with so-called 'subscribing members.'[106] Annual General Meetings, however, serve little more purpose than to elect the President and other members of the Board, the 'governing body of the Institute.'[107] The Board is comparatively small, consisting of the President and Chairman of BSI, five managers from the group,[108] and 'not more than ten,' and currently five, 'other persons' who are 'appointed individually on the basis of the expertise and experience each of them can contribute and collectively with regard to the breadth of interests supporting and served by the Institute.'[109]

6.2 Procedures for Standardisation

The allocation of powers and responsibilities concerning the actual standards work in BSI is very decentralised. The Board's involvement is limited to establishing the Standards Board.[110] Apart from the general procedural obligation of 'ensuring that the needs of all stakeholder interests are

[102] A recent major business venture consisted of buying up KPMG's ISO certification business in the US. BSI, 'BSI buys the Canadian and US ISO registration business of KPMG to become No 1 in North America', News Release, 21 January 2002.

[103] Kevin Wilson was brought in as Chief Operating Officer to 're-establish operational focus' in May 2000. Permanent new management was brought in 2002.

[104] This 'united face to the world' sports a 'vibrant blue and a stronger yellow', designed 'to reflect the Group's core values of integrity, authority, and independence.'

[105] BSI, Annual Review & Summary Financial Statements, 2002.

[106] BSI Bye-law 1 describes 'committee members' as 'any person serving on the Board, a Business Board, a Council or a Committee of the Institute during the period of such service.' A 'subscribing member' is any person or Body paying membership fees.

[107] Article 5, BSI Royal Charter. Members of the Board are actually appointed by the Board itself, subject to 're-election' by the Annual General Meeting. BSI Bye-law 8(g).

[108] The Finance Director, the Director of the Standards Board, the Director of 'Global Quality Services', BSI's inspection and certification business, the Chief Operating Officer, and the Director of Legal Affairs.

[109] BSI Bye-law 8(g). These interests are currently represented, *inter alia*, by a managing Director of Credit Suisse First Boston, a Director of Kingfisher, and a senior partner with Ernst & Young.

[110] BSI Bye-laws 20 and 23.

considered in the development of standards', the Standards Board, in turn, largely limits itself to setting up Sector Boards.[111] The latter are responsible for authorising new work, approving the 'constitutions' of Technical Committees,[112] and appointing TC chairpersons.[113] And these, in turn, have the authority to formally approve British Standards.[114]

BSI's Bye-laws lay down the skeleton institutional structure of standards work and the general obligation that all 'Councils and Committees shall be representative of the respective interests of users, manufacturers, Government Departments and other persons or Bodies concerned with their work.'[115] The detailed procedural framework is established in British Standard 0, the bulky 'Standard for Standards.'[116] That document summarises procedural safeguards in three basic principles: balanced participation, transparency, and consensus.[117]

To achieve balanced interest representation, committee members are drawn 'wherever possible' from 'representative organisations,' the stated intention being that groups with a similar interest are kept informed and contribute through a single channel. Representation of individual companies is permitted only in exceptional circumstances and then only if there is no representation through a relevant trade organisation or no trade organisation exists.[118] Consumers and small businesses are organised in Policy

[111] Article 5.5.1, BS 0–2. There are Sector Boards for Building and Civil Engineering, for Engineering, for Health and Environment, Materials and Chemicals, the Elecrotechnical Sector, and for Consumer Products and Services. The chairpersons of Sector Boards automatically sit on the Standards Board.

[112] Article 6.2.2, BS 0–2. The clause makes a distinction between 'constitutions', that is, the bodies represented, and the membership, that is, the individual representatives nominated by these bodies. The Standards Board has 'ultimate authority.'

[113] Article 5.5.2, BS 0–2. Article 6.9.2.3 obliges chairmen to act impartially and to declare their position if they have a direct personal interest or commercial interest in a point of discussion.

[114] Article 8.6.11, BS 0–2. Signature of the Secretary of the Sector Board is necessary, but only to 'endorse completion of the task delegated to the technical committee.' Article 8.6.13, BS 0–2.

[115] BSI Bye-law 21.

[116] The current version of BS 0 dates from 15 August 1997.

[117] Article 6.1, BS 0–1. The clause also lists giving precedence to international agreement, adhering to rules for drafting and presentation and respect for BSI's assertion of copyright among these 'safeguards'. According to Article 6.1.1, BS 0–2, the basic principles of standards work in the UK require that BSI a) carries out its task in the public interest and b) has an authoritative body of opinion backing every British Standard. These, in turn, require four activities: to seek the expression of all significant viewpoints; to secure the representation of significant interests at all levels; to make decisions by consensus, and to consult the public widely.

[118] Article 6.3.1, BS 0–2. Article 6.9.1.4 casts committee members explicitly in the role of conduit between the committee and the organisations they represent. Note that Christel Lane attributes the 'cognitive and normative deficit in relation to technical standards in many British industries' in large part to a lack of effective trade associations in the UK. See Lane, above n 87, 208. Cf Lane and Bachmann, 'Co-operation in Inter-Firm Relations in Britain and Germany: the Role of Social Institutions' (1997) 48 *B J Soc* 226.

Committees set up 'to harness collectively the commitment and focus the interest of particular stakeholder groups.'[119] BS 0 is clear about the paramount importance attached to the principle of interest balance:

> The fairness of representation on any committee should be equal to satisfying external scrutiny in the event of challenge. . . . The quality of standards and their acceptance, particularly by the courts, depends largely upon the widest and most authoritative representation available. Any imbalance in the constitution of committees could result in the production of an inadequate standard which, if discredited by a court decision, might jeopardize the status of standards generally.[120]

BS 0 tacitly assumes that committees thus constituted are unfit for technical work. Committee work 'should be kept at a minimum in the initial draft stages'. Wherever possible, these drafts should be produced 'by small panels or a single person.' Alternatively, drafts should be drawn from 'competent technical bodies or associations that have an accepted national status,' or use could even be made of 'company standards of an influential manufacturer or end user.'[121] Once in the realm of the committee itself, 'much of the detailed work' should still be delegated to subcommittees or panels or temporary working groups.[122]

The completed draft is sent out for public comment via notice in the monthly *Update Standards*. The committee is to 'consider' all comments. In 'ensuring that the committee takes all comments properly into account,' inviting major contributors to discuss their comments with the committee if they do not belong to an organisation already represented on it should 'always be considered.'[123] The system of representatives of 'nominating organisations' functions as a parallel system of public review, where individual committee members are charged with the task of communicating effectively with their constituents. BS 0 is careful to protect the social autonomy of the committee. Names of committee members are not made public by BSI, 'so that individuals serving voluntarily on committees are not exposed to lobbying or media attention.'[124] Moreover,

> Within a committee, it is important that members can express their view freely in the process of reaching consensus by reconciling conflicting

[119] Article 5.5.3, BS 0–2. Article 6.3.2 instructs trade union representation, 'especially desirable' in the preparation of standards relevant to health and safety at work, to be sought through the Trade Union Congress.

[120] Article 6.3.1, BS 0–2. Article 6.4, BS 0–1 qualifies the enthusiasm with the remark that 'the need for balanced representation should not lead to committees of unmanageable size.'

[121] Article 8.6.8, BS 0–2.

[122] Article 6.5, BS 0–2.

[123] Article 8.6.10, BS 0–2.

[124] Article 6.2.2, BS 0–2. In BSI, *British Standards and the Law: Statement of Principles*, November 2000, para 4.3, this policy rationale is supplanted with warnings about the Data Protection Act 1998.

arguments. Transparency in the preparation of standards does not therefore extend to making committee proceedings accessible to the news media.[125]

The chairman of the committee determines whether there is consensus on a final draft; in the affirmative, he formally approves the standard.[126] The principle of consensus is taken seriously: BS 0 is adamant that 'differences of view on policies or on the substance of a standard are not resolved by a vote.'[127] Unresolved problems in TCs are hence to be taken to the chairman and secretary of the relevant Sector Board who enter into 'discussions' with everyone involved. If agreement is still not reached within the TC, there are two options. In case it is concluded that a resulting standard would in practice remain a matter of 'continuing contention', the project is to be abandoned. If, on the other hand, it seems that an 'acceptable standard can be prepared', the matter is referred to the Sector Board and, if need be, to the Standards Board.[128] The 'appeals procedure' before a panel appointed by the latter is explicitly not an adversarial dispute resolution mechanism; indeed, cross-examination by one party of the other party's evidence to the panel is expressly prohibited. Instead, the panel's aim is to determine whether it can recommend to the Standards Board a line of action 'likely to achieve a reasonable degree of support and optimum use of any resulting standard.'[129]

6.3 Public Recognition of Standardisation

The state and the legal system have long kept standards at more than arm's length. Christel Lane blames 'the abstentionism of British law' and the 'problems of low official endorsement, together with the only patchy reputation of British specification standards' for the low levels of use and understanding of technical standards in the UK.[130]

Government recognition of BSI has been expressed in a *Memorandum of Understanding* since 1982, replaced with new versions in 1995 and 2002.[131] Moreover, in 2000 the Department of Industry and Trade and BSI agreed

[125] Article 6.5, BS 0–1. BSI makes it clear that it will not give access to the minutes of committee proceedings save under compulsion of law. BSI, *British Standards and the Law: Statement of Principles*, November 2000, para 4.3.

[126] Article 8.6.11, BS 0–2.

[127] Article 6.1.2, BS 0–2.

[128] Article 8.10.2, BS 0–2.

[129] Article 8.10.3, BS 0–2.

[130] Lane, above n 87, 209, 212.

[131] The latest version is the Memorandum of Understanding between the United Kingdom Government and the British Standards Institute in respect of its activities as the United Kingdom's National Standards Body, signed on 20 June 2002. The Government's recognition of BSI as the NSB and the national member of ISO and CEN, in Article 3.1, is coupled to its commitment to 'respect the independence of BSI', Article 4.3 (i).

on a document expressing 'a shared understanding' of 'the public policy interest in the UK in standardisation.'[132] The parties to the MoU make no secret of the domestic policy consequences of the Europeanisation of standardisation:

> They recognise that the UK is expected to maintain a standards infrastructure consistent with European standards policy, and must meet obligations of EC law. They recognise that the UK's interests will be furthered if they inform and co-operate with each other and adopt compatible policies in their respective spheres of activity. They agree that it is beneficial, therefore, to promote the strength and influence of the NSB.[133]

In 2003, DTI, BSI and the Confederation of British Industry joined forces in setting up the 'National Standardization Strategic Framework,' intended to 'raise the game' across the UK and galvanise industry interest in British standards-setting, hauled as a platform for innovation and a vehicle to open up international markets, increase market confidence and create competitive advantage.[134]

Traditionally, the Government has been allocating public funds to BSI relatively generously, amounting to some £6 million in 2001.[135] In the light of BSI's rapid corporate diversification, the 2002 Memorandum of Understanding explicitly 'ring-fences' those moneys to the institute's public interest activities as the National Standards Body and obliges BSI not to

[132] DTI and BSI, *The Public Policy Interest in the UK in Standardisation*, October 2000, Summary, paras 4, 11 and 12. The underlying mantra reads 'DTI and BSI share an understanding of these public policy interests, and how the constitutional structure provides a framework for pursuing them.' The Memorandum of Understanding incorporates the document in that it 'will be construed' in accordance. Article 2.

[133] Article 2.6, Memorandum of Understanding. According to Article 2.7, the Government is to 'play an active role in developing European standards policy with European governments and EU institutions,' whereas BSI is to 'play a full role in developing European standards policy in European standards fora … in furtherance of standardisation policy aims discussed with the Government.' BSI's strategy in European and international standards bodies seems largely congruent with general UK involvement in European integration. See Article 8.5.3, BS 0–2 ('If a UK vote is cast against a new project, but the project is accepted by a majority of member bodies, the position of BSI should be reconsidered by the mirror committee. In this situation it may be advisable to participate in the work so as to exert some influence on the project in its formative stages. This may help to prevent the publication of a standard that would have an adverse commercial effect for the UK'.).

[134] The 'master document' and various follow-ups are available on http://www.nssf.info.

[135] BSI, Annual Review & Summary Financial Statements, 2002. Peter Swann's excellent report on the economics of standardisation was commissioned by DTI in an exercise to review the funding arrangements. See Swann, *The Economics of Standardisation*, Final Report for Standards and Technical Directorate, Department of Trade and Industry, 11 December 2000, 57 ('In short, the DTI's current programme finds a clear rationale in view of our analysis but is, if anything, less ambitious that it could be.') Cf Lane, above n 87, 205 (in comparison with DIN, 'the relatively undistinguished performance and more precarious financial situation of BSI render it fairly dependent on government support and vulnerable to government supervision.')

favour its own 'other commercial operations,' including its own confirmity assessment activities.[136]

The Memorandum of Understanding 'confirms' the status of British Standards, including those of European or international origin, as 'agreed national technical criteria developed and used, *inter alia*, to serve the public interest.'[137] BSI commits itelf to co-operate with the Government to use standardisation 'to support policy,' and more specifically, to ensure, 'through appropriate facilitation, the production and maintenance of any standard required by the Government for legislation (whether referenced in the legal instrument or othewise indirectly required) or for public procurement purposes.'[138] Government representatives are to participate 'appropriately' at all levels of standards development and will indicate, at the draft stage, whether any particular standard 'is likely to be acceptable to the Government for regulatory or purchasing purposes.'[139] As for the procedural quality of the standards work, the Government endorses BS 0 and forces BSI to ensure that any amendments to it will not prejudice the aims and objectives of the Memorandum.[140] Generally,

> BSI will seek a fair and acceptable representation of all relevant interests in its work and encourage their full participation in producing British Standards and in formulating the UK position on proposed European and international standards which not only reflect sound and technical practice but also take fully into account the commercial needs of both manufactures and users. If work on standards or other standardisation products is funded or partly funded by participants, BSI will take care that opportunities for participation are available to other stakeholders as appropriate.[141]

6.4 Legal Recognition of Standardisation

BSI's recognition in law is minimal. Under the Restrictive Trade Practices Act 1976 standards approved by BSI, as opposed to standards set by other organisations, were exempt from the obligation to notify anti-competitive agreements to the Office of Fair Trading.[142] That privilege ceased when the

[136] See Article 4 (3)(iv), Article 5, and Article 6.5, Memorandum of Understanding. Cf Article 9 (BSI obliged to raise awareness about standardisation and 'to avoid confusion with its non-NSB commercial activities.')

[137] Article 1.4, Memorandum of Understanding. Cf Article 2.4 (stating a clear preference for formal standards 'because other standardisation products do not necessarily provide the full benefits of formal standards to all stakeholders including, for example, consumers.')

[138] Article 4.1 (ix) and (v), Memorandum of Understanding.

[139] Article 8.4, Memorandum of Understanding.

[140] Article 8.1, Memorandum of Understanding.

[141] Article 8.3, Memorandum of Understanding.

[142] Standards adopted by other organisations had to be approved by the Secretary of State. See eg SI 1995/3130, The Restrictive Trade Practices (Standards and Arrangements) (Services) Order 1995 (approving standards by Electricity Association Services Ltd).

1976 Act was repealed by the Competition Act 1998.[143] Under the Consumer Protection Act 1987 safety standards set by 'any person' are relevant in determining whether the general safety requirement is met. An amendment in Parliament to limit that privilege to BSI and CEN standards was withdrawn after the Minister classified as 'groundless' fears that any company could just write its own safety standards and comply with the general requirement.[144]

Despite its 'private' status, it seems clear that BSI will not be able to escape judicial review. Since the 1987 case of *Datafin*,[145] there has been a much debated move in British courts extending public law to all sorts of self-regulating bodies.[146] BSI itself seems prepared and knows what judicial review will turn on:

> It has been held by the courts that the decisions of a private organisation engaged in activities that may affect the rights of persons and are of a public nature are subject to judicial review. The integrity of British Standards relies on compliance with the procedures established to underpin it.[147]

Dorgard, a 2000 High Court decision, constituted a narrow escape both for BSI and for the court itself.[148] At issue was a fire door release mechanism manufactured by Dorgard which operated by means of a plunger. The relevant standard, BS 5839: 1988, did not include plunger type devices. Nevertheless, BSI Testing issued the company a certificate of compliance in 1997. In 1998, BSI informed Dorgard that the certificate was wrongly issued, asked for the certificate to be returned and demanded that the company cease using it to promote its product. Dorgard refused. Things turned nasty when 'damaging rumours' began circulating throughout the

[143] The OFT nonetheless takes a benign view of standards. See OFT 408, Guideline on *Trade Associations, Professions and Self-Regulating Bodies*. See below.

[144] Hansard vol 116, columns 345–46. It should be added that the Minister's argument was based in large part on the 1987 Approval of Safety Standards Regulations, SI 1987/1911, which provided for a mechanism by which standards could be 'approved' by the Minister as complying with the general safety standards, rather than just being 'factors to be considered.' These would 'most likely' be BSI or CEN standards. That arrangement, however, was repealed by the 1994 General Product Safety Regulations, SI 1994/2328, in conformity with EC law. See below.

[145] *R v Panel on Take-Overs and Mergers, ex parte Datafin* [1987] QB 815.

[146] See eg Borrie, 'The Regulation of Public and Private Power' [1989] *Public Law* 552; Black, 'Constitutionalising Self-Regulation' (1996) 59 *MLR* 24; Alder, 'Obsolescence and Renewal: Judicial Review in the Private Sector' in Leyland and Woods (eds), *Administrative Law Facing the Future* (Blackstone, London, 1997) 160; Harlow and Rawlings, *Law and Administration* (Butterworths, London, 1997) 343 ff; Oliver, *Common Values and the Public—Private Divide* (Butterworths, London, 1999) 85 ff. See more generally Birkinshaw, Harden and Lewis, *Government by Moonlight—The Hybrid Parts of the State* (Unwin Hyman, London, 1990). BSI, it should be added, features nowhere in this literature.

[147] BSI, *British Standards and the Law: Statement of Principles*, November 2000, para 3. This document also claims that 'the law', *sic*, 'accepts that standards are produced and promulgated in the public interest.'

[148] *Regina v British Standards Institute ex parte Dorgard* [2001] ACD 15.

industry about the status of the plunger device, Dorgard decided to send newsletters to fire brigades 'to set the record straight,' and BSI attacked that record publicly. Even if Mr Justice Scott Baker considered there to be a 'clear arguable case that BSI is an entity which is amenable in appropriate circumstances to the supervision of this Court by way of judicial review,' he chose to qualify this particular dispute as arising out of 'a private commercial transaction':

> This Court is concerned with the supervision of public bodies. It is not concerned with private disputes of a commercial nature between a private individual and a company and a body which may exercise functions to the public at large. . . . The boundary between pubic and private law is sometimes easier to recognise than describe. However, I have come to the conclusion that this is not an appropriate case for consideration by way of judicial review.

By focusing on the sad story of the certificate and the ensuing mayhem rather than on the standard itself, the Court saved itself a lot of trouble.[149] For one thing, the judge considered it 'conceivable' that 'there could have been' a public law issue about whether a BSI standard should have been issued to cover the applicant's product. Judicial review of the relevant committee's decision to refuse to include plunger type devices in the British Standard, though complicated, could just about be imagined. Stopping short of substantive review, one would hope, the Court's probe presumably would be limited to an inquiry into the committee's adherence to BS 0.[150] The real mess would have come from an issue the Justice chose to ignore: Dorgard's submission that BS 5839 was superseded by a European standard and BSI's vigorous denial of that assertion.[151] Apart from the substantive question, this time inescapable, of whether BSEN 1155 indeed covers plunger type devices for purposes of fire safety, judicial review of this question would open up the possibility of British public law enforcing a private law obligation between a national private organisation and a private association under Belgian law.

7. FRANCE

7.1 The *Association Française de Normalisation*

France's tradition of regulating the standardisation process dates to 1918, when a purely administrative permanent standards commission was set

[149] Technically, the action was for permission to apply for judicial review.

[150] Dorgard was quick to point out that the relevant committee 'from time to time includes representatives of our competitors.'

[151] BSEN 1155: 1997 Building hardware: Electrically powered hold open devices for swing doors—Requirements and test methods.

up.[152] The *Association Française de Normalisation*, AFNOR, was founded in 1926. By decree of 1930, a new regulatory framework was set up recognising AFNOR's role in standardisation subject to supervision of the newly founded administrative *Comité Supérieur de Normalisation*.[153] That system underwent several more changes until the present regulatory framework was put in place in 1984, coinciding with the advent of the New Approach. Though formally an association under private law, AFNOR is subject to extensive government control and regulation, has been recognised as having a mission of public service and has been granted public law powers:[154] it has hence been described as an 'association administrative.'[155] The tension between public and private standards setting has, then, been resolved by devolving public power to a heavily regulated amalgam of public and private interests incorporated in a 'regulatory association.'

'Under control' of the Minister of Industry, AFNOR is charged with a 'general mission' of co-ordination, diffusion and promotion of standardisation and of representing 'French interests' in 'international non-governmental standards bodies.'[156] A Management Board of between 26 and 38 members runs the association, elected in great majority by the General Assembly. The statutes prescribe that 60% of the Board has to consist of representatives of 'the professions', and further demand three representatives of consumer interests. Six seats on the Board are reserved for public officials representing various ministries.[157]

7.2 Procedures for Standardisation

Standards are to be drafted by technical committees operating within *Bureaux de Normalisation 'a compétence sectorielle'*, which are to be publicly

[152] *Décret instituant la Commission Permanente de Standardisation,* JO 12/6/1918, p 5068.

[153] *Décret instituant le Comité Supérieur e Normalisation,* JO 1/5/1930, p 4843. This committee was composed of representatives of the public authorities and of 'grands groupements scientifiques, industriels et commerciaux.'

[154] See Conseil d'Etat, 14 October 1991, *Conchyliculture*, No 90260; Conseil d'Etat, 17 February 1992, *Textron,* No 73220, both published in (1992) *La semaine juridique (JCP)*, ed G, 428. Recent affirmation in Conseil d'Etat, 8 March 2002, *Plettac Echafaudages*, No 210043.

[155] Champigneule-Mihaïlov, 'Les aspects Juridiques de la Normalisation en France' in Falke and Schepel (eds), above n 41, 231, 258. Laurence Boy likens AFNOR to an independent regulatory authority, combining the logic of the market with 'une logique de mission de service public.' Boy, 'La Valeur Juridique de la Normalisation' in Clam and Martin (eds), *Les Transformations de la Régulation Juridique* (LGDJ, Paris, 1998) 183, 192. On French corporatism embodied in 'service public', see generally eg Jobert and Muller, *L'Etat en Action—Politiques Publiques et Corporatismes* (PUF, Paris, 1987).

[156] Article 5, Décret 84–74 *fixant le statut de la normalisation*, JO 1/2/1984, p 490, as amended by Décret 90–653, JO 25/7/1990, p 8904, Décret 91–283 JO 20/3/1991, p 3873 and Décret 93–1235 JO 17/11/1993, p 15850.

[157] Article 5, AFNOR statutes. Two seats are reserved for the association's staff. The Assembly further elects two 'qualified persons', and one representative each for 'social partners' and 'collectivités territoriales.'

recognised by decision of the Minister of Industry and other interested ministers after hearing the Board of AFNOR. AFNOR is to designate the competent Bureau for each standards project. In absence of competent Bureaux, AFNOR can establish standards committees itself.[158] They currently number over 30, and range from ministerial departments to trade associations.[159]

AFNOR is charged with the task of ensuring that 'major interested parties' are represented in TCs.[160] By Directive, this provision has been refined as follows:

> Les commissions de normalisation chargées d'élaborer les projets de normes doivent permettre l'expression la plus large d'acteurs socio-économiques intéressés. Dans le respect de ce principe général, l'Association française de normalisation et les Bureaux de normalisation peuvent toutefois en réserver l'accès à ceux qui s'impliquent réellement dans les travaux de normalisation, notamment au travers d'un soutien financier et/ou logistique.
>
> Cette dernière disposition ne peut être appliquée à des organismes représentatifs d'intérêts à dimension sociale prépondérante et aux moyens fianciers limités tels que, notamment, les associations de consommateurs ou de protection de l'Environnement.[161]

Draft standards are then to be put through public review by AFNOR, by way of notices in the *Journal officiel* and the *Bulletin officiel de la normalisation*. The competent TC is then to review and 'take account' of all comments received. In case objections persist, the Board of AFNOR is empowered to take a decision.[162] Standards are formally adopted by AFNOR's Board, which is allowed to delegate this task to its Director General.[163]

7.3 Public Control over Standardisation

Public control over French standardisation is tight. As a body of recognised public utility, AFNOR needs approval of the Minister of the Interior

[158] Articles 6 to 9, Décret 84–74.

[159] For the full list, see Champigneule-Mihaïlov, above n 155, 271.

[160] Article 7, Décret 84–74. This includes the right for AFNOR itself 'de plein droit' to participate in every single TC.

[161] Article 5, *Directive relative à l'établissement des normes*, 7 April 1997. The competence to establish 'directives générales' which have to be followed in standards work stems from Article 2, Décret 84–74. For an explanation of the status of the instrument of 'Directive' in French administrative law, see eg Chapus, *Droit Administratif Général* (Montchrestien, Paris, 2000) vol 1, 509 ff. ('Les directives ne décident pas: elles orientent.' Notwithstanding this, they are binding on the regulated as well as on the issuing regulator, and can be challenged in administrative court.)

[162] Article 10, Décret 84–74. A draft standard is put through public review 'afin de contrôler sa conformité à l'intérêt général et de vérifier qu'il ne soulève pas aucune objection de nature à en empêcher l'adoption.'

[163] Article 11, Décret 84–74.

upon advise of the *Conseil d'Etat* for all modifications made to the statutes.[164] Unsurprisingly, then, the statutes provide that the election of the President and the appointment of the Director General are both subject to government approval.[165]

French standardisation law places responsibility for standards policy on the Minister for Industry. He is to establish general guidelines and controls French standards bodies.[166] An interministerial standards group is constituted to assist the Minister, consisting of 'responsables ministériels pour les normes' of all interested ministries.[167] An interministerial delegate is appointed by decree to act as Government commissioner in AFNOR and to co-ordinate all government involvement in the standardisation process.[168] That involvement extends over the whole process. The delegate can ask for the preparation of a standards project.[169] Representatives of the public authorities can, of course, participate in TCs.[170] More significantly,

> Les départements ministériels font part à l'Association française de normalisation, au cours de l'instruction, des modifications qu'ils souhaitent voir apporter aux avant-projets de normes. Les difficultés qui peuvent résulter de cette disposition sont portées devant le commissaire à la normalisation.[171]

In case of European standards, AFNOR is to 'consult' the delegate at least four weeks before the formal vote in CEN takes place.[172] All of this takes place in the shadow of the delegate's right of veto over the formal adoption of standards.[173]

In light of the tight public control over the 'private' standardisation process, it is perhaps unsurprising that the law provides for the possibility or rendering the application of standards obligatory by simple executive decree.[174] And in that light, in turn, it seems logical that formal

[164] AFNOR's 'public utility' was recognised by Decree, JO 12/3/1943, p 722. The association hence needed government approval for a change in the statutes upon the move of its headquarters from Courbevoie to Saint-Denis-La-Plaine. See *Arrêté approuvant une modification des statuts portant sur le transfert du siège d'un établissement d'utilité publique*, JO 30/1/2002, p1990.

[165] Articles 5 and 9 AFNOR Statutes.

[166] Article 2, Décret 84–74.

[167] Articles 3 and 14, Décret 84–74.

[168] Article 3.1, Décret 84–74. He has the right to participate in the Board's meetings. Article 5, AFNOR Statutes.

[169] Article 9, Décret 84–74.

[170] Generally, public participation in standards work seems limited to central government. See Tambou, 'Les Collectivités Locales Face aux Normes Techniques' [2000] *AJDA* 205, 210.

[171] Article 10, Décret 84–74.

[172] Article 14, *Directive relative à l'établissement des normes*, 7 April 1997.

[173] Article 11, Décret 84–74. The delegate has one month to exercise his right. See Article 13, *Directive relative à l'établissement des normes*, 7 April 1997.

[174] Article 12, Décret 84–74. The obligatory application is subject to the possibility of derogation regulated in Article 18. See below. The fundamental difference between private, if formally adopted, standards and mandatory standards is not clear to everyone. See

adoption of a standard has been considered by the *Conseil d'Etat* to be not just a 'recommendation', but a decision of 'un caractère réglementaire' whose legality can be challenged in administrative court.[175] This particular legal status of French standards has led to some speculation as regards the validity in French law of AFNOR's obligations under CEN's statutes and internal regulations. Gambelli maintains that AFNOR's public service mission overrides the association's private law obligations to CEN and concludes that AFNOR is perfectly free to refuse to transpose a European standard it doesn't like.[176] The argument seems a bit futile in view of the 1997 Ministerial Directive which instructs AFNOR 'dans tous les cas' to follow the internal regulations of CEN concerning standstill and transposition of standards.[177]

8. SPAIN

Up until the country's entry into the European Community, standardisation in Spain was carried out by the *Instituto Nacional de Racionalización y Normalización*, IRANOR, a public body fully incorporated into the public administration. The Standards law of 1985 rearranged the system with the explicit objective of aligning it to European models of private standardisation.[178] That law, closely following the French example, placed standardisation under the control of the Minister of Industry and Energy and established a Supreme Standards Council, an administrative unit that was

Tambou, above n 170, 207 ('La confusion entre normes privées et normes réglementaires existe dans l'esprit de la plupart des acteurs locaux. Cela démontre l'absence générale de connaissance du système de normalisation et renforce l'idée selon laquelle les collectivités locales attribuent presque systématiquement un caractère obligatoire aux normes.')

[175] Conseil d'Etat, 14 October 1991, *Conchyliculture*, No 90260, published in (1992) *La semaine juridique (JCP)*, ed G, 428. Standards are, hence, 'administrative acts' for all practical purposes. Gambelli, *Aspects Juridiques de la Normalisation et de la Réglementation Technique Européenne* (Eyrolles, Paris, 1994) 88, however, coins the neologism of 'acte administratif indicatif'. Champigneule-Mihaïlov, above n 155, 268, separates the act of adoption of the standard from the standard itself and contends that a standard could still be seen as 'a private act elaborated by a private organisation.' She doesn't bother to inform her readers how an administrative judge is to evaluate the legality of the adoption of a standard, without which a standard does not come into being, without pronouncing himself on the legality of the standard itself.

[176] Gambelli, above n 175, 89. The 'interministerial delegate' in this scheme of things, can also exercise his right of veto to obstruct the adoption of a European standard. Gambelli later presented the flip side of the argument, perhaps more suited to a European audience. See Gambelli, 'Technical Standardization in France: Evolution of its Legal Aspects in the New European Framework' in Joerges, Ladeur and Vos (eds), above n 89, 101, 104 ('In our view the public service mission given to AFNOR in France would enable the French State to impose inclusion of the standard in the national collection. Is the same true of other countries?').

[177] Article 6, *Directive relative à l'établissement des normes*, 7 April 1997.

[178] Real Decreto 1614/85, *Ordenación de actividades de normalización y certificación*, BOE 12/9/1985, núm 219, p 2219.

to promote and co-ordinate standardisation and prepare standards programmes. The technical standards work was to be entrusted to private non-profit bodies to be accredited to that end under conditions imposed by the law. The conditions include the commitment to modify statutes according to requirements imposed by the Minister, obligatory representation of public authorities in regulatory organs, and balanced interest representation in technical committees.[179] The law further regulated public enquiry to start with notice in the official journal, with special provision for the consideration of comments received by the public authorities with the final decision on disagreements firmly in public hands.[180] The law also gave the power to classify standards by simple executive order as mandatory 'official standards', fully incorporated in the legal order and published integrally in the official journal.[181] In 1986, AENOR was accredited as the Spanish standards body;[182] despite the theoretical possibility of accrediting several standards bodies, there doesn't seem to have been any question ever of creating a pluralistic standardisation system. The system was overhauled in 1992, with the Law on Industry,[183] and 1995, with the approval of a new Regulation for the Infrastructure of Industrial Quality and Safety.[184]

The new framework is focused primarily on certification. Its express intention is to adapt the Spanish regulatory framework to that of the Internal Market, and to the 'new approach' in particular, implying a shift from administrative authorisation of products to certification by manufacturers themselves or by private entities under supervision of the public authorities.[185]

As for standardisation, the new system maintains the accreditation technique, this time under the responsibility of the *Consejo de Coordinación de la Seguridad Industrial*, an administrative body pertaining to the Ministry of Industry, Commerce and Tourism.[186] The standards body is to organise itself 'in accordance with European Union rules and regulations in order to align itself with similar bodies in the Member States.'[187] The law still demands representation of interested parties and public authorities in its regulatory organs and standards committees, and adds the provision that

[179] Article 5, Real Decreto 1614/85.
[180] Articles 5 (2) (d) and 8, Real Decreto 1614/85.
[181] Articles 1 and 9, Real Decreto 1614/85.
[182] By Order of the Minister of Industry and Energy of 26/2/1986.
[183] Ley 21/1992 de Industria, BOE 23/7/1992, núm. 176, p 25498.
[184] Real Decreto 2200/1995 *por el que se aprueba el Reglamento de la Infrastructura para la Calidad y la Seguridad Industrial*, BOE 6/2/1996, núm. 32, p 3929.
[185] Recitals of both legal instruments. The privatisation exercise was not finished until the publication of Real Decreto 1849/2000 *por el que se derogan diferentes disposiciones en materia de normalización y homologación de productos industriales*, BOE 2/12/2000, núm 289, p 42320 (abolishing remaining instances of sector-specific administrative ratification of standards).
[186] Set up by Article 18, Ley 21/1992.
[187] Article 10, *Reglamento de la Infrastructura para la Calidad y la Seguridad Industrial*.

the latter cannot start their activities without permission from the Government.[188] References to drafts, approved and annulled standards are to be published in the official journal.[189] Prices of standards are to be fixed in annual conventions to be signed by the standards body and the public administration. The category of 'official standards' ceases to exist.[190]

AENOR has a membership of around 1000, the bulk consisting of either trade associations or individual undertakings. Votes in the General Assembly are weighted mainly on the basis of turnover.[191] The association hosts 150 technical committees responsible for a catalogue of some 16500 standards. The Assembly's main function consists of electing the 70 strong *Junta Directiva*, or Management Board; 10 seats on the Board are reserved for the public authorities, and a further 8 for various public and private organisations of public interest.[192] Only 6 undertakings and 1 physical person are allowed in the Board; trade associations are allocated 45 seats, with clear and rigid rules assuring that all sectors are represented.[193] The Board constitutes and disbands technical committees and has the power to ratify, annul or revise standards.[194] Much of the actual work is carried out by the Director General, who also presides over the *Comisión Técnica de Normalización*, which has to be consulted for all major technical decisions. This Standards Board, again, counts with an ample representation of public authorities and consumer organisations.[195]

Technical Committees are to have balanced interest representation and always include a member of AENOR staff; experts on TCs do not have to represent AENOR members. Though normally in the hands of the association itself, the secretariat can be carried out by trade associations upon a written agreement of collaboration with AENOR. The internal regulations demand consensus '*en la medida de lo posible*' for all decisions taken by TCs. If a vote should prove necessary on the approval of a standard, a majority of two thirds is needed.[196]

[188] Above, Article 10. There should be equal representation of the central government and of the *comunidades autónomas*.

[189] Above, Article 11.

[190] It is not clear what this means for existing official standards.

[191] Articles 16 and 69, AENOR *Reglamento de régimen interior*. 'Corporate' members are hence allotted up to 800 votes depending on aggregated turnover; consumer organizations get 100 votes, whereas individual undertakings can get a maximum of 300 votes depending, again, on turnover. Physical persons get one vote.

[192] Above, Article 18.1. This includes 2 representatives of consumers and trade unions.

[193] Above, Articles 18.1 and 18.2.

[194] Article 18 o) and q), AENOR Statutes.

[195] Article 26 AENOR *Reglamento de régimen interior*.

[196] Articles 5.3.2 and 5.3.3, AENOR *Reglamento de los Comités Técnicos de Normalización*.

9. ITALY

The *Ente Nazionale di Unificazione* (UNI), established in 1921, had perhaps its heyday in the fascist period, co-opted and supported as it was in the State's corporatist system. In the postwar period, however, it has long led an obscure and unproductive life of neglect by both the political and industrial systems.[197] In face of a legal order characterised by an approach which has been labelled 'marcatamente pubblicistico' as regards technical regulations and standards,[198] UNI has long operated in a complete regulatory void. All of that has been said to have changed after the New Approach came 'to the rescue.'[199] The government implemented the Information Directive by placing UNI under administrative control,[200] and has shown signs, however hesitant and incoherent, of pursuing a policy of using standards for regulatory purposes. For example, the 1971 law on safety on gas equipment requires manufacture conform the '*regole della buona tecnica'* and considered that requirement fulfilled in case of compliance with UNI standards. That extended, however, only to those UNI standards that were 'adopted' by the Minister.[201] The 1990 law on installations requires manufacture according to the '*regole dell'arte*' and considers that requirement fulfilled in case of compliance with UNI standards.[202] This time, however, administrative interference is limited to the provision that those standards are developed 'also' on the basis of 'indications' of the Minister.[203] The standardisation community, however, is still far from happy:

> In the absence of a clear definition and validation of the different roles of the public sphere and the private sphere, the public authorities have continued the policy of the old approach which, rather than leading to new synergies with the standards bodies, has led on various occasions to incoherent and contrasting actions on both national and Community level, thus holding back the operational capacity necessary to face the new European reality.[204]

[197] See generally Elias, above n 32.

[198] Caia and Roversi-Monaco, 'Amministrazione e Privati nella Normativa Tecnica e nella Certificazione dei Prodotti Industriali' in Andreini, *et al,* (eds), *La Normativa Tecnica Industriale—Amministrazione e Privati nella Normativa Tecnica e nella Certificazione dei Prodotti Industriali* (Il Mulino, Bologna, 1995) 13, 15.

[199] Cagli, 'Organizzazione e Procedure dell'attivita' Amministrativa Tecnica nel Settore dei Prodotti Industriali' in Andreini, *et al*, (eds), above n 198, 165, 186.

[200] See Article 4, Legge 317/1986, *Attuazione della direttiva n 83/189/CEE relativa alla procedura d'informazione nel settore delle norme e delle regolamentazioni tecniche,* as since amended.

[201] Article 3, Legge 1083/1971, *Norme per la sicurezza dell'impiego del gas combustibile*.

[202] Article 7, Legge 46/1990, *Norme per la sicurezza degli impianti*.

[203] Article 6, DPR 447/1991, *Regolamento di attuazione della legge di 5 marzo 1990 in materia di sicurezza degli impianti*.

[204] Andreini, 'La Normativa Tecnica tra sfera Pubblica e sfera Privata' in Andreini, *et al*, (eds), above n 198, 45, 85. Translation mine. Pierangelo Andreini is a prominent member of various governing bodies of UNI.

Be that as it may, UNI has enjoyed impressive growth and increased attention in the new situation. Over the last decade alone, it has more than doubled both its membership to over 7000, and its income to over 15 million Euro. It has also tripled its yearly output of standards to 1467 in 2001; 1300 of those were European standards. The organisation's total number of published standards currently stands at almost 14000.[205] And yet, as Alberto Predieri sees it:

> The capacity of Italy to participate actively in the harmonisation of technical regulations and standards has been curtailed by the insufficient development of both public and private technical infrastructures. A solid national system of standardisation is rendered necessary exactly because of the multiplication of fora where it is necessary to intervene to defend the industrial and social interests of a country. In all those respects, Italy still appears to be in a disadvantage compared to the other main European countries.[206]

UNI is a non-profit private law association with legal personality, and as such needs Government approval of its statutes.[207] The organisation's governance structure, as well as the composition of the various governing bodies, are rigidly imposed by the statutes, effectively precluding any significant exercise of associational democracy and requiring abundant representation of the public authorities on all levels. The organisation has a quasi-federate structure, operating through *enti federati*, sectoral standards bodies established by and functioning within trade and industry associations. They are 'recognised' as such on the condition that they subscribe to the objectives and procedures established by UNI, which automatically gives them the status as UNI members and gives them the right to be represented individually on the Management Board, and collectively on the Executive Board.[208] UNI, in turn, is automatically represented on the governing bodies of the *enti federati*. Currently, there are 14 such sectoral bodies. The *Consiglio Direttivo* is further composed of eight members elected by the members organised in the Assembly, 13 representatives of various ministries and public agencies, the President of the *Comitato Italiano Elettrotecnico*, one representative each of what effectively are the social partners, and the President and Vice-Presidents of the *Commissione Centrale Tecnica* (CCT), the apex of UNI's technical structure.[209] The

[205] UNI, *L'UNI nel tempo (1991–2001)*, (http://www.uni.com).

[206] Predieri, 'Le Norme Tecniche nello stato Pluralista e Prefederativo' (1996) 10 *Diritto dell'economia* 251, 271 ff. Translation mine.

[207] UNI's present statutes were approved by ministerial decree published in GU 7/12/1991.

[208] Articles 4, 22, and 25, UNI Statutes.

[209] Article 22, UNI Statutes. As regards the public authorities, the Ministry of Industry and the *Comitato Nazionale delle Ricerche* have the right to two representatives each; other 'interested' ministries, currently eight, to one. Bizarrely, there is one seat reserved to the *Ferrovie dello Stato*, the national railway company. The employers' organisation *Confindustria* and the INAIL, the national institute for insurance against accidents at work, sit on the Board thanks to the clause reserving seats for big financial contributors.

Consiglio elects UNI's President and Vice-Presidents and appoints the association's Director. Together with the President of the CCT and representatives of the Ministry of Industry, the *Comitato Nazionale delle Ricerche*, and the *enti federati* they form the *Giunta esecutiva*, or Executive Board, which runs the association on a day to day basis.[210]

The technical work is carried out under the responsibility of the populous *Commissione Centrale Tecnica*, which consists of representatives of all the public authorities that are represented on the *Consiglio*, of a maximum of five 'experts' appointed by the *Consiglio* itself, and further of the chairmen of all 54 Technical Committees and nine Sector Boards, and the technical directors of all 14 *enti federati*.[211]Technical Committees operate either under the aegis of UNI itself, or within the *enti federati*. Either way, they are to have an 'equitable' representation of 'technical elements', manufacturers and producers and consumers. 'Interested' public authorities have the right to send representatives to TCs as full members.[212] UNI's Technical Committees are set up by the Executive Board, which, on a proposal of the CCT, also appoints their individual members.[213] Technical Committees are to take decisions by consensus; if such is not possible, dissenters may attach a statement of objections to the draft for consideration.[214]

Standards developed within the *enti federati* 'may' be subjected to an internal round of public review and are adopted according to the procedures laid down by their own statutes. Once adopted, they are transmitted to UNI and put through the same procedures as those leading up to adoption of an UNI standard.[215]

Draft standards are subjected to a review by the competent Sector Board for consistency and compliance with procedural guidelines. They are then subjected to public inquiry; the TC and the Sector Board take account of comments and objections are produce a final draft which is submitted for approval by the TCC. Final adoption of the standard is a matter for UNI's President.[216]

10. THE NETHERLANDS

The *Nederlands Normalisatie Instituut (NEN)* is a foundation and as such does not have members.[217] A Board of seven members runs the organisation, one of whom is appointed on binding nomination of the Minister of

[210] Article 25, UNI Statutes.
[211] Article 31, UNI Statutes.
[212] Article 30, UNI Statutes.
[213] Article 25, UNI Statutes.
[214] Article 14, *Regolamento commissioni tecniche dell'UNI*.
[215] Article 36, UNI Statutes.
[216] Article 37 UNI Statutes.
[217] The Dutch standards body changed its acronym from NNI to NEN in 2000.

Economic Affairs.[218] Largely populated by industry representatives, the Board is advised by an Advisory Board and a Policy Board with wider interest representation. The actual standards work is carried out by Standards Committees under the aegis of several Policy Committees. All interested parties are invited to participate on all levels: draft standards are circulated in successive internal and external 'critique-rounds'; for all practical purposes a system of public review. Comments are to be dealt with in writing, and appeal of Standards Committees' decisions is open with the Policy Committees. NEN has a catalogue of some 15.500 standards, of which over 8000 are identical with international or CEN standards.[219]

There is no legislative provision regulating standardisation in the Netherlands. NEN and the Dutch Electrotechnical Committee (NEC) have bound themselves by private law contract with the State to carry out the obligations incumbent on national standards bodies under the Information Directive.[220] The prevailing opinion seems to be that NEN cannot be classified as an 'independent administrative body,' as no public authority has been transferred to it.[221] Public policy in the area of standards is co-ordinated by the Interdepartmental Commission for Standardisation (ICN), which brings together officials from various ministries.[222]

In 1994, the Ministry launched its large scale 'Market Mechanism, Deregulation and Quality of Legislation' project, designed to develop more market-oriented forms of regulation in different policy areas. In that framework, the Minister announced a policy of increased reliance on private standards in the 1995 policy statement 'Standards, Certificates and Open Borders.'[223]

In reaction to its stated enthusiasm to rely on standards, the government came under pressure to establish some sort of regulatory framework in which to embed procedural control over NEN.[224] In 1997, it announced to

[218] This obligation results from NEN's Articles of Association and not from public law. The Minister also has power of approval over the appointment of the Chairperson from among the members of the Board.

[219] NEN, Jaarverslag 2000, 8.

[220] *Overeenkomst informatieprocedure normalisatie*, Staatscourant 4/7/1995, no 126.

[221] See Stuurmans and Wijnands, 'Legal Aspects of Standardisation in the Netherlands' in Falke and Schepel (eds), above n 41, 557, 579.

[222] The ICN is chaired by an official from the Ministry of Economic Affairs. Further ministries represented include Internal Affairs, Justice, Finance, Agriculture and Fisheries, Social Affairs and Employment, Health and Housing.

[223] Kamerstukken II, 1994–95, 21670, nr 8. In 1997, that statement was followed up by the 'Standardisation and Certification' Report; Kamerstukken 1995–96, 24306, nr 15; in 2000, the project finished with 'The Standard is International.' Kamerstukken 2000–1, 21670, nr 10. My translation does not quite capture the rather tiresome pun in 'Internationaal is de norm.' All documents are published on www.minez.nl.

[224] Cf Stuurmans, *Technische Normen en het Recht* (Kluwer, Deventer, 1995) 190 ff (arguing for tighter administrative control, even if stopping short of substantive review).

Parliament its intention to start consultations on a 'Standardisation Code', whose primary focus was to be the conditons and mechanisms of inclusion of interested parties in the process.[225] Those consultations, however, did nothing but prove the widely divergent positions of the various interested circles, including government departments and NEN, on the subject. The government also rejected proposals to draw up an 'Acceptation Code' which would list the conditions standards should fulfil in order to be deemed suitable for reference in public law on constitutional grounds:

> Such a code does not accord with the government's own responsibility for the contents of regulation, which includes the references to standards. The government has to scrutinise whether a standard adequately substantiates the requirements set in regulation, and whether the standard carries the support of broad sectors of society.[226]

Unwilling to commit itself to privileging standards drafted and approved acording to the principles and procedures such codes would lay down, the government launched another scheme to address the problem of lack of interest participation in NEN. In December 2001, the Government signed a Memorandum of Understanding with the leading associations of employers, employees, small-and-medium enterprises and standardisation circles to provide for collaboration in the so-called 'Visibility' project. Allocating close to 2 million Euro to the project, the government hopes that this, yet another 'platform', will produce procedures and mechanisms to promote an 'efficient, transparent and accessible standardisation process', to increase coordination of Dutch interests in European and international standardisation and to enhance understanding of the role standards can play in the public interest.[227]

11. IRELAND

Be it for lack of industry interest and resources or for political reasons, standardisation in Ireland has remained a public affair. The most striking feature of the legislative history is, indeed, how little has changed over the last fifty years. The Industrial Research and Standards Act of 1946 concentrated standards work, hitherto carried out by various non-statutory public bodies, in one central organisation. As part of Institute for Industrial Research and Standards, a seven member Standards Committee appointed by the Minister for Industry and Commerce was thus charged with the elaboration of standards:

[225] Letter from the Ministers of Economic Affairs and Justice to Parliament, 30 May 1997, Kamerstukken 1996–97, nr 47.

[226] 'Internationaal is de Norm', 15. Translation mine.

[227] *Memorandum of Understanding voor samenwerking van belanghebbende partijen in het project Kenbaarheid van normalisatie en normen*, signed on 20 December 2001.

(1) The Institute shall formulate for the Minister specifications for such commodities, processes and practices as the Minister may from time request.
(2) In formulating specifications under subsection (1) of this section the Institute shall comply with the directions of the Minister.
(3) The Minister, on obtaining a specification from the Institute, may by order declare the specification to be a standard specification for the commodity, process or practice to which it relates.[228]

The 1961 Industrial Research and Standards Act gave the Institute the power to declare a standard specification 'with the consent of the Minister,' provided for publication of notice of such declaration in *Iris Oifigúil* and regulated the publication and sale of standards.[229] The outfit was subsequently moved to the newly founded *Eolas* in 1987,[230] before it was established as the National Standards Authority of Ireland as a subcommittee of another agency, *Forfás*, in 1993.[231] In 1996, the NSAI was established as an autonomous statutory agency, allegedly under pressure of the European Commission.[232]

The NSAI is a body corporate with the power to sue and be sued in its own name; the Authority consists of 13 members who constitute the Board 'appointed by the Minister from among those interests involved in the process of standardisation and certification, without any single interest dominating.'[233] The Board has the power to set up 'such and so many consultative committees as it considers proper to advise and assist on the technical contents of standards.'[234] No guidelines or regulations setting out the procedures to be followed are in existence. It is a modest operation. There are 14 such committees with some 800 members, who spend the vast majority of their time and effort on European and international work; only

[228] Article 20, Industrial Research and Standards Act, SI 25: 1946.
[229] Articles 20 (3) and 21, Industrial Research and Standards Act, SI 20: 1961.
[230] See the Science and Technology Act, SI 30:1987.
[231] On the basis of Article 9 and 10, Industrial Development Act, SI 19: 1993.
[232] National Standards Authority of Ireland Act, SI 28: 1996. The Government introduced the Bill on the understanding, or at least the pretence, that it be a *legal* necessity flowing from the New Approach. Mr Rabbitte, Minister of State: 'The main purpose of bringing this Bill before the House is to establish the NSAI as an independent and autonomous agency and in so doing to underpin and enhance its role in the development and certification of a wide range of standards. The need to establish this agency on a legally independent basis results from a requirement of the European Commission and the necessity for the NSAI to have an administrative structure which is seen to be independent of all other client agencies. The current administrative and operational basis, as a committee within the orbit of Forfás, is not in line with these requirements and accordingly this legislation will give effect to the change in its status which my Department has been independently advised as being legally necessary.' *Dáil Ēireann*, vol 464, 2 May 1996. Either this was a deliberate falsehood, or the quality of the Departments legal counsel must be put into question.
[233] Article 4, First Schedule, SI 28: 1996.
[234] Article 10 (2), SI 28: 1996. Article 10 (3) gives explicit permission to populate these committees with persons who are not members of the Authority or its staff.

a handful of indigenous Irish standards are published every year. Total costs in 1999 amounted to some 12 million Euro; the Authority was able to earn some 9 million Euro in certification fees, and another half a million in standards sales.[235]

If, hence, the NSAI in practice does little more than facilitate communication and consultation processes on European standards, the legislative provisions have changed little since 1946, and hardly at all since 1961. The Authority is still to formulate 'for the Minister' such standards 'as the Minister may request' in a way that complies 'with the directions of the Minister' and may only adopt such specifications as Irish Standards 'with the consent of the Minister.'[236] And so legal fictions full of nostalgia of public control over national co-regulation are to compensate for the loss of power to transnational private parties.

12. CONCLUSION

In terms of shifting power relations, it can be helpful to think of European standardisation as a set of vertical relationships—between the European Community and its Member States and, and between European standards bodies and their national members. From that angle, the development of the whole system has been rather predictable: power drifts away from nation states towards the European level. It can also be helpful to think of it in terms of a set of horizontal relationships—between the European Community and the European standards bodies, and between national public authorities and national standards bodies. From that angle, the story pretty much remains in established canons: power drifts away from public authorities towards 'private governments'. Slightly more surprising is the view gained from looking at diagonal relationships. Supranational private power can be blocked by national public power; supranational public power can easily run up against national private power. One can, of course, put all of this through the 'multi-level governance' grinder, add a pinch of 'polycentricity,' and conclude that the underlying distinctions between the national and the European, and between the 'state' and the 'market', are becoming less and less relevant. And so they are. There are other distinctions however, that are becoming more and more relevant. That between society and the politico-legal

[235] NSAI, 1999 Annual Report.

[236] Article 16, SI 28: 1996. Article 28 (1) further gives the Minister the power to prohibit by regulations the manufacture and sale of practices or commodities unless these comply with Irish Standard Specifications 'or with equivalent standards of another Member State.' That power only extends 'for the purpose of promoting the safe use by the public of a commodity intended for sale to the public and for promoting safe practices.' Any such regulations, moreover, must, as soon as possible, be brought before Parliament, which has the right to annul them within three weeks. Article 28 (2).

system, for example. On the national level, the shock of collapsed distinctions between what is irreducibly public and what is irredeemably private, between what is 'law' and what is mere fact, has been absorbed largely by the assumption of a more or less coherent cognitive and normative *social* framework. As long as standards can somehow be posited as inherently social, as finding their roots in widely shared attitudes towards risk and technology, as reflecting a widely respected professional 'common sense', it doesn't really matter whether such standards are issued with or without public involvement, whether they spring from privatised public institutions or from publicly disciplined private institutions. The Europeanisation of standardisation inevitably uproots standards from such social bedding. In that event, standards will be unfit for a role of linking socially accepted behaviour and legally institutionalised requirement. If anything, then, the challenge for European standardisation is to transform the system from a mechanism of diffusing power among states and markets into a mechanism for the social construction of 'common sense.'

5

Standards and Codes in the United States

1. INTRODUCTION

ACCORDING TO ANSI, the voluntary standardisation system in the United States is the 'most effective and efficient in the world'.[1] Samuel Krislov doubts if one could even speak of a 'system'.[2] The dominant characteristic of the system is its high degree of decentralisation. There are an estimated 49,000 private standards in place in the United States, developed by over 600 trade associations, professional societies and other organisations.[3] Some of these standards, and some of these standards bodies, are in outright competition with each other; others coordinate their activities in co-operation arrangements. Most standards are traditional voluntary standards; others, however, are developed with the explicit intention to get them adopted into law. This chapter will first describe the outlines of the private standardisation system and its main components. The latter part of the chapter deals with codes and standards in the construction sector and the ways these are incorporated into state and municipal law.

2. THE PRIVATE STANDARDISATION SYSTEM

The *American National Standards Institute*, set up in 1918 by three government agencies and five engineering societies,[4] co-ordinates the standardisation system. It does not develop standards itself, limiting itself to

[1] Testimony by Amy A Marasco, Vice-President and General Counsel, American National Standards Institute, before the Federal Trade Commission, 1 December 1995.

[2] Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, Pittsburgh, 1997) 104.

[3] For a full overview, see Toth (ed), *Standards Activities of Organizations in the United States*, NIST SP 806 (Government Printing Office, Washington, 1996) the latest update of what is known as the 'Standards Directory'. A full list of standards developers can be found at http://www.nssn.org.

[4] The organisation was originally called the American Engineering Standards Committee, and went through life afterwards as the American Standards Association.

accrediting standards developers and approving their standards as American National Standards. Currently, these number a little over 10000.[5] It further serves as the United States member of international standards bodies and co-ordinates American participation in international technical committees. It receives negligible financial support from the government, supporting its 17 million dollar budget mainly through membership fees and sales of publications.[6] Krislov describes the organisation as an abandoned child, clearly a government offspring 'which the government now generally regards as an excuse for its own inactivity and as a mask for business's preference for nonregulation.'[7] Government recognition of its role is expressed through the Memorandum of Understanding signed in 1998 with the National Institute of Standards and Technology, a federal government agency. The MoU is designed to 'enhance and strengthen the national voluntary consensus standards system of the United States and to support continued US competitiveness, economic growth, health, safety, and the protection of the environment.' NIST undertakes to encourage and coordinate the use of voluntary standards among federal agencies; ANSI is to oversee a system of standardisation 'firmly based on the principles of openness, balance of interests, due process and consensus.'[8]

ANSI membership is divided into three main categories—company members, government members and organisational members.[9] These three have their respective Membership Fora. ANSI has further set up a Consumer Interest Forum, a hybrid group consisting of 'knowledgeable representatives from Consumer organisations, producers, retailers, distributors, industry councils and government.'[10] The Chairpersons of all four fora have a seat on the Board of Directors as of right, as do the presidents of the most important committees. The remainder of the Directors used to be allocated in the By-laws to different constituencies, but those provisions have not survived the 2002 overhaul of the By-laws.[11] It is still

[5] ANSI, 2002 Annual Report. This is down significantly from a top of over 14000 in the late 1990s, thanks mainly to a concerted effort to weed out overlapping and outdated standards.

[6] ANSI, 2002 Annual Report. More than ten million dollars were earned from publications. NIST has given a grant of half a million dollars for ANSI's international work over the last few years.

[7] Krislov, above n 2, 114.

[8] Memorandum of Understanding between the American National Standards Institute and the National Institute of Standards and Technology, Signed 24 September 1998.

[9] Section 2.01, ANSI By-laws, 2002. Further categories are Individual Members, Educational Members and International Members. The latter are excluded from voting; see Section 2.07.

[10] Section 6.16.4, ANSI By-laws, 2002. Consumers are defined as 'those individuals who use goods or services to satisfy their individual needs and desires, rather than to resell them or to produce other goods and services'.

[11] Section 3.02, ANSI By-laws 2002.

safe to say, however, that the Directors-at-large will be dominated by representatives of several multinationals, of the most relevant government agencies and of the most important standards developing organizations.[12]

The Board nominates the members of the Board's Committees; in case of the Executive Committee, this has to be done according to precise requirements.[13] The Chairperson of the Board also appoints members to the Institute Program Oversight Committees endeavouring 'to ensure representation of all membership groups concerned'.[14] These include the Executive Standards Council, responsible for procedures and criteria of standards development, and the Board of Standards Review which adopts and withdraws American Standards by affirmative vote of at least two thirds of its members.[15]

ANSI has currently 267 accreditations to 193 distinct entities as 'standards developers'. These fall into three categories. 97 of them are organisations that develop or maintain standards according to ANSI's procedures for 'canvassing'. These include the Federal Highway Administration, but such organisations as the Book Manufacturers Institute, responsible for the American Standard on fabrics for book covers, and the National Golf Car Manufacturers Association are more representative for the category. 'Canvassing' is basically a formalised public review process, usually conducted contemporaneously with that process and always after the draft standard has already been elaborated.[16] Further, there are 100 Committees, set up especially to develop and maintain a certain standard or well-defined sector. Committees overarch any single organisation and are usually instituted either for sectors where there is 'a wide range of interests involved' or, more likely, to resolve turf battles between organisations.[17] Committees may adopt ANSI's Model Procedures,[18] or adopt their own procedures as long as they are consistent with ANSI's basic requirements. A disproportionate number of Committees deal with electrotechnology, with the National Electrical Manufacturers Association

[12] Among its 42 Directors, the 2003 Board features representatives of Motorola, Siemens and IBM; of the CPSC, the FDA, the EPA, NASA and NIST, and of Underwriters' Laboratories, the American Society for Testing and Materials, the American Society of Mechanical Engineers and the National Fire Protection Association.

[13] Section 5.031, ANSI By-laws 2002.

[14] Sections 6.10 and 6.11, ANSI By-laws, 2002.

[15] Section 5.1, Operating Procedures BSR, Approved by the Board of Directors July 1998. If BSR Members have any ties with the organisation proposing the standard, a 'conflict of interest' is presumed and the member is required to disqualify himself from voting and deliberating.

[16] ANSI Procedures for the Development and Coordination of American National Standards, 2002, Annex B. The standard developer is to establish a 'canvass list' of all affected parties subject to the general balance of interest rules, and submit that list for approval to ANSI Further procedures do not differ much from the general public review process.

[17] The 'wide range' is ANSI's rationale. ANSI Procedures, Annex E.

[18] ANSI Procedures, Annex A.

(NEMA) alone holding 24 Secretariats. Finally, 70 bodies have the status of fully accredited organisation, following their own operating methods and procedures, to be approved by ANSI. This category includes all the major standards bodies, from the American Petroleum Institute (API) to ASME and the Society of Automotive Engineers (SAE).

Whatever the specific mechanism used for the development of American National Standards, ANSI insists that its 'minimum acceptable due process requirements for the development of consensus' be met.[19] First, participation in the process is to be open to 'all persons who are directly and materially affected by the activity in question,' and may not be hindered by 'undue financial barriers. ' Voting membership on the consensus body shall not be conditional upon membership in any organisation or 'unreasonably restricted on the basis of technical requirements or other such requirements.'[20] Second, there shall be a balance of interests in the standards development process, defined as the absence of 'dominance' by one single interest category, individual or organisation.'[21] Third, an 'identifiable, realistic and readily available appeals mechanism for the impartial handling of procedural complaints regarding any action or inaction' is to be instituted.[22] Fourth, standards are to be based on consensus, defined as follows:

> 'Consensus' means substantial agreement has been reached by directly and materially affected interest categories. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution.[23]

All draft standards are to be notified in *Standard Action* for public review.[24] The standard developer is obliged to make 'an effort' to resolve all comments, and each objector is to be given a reasoned statement explaining the disposition of the objection. Should no resolution be

[19] To that end, ANSI has published *ANSI Essential Requirements: Due Process Requirements for American National Standards*, in 2003.

[20] *ANSI Essential Requirements*, Section 1.1.

[21] *ANSI Essential Requirements*, Section 1.2. 'Dominance' is defined as 'a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.' Section 1.3 demands that 'participants from diverse interest categories' be sought in order to achieve 'balance'. Section 2.3 notes ambiguously that, 'historically', the criteria for balance are that 'a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety or b) no single interest category constitutes a majority of the membership of a consensus body dealing with product standards.'

[22] *ANSI Essential Requirements*, Section 1.7. Elaboration in Section 2.7.

[23] ANSI Procedures, Section 1.3. See also the procedural elaboration in *ANSI Essential Requirements*, Section 2.6.

[24] *ANSI Essential Requirements*, Section 2.4. The comment period is a minimum of sixty days, reduced to 45 if the standards developer is able to transmit the draft electronically within one day of a request.

achieved, the objector must be informed of the existence of the appeals mechanism within the standards developer's procedures. Moreover, unresolved objections are to be fed back into the consensus body in order to allow all members the opportunity to respond, reaffirm or change their vote.[25] The standard is then submitted for approval to the Board of Standards Review, which has to satisfy itself 'on the weight of the evidence presented' that the standard was developed in accordance with the procedures upon which the standards developer was accredited, that due process was afforded and consensus achieved, that all appeals have been completed, and that the standard is not in conflict with an existing American National Standard.[26]

All development of American National Standards is subject to a double possibility of appeal, one at the SDO level and another one at ANSI level. Canvassing bodies are to set up an 'impartial appeals body composed of at least three individuals knowledgeable as to the policy or other concerns related to the appeal.'[27] The Model Procedures for Committees are tougher, requiring a three-member panel, two of whom are to be acceptable to either party, and imposing conflict of interest criteria.[28] ANSI's Board of Appeals hears complaints either against the SDO's appeal board decision or against ANSI itself.[29]

The NFPA, ASTM, NSF International and UL have the status of 'audited designator', a privilege reserved for those organisations with a 'consistent record of successful voluntary standards development'.[30] What it means is that they have been granted the authority by ANSI to designate their standards ANS on their own accord, without the approval of the Board of Standards Review. Appeal against decisions of these bodies is open at ANSI in an especially arduous procedure. If the appeals process available at the 'audited designator' is completed, complaints can be sent to ANSI's Executive Standards Council. If that body sees any merit in the complaint, it can request a written response from the standards developer. If it is still not satisfied, it may schedule an 'audit' to discuss the matter. If after that it is still unconvinced, the Council can decide on additional action provided it gives the audited designator 'full notice and opportunity to be

[25] *ANSI Essential Requirements*, Section 2.5.
[26] *ANSI Essential Requirements*, Section 4.2.1.1.
[27] ANSI Procedures, Section B 7.
[28] ANSI Procedures, Section A 12.4.
[29] ANSI Procedures, Section 5.2.
[30] *ANSI Essential Requirements*, Section 5. There is a 'presumption' of this condition being fulfilled when 'a) the developer has been involved in voluntary standards development work for at least five years, b) during that period, BSR has approved at least ten of the developer's standards, and c) no standard submitted by the developer during the five year period was finally denied ANS status by ANSI due to a failure to adhere to the principles and procedures upon which the developer's accreditation was based.'

heard'. Appeal against the Council's decision, then, is open at ANSI's Board of Appeals.[31]

The *American Society for Testing and Materials* is by far most productive standards body in the United States. Founded in 1898, it has more than 10.000 standards in place. ASTM has over 30.000 volunteer members sitting on 132 main technical committees covering technical sectors. Standards are drafted by task groups and reviewed at subcommittee level. They are then transmitted simultaneously to the main committee and to the Society as a whole. Procedures on all levels are described by the hefty 'Green Book', the *Regulations Governing ASTM Technical Committees*.[32] A standing committee, COTCO, is charged with the development, maintenance and enforcement of the regulations. Final approval of a standard is subject to another review of due process requirements by a separate committee. Appeals are heard by an administrative committee. ASTM finances itself entirely, predominantly from sales of standards and other publications;[33] it does not engage in product certification. ASTM was a founding member of ANSI, but the two organisations have since developed less than friendly relations amidst accusations of turf grabbing.[34] In December 2001, the organisation announced it was keeping with the times and changed its name to *ASTM International*.[35]

The *American Society of Mechanical Engineers* was established in 1880. It has a staggering 125.000 individual members and publishes over 600 codes and standards. Its main claim to fame is the Boiler and Pressure Vessel Code, incorporated into law throughout the United States and Canada. After it was slapped a 9.5 million dollar antitrust verdict in the *Hydrolevel* affair,[36] it has worked hard to make its procedures full-proof and ANSI accredited.[37] ASME too changed its name to the inevitable *ASME International*, considers itself an 'international' standards body, and lobbies hard to convince US officials to adopt and defend that position in WTO talks.[38] It is now even confident enough to object to ISO and CEN

[31] Article 18, Operating Procedures of the ANSI Executive Standards Council, 2001.

[32] The latest version dates to March 2000.

[33] Over 2000, the association generated a little over 35 million dollars, of which 24.5 million came from publication sales. Members' administrative fees accounted for 2.3 million. ASTM, 2000 Annual Report.

[34] Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990) 27.

[35] ASTM, Press Release, 'ASTM International—Name Change Reflects Global Scope', 7 December 2001. The name change is underlined by a new logo with the tag line 'Standards Worldwide.'

[36] See *American Society of Mechanical Engineers v Hydrolevel Corp* 456 US 556, 571 (1982).

[37] See Procedures for ASME Codes and Standards Development Committees Operating Under Redesigned Process, 5th Revision, June 1999, approved by ANSI's Executive Standards Council on 12 January, 2000.

[38] See eg General Position Paper of ASME International on Standards and Technical Barriers to Trade, March 1997, and ASME's comments following the 'Solicitation of Public Comments regarding US Preparations for the World Trade Organization's Ministerial

being qualified as 'consensus standard organisations' in federal legislation under the theory that these organisations achieve, if anything, 'political' and not technical consensus.[39]

Underwriters Laboratories was set up in 1894 by insurance companies eager to reduce payouts. Its main business is and has always been safety testing and certification. In 1998, its UL mark appeared on close to 15 billion new products. It has 750 standards in place, covering anything from pressure cookers to ice makers. Via a mechanism established in a Memorandum of Understanding with the *Canadian Standards Association*, 66 of these are bilaterally harmonised. A mere 30 are harmonised with IEC standards. Unlike ASME's, UL's reputation is excellent, its history devoid of scandals. Up until recently, UL developed its standards mostly in-house, using the 'canvass method' to determine consensus and gain ANSI recognition.[40] Cheit noted that UL submits its standards for approval to ANSI 'largely as a matter of courtesy without any practical significance for the recognition or use of UL standards.'[41] In 2000, UL has changed its standardisation procedures to increase participation from consumers and regulators, providing for input from interested circles from the earliest stages on in its *Standards Technical Panels.* In August 2000, ANSI granted UL the status of 'audited designator', giving UL the right to publish its standards as 'American Standards' without the need to go through ANSI's Board of Standards Review. Despite charging handsomely for its services, it is officially a non-profit organisation and enjoys the tax exemption to go with it.[42]

Set up in 1896 to deal with fire sprinklers, the *National Fire Protection Association* has some 65.000 members. Over 6000 volunteers on 200 technical committees administer some 300 codes and standards. After being scathed by the Supreme Court in 1992 for sloppy procedures and lack of oversight,[43] it has tightened up its internal regulations considerably and is now an 'audited designator'. The Association is governed by a Board of

Meeting 1999', Federal Register of 19 August 1998, 44500, of the Office of the US Trade Representative by letter of 14 October 1998.

[39] The Fastener Quality Act, Public Law 101–592, 1990, as amended by Public law 106–34, 1999, recognises national and international 'consensus standards' for certain purposes and explicitly mentions ASTM, ASME, SAE and ISO NIST published a 'provisional list' of recognised 'consensus standard organizations' in the Federal Register of 26 September 1996, 50582–50583, including CEN (as well as the 'European Community'). By letter of 27 November 1996, ASME objected to the inclusion of CEN and ISO on the grounds that they are 'political' organisations incapable of meeting the criteria of openness, balance of interest and due process.

[40] UL also has the status of 'accredited organisation' and has produced written procedures accordingly. The method, however, has never been very popular.

[41] Cheit, above n 34, 98.

[42] The IRS challenged the exemption in the early 1940s and was comforted in federal court, *Underwriters Laboratories v Commissioner of Internal Revenue* 135 F 2d 371, 373 (10th Cir 1943) (UL 'may be good business, but it is not charity'). See Cheit, above n 34, 95.

[43] *Allied Tube & Conduit Corp v Indian Head, Inc* 486 US 492 (1988).

Directors elected by the members, which in turn appoints a 13 member Standards Council to which it delegates all decision-making on the process of standardisation.[44] The standardisation process itself is arduous, requiring balanced interest representation on TCs,[45] two rounds of public review with the obligations to take proposals and comments into account and state reasons for rejection or adoption,[46] and a vote at the biannual membership meeting.[47] Almost any decision along the way in the process can be appealed at the Standards Council, from decisions to appoint nominees to a TC to the technical validity and fairness of the final adopted document.[48] The NFPA publishes the *National Electric Code* which has had a near monopoly throughout the country for decades. Other important NFPA codes are the *Fire Prevention Code*, the *National Fuel Gas Code* and the *Life Safety Code*.

3. THE BATTLE OF THE BUILDING CODES

The NFPA has recently branched out towards the development of other codes, notably a *Building Code*, which has put the organisation in the eye of a storm that is shaking the entire construction industry. That sector displays several characteristics that make it an obvious choice for illustrating the American standards system and its regulatory context. More than half of all US standards developers prepare and maintain the more than 11.000 standards applicable to the sector, of which a significant part are overlapping or in outright competition.[49] Standards activity in the sector is, moreover, not only more decentralised but also more 'politicised' than in any other sector. 200 out of 300 trade associations engaged in standardisation are active in building and construction. In several sectors manu-

[44] See the 2000 version of NFPA's *Regulations Governing Committee Projects*.

[45] See Section 3–2.5, *Regulations Governing Committee Projects*. Members are categorised into manufacturers, users, installers, enforcing authorities, consumers, labour, insurers etc. No one interest is to be represented by more than one-third of the voting members. Decisions in TCs are taken by two-thirds majorities.

[46] The TC develops a draft, notice of which is published widely, including in the *Federal Register*. Next, the TC is to prepare a Report on Proposals, specifying all action agreed on in the TC on public proposals as well as proposals originating in the TC itself, complete with technical reasons for adoption or rejection and results of balloting. This ROP is then submitted for a 60 day Comment period. The TC then prepares a Report on Comments according to the same principles.

[47] All members can vote. 'Packing' of the General Assembly, as was the case in *Allied Tube*, above n 43, is thus still possible. However, two mechanisms are in place to avoid trouble. First, the Council reviews all action taken by the annual meeting before issuing the standard. Moreover, any amendments proposed by the annual meeting have to go back to the TC for approval by two thirds of TC members.

[48] Section 1–6.1, *Regulations Governing Committee Projects* ('Anyone can appeal to the Council concerning procedural or substantive matters related to the development, content, or issuance of any Document of the Association . . .').

[49] Figures from Toth (ed), above n 3, 9.

facturers, engineers, contractors and other groups all have their own standards organisation, and more often than not most of them are accredited by ANSI.

The regulatory framework for the construction industry in the United States is a fantastically complicated combination of public law, semi-public 'model codes' and private standards.[50] A matter of state or municipal jurisdiction depending on the State, public building regulations almost everywhere rely heavily on model codes drafted by private associations; these model codes, in turn, refer liberally to private standards drafted by yet other organisations.[51]

Until recently, the system was characterised by a fairly clear division of labour. With the exception of the NEC, the dominant model codes were all written by private not-for-profit organisations of public regulators and inspectors. After a process of consolidation, three large regional organisations remain: the *International Conference of Building Officials* (ICBO), based in California, which publishes the 'Uniform Codes'; the *Building Officials and Code Administrators* (BOCA), based in Illinois, publishers of the 'National Codes', and the *Southern Building Code Congress International* (SBCCI) of Alabama, which publishes the 'Standard Codes'.[52] Even if they have membership categories for individuals and companies, voting rights are limited to 'governmental units or departments engaged in the administration or formulation of laws and ordinances relating to building construction.'[53] Acting as a conduit between private standards and public law, these organisations seem to combine the best of all worlds: pooling expertise outside the structures of the legislature, yet invested with the authority and legitimacy of public office, 'their functions are what an idealised legislative committee would be expected to perform but would seldom have the technological skills to do.'[54] In the words of the First Circuit,

> Groups such as BOCA serve an important public function; arguably they do a better job than could the state alone in seeing that complex yet essential regulations are drafted, kept up to date and made available.[55]

[50] The only major law review article to make some sense of it is the eerily contemporary Thompson, 'The Problem of Building Code Improvement' (1947) 12 *L & Contemp Prob* 95.

[51] NFPA's *Regulations Concerning Committee Projects* define 'Code' as 'a standard that is an extensive compilation of provisions covering broad subject matter or that is suitable for adoption into law independently of other codes or standards.' A 'standard', in turn, is 'a document, the main text of which contains only mandatory provisions using the word "shall" to indicate requirements and which is in a form generally suitable for mandatory reference by another standard or code or for adoption into law.' Section 3–3.6.1.

[52] For a concise history, see CABO, *An Introduction to Model Codes*, 1997.

[53] Article II (1)(1), ICBO By-laws.

[54] Krislov, above n 2, 238.

[55] *Building Officials and Code Administrators v Code Technology* 628 F 2d 730, 736 (1st Cir 1980), a case dealing with an assertion of copyright on a code adopted into law.

Concerns about the impact of three different sets of codes on the competitiveness of the US construction industry and the uncertainty created among State legislators being faced with divergent requirements from which to choose led to considerable pressure for yet more centralisation. Consequently, the three set up the *International Code Council* (ICC) in 1994 with the specific objective of establishing a single comprehensive set of nationally uniform codes. Further steps towards a complete merger of the three organisations are under way.[56]

The ICC has registered a trademark for *International . . . Code*, and has in recent years published the *International Fire Code*, the *International Plumbing Code*, the *International Mechanical Code*, the *International Fuel Gas Code,* the *ICC Electrical Code*, and the jewel in the crown, the *International Building Code*.[57]

Thwarting these efforts towards unification, the NFPA has launched a full scale assault on the near monopoly of these semi-public model codes. It has registered a trademark for *Comprehensive Consensus Codes (C3)*, and has, through several strategic partnerships, in recent years produced the whole set, consisting of NFPA 1–the *Uniform Fire Code*, the *Uniform Plumbing Code*, the *Uniform Mechanical Code*, NFPA 70–the *National Fuel Gas Code*, the *National Electrical Code*, and the jewel in the crown, NFPA 5000–the *Building Construction and Safety Code*.[58]

The United States now has two sets of uniform national codes for the whole construction industry in fierce competition. This Battle of the Codes is fought in both industry and legislative circles, and spreads to different professional groups and different groups of regulators. On one level, it is surely a clash of cultures—the private standardisation process dominated by industry and the engineering profession on the one hand, public regulators and officials on the other. The Codes in the C3 set are all produced through ANSI-accredited procedures; ICC Codes, on the other hand, are produced through a process that, though open to input from all interested circles, restricts voting rights to public officials.[59] On another level, however, it is just a sad saga of organisational turf grabbing.

[56] The ICC adopted amended and restated By-laws in July 2002 which pave the way toward full merger. For a transitional period, the three organisations will each have a third of the seats on the Board and a fair share of high officers through a complicated rotation system. Eventually, the membership will elect Board members without restrictions of origin. See Article V, ICC By-laws.

[57] The ICC claims to offer 'the first family of comprehensive, coordinated model codes.' See ICC, Press Release, 'Building Success—International Codes Being Adopted Across United States' 26 June 2001.

[58] The NFPA now claimed to offer 'the only full set of integrated codes for the built environment.' See NFPA, Press Release, 'NFPA Building Code Moves Forward', 7 August 2001.

[59] Section 1.2, *ICC Code Development Process for the International Codes*, describes the objectives as of the process as '(1) The timely evaluation and recognition of technological developments pertaining to construction regulations; (2) The open discussion of proposals by all parties desiring to participate, and (3) The final determination of Code text by officials representing code enforcement and regulatory agencies.'

3.1 The Battles of the Model Codes

3.1.1 Fire Codes

The *Western Fire Chiefs Association* has administered the *Uniform Fire Code*, the most widely used fire code in the country, since 1971. Set up in 1891, the WFCA has much the same structure as the Building Official organisations, allowing representatives of various interests on committee and subcommittee level, but limiting voting rights to public officials. In 1991, WFCA set up the *International Fire Code Institute* together with ICBO and the *International Association of Fire Chiefs*, fondly known as the 'I-Chiefs'. The organisations duly published a joint *Uniform Fire Code* until the IFCI Board decided in 1995, after the ICC was set up, to discontinue work on the UFC and concentrate efforts on an *International Fire Code*. The WFCA saw itself marginalised in the new environment, and requested the ICC Board in 1996 for a 'defined position' in the IFC process, only to be denied. They requested the I-Chiefs' endorsement for the UFC with similarly disappointing results.

Meanwhile, in 1997, the NFPA and the ICC reached agreement on developing a joint fire code using a parallel development process. That agreement collapsed a year later in acrimony.[60]

The WFCA went ahead to publish a 2000 *Uniform Fire Code*. It set up a new *Uniform Fire Code Association*, in order to encourage further participation by non-fire service members. In the UFCA, the WFCA appoints four Board members, with the other four elected by the UFCA membership. ICBO went on to publish a 2000 *International Fire Code* through the ICC. For its part, it created a new *Fire Service Division* to give ex-IFCI members a voice in the IFC development process.[61] With the acquisition of full ownership rights of the IFCI from the WFCA in August 2000, ICBO has regained control of all copyright and other property rights relating to the *International Fire Code*.[62]

An anti-ICC coalition seemed ever more necessary. In 1999, WFCA announced a Memorandum of Understanding with the *International Association of Plumbing and Mechanical Officials* (IAPMO), that included technical co-operation and cross-licensing of references and duplications on the Uniform Fire Code and IAPMO's Plumbing and Mechanical Codes.[63] Then, in January 2000, the WFCA reached agreement with the NFPA to jointly develop a new fire code, integrating the UFC with NFPA's

[60] ICC, Press Release, 'ICC and NFPA Joint Fire Code Development Collapses', 20 February 1998.

[61] ICBO, Press Release, 'New Organisation Focuses on Public Safety and Fire Prevention', 21 March 2000.

[62] ICBO, Press Release, 'WFCA Transfers Ownership of IFCI to ICBO', 18 August 2000.

[63] IAPMO, Press Release, 'IAPMO and WFCA Reach a Historic Agreement', 2 March 1999.

Fire Prevention Code.[64] Developed under NFPA's ANSI-accredited standards developed process, the initial draft of *NFPA 1–Uniform Fire Code* was published in February 2001.[65] For the WFCA, then, something of a culture shock is at stake. The UFC will transform from a code promulgated by regulators to a code established through the ANSI consensus process.

3.1.2 Plumbing and Mechanical Codes

The *International Association of Plumbing and Mechanical Officials* (IAPMO) was founded in 1926. Originally a California based organisation, it has steadily increased its membership and sphere of influence eastward.[66] Until very recently, it was organised along the same lines as the Building Officials organisations. In 1994, the Annual Conference modified the By-laws of the association to extend voting rights to other membership categories than just regulators. In 2000, it teamed up with the NFPA to develop national plumbing and mechanical codes as part of NFPA's Consensus Code set under ANSI-accredited procedures. In 2001, ANSI approved IAPMO's application for accreditation under the Organisational method.[67] Even if it has taken the consequences of the evolution a step further than the WFCA, the reasons for it are much the same.

IAPMO had been publishing the dominant Uniform Plumbing Code for decades when competition was mounted by the ICC, whose very first code was the 1995 *International Plumbing Code*. IAPMO countered in that same year with an agreement with two major trade associations of contractors, the *National Association of Plumbing, Heating and Cooling Contractors* (NAPHCC) and the *Mechanical Contractors Association of America* (MCAA). That agreement had two purposes. First, IAPMO joined the two trade associations in the secretariat of the ANSI A40 Committee, responsible for the ANS 'Safety Requirements for Plumbing.' Second, anticipating a protracted ANSI process, the trade associations obliged themselves to support and co-sponsor a new edition of the Uniform Plumbing Code. In 1996, however, ANSI suspended the A40 committee to investigate allegations from labour unions and from the *Plastic Pipe and Fittings Association*

[64] NFPA, Press Release, 'NFPA and WFCA Sign Agreement to Jointly Develop Harmonised Fire Code', 19 January 2000. The 'I-Chiefs' came on board later. See NFPA, Press Release, 'NFPA and IAFCA Enter New Agreement for Greater Participation of Chiefs on Code Process', 13 June 2003.

[65] See NFPA, News Release, 'Joint Fire Code Initial Draft Released—NFPA and Western Fire Chiefs create NFPA 1—Uniform Fire Code', 9 February 2001 ('We have taken the two most popular fire codes and combined them into what is destined to be the most widely used code.')

[66] The association began life as the Plumbing Inspectors Association of Los Angeles; the geographic denomination has evolved further from 'Southern California' (1928); 'California' (1930); 'Pacific Coast' (1935); 'Western' (1945) to 'International' (1967).

[67] IAPMO, News Release, 'IAPMO Achieves Additional ANSI Accreditation', 31 May 2001.

that the committee had violated ANSI procedures and requirements of balanced interests.[68] In 1999, ANSI's Board of Appeals withdrew the committee's accreditation and ANSI withdrew the 'Safety requirements' as an American Standard. Meanwhile, IAPMO published the 1997 Uniform Plumbing Code as an amalgamation of the ANSI standard, the previous UPC and the NAPHCC's *National Standard Plumbing Code*. Under the agreement with NFPA, IAPMO has now developed a *Uniform Plumbing Code* under the ANSI-accredited organisation method.[69]

Provisions on heating and comfort cooling systems were included in Building Codes until the technology advanced so rapidly that specialisation became necessary. In 1967, ICBO and IAPMO entered into an agreement to promulgate a joint *Uniform Mechanical Code*. The two organisations set up joint code change committees, jointly owned the copyright and jointly published the Code up until the 1991 edition. The two organisations have been unable to reach a new agreement ever since. In 1994, they published competing Uniform Mechanical Codes. The full bitterness of the dispute came to light when the California Building Standards Commission decided to reference ICBO's version of the *Uniform Mechanical Code*. IAPMO challenged that decision in state courts, first on procedural grounds and then on the grounds that the Commission was obliged by statute to adopt the joint 1991 version of the Code. The provision at issue in the California Building Standards Law read:

> The building standards contained in the Uniform Fire Code of ICBO and WFCA, the Uniform Building Code of ICBO, the Uniform Plumbing Code of IAPMO, the National Electric Code of NFPA and the Uniform Mechanical Code of ICBO and IAPMO, as referenced in the California Building Standards Code, shall apply to all occupancies throughout the state and shall become effective 180 days after publication in the California Building Standards Code by the California Building Standards Commission.[70]

IAPMO argued that the list of codes should be amended by the legislature before the Commission could decide to reference a different code. In *IAPMO v California Building Standards Commission*, the Court, naturally,

[68] As gleefully reported in 'ANSI rules in A40 Plumbing Code Appeal', *CABO Newsletter*, August 1996, cited abuses consisted in 'evidence of dominance of IAPMO and plumbing interests in general', and 'sufficient evidence to demonstrate that IAPMO is improperly using the ASC A40 to advance the interests of its own organisation and its members, and to exclude the consideration of minority viewpoints.'

[69] See IAPMO, Press Release, 'Leading Code Development Organizations Contribute to The Consensus Codes Set', 27 June 2000; IAPMO, Press Release, 'IAPMO issues 2003 Uniform Plumbing Code and Uniform Mechanical Code', 24 March 2003, and IAPMO, Press Release, 'Uniform Plumbing Code, Uniform Mechanical Code receive American National Standard Designation', 10 September 2003.

[70] Section 18938 (b), State Building Standards Law, Health and Safety Code. Section 18916 defines 'model code' as to 'include, but not be limited to', ICBO's Uniform Building Code, IAPMO's Uniform Plumbing Code, the joint Uniform Mechanical Code, NFPA's NEC, and the joint ICBO/WFCA Uniform Fire Code.

dismissed the claim with indignation as it would require the Commission to adopt outdated and undesirable standards and would amount to unlawful delegation to private parties:

> IAPMO could effectively veto any effort by the Commission and state agencies charged with regulatory authority to adopt a more recent and updated version of the model code. A private entity such as IAPMO cannot lawfully be granted such power over the regulatory authority of the state.[71]

As noted, both camps later consolidated their positions by seeking new alliances. In 1996, the ICC published its *International Mechanical Code*; IAPMO entered into agreement with NFPA to publish a joint *Uniform Mechanical Code* in 2003.[72]

IAPMO's 'consensus' process takes place under protection of the NFPA. IAPMO's 'Regulations Governing Committee Projects' largely mirror NFPA's procedures and arrangements on consensus, balanced membership, review periods, and final voting in Association meetings. IAPMO's Standards Council, however, is appointed by the NFPA Standards Council, with the latter hearing appeals against actions taken by the former.[73]

3.1.3 Fuel Gas Codes

It is only thanks to the considerable clout of the national trade association of natural gas distributors, the *American Gas Association* (AGA), that a similar polarisation of positions has not led to the same kind of hurtful competition between the NFPA's *National Fuel Gas Code* and the ICC's *International Fuel Gas Code*. The AGA, itself an ANSI-accredited standards developer, brings together some 200 gas companies who together account for 90% of all gas delivered in the United States. Ever since the first edition of the NFGC in 1974, the AGA has cosponsored the Code together with the NFPA. The Code is developed in a parallel process through both the NFPA 54 Committee and the ANSI-accredited Committee Z233; it is adopted and published both as an NFPA Code and as an ANSI standard.

[71] *International Association of Plumbing and Mechanical Officials v California Building Standards Commission* 55 Cal App 4th 245, 255–56 (1997).

[72] See IAPMO, Press Release, 'IAPMO issues 2003 Uniform Plumbing Code and Uniform Mechanical Code', 24 March 2003, and IAPMO, Press Release, 'Uniform Plumbing Code, Uniform Mechanical Code receive American National Standard Designation', 10 September 2003.

[73] Sections 2.1 and 1–7.1, IAPMO Regulations Governing Committee Projects. Section 1–7.1 reads: 'The IAPMO Standards Council has been delegated the responsibility for the administration and the codes and standards development process and the issuance of the Documents. However, where extraordinary circumstances requiring the intervention of the NFPA Standards Council exist, the NFPA Standards Council may take any action necessary to fulfil its obligations to preserve the integrity of the standards development process. Anyone seeking such intervention of the NFPA Standards Council may petition the NFPA Standards Council concerning IAPMO Standards Council action on any matters.'

In practice, all 27 members of the NFPA Committee sit on the 37 member ANSI Committee. On both, the AGA has 4 seats; representatives of IAPMO, SBCCI and UL sit on both; representatives of BOCA, the I-Chiefs, the *American Iron and Steel Institute* and of course the NFPA itself sit only on the ANSI Committee.

When the ICC started to develop the IFGC, the AGA signed an agreement to ensure its influence in that process as well.[74] The agreement marked the first time the Building Officials ever allowed representatives of private industry on their code development committees; for a long time, the IFGC Committee was the only ICC committee which was not in majority made up of public officials. Besides AGA participation in the code development process, the agreement also extends to copyright issues and allows the incorporation of whole excerpts from the NFGC into the IFGC. For those parts, any changes in the National Code will automatically be reprinted in the International Code.[75]

3.1.4 Electrical Codes

The one single event that apparently really broke down relations between NFPA and the ICC was the 1999 trademark dispute between the two over the designation *International Electrical Code*. When the NFPA used the designation *International Electrical Code Series* on the 1999 National Electrical Code, the ICC filed a lawsuit for infringement of its *International . . . Code* trademark, alleging that the designation could induce users to believe that the ICC had been involved in the development of NFPA's code. The NFPA countersued, alleging that the ICC's *International Electrical Code* infringed upon its rights, and induced people to believe that the ICC code had been developed by the same process and people responsible for the highly respected National Electrical Code. The lawsuit was reason for NFPA to terminate all negotiations with the ICC.[76] Even after a settlement was reached, according to which the ICC now calls its document the *ICC Electrical Code* and NFPA recognises the ICC's rights over all other *International . . . Codes*,[77] the two have not been able to sit around a table again.

The *ICC Electrical Code* is presented as an 'administrative' code geared towards the adoption, implementation and enforcement of the NEC in such a way as to ensure compatibility with the other International Codes.

[74] See ICC, Press Release, 'AGA and ICC Sign Agreement on New International Fuel Gas Code', 8 August 1997, and 'AGA Cosponsors new Fuel Gas Code with International Code Council', *American Gas Magazine*, October 1997.

[75] See AGA, *Comparison of the 2000 International Fuel Gas Code and the 1999 National Fuel Gas Code*.

[76] ICC, Press Release, 'ICC Trademark Infringement Complaint Filed Against NFPA', 13 April 1999.

[77] ICC, News Release, 'ICC and NFPA Settle Trademark Dispute', 9 December 1999.

It does, however, contain prescriptive requirements and has the NFPA fuming with rage. The NFPA's cause was helped a lot by the announcement of the *National Electrical Manufacturers Association* in August 2000 that it approved direct adoption of the NEC and didn't see the benefits of ICC's code.[78] The ICC has apparently backed off and has affirmed that it 'has no plans for the development of an electrical code that would duplicate the purpose and then compete with the National Electrical Code.'[79]

3.1.5 Building Codes

In August 1999, several major organisations, most notably the National Conference of States on Building Codes and Standards, the American Institute of Architects and the Building Owners and Managers Association,[80] formed the 'Get it Together Coalition' in their concern at the prospect of two sets of competing and inconsistent codes. The Coalition urged ICC and NFPA to resolve their differences and offered its services for mediation.[81] The Coalition's proposals were politely refused by both organisations. The futility of the effort became all too apparent with the announcement in March 2000 that the NFPA's Board of Directors had decided unanimously to go ahead with the development of its own consensus building code, NFPA 5000, inevitably a rival document to the ICC's flagship, the much publicised 2000 International Building Code.[82] In January 2001, members of the GIT Coalition announced a shift of focus

[78] NEMA, Press Release, 'NEMA Approves Direct Adoption of Latest National Electrical Code', 29 August 1999. NEMA, it will be recalled, is an ANSI-accredited standards body itself.

[79] ICC, Press Release, 'ICC Sees No Need for Another Electrical Code', 6 June 2001 ('The public's safety is best served by eliminating the redundancy of multiple codes and we encourage other national codes and standards to join with us in serving our most important constituency—the public.') Cf NFPA, Press Release, 'ICC Abandons ICC Electrical Code?', 27 June 2001 ('ICC now recognises what every state in the US already has—the essential role that the NEC plays in public safety and that there is no need for the ICC Electrical Code.')

[80] Further participating organisations were the American Wood Council, the American Society of Interior Designers, the Associated General Contractors of America, the Chlorine Institute, the International Council of Shopping Centres, the National Association of Industrial and Office Properties, the National Institute of Building Sciences, the National Multi Housing Council and the National Realty Committee.

[81] Letter to the Chairmen of ICC and NFPA of 23 August 1999.

[82] Cf ICC, Press Release, 'ICC Asks NFPA: "Why Another Building Code?"', 22 March 2000; and ICC, Press Release, 'ICC Willing to Continue Pursuit of Joint Family of Model Codes with NFPA', 17 May 2000. The NFPA's announcement caused a storm of protest among all sorts of organisations. See eg SBCCI, Press Release, 'Real Estate Associations Urge Adoption of New International Building Codes', 22 December 1999. Cf Miller, 'The NFPA Building Code—A Bold New Era', *NFPA Journal*, May/June 2000 ('Anyone who knows how long and how many times we tried to collaborate with the ICC cannot doubt NFPA's good faith. Anyone who wants the convenience of a single set of codes and the quality of true, open, full consensus codes cannot doubt the need for NFPA's Consensus Codes Set. . . . This is the right approach and the right time to act. Today, we take the NFPA mission of reducing loss through science and consensus into the new millennium.')

away from seeking reconciliation of the rival model code organisations towards the active engagement within both organisations 'to make their respective building codes consistent and compatible', to actively support 'the adoption of a coordinated set of model codes and standards at the state and local level.'[83] The NCSBCS, meanwhile, keeps on calling on both NFPA and ICC to come together. Even after the publication of NFPA 5000 in 2002, the organisation is still pressing for the two warring associations to open up a dialogue, resolve past differences, and establish a timetable to develop a single family of coordinated construction codes and standards.[84]

The building code saga epitomises in many ways the general dilemmas of standardisation; that of competition versus uniformity, and that of industry self regulation versus public rulemaking. The ICC has been modifying its procedures almost continually over the last few years in an effort to accommodate industry demands of more participatory rights and to substantiate its 'consensus' claim. The breaking point came in 2000, when the ICC Board of Directors was faced with conflicting resolutions from the floors of the Annual meetings of ICBO, BOCA and SBCCI. ICBO was adamant that the role of public regulators in the system not be diluted and insisted on maintaining the 'governmental consensus process.'[85] BOCA, on the other hand, passed a resolution demanding radical change in an effort to rally support for the International Codes among all circles:

> Whereas a consensus process will provide all interests in the construction industry a more definite role and responsibility in the development of the International Codes while maintaining a balance of interests in the decision-making process and avoiding domination by proprietary interests, and

[83] BOMA International, Press Release, '"Get it Together" Coalition Shifts Focus', 21 January 2001. Consider BOMA's policy statement on the International Codes: 'BOMA International should actively and aggressively participate in the development of the NFPA Consensus Codes: however, BOMA's participation in the NFPA process does not represent an endorsement of the NFPA process or the NFPA Consensus Codes in any way. The goal of BOMA's participation in the NFPA process is to perfect NFPA 5000 by making it as close as possible to the International Building Code (IBC), including any changes to the IBC that BOMA sees fit to adopt.' See also AIA, Press Release, 'AIA To Develop Codes Programs to Assist Local/State Constituents', 1 March 2001 (AIA Board of Directors approves motion supporting continuing efforts to effect a single family of codes by providing resources to a) undertake a cooperative effort with ICC to implement adoption of a single family of codes, b) support AIA components and members in their efforts to adopt a single family of codes in political subdivisions throughout the United States; and c) continue the AIA's participation in the NFPA code development process.') Both associations welcomed the move as an endorsement of their own efforts. See NFPA, Press Release, 'NFPA Welcomes Involvement of "Get it Together Coalition"', 8 February 2001; and ICC, Press Release, 'ICC responds to "Get it Together Coalition" Change of Focus', 8 March 2001.

[84] See NCSBCS, 'Update to Nation's Governors on Enhancing Public Safety and the States' Role in the Global Economy Through Uniform Construction Codes and Standards', 16 August 2003. The Update includes the polite but unpromising answers by the respective CEOs. BOMA has long given up conciliation efforts. See BOMA, Press Release, 'BOMA International Approves Formal Policy Against NFPA Building Code', 2 July 2002.

[85] Resolution 13a, ICBO Annual Conference, 8 September 2000, San Francisco, California.

> Whereas the utilization of a consensus process by the International Code Council in the development of the International Codes will expand the participatory rights to all segments of the industry and increase support for the International Codes; now, therefore,
>
> Be it resolved that the ICC Code Development Process must be open, fair and permit participation by all interests without domination by any single or proprietary interest; and
>
> Be it further resolved that we encourage the ICC Board to adopt an ICC consensus process which is both timely and appropriate for the continued development of the International Codes and will serve the goal of a single family of codes for the United States.[86]

The SBCCI, finally, urged the Board merely to 'implement an appropriate consensus process, that will expand the participatory rights to *all* BOCA, ICBO and SBCCI members.'[87]

The process now established involves a Code Development Committee that is to give due consideration to any code change proposal brought forward by 'any interested person, persons or group.'[88] Committees are opened to non-officials and non-members of ICC and are explicitly designed to display a balance of interests. Even if a minimum of 33% of regulators is still prescribed, users and producers are invited in with full rights.[89] Committee action takes place during public hearings after assembly deliberation on each and every code change proposal. Acting by majority, the committee can accept, accept with specific modifications or disapprove. Subsequently, the assembly gets a chance to vote on the committee's actions, needing a two-thirds majority to approve proposals and a simple majority to defeat them.[90] As of 2000, assembly voting during public hearings is open to *all* members of ICBO, CABO and SBCCI, not just to public officials.[91] The proposals are then subjected to a public comment procedure, upon which a final vote is held during the different Annual meetings of the three organisations. Voting for final action, however, is still restricted to the public official membership categories.[92]

[86] Resolution 2000–7, ICBO Annual Conference, 19 September 2000, Rochester, New York.
[87] Resolution 1, SBCCI Annual Education and Research Conference, 9 October 2000, Nashville, Tennessee.
[88] Section 3.1, ICC Code Development Process for the International Codes. Each proposal has to be accompanied by a statement of reasons for the desired change, has to be based on technical information and substantiation, has to include a bibliography, and has to be accompanied by a signed copyright release. Section 3.3.4.
[89] See ICC, *Policy re: Committees and Members*, CP #7–2000.
[90] Sections 5.6 and 5.7, ICC Code Development Process for the International Codes.
[91] Section 5.7.4, ICC Code Development Process for the International Codes.
[92] Section 7.4, ICC Code Development Process for the International Codes.

3.2 Between Standards, Codes and Law

The major standards bodies have an obvious interest in ensuring the adoption of their standards in the prevalent model codes. One way of going about this is by forging organisational ties.[93] Perhaps the issue can be best illustrated in the plumbing standards business. BOCA, NFPA, and IAPMO all sit on the Standards Committee of the American Association of Sanitary Engineering, together with representatives of the Plumbing Manufacturers Institute, another ANSI-accredited SDO.[94] ASSE has openly come out in favour of the UPC, 'proud to support IAPMO and NFPA in their endeavours to develop codes using an open, ANSI-approved process.'[95] The ASSE sits on IAPMO's Plumbing Code Technical Code Committee, together with representatives of fellow ANSI-accredited standards developers NFPA, UL, AGA, PMI, and the Cast Iron Soil Pipe Institute, and the NAPHCC, the MCAA, the Plastic Pipe and Fittings Association, the American Society of Plumbing Engineers, the Copper Development Association and the Plumbing and Drainage Institute.[96]Another way is to tie in certification services. IAPMO's plumbing and mechanical codes have traditionally included references to NSF International standards.[97] In 1998, the organisations' respective certification branches reached an agreement to offer 'one-stop shopping' product testing, evaluations and facility testing.[98] A less intricate but equally effective way is to sell each other's products: ICC offers a single booklet containing all 200 ASTM standards referenced in the

[93] *Engrenage* is also a function of personal career-paths. The current President of ANSI, Mark Hurwitz, has held leadership positions in both the AIA and in BOMA International.

[94] Other represented organisations are the Canadian Standards Association, several consulting firms, and manufacturers.

[95] IAPMO, Press Release, 29 September 1999, quoting Diane Corcoran, Executive Secretary of ASSE.

[96] NFPA has similar relations with the American Society of Heating, Refrigerating and Air-Conditioning Engineers. ASHRAE has come out in favour of the NFPA. See NFPA, Press Release, 'ASHRAE Offers Its Energy Standards For Use in Consensus Codes Set', 29 August 2000. Note that ASHRAE's By-laws, Section 7.10, provide that the activities of its Standards Committee 'shall be solely for the development of engineering science, and the committee shall not engage in activities designed to influence legislation.' ASHRAE sits on NFPA's Building Structures Technical Committee, as do ASME and UL. Further seats on that committee are taken by BOMA, AIA, and NAHB of the Coalition, state officials, and several industry groups such as the National Elevator Industry Inc, the North American Insulation Manufacturers Association, and the Air-Conditioning Contractors of America. Consumer interests are represented through the Eastern Paralyzed Veterans Association.

[97] On NSF's information, the UPC references 11 NSF standards, the SBCCI code 6, and BOCA and CABO codes 2. The new IPC wisely references 9.

[98] See NSF, Press Release, 'NSF and IAPMO Address Industry Needs', 16 October 1998. Note, however, that NSF makes a point of stating that 'this agreement is not an endorsement by NSF of the Uniform Plumbing Code (UPC) over other model codes or code writing organizations.'

International Codes; all those codes, in turn, can be bought in ANSI's online electronic standards store.[99]

As part of its 'public filter' function, the ICC demands minimum procedural guarantees over the standards it references. ICC's *Code Development Process* makes it thus a condition for a standard to be considered for reference in the International Codes that it be 'developed and maintained through a consensus process such as ASTM or ANSI.'[100] How serious the ICC takes this procedural control over standards is illustrated by the fact that acceptance of standards developed under ANSI's canvass method has been made conditional on compliance with ICC's modifications of the relevant procedures.[101] Meanwhile, the ICC is branching out into the classic standards area by setting up several Consensus Committees of itself to develop various standards. ANSI approved the procedures especially written for the development of these consensus standards in 1999.[102]

One level up, both the ICC and the NFPA lobby hard to get their codes adopted into law. To a very limited extent, the battle extends to federal government programs. The NFPA has reason to be upset with the sponsors of the Code and Safety for the Americas Act of 2001. The Act identifies 'a need in El Salvador, Ecuador and other Latin American countries for a complete, updated family of codes.' It also discerns an interest of the US in ensuring that these countries have such a code. After all, 'if proper building codes are followed in the construction of buildings in Latin America, buildings will be safer, and, therefore, the need for United States' disaster assistance in the wake of disasters will be less.' Hence, the Act authorises the President to carry out a program of assistance and makes the funds available for a) the training of Latin American professionals in the public and private sectors in the International Code, and b) the translation into Spanish of the whole set of ICC codes.[103] The ICC, on the other hand, has

[99] The latter possibility is fairly recent. See ANSI, Press Release, 'ANSI and ICC Partner on Distribution of International Codes', 7 May 2002.

[100] Section 3.6.3 (2), ICC Code Development Process for the International Codes.

[101] Section 3.6.3 (2), ICC Code Development Process for the International Codes, as amended by the Board of Directors in July 1999. The ICC *Modifications to the ANSI General Procedures and to ANSI Annex B—procedures for Canvass by an Accredited Sponsor* include the obligation to produce a written set of procedures, the obligation to make public to all interested parties the membership roster of the consensus body, and a prohibition of concurrent public review and consensus body balloting.

[102] See the *Consensus Procedures of the International Code Council*, approved by ANSI in June 1999. ICC/ASC 117 is an ANSI-accredited committee for accessibility standards for the disabled in buildings and facilities. ICC is further engaged in ANSI-accredited standards development for hurricane-resistant construction, storm shelters, log structures, manufactured housing, and amusement parks.

[103] HB 2567, Sections 2 (findings) and 3 (authorization of assistance), s 1197. Not deterred, the NFPA launched its own expansion program into Latin America. See NFPA, Press Release, 'NFPA Partners with PKC to offer Spanish Language Seminars in Latin America and Spain', 24 July 2001. This adds to the NFPA's efforts to break into China. See NFPA, Press Release, 'China Fire Protection Association agrees to Translate and Distribute key NFPA Codes', 2 November 2000.

a problem with the 'Heather French Henry Homeless Veterans Assistance Act', which makes *per diem* payments for caring for veterans conditional on the relevant facility meeting the requirements on NFPA's Life Safety Code.[104]

But the main battleground consists in efforts to get codes adopted into state law.[105] With the vital exception of California, the NFPA is making very little headway with its Building Code; 32 States and hundreds of local jurisdictions have adopted the IBC. The ICC's feeble efforts to undermine the NEC are equally unsuccessful; the NFPA Code has been adopted in 48 States. For all other codes, however, competition is fierce.[106]

One arena for ferocious lobbying efforts is the National Conference of States on Building Codes and Standards, an inter-state organisation that sets out to 'provide the public and private sectors a national forum for coordinating building code and public safety interests.' Its policymaking body consists of the chief building regulatory officials of every state in the country; the organisation is further composed of several Standing Committees and Member Fora for different categories of membership. It is in these bodies that the rival code organisations seek to have their voices heard in what to them is an organisation of obvious importance, given their vital interests in having their codes adopted. The Private Sector Members Forum is dominated by representatives of ICC, ICBO and BOCA on the one hand, and the NFPA on the other. Also represented are UL and NSF International. All these organisations sit on the Codes and Standards Evaluation Committee, together with state officials, a representative of the AIA, and representatives of several trade associations.[107] The organisational *engrenage* works both ways, however: the NCSBCS itself sends delegates to the ICC, ICBO, CABO, SBCCI and to ANSI, ASHRAE, the NFPA, and the AIA.

[104] See Section 15, HR 936. According to the ICC, 'the exclusive reference to the Life Safety Code/NFPA 101 places the state and local jurisdictions that use the codes developed by the ICC (97% of those jurisdictions that enforce building codes), at a disadvantage. These jurisdictions would now be faced with the dilemma of having to enforce two sets of duplicative and conflicting regulations. NFPA itself has made a statement to the effect "that for Congress to select a winner is contrary to government policy." ICC agrees with this position.' Letter from Sara Yerkes, ICC Government Relations Director, to Representative Christopher Smith, 26 September 2001.

[105] NCSBCS, Press Release, 'States Pressed to Make Decisions on Construction Codes', 25 February 2001. See also NCSBCS, 'Update to Nation's Governors on Enhancing Public Safety and the States' Role in the Global Economy Through Uniform Construction Codes and Standards', 16 August 2003 (complaining of 'aggressive lobbying efforts' of resources being drawn away from code enforcement to technical comparison work of the different codes, and of turning fire and building services within states into adversaries.)

[106] For the Plumbing and Mechanical Codes, the split is pretty much East-West, reflecting IAPMO's traditionally western constituency and with the ICC codes hardly crossing the Rocky Mountains.

[107] The Door & Access Systems Manufacturers Association and the National Wood Window and Door Association. DASMA is an ANSI-accredited standards developer.

3.3 State Codes

Meanwhile, several states are in the process of revamping the arrangements in place for the promulgation of building codes. Much in the same spirit of market integration and harmonisation of requirements that spurred the creation of the ICC, the general trend among states is to centralise building codes at state, rather than local, level.[108] The legislative findings of the Louisiana State Uniform Construction Code may serve to illustrate the general sentiment:

> (1) That a multiplicity of construction codes exists in this state and some of these codes contain needless restrictions which limit the use of certain materials, techniques, or products without any benefits to the public. However, the variation of construction standards caused by the multiplicity of codes slows the process of construction and increases the costs of construction.
> (2) That the way to insure uniform, modern construction codes and regulations throughout the State of Louisiana which lower the cost of housing and other construction without any detriment to the public health, safety, and welfare is to adopt a uniform state construction code.[109]

The logical consequence is then for the State to adopt a model code:[110]

[108] In Michigan, the 'Stille-Derossett-Hale Single State Construction Code Act', Public Act 245 of 1999, prohibits local government from adopting their own codes. See Michigan Compiled Laws 125.1504. The Virginia Uniform Statewide Building Code 'shall supersede the building codes and regulations of the counties, municipalities and other political subdivisions and state agencies'. See Section 36–98, Code of Virginia. In Rhode Island, local cities and towns shall be prohibited from enacting any local building codes and ordinances after the adoption of the state building code. Rhode Island Statutes 23–27.3–100.1.7. It is settled caselaw in California that the State Building Code preempts municipal law. Cf *California Apartment Association v City of Fremont*, 97 Cal App 4th 693 (2002). Another, related, problem is the centralisation across the various state agencies responsible for the different codes. See eg Office of the Legislative Auditor, Minnesota, *State Building Code—A Program Evaluation Report* (St Paul, January 1999) (discussing options to improve co-ordination between the five State agencies responsible for adoption and administration of different codes).

[109] Louisiana Revised Statutes, 40–8–1727. Almost identical wording can be found in eg the 1999 Pennsylvania Construction Code Act. See Section 102 (a) of Public Law 491, 1999, enacted as Pennsylvania Statutes 7210.101 *et seq*.

[110] Some States, however, shortcut the necessity to adopt state-wide legislation by simply obliging counties and towns to adopt a model code. Thus, South Carolina law provides: 'Municipalities and counties shall adopt by reference only the latest editions of the following nationally recognized codes and the standards referenced in those codes for regulation of construction within their respective jurisdictions: building, residential, gas, plumbing, mechanical, fire, and energy codes as promulgated by the Southern Building Code Congress International, Inc, and the National Electrical Code, as published by the National Fire Protection Association.' Code of Laws of South Carolina, 6–9–50. In South Dakota, any ordinance of a local unit of government prescribing standards for new construction 'shall comply with' the 1997 Edition of the UBC or the 2000 Edition of the IBC See South Dakota Codified Laws 11–10–5. Oklahoma directs municipalities to adopt either the BOCA Basic

(3) That the model codes of the Southern Building Code Congress International, Inc. and the National Electrical Code, published by the National Fire Protection Association, are construction codes which have been widely adopted in this state, and adoption of these nationally recognized codes will insure that the state has a uniform, modern construction code which will insure healthy, safe, and sanitary construction but also less expensive construction for the citizens of this state.[111]

In practice, virtually all States now adopt model codes of some national code organisation or other without significant modifications.[112] A useful measure of the development is the manner in which federal Circuit courts approach the question of whether nor not to uphold the model code organisations' copyright assertions on adopted codes. In 1980, the First Circuit refused to rule on the matter in any definite fashion given 'a possible trend towards state and federal adoption, either by means or incorporation by reference, or otherwise, of model codes.'[113]

In 2001, the Fifth Circuit noted that 'today, the trend toward adoption of privately promulgated codes is widespread, and the social benefit from it is great.'[114] The policy rationale in favour of copyright protection is then expressed in damning terms for the ability of public regulators to take on the task of writing codes themselves:

> We believe that if code writing groups like SBCCI lose their incentives to craft and update model codes and thus cease to publish, the foreseeable outcome is that state and local governments would have to fill the void directly, resulting

Building Code, ICBO's Uniform Building Code, the SBCCI's Southern Standard Building Code or 'any other code which the governing body of the municipality deems desirable to promote safety, energy efficiency, health and welfare.' See Oklahoma Statutes, Section 11–14–107. Arizona allows counties to adopt 'any building, electrical or mechanical code that has been promulgated by any national organization or association that is organized and conducted for the purpose of developing codes.' Arizona Revised Statutes, Section 11–861. In *Washburn v Pima County*, 81 P 3d 1030 (Ariz 2003), an Arizona Court of Appeals rejected the theory that the word 'code' prevents counties from adopting ANSI *standards*. After 28 August 2001, all counties in Missouri seeking to adopt a building code must adopt 'a current, calendar year 1999 or later edition, nationally recognized building code, as amended.' Missouri Revised Statutes Section 64.196.

[111] Louisiana Revised Statutes, 40–8–1727. Section 1728 was amended in 2003 to adopt the IBC as of 1 January 2004; all political subdivisions of the State are required to adopt the IBC.

[112] In *State v Fowler*, 114 So 435 (Fla 1927), the Florida Supreme Court struck down a piece of legislation leaving it up to a Commission to write a plumbing code on the basis of 'basic principles' adopted by the Building Code Committee of the Department of Commerce, an outfit set up by Hoover in 1921 and disbanded in 1934. In 1947, Louis Jaffe wondered out loud about the implications of such a doctrine for the British Parliament. See Jaffe, 'An Essay on Delegation of Legislative Power' (1947) 47 *Colum L Rev* 359 (I), 362–63 ('The Florida legislature might do worse than spend its time adopting a plumbing code, as the courts have compelled it to do. It may call in experts or set a committee to work. But imagine the Mother of Parliaments sitting down to debate the Empire's drains!').

[113] *Building Officials and Code Administrators v Code Technology* 628 F 2d 730, 736 (1st Cir 1980).

[114] *Veeck v Southern Building Code Congress International* 241 F 3d 398, 411 (5th Cir 2001).

in increased governmental costs as well as the loss of the consistency and quality to which standard codes aspire.[115]

3.4 Between Administrative Process and Private Consensus

Legislative techniques differ widely. In some States, legislation bluntly obliges the competent authority to adopt a designated code.[116] On the other hand, the competent authorities in other States have, at least nominally, some degree of discretion in picking the winning code.[117] The New Jersey Statutes, for example, provide that the State codes 'shall be adoptions of the model codes of the Building Officials and Code Administrators International, Inc., the National Electrical Code, and the national Standard Plumbing Code, provided that for good reasons, the commissioner may adopt as a subcode a model code or standard of some other nationally recognized organization upon a finding that such model code or standard promotes the purposes of this act.'[118] In 1988, the Superior Court held that this language, or rather, the legislative history of the provision, limits the

[115] Above, 406, reversed upon rehearing *en banc* in *Veeck v Southern Building Code Congress International* 293 F 3d 791, 799 (5th Cir 2002) ('Even when a governmental body consciously decides to enact proposed model building codes, it does so based on various legislative considerations, the sum of which produce its version of "the law." In performing their function, the lawmakers represent the public will, and the public are the final "authors" of the law.')

[116] In Pennsylvania, accordingly, the Department of Labor and Industry is to enact regulations adopting the UBC; Pennsylvania Statutes, Section 7210.301 (a) (1). In recognition of the ICC, the Act also prescribes adoption of the ICC One and Two Family Dwelling Code, Section 7210.301 (a) (2), and the IFGC, Section 7210.301 (b). The Bill originally prescribed adoption of IAPMO's plumbing and mechanical codes, but that section was struck down when Senate Bill 647 was introduced in the House of Representatives. The Act makes allowance for updated codes, instructing the adoption of new codes by 31 December of the year BOCA or ICC issues it. Section 7210.304 (a). In Michigan, the 'Stille-Derossett-Hale Single State Construction Code Act', Public Act 245 of 1999, provides that the State construction code 'shall consist of' the IBC, the IMC and the IPC plus the NEC. See Michigan Compiled Laws 125.1504 *et seq*. Maryland adopts the International Building Code by dynamic reference. See Code of Maryland, Sections 83B6–402 (a) ('The Department shall adopt by regulation, as the Maryland Building Performance Standards, the IBC'); and 401 (e) ('IBC means the first printing of the most recent edition of the IBC to be issued periodically by ICC'). The 2002 New Hampshire Act relative to the adoption of a state building code defines the state building code as the 'adoption by reference' of the 2000 IBC, IPC, and IMC and the 1999 NEC. See Revised Statutes of New Hampshire, 155-A:1 (IV).

[117] In Minnesota, '[t]he code must conform in so far as practicable to model codes generally accepted and in use throughout the United States.' Minnesota Statutes, Chapter 16B 61 (1). The Utah Uniform Building Standards Act discriminates, on the one hand specifically obliging the adoption of the NEC, and on the other hand providing that the building code, the plumbing code and the mechanical code should be one 'promulgated by a nationally recognized code authority.' Utah Code 58–56–4 (2). The Rhode Island State Building Code Act provides that the building code 'shall be reasonably consistent with recognized and accepted standards adopted by national model code organizations and recognized authorities'. Rhode Island Statutes 23.27.3–100.1.5. Cf the Iowa State Building Code Act, Iowa Statutes, 103A 8, and the Montana Building Construction Standards Act, Montana Code 50–60–203 (2).

[118] New Jersey Permanent Statutes, 52: 27D-123 (5) (b).

authority of the public authorities to adopting these model codes in their entirety, having to rely on a 'national process' for amendments.[119]

Be it for amendments or for entire codes, States generally provide for a mechanism to put model codes through some sort of administrative rule-making process. Thus, before adopting the International Building Code as the 'Maryland Building Performance Standards', the Department of Housing and Community Development is required to (a) review the IBC to determine whether modifications should be incorporated; (b) accept written comments and hold a public hearing on any proposed modification, and (c) take into consideration comments received during this process.[120] Several, though by no means all,[121] States take the involvement of interested parties further and set up 'balanced' boards and commissions of all descriptions and powers.[122] In some States, this is an *ad hoc* technique to facilitate the process of taking sides in the 'Battle of the Codes'.[123] More often than not, however, these boards operate on a permanent basis.[124]

[119] *New Jersey Builders Association v Coleman* 545 A 2d 783, 785 (NJ Super 1988). The Commissioner of Community Affairs' replacing the thermal efficiency standards in the BOCA National Energy Conversation Code with standards required by the US Farmers Home Administration was hence considered *ultra vires*. In obscure fashion, the Statute now limits the authority of the Commissioner to adopt 'any revisions or amendments of model codes which would not be inconsistent with the intent and purpose of the act.' New Jersey Statutes 52: 27D-122.1.

[120] Code of Maryland 83B-6–403 (a). The Department may not adopt any modification that is more stringent than the requirements in the IBC itself. 83B-6–403 (b).

[121] Alabama law does set up a 'Building Commission' with the power to 'adopt, promulgate and enforce a state building code', Code of Alabama 41–9–171, but restricts membership to that Commission to the Governor, the State Health Officer, the Director of Finance, the State Superintendent of Education, and four members each from the Senate and House. Code of Alabama 41–9–140.

[122] The technique is also used in States with decentralised code adoption arrangements. Arizona obliges counties adopting a code to set up 'advisory boards' to 'determine the suitability of alternative materials and construction and to permit interpretations of the provision of such code. Each board is to consist of an architect, a professional engineer, a general contractor, a person 'representing the public', and 'a person engaged in the electrical, mechanical or plumbing trade', at least 'to the extent the persons meeting the qualifications are available within the county.' Arizona Revised Statutes 11–826 (A). In South Carolina, municipalities and counties who 'contend' that the SBCCI codes and the NEC they are authorized to adopt do not meet their 'needs' must seek approval for any variations and modifications from the South Carolina Building Codes Council. Code of Laws of South Carolina 6–9–60 (A).

[123] See *infra*. Another *ad hoc* body is the Missouri Governor's Commission for the Review and Formulation of Building Code Implementation set up by the House Committee Substitute for Senate Concurrent Resolution No 5, adopted by the Senate of 5 February 1999, and concurred in by the House on 29 April 1999, set up to deal with the advent of the IBC. The Commission consisted of two members each of House and Senate, a number of high State officials, and 14 'citizen members' from among building officials, contractors, engineers, home builders, etc. On 1 December 1999 the Commission issued its report and recommendations, fully endorsing the IBC.

[124] That does not necessarily mean that they are relieved from 'Battle of the Codes' duties, though. The New Hampshire State Building Code Review Board, consisting of fire chiefs, building officials, engineers, contractors, and plumbers, is instructed 'to review the NFPA Building Code when it is published in order to evaluate whether the state should continue

Their composition varies a little across States, but in general they include the familiar categories and professions of architects, engineers, contractors, building officials, fire officials, home builders, and sometimes require representation of the 'public at large' or at least the disabled.[125] Significantly, it is not uncommon for legislative provisions to give State chapters of national professional and trade associations, some of which engaged in standard-setting and code development themselves, the power to provide binding lists of nominees for the Governor to choose from.[126] Strangely enough, there seems to be hardly any logical connection between the extent of the powers granted to these boards in the public code adoption process and the amount of discretion the legislation allows in choosing between rival codes. Washington legislation bluntly provides that

> There shall be in effect in all counties and cities the state building code which shall consist of the following codes which are hereby adopted by reference:
>
> (1) Uniform Building Code and Uniform Building Code Standards, published by the International Conference of Building Officials;
> (2) Uniform Mechanical Code, including Chapter 13, Fuel Gas Piping, Appendix B, published by the International Conference of Building Officials;

with the International Building Code, switch to other codes or adopt a combination of codes.' See New Hampshire Revised Statutes 155-A:10.

[125] See eg the composition of the Codes and Standards Committee of Connecticut as prescribed by General Statutes of Connecticut 29–251 (two architects, three professional engineers, two builders or superintendents of construction, a public health official, two building officials, two local fire marshalls, one representative of organised labour, and four public members one of whom 'shall have expertise in matters relating to accessibility and use of facilities by the physically disabled'); the Rhode Island Building Code Standards Committee as prescribed by Rhode Island Statutes 23–27.3–100.1.4 (twenty-five members, of whom two architects, three professional engineers, a landscape architect, a certified electrical inspector, two builders, one public health official, one qualified fire code official, an electrician and a master plumber from the Building Trades Council, two members of the 'general public', three building officials, one member each from the House and Senate, and a minimum housing official.) Cf General Laws of Massachusetts 143–93 (State Board of Building Regulations and Standards), Revised Code of Washington, 19.27.070 (1) (Washington State Building Code Council; the added requirement here is that at least six of the 15 members must reside 'east of the crest of the Cascade mountains.'); 20 Illinois Compiled Statutes 3918/10 (Illinois Building Commission); and Code of Laws of South Carolina 6–9–90 (B) (South Carolina Building Codes Council).

[126] Thus, the non-public members of the Virginia State Building Code Technical Review Board are appointed by the Governor from slates presented by the AIA, the Virginia Society of Professional Engineers, the Home Builders Association of Virginia, the Associated General Contractors of America, the Virginia Building Officials Conference, the State Fire Chiefs Association of Virginia, the Virginia chapters of BOMA and the National Apartment Association, and the Virginia Association of Plumbing-Heating-Cooling Contractors. Code of Virginia 36–108. For appointments on the Kentucky Board of Housing, Buildings and Construction, the Governor is to select from lists submitted by the Kentucky Firemen's Association, the Kentucky Society of Architects, the Kentucky Society of Professional Engineers, the Code Administrators Association of Kentucky, the Kentucky Association of Plumbing, Heating and Cooling Contractors, the Mechanical Contractors Association and the National Electrical Contractors Association. Kentucky Revised Statutes 198B020 (1).

(3) The Uniform Fire Code and Uniform Fire Code Standards, published by the International Fire Code Institute: Provided, that, notwithstanding any wording in this code, participants in religious ceremonies shall not be precluded from carrying hand-held candles;
(4) Uniform Plumbing Code and Uniform Plumbing Code Standards, published by the International Association of Plumbing and Mechanical Officials: Provided, that chapter 11 and 12 of such code are not adopted.[127]

On the face of it, this does not seem to leave any room an elaborate adoption process or any logical need for mechanisms of interest-representation. And yet the Washington State Building Code Council, a balanced committee, has the power not just to 'regularly review updated versions of the codes referred to', but actually to adopt the codes.[128] On the other hand, the Virginia Statewide Building Code is to be formulated with

> due regard for generally accepted standards as recommended by nationally recognized organizations, including, but not limited to, the standards of the Southern Building Code Congress, the Building Officials Conference of America and the National Fire Protection Association.'[129]

With that amount of discretion, it could appear that the task of adopting the code would be thought to necessitate the kind of pluralism of interests and expertise that a balanced committee could provide. And yet, the Code is adopted by the Board of Housing and Community Development, a state agency, in accordance with the notice and comment procedures of the State Administrative Process Act.[130] The role of the balanced State Building Code Technical Review Board is limited to hearing appeals and making 'recommendations' about desirable modifications to the Code.[131]

[127] Revised Code of Washington, 19.27.031. Cf Washington Administrative Code, 51–40–003 (1997 UBC), 51–46–003 (1997 UPC), 51–42–003 (1997 UMC), and 51–44–003 (1997 UFC).

[128] Revised Code of Washington, 19.27.074. Connecticut law prescribes the IBC General Statutes of Connecticut, 29–252 (State Building Code 'shall be revised no later than July 1, 1998, to incorporate such revisions adopted by the Building Officials and Code Administrators International, Inc. in 1996 as they deem necessary, and thereafter to incorporate any necessary subsequent revisions adopted by said organization or by the International Code Council, Inc, not later than 18 months following the date of first publication of said subsequent revisions.') The balanced Codes and Standards Committee is given joint adoption powers together with public agencies. See General Statutes of Connecticut, 29–252 ('The State Building Inspector and the Codes and Standards Committee shall, jointly, with the approval of the Commissioner of Public Safety, adopt and administer a State Building Code.') Cf General Statutes of Connecticut 29–291 (Commissioner of Public Safety to serve as State Fire Marshall) and 29–292 (State Fire Marshall and Codes and Standards Committee jointly to adopt State Fire Code).

[129] Code of Virginia, 39–99 (B).

[130] Code of Virginia 36–100. The statute also provides for a public hearing before any action under the APA is taken, and the requirement on the Board, in addition to the normal notice requirements, to notify in writing the building official of 'every city or county in the Commonwealth.'

[131] Code of Virginia 36–114 (Appeals) and 36–118 (Interpretations and recommendations).

The Kentucky Board of Housing, Buildings and Construction, a balanced committee, has the sole power to promulgate and amend the Uniform State Building Code.[132] The Department of Housing has to limit itself to making recommendations on the advisability of suggested amendments from any interested party.[133] Charged with the promulgation of, it may 'select from' the model codes offered by 'such model agencies as BOCA, ICBO, SBCCI; and other nationally recognized organizations which may include government agencies.'[134] However,

> The board may adopt a model code promulgated by a model code agency only if that agency provides a method for democratic participation by the board an any local governments which may enforce the code, in a continuing review and possible adoption of new materials, technologies and techniques in the building industry.[135]

In all stages of the process, the Board must follow the notice and comment procedures of the state Administrative Procedure Act.[136] Administrative procedure is not sufficient for the Rhode Island legislature. Giving the authority to adopt codes and standards 'which shall, in general, conform with nationally recognized model codes' to the balanced Building Codes and Standards Committee subject to notice-and comment and record-keeping obligations, the statute subsequently provides:

> There shall be established a legislative regulation committee that shall review, approve, or reject, in total or in part, the state building code regulations proposed by the building code standards committee prior to their being filed with the secretary of state.[137]

3.5 The Battles of State Codes

The New York Uniform Fire Prevention and Building Code Act from 1981, though still on the books, is outdated.[138] The Act set up a Council to adopt the New York building code, chaired by the Secretary of State and

[132] Kentucky Revised Statutes 198B050 (1).
[133] Kentucky Revised Statutes 198B080 (1).
[134] Kentucky Revised Statutes 198B050 (3).
[135] Kentucky Revised Statutes 198B050 (4).
[136] See Kentucky Revised Statutes 13A015. The Massachusetts State Board of Building Regulations and Standards, see above, has the sole power to adopt and maintain the building code. General Laws of Massachusetts 143–94. Petitions for amendments may be made by 'any person' are to be discussed at public hearings twice annually. Amendments are adopted by simple majority of the Board. General Laws of Massachusetts 143–97.
[137] Rhode Island Statutes, 23–27.3–109.1 The committee consists of four members of the House and three members of the senate.
[138] Sections 370 *et seq*, Article 18, Executive Law, New York State Consolidated Laws. Section 377 instructs a uniform building code to be formulated and come into effect in 1984. Section 373-a mandates a study to be conducted for that purpose on the BOCA Building Code and NFPA's fire code.

consisting in majority of various state and local code officials, with an added contingent of builders, trade union representatives, and 'a person with a disability.'[139] Until recently, the State wrote its own idiosyncratic codes. In 1999, however, the Council decided to adopt the International Code family.[140] To that end, the Council has fashioned an elaborate process that largely mirrors the ICC code development process for purposes of the State Administrative Procedure Act. Technical subcommittees have been set up for every subcode, ensuring representation of state and local officials, and of various interest groups. These subcommittees, then, are charged with preparing recommendations for modifying the various International Codes, relying heavily on ICBO's services as a 'conduit'. In clear recognition of where the power now really lies, the Department of State has recently taken the step of purchasing membership to ICBO for every single municipality in the State enforcing the Uniform Code, 'giving code enforcement officials around the state the opportunity to participate with full voting rights in the code development hearings.'[141]

After a series of public meetings, the various subcommittees submitted their drafts to the Council in December 2000. In accordance with the SAPA, the Council, then, transmitted a Draft Notice of Proposed-Rulemaking to the Governor's Office of Regulatory Reform in March 2001. After objections from the GORR were incorporated, the Council finally published a Notice of Proposed Rulemaking in the *State Register* on 3 July 2001.[142] That notice, in turn, sparked off another round of public consultation that culminated in a Notice of Revised Rulemaking published on 9 January 2002, which, yet again, started a period of public comment.[143] The Council formally adopted the Code on 6 March 2002.[144]

In California, the Court of Appeal's judgment in *IAPMO v California Building Standards Commission* upset the statutory scheme of basing the state code on the model codes of specific organisations. To interpret the statute as 'freezing' the six listed codes, so the Court, would push the act

[139] Section 374.

[140] New York State Bill S02959 would have amended Article 18 of the Executive Law so as to inscribe into the statute the obligation to base the code on the NFPA Fire Code and on BOCA codes. The bill was never chaptered.

[141] NYS Department of State, Press Release, 'New York State's Code Enforcement Officials Receive Memberships to National Organization, First Opportunity to Participate in Upcoming Code Development Hearings', 7 September 2001.

[142] See NYS Department of State, Code Adoption Status Report, 9 January 2002 (www.dos.state.ny.us).

[143] The proposed rulemaking adds Chapter 33, Subchapter A, Parts 1220–26 to the New York Compilation of Codes, Rules and Regulation adopting the various codes. The wording used for is now 'a publication entitled the Residential/Building/Plumbing/Mechanical/Fuel Gas/Fire/Property Maintenance Code of New York State, 2002 Edition, published by the International Conference of Building Officials (ICBO).'

[144] ICC, News Release, 'Governor Pataki Announces New York Has Adopted the I–Codes', 11 March 2002. Cf New York Department of State, 'Updated Code Adoption Status Report', 16 April 2002.

'over the line of unlawful delegation of the lawmaking power.' Hence, the Court chose to read the act as permitting, maybe even encouraging, but not requiring adoption of the codes issued by the organisations named in it.[145] All of this put the Commission under considerable pressure. Chaired by the Secretary of the State Consumer Services Agency, the Commission consists of eight members appointed by the governor from among interest categories prescribed by statute.[146] Even if the Commission is authorised to set up technical advisory panels, the statute clearly does not envisage an elaborate adoption process. Faced with the task of reaching agreement on the choice of code, the Commission decided to set up a 'Code Advisory Group' in 1998 'to formulate, implement, and oversee a process by which state agencies select single-subject matter model codes,' to which it invited 33 public and private organisations representing all interested parties.[147] The group was later renamed the '2000 Code Partnership' in order to identify more closely 'the public and private partnership efforts of the group.'[148] In September 2000, the group completed its work and recommended adoption of the International Building Code. In October, however, the Commission decided to ignore the proposal and continued to rely on the 1997 Uniform Building Code, on the WFCA's fire code, and on IAPMO's mechanical and plumbing codes.[149] Part of the equation, no doubt, was a legislative initiative that would have reached much the same objective. A Bill was introduced in the Assembly in 1999 that directly overturned the Court's decision. Deleting all permissive language in the statute, the Bill would force the Commission to base the State Building Code on exactly the same codes as the ones the Commission had

[145] *International Association of Plumbing and Mechanical Officials v California Building Standards Commission* 55 Cal App 4th 245, 254–55 (1997), (on the well-established principle of statutory construction that, where an act is susceptible to two equally reasonable constructions, one of which would render it unconstitutional, courts are to opt for the other).

[146] Section 18921, California Health and Safety Code. Members have to include an architect, a structural engineer, a 'mechanical or electrical engineer or fire protection engineer', a licensed contractor, a representative of organised labour, a local fire official, a local building official, and a disabled person. For several years, the Commission's vice-chair was Fady Mattar, past chairman of IAPMO's code standards committee, and chair of ASHRAE's code committee.

[147] California Building Standards Commission, Resolution 98–2 (www.bcs.ca.gov/policy/policy_98_2.htm). The organisations include the California Council of the AIA, BOMA, the California Fire Chiefs Association, the Structural Engineers Association of California, the Association of General Contractors, the California Building Industry Association and other industry associations, the California Building Officials, the Hotel & Motel Association, the state's two main universities, and several state agencies.

[148] California Building Standards Commission, Resolution 98–4 (www.bcs.ca.gov/policy/policy_98_4.htm).

[149] To predictably different reactions of the NFPA and the ICC. Cf NFPA, Press Release, 'California Rejects Effort to Base Building Code on International Building Code', 7 October 2000; and ICC, Press Release, 'California Building Standards Commission Ignores Own Experts' Recommendation to Adopt the International Building Code', 3 November 2000.

chosen.[150] After much angry debate, the Commission updated its choice to NFPA 5000 and the Uniform Fire Code in July 2003.[151]

Florida amended its building code legislation in 1998, deciding to centralise what was previously local governments' prerogative.[152] The legislation sets up a Florida Building Commission that is to 'select from available national or international model building codes, or other available building codes and standards currently recognised by the laws of this state, to form the foundation of the Florida Building Code.'[153] The composition of that Commission, in turn, looks rather a lot like a consensus committee. Chaired by an AIA member, the Commission boasts local code officials, architects, contractors, engineers, manufacturers, insurers and the token 'representative for persons with disabilities.'[154] In February 2000, the Commission adopted a code based on ICC codes as an administrative rule. In June 2000, the legislature adopted that rule as the Florida Building Code.[155]

In Oregon, responsibility for the promulgation of the state building code is given to the Director of Consumer and Business Services,[156] subject to notice and comment procedures under the State administrative procedure act.[157] In addition, however, the statute also provides that 'any interested person' may propose amendments to the various specialty codes making up the state building code at any time.[158] These proposals go through 'advisory boards', whose approval is necessary in order for the Director to be able to adopt such amendments.[159] The statutory provisions regarding the composition of these 'advisory boards' read like the interest categories of standards bodies. The Building Codes Structures Board, for example, is composed of an architect, a homebuilder, an engineer, an energy supplier,

[150] See Assembly Bill 1626, amending, *inter alia*, sections 18916 and 18938 (b) of the California Health and Safety Code. Allegedly, the Bill, sponsored by Democrats, was meant as payback for trade union support for the election of Democratic Governor Davis. Cf 'Bill Fuels Debate on Building Code', *LA Times*, 12 May 1999. The Bill's fate is unclear at the time of writing.

[151] See NFPA, Press Release, 'California adopts NFPA 5000, Building Construction and Safety Code, and NFPA 1, Uniform Fire Code', 30 July 2003; and ICC, Press Release, 'Failure of California Commission Creates Construction Industry Crisis', 31 July 2003.

[152] See Florida Department of Community Affairs, *Development of the Florida Building Code, A Report to the 2000 Legislature by the Florida Building Commission*, 2000.

[153] Florida Statutes, Title III, 553.73 (3).

[154] Fully circumscribed in Florida Statutes, Title III, 553.74.

[155] See House Bill 219. Cf Florida Department of Community Affairs, 2000 Bill Analysis on HB 219 (www.dca.state.fl.us/fhcd/fbc/legislative/219.htm). For ICC's delight, see ICBO, Press Release, 'Florida Adopts State Code Based on IFGC, IMC, IPC, IBC', 26 June 2000.

[156] Oregon Revised Statutes, 455.020.

[157] Oregon Revised Statutes, 455.030 (1). Cf Oregon Administrative Rules 918–008–0000 *et seq*, (Department of Consumer and Business services, Building Codes Division, Code Development Rules).

[158] Oregon Revised Statutes, 455.030 (4).

[159] Oregon Revised Statutes, 455.030 (5).

a building official, owners/managers of commercial and residential buildings, a low income housing representative, a representative of a recognized environmental group, and a person recommended by the Oregon Disabilities Commission.[160]

Even if the statute makes no reference to any one model code or code writing association,[161] in practice the state building code consists of an amalgam of NFPA electrical standards, IAPMO's plumbing code and ICC codes.[162] In view of the 'turmoil created at national level' after the NFPA's falling out with the ICC, the Building Codes Division announced it would stay with the UBC until it has had the time to review both NFPA 5000 and the IBC in order to make an informed decision 'as to which new code is best for Oregon.'[163] The Code Review Committee appointed to that purpose published its report in December 2002, endorsing the ICC codes.[164]

4. CONCLUSION

Perhaps more than anything else, the whole story illustrates a general trend towards the blurring of public and private roles in market regulation. Where public officials flock to all kinds of private associations to participate in standards and codes development, private associations take on a prominent role in administrative rulemaking. Where private standards bodies are tightening up their internal procedures that start looking more and more like administrative rulemaking procedures, States are devising regulatory adoption procedures of codes and standards that look more and more like balanced private standards committees. Instead of a division of labour between industry self-regulation on one level in the process and official authority on another, the system rehearses the conflicts between expertise and public participation, and between the putative 'public interest,' as embodied in public officials, and proprietary interests, at all levels.

[160] Oregon Revised Statutes, 455.132. Cf eg ORS 455.138 (setting up the Electrical and Elevator Board); and ORS 639.115 (setting up the State Plumbing Board).

[161] ORS 446.185, on manufactured housing standards, does require state standards to be 'reasonably consistent with nationally recognised standards.' ORS 460.730, on the electrical code, and 447.020, on the plumbing code, do without any reference to outside sources.

[162] See Oregon Administrative Rules 918–440–0010 ('the Oregon Mechanical Specialty Code is the 1998 International Mechanical Code as amended by the Building Code Division.'); OAR 918–460–0010 (Oregon Structural Specialty Code is 1997 Uniform Building Code); 918–480–0005 (same for 1998 International One and two Family-Dwelling Code); and 918–480–005 (1997 Uniform Plumbing Code); and OAR 918–305–0000 (lending a presumption of conformit y with the State Electrical Specialty Code to compliance with NEC).

[163] Department of Business and Consumer Services, Building Codes Division, Administrator's Message, 'Changing Building Codes' (undated, at www.cbs.state.or.us/external/bcd/admmsg.htm, last revised on 14 May 2001).

[164] Comparison of NFPA and ICC: Final Report and Recommendation to the Building Codes Division and the Oregon State Fire Marshall's Office, 20 December 2002.

6

International Harmonisation of Standards

1. INTRODUCTION

IN A FAMILIAR NARRATIVE, international trade law has matured from its infant years when all it was really interested in was the disappearance of tariff barriers. These, the riper years, are all about tackling 'non-tariff barriers to trade'—that is, virtually every instance of State regulation of the economy that constitutes, or can be construed to constitute, an obstacle to global open markets.[1] National and regional health and safety regulations of industrial products are now readily conceptualised as 'Technical Barriers to Trade.' That sounds more elegant than 'measures having equivalent effect to quantitative restrictions to trade,' but the general idea is the same as the one underlying Article 28 EC.[2] The role private standards play in the effort to integrate markets internationally is familiar as well.[3] In what has been called a 'slow motion *coup d'état* against

[1] The evolution is analysed with great elegance and insight in Howse, 'From Politics to Technocracy—And Back Again: The Fate of the Multilateral Trading Regime' (2002) 96 *AJIL* 94. The related ethos is described with great elegance and insight in Kennedy, 'The International Style in Postwar Law and Policy: John Jackson and the Field of International Economic Law' (1995) 10 *Am U J Int L & Pol* 671.

[2] See Micklitz, 'International Regulation on Health, Safety and the Environment—Trends and Challenges' (2000) 23 *JCP* 3, 21 (considering how the European legal order may serve as a blueprint for the development of GATT/WTO law, which would entail a regulatory approach where international trade and product safety are integrated). Cf Nicolaïdis and Egan, 'Transnational Market Governance and Regional Policy Externality: Why Recognize Foreign Standards?' (2001) 8 *JEPP* 454 (arguing that the EU has managed to 'export' much of its regime to the international level thanks to 'first mover advantage'). On the overlapping and interlocking trade arrangements generally, see eg Weiler (ed), *The EU, the WTO and NAFTA: Towards a Common Law of International Trade* (OUP, Oxford, 2000); de Búrca and Scott (eds), *The EU and the WTO: Legal and Constitutional Issues* (Hart Publishing, Oxford, 2001); Snyder, 'The Gatekeepers: The European Courts and WTO Law' (2003) 40 *C M L Rev* 313.

[3] See generally eg Sykes, *Product Standards for Internationally Integrated Goods Markets* (Brookings Institution, Washington, 1995); Kloiber, 'Removing Technical Barriers to Trade: The Next Step Towards Freer Trade' (2001) 9 *Tulane J Int & Comp L* 511. From a political economy perspective, Egan, 'International Standardization, Corporate Strategy and Regional Markets' in Greenwood and Jacek (eds), *Organized Business and the New Global Order* (St Martin's Press, New York, 2000) 204; Casella, 'Product Standards and International Trade: Harmonization Through Private Coalitions?' (2001) 54 *Kyklos* 243.

accountable, democratic governance,'[4] international trade agreements increasingly privilege technical regulations and standards that are based on 'international standards.' And so the panic starts:

> As they largely immunize domestic standards from attack, the work [of international standardizing organizations] is extremely important. The stringency of a country's chosen standard vis-à-vis the comparable international standard is key to an initial determination of whether such a measure is or is not consistent with the given trade agreement. This naturally puts such hitherto 'back room' organizations in a new light. How are such institutions governed? To whom are they accountable? To what extent do they permit public participation? How are their standards actually developed?[5]

This chapter will try and provide some answers to these questions, and others. The first section will discuss the regime on international standards under the WTO Technical Barriers to Trade Agreement,[6] the debates surrounding it and some of the issues it engenders. This section is largely written in the admittedly reductive perspective of relations between the European Union and the United States.[7] The latter section discusses the role of standards in free trade arrangements on the American continent, from NAFTA to *Mercosur* to the nascent regime of the Free Trade for the Americas Agreement.

2. STANDARDS AND INTERNATIONAL FREE TRADE

2.1 Transnational Private Governance in the WTO

In the WTO regime, Technical Barriers to Trade are to be lifted by Members' relying on 'international standards.' The problem is that it is by no means clear what an 'international' standard is. A comparison with the SPS Agreement brings out questions of the interaction of two sets of

[4] Wallach, 'Accountable Governance in the Era of Globalization: the WTO, NAFTA, and International Harmonization of Standards' (2002) 50 *U Kansas L Rev* 823, 826. More worries in Shapiro, 'International Trade Agreements, Regulatory Protection, and Public Accountability' (2002) 54 *Admin L Rev* 435.

[5] Trebilcock and Howse, *The Regulation of International Trade*, 2nd edn (Routledge, London, 1999) 150.

[6] For a discussion of the 'old' regime, see eg Nusbaumer, 'The GATT Standards Code in Operation' (1984) 18 *JWT* 542.

[7] For the role of standards in *bilateral* EU–US arrangements, see Shaffer, 'Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance Through Mutual Recognition and Safe Harbor Agreements' (2002) 9 *Colum J Eur L* 29. On the issue of the legality of the EU's bilateral agreements under WTO law, see Beynon, 'Community Mutual Recognition Agreements, Technical Barriers to Trade and the WTO's Most Favoured Nation Principle' (2003) 28 *ELR* 231. Cf Trachtman, 'Toward Open Recognition? Standardization and Regional Integration under Article XXIV of GATT' (2003) 6 *JIEL* 459.

dichotomies, 'science' and 'politics' on the one hand, 'public' and 'private' on the other. A discussion of the ISO will stake out the claim of the most obvious 'international' standards organisation. An analysis of the debates raging in the WTO between the European Union and the United States on the definition of 'international standard' may serve to bring matters of legitimacy of transnational private governance into sharper focus.

2.1.1 Standards Under the TBT Agreement

The WTO Agreement on Technical Barriers to Trade relies to a large extent on standardisation for the harmonisation of technical regulations. It pursues a parallel strategy to this end: the 'public leg', the TBT Agreement itself, lays down the fundamental rule that Members' technical regulations 'shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking into account the risks non-fulfilment of these objectives would create.'[8] The legitimate objectives that are explicitly mentioned are the protection of health, safety and the environment, the prevention of deceptive practices and national security; the list is non-exhaustive.[9] The general rule is flanked by three other obligations. First, there is a rather toothless mutual recognition clause to the effect that Members 'shall give positive consideration' to accepting other Members' regulations as equivalent, 'provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.' Second, 'wherever appropriate', members are to draft their product requirements in terms of performance rather than in terms of design. The third and most elaborate obligation is to use international standards. Article 2.4 provides:

> Where technical regulations are required and international standards exist or their completion is imminent, members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means of the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

A refutable presumption of not being an 'unnecessary obstacle to trade' is then bestowed on those regulations that pursue the legitimate objectives

[8] Article 2, TBT Agreement. Alan Sykes argues that the 'least restrictive means' test in WTO law is roughly co-extensive with cost-benefit analysis. See Sykes, 'The Least Restrictive Means' (2003) 70 *U Chi L Rev* 403. The late Robert Hudec singled out Article 2 TBT as a model for dealing with cases of de facto discrimination under Article III GATT and Article XVII GATS. See Hudec, 'GATT/WTO Constraints on National Regulation: Requiem for an "Aims and Effects" Test' (1998) 32 *Int Lawyer* 619, 644.

[9] The parallel with the EC Treaty regime on the free movement of goods is explored in Scott, 'Mandatory or Imperative Requirements in the EU and the WTO' in Barnard and Scott (eds), *The Law of the Single European Market—Unpacking the Premises* (Hart Publishing, Oxford, 2002) 269.

explicitly mentioned and are in accordance with international standards. Members are further required 'to play a full part' in international standardisation activities for those products they have adopted, or expect to adopt, technical regulations for.

The 'private leg' of the TBT is the Code of Good Practice for the Preparation, Adoption and Application of Standards. The Code is applicable without ado to public standards bodies; for non governmental bodies and regional bodies of which their standards bodies are members, states 'shall take such reasonable measures as may be available to them' to ensure that they accept the Code.[10] Standards bodies that accept and comply with the Code shall be acknowledged by members to comply 'with the principles' of the TBT Agreement. As of March 2004, 142 standards bodies from 103 Members had accepted the Code, of which, according to the WTO's classification, 73 are central government bodies.[11] All European bodies,[12] and at least all CEN members have accepted the Code.[13]

The Code imposes obligations on standards bodies that largely run parallel with members' obligations under the TBT. They shall ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to trade.[14] Where international standards exist, standards bodies are to use them as a basis for their own standards unless this would be 'ineffective or inappropriate.' Standards bodies are to 'play a full part' in the work of 'relevant international standardising bodies' and are to make 'every effort' to avoid duplication or overlap of work. Centralisation of standards work is encouraged by the obligation on national standards bodies to 'make every effort to achieve a

[10] Article 4, TBT Agreement.

[11] The classification is less than reliable however. IBN, a private association, is classified as a central government body, whereas ELOT, a government corporation, features as a non governmental body. To add to confusion, two standards bodies are classified as 'parastatal' (Kenya Bureau of Standards and Malawi Bureau of Standards), two others as 'statutory bodies' (Bureau of Indian Standards and Zambia Bureau of Standards), one as an 'autonomous body' (Pakistan Standards Institute), and most bizarrely, one as a 'central government/non governmental' body (Standardisation Council of Indonesia). See the list published as G/TBT/CS/2/Rev.10 on 4 March 2004 by the WTO Committee on Technical Barriers to Trade. The source of all terminological evil is ISO's *WTO TBT Standards Code Directory*, or rather, the information provided by national standards bodies.

[12] CEN, Cenelec and ETSI are the only three non-national bodies on the list. G/TBT/CS/2/Rev.10. Observance of the Code is 'expected' of them in Section 4, *General Guidelines for the Co-operation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association* (2003) OJ C 91/7.

[13] The Malta Standards Authority accepted the code in January 2001. As for Cenelec members, the electrotechnical committees of Austria (ÖVE), Italy (CEI), Norway (NEK), Sweden (SEK) and Switzerland (SEV) have accepted the Code separately; Belgian CEB and Dutch NEC have not done so. There is generally a widely divergent practice for those countries with decentralised systems. For the US, only ANSI has accepted the code; for Canada, only the SCC; Mexico and Japan, on the other hand, list eight and twelve standard bodies respectively. See G/TBT/CS/2/Rev.10.

[14] Article F, Code of Good Practice, Annex 3 to the TBT Agreement.

national consensus on the standards they develop.' Standards are to be drafted in terms of performance, rather than design requirements. The Code also requires that standards bodies 'take into account' comments received by other standards bodies during public inquiry, and deliver a written explanation of the reasons for deviation from relevant international standards.

2.1.2 Standards Under the SPS Agreement

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) envisages a similar general scheme of reliance on international standards.[15] The differences between the two, however, are far more illuminating than the similarities.[16] Two interrelated points stand out. First, the SPS contains a much stricter obligation for Members to base their measures on 'international standards, guidelines or recommendations' than the TBT does. The presumption of conformity is not drafted negatively, but positively: measures which conform to international standards are not just 'not unnecessary obstacles to trade' but are deemed to be 'necessary to protect human, animal or plant life.'[17] Second, the SPS is much more 'scienticist' than the TBT.[18] There is a general obligation to base all measures on 'scientific principles' and not to maintain them 'without sufficient scientific evidence'. Deviance from international standards is allowed only if members can provide a 'scientific justification'.[19]

[15] See eg Hilf and Reuß, 'Verfassungsfragen Lebensmittelrechtlicher Normierung im Europäischen und Internationalen Recht' (1997) *ZLR* 289.

[16] See Marceau and Trachtmann, 'The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade—A Map of World Trade Organization Law of Domestic Regulation of Goods' (2002) 36 *JWT* 811, 841 (contrasting the 'refined system of applied subsidiarity' under the SPS Agreement with the 'less complex, less subtle' requirements under the TBT Agreement.)

[17] The Appellate Body has rightly overturned a Panel's interpretation that would equate measures 'based on' international standards as in Article 3.1 of the SPS Agreement to standards that 'conform to' such standards as in Article 3.2. Such an interpretation, so the AB, would vest international standards with 'obligatory force and effect' and transform them into 'binding norms.' *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body of 16 January 1998, WT/DS26 and 48/AB/R, paragraph 165.

[18] See eg Walker, 'Keeping the WTO from Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute' (1998) 31 *Cornell Int L J* 251; Scott, 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO' in Weiler (ed), above n 2, 125; Howse, 'Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization' (2000) 98 *Mich L Rev* 2329; Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years' (2000) 32 *NYU J Int L & Pol* 865; Sykes, 'Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View' (2002) 3 *Chi J Int L* 353.

[19] Article 3.3, SPS Agreement. See *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body of 16 January 1998, WT/DS26 and 48/AB/R, para 176.

Unless one believes there is something inherently more dangerous and scientifically complicated about, say, bottled mineral water than about industrial presses, the only reason for these differences is that the SPS explicitly relies on *public* international standards bodies, most notably the Codex Alimentarius Commission (CAC), a joint committee of the WHO and the FAO. CAC is an intergovernmental organisation that adopts standards by simple majority vote.[20]

It is relatively comprehensible that states are more willing to bind themselves to decisions taken by an intergovernmental organisation of which they themselves are members. Less obvious is the way the SPS Agreement directly links political acceptability with epistemic authority. And Codex is logically a political organisation. Attempts have been made to increase its scientific credibility, including the consultation of 'experts committees'[21] and efforts to separate 'risk assessment' from 'risk management', that is, scientific decision-making from political decision-making. However, the organisation is beleaguered by disagreement about the proper respective roles of science and 'other legitimate factors' in standard-setting.[22] The United States submitted this warning to the SPS Committee in 1998:

> [T]here have been suggestions in these organisations that policies be altered to allow for the development of health standards which may not be science-based. Such policy changes would threaten the objectivity and reliability of the international standards-setting process, frustrate WTO members' desire to further the use of international standards, and undermine the effective implementation of the SPS Agreement.
>
> The principle that national health measures and international SPS standards must be based on science is fundamental to the effective implementation of the SPS Agreement. The Committee should encourage members to ensure that their agreement on this principle is reflected in their participation in the standards-setting organisations, ensuring that international standards, guidelines and recommendations continue to be based on health-related scientific evidence.[23]

[20] A good general discussion is Streinz, 'Die Bedeuting des WTO–Übereinkommens für das Lebensmittelverkehr' (1996) 36 *JUT* 435. Before the CAC shot to prominence by virtue of the SPS, Codex standards had no legal significance whatsoever, and national governments were free to adopt them or not. The Commission has stated that it wants to see the voting arrangements changed in view of the changed status of Codex standards. See its answer to Question E–2929/96 by M Thyssen (1997) OJ C 91/50. The European Community has acceded to the CAC in December 2003. The road was cleared by Council Decision 2003/822/EC (2003) 36 OJ 435 L 309/14.

[21] Most notably the Joint FAO/WHO Committee on Food Additives, fondly known as JECFA.

[22] See generally the Report of the Thirteenth Session of the Codex Committee on General Principles, Alinorm 99/33, CL 1998/32–GP, September 1998.

[23] *Use of International Standards Under the SPS Agreement*, Submission by the United States, G/SPS/GEN/76, 4 June 1998. See generally Salter, *Mandated Science: Science and Scientists in the Making of Standards* (Kluwer, Dordrecht, 1988) 67 ff, on the 'scientific' nature of Codex debates in the different fora. Cf Stewart and Johanson, 'The SPS Agreement of the World Trade Organisation and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Convention and the International Office of Epizootics'

2.1.3 The International Standards Organisation

Founded in 1926 under the accurate if laborious name International Federation of National Standardizing Associations, the International Organisation for Standardization reconstituted itself under the current name in 1946. Over the last 17 years, ISO has doubled its portfolio from 6789 to over 13500 standards in 2002, elaborated by some 30.000 experts organised in some 700 Technical Committees and Subcomittees and over 2000 Working Groups.[24] The organisation has 94 full national members with voting rights, 37 'correspondent' members and 15 'subscriber' members.[25] The full members are united in the General Assembly to elect 18 from their midst who, together with the President, Vice-Presidents, Treasurer and Secretary-General form the Council, the organisation's governing body. The Council in turn appoints the twelve members of the Technical Management Board (TMB), which controls the technical work. A proposal for a new field of standards work can be made by national members, almost any body within ISO or by 'another international organisation with national body membership.'[26] The TMB circulates the proposal and can decide to set up a new Technical Committee, or assign the work to an existing TC, if at least a 2/3 majority of the national bodies voting are in favour of the proposal and at least 5 members express their interest to participate actively.[27] The TMB assigns the secretariat of the TC and appoints the chairperson. Technical Committees may set up Subcommittees subject to ratification by the TMB.

Every national body has the right to participate in TCs and SCs; it can do so as an active member, or P-member in ISO jargon, or as an observer, or O-member. Even if it decides not to participate at all, it still has the right to vote on enquiry drafts and final drafts.[28]

Members are under an obligation to organise their national input in an efficient and timely manner, 'taking account of all relevant interests at their national level.'[29] Though insisting on the cardinal importance of its

(1998) 26 *Syracuse J Int L & Commerce* 27 (worrying about the 'politicization' of international standards-setting in light of its heightened importance under the SPS Agreement.).

[24] *ISO in Figures*, January 2004. In 2002, ISO published 889 new standards.

[25] The status of 'correspondent member' fits organisations in countries which 'do not yet have a fully-developed national standards activity.' They range from DPS–Albania to ITCHKSAR–Hong Kong to UNBS–Uganda. Subscriber membership should allow very small economies to maintain contact with international standardisation. CEBENOR–Benin and LSQAS–Lesotho are examples.

[26] Article 1.5.4, ISO/IEC Directives Part 1: Procedures, 4th edn, 2001.

[27] Above, Article 1.5.7.

[28] Above, Article 1.7.1. P-members have the obligation to vote on all questions formally submitted for voting in the TC/SC and to participate in meetings. Failure to do so results in relegation to O-member status. O-members receive all committee documents and have the right to submit comments and to attend meetings.

[29] Above, Article 1.7.1.

'intergovernmental' structure, ISO does acknowledge that wide acceptance of international standards depends on involvement of all interested circles. It just passes the buck to the national level:

> ISO recognizes as a basic principle of standards activities that the interests of governments, manufacturers, all categories of users and consumers, and any others concerned, should be taken into account. This implies that, for standardization work at the international level, delegations to technical committee meetings should be in a position to represent all interests within their respective countries.[30]

The itinerary of a standard takes three years at best, with votes at various stages. Proposals for new items have to be accepted by a majority of P-members with a minimum of 5 P-members pledging to participate actively in the development of a working draft by nominating experts to a working group.[31] That working draft is then circulated among P—and—O-members for comments, and revised in light of these comments. This goes on and on, with national bodies having three months to comment:

> Consideration of successive drafts shall continue until consensus of the P-members of the technical committee or subcommittee has been obtained or a decision to abandon or defer the project has been made.[32]

However,

> Within ISO, in case of doubt concerning consensus, approval by a two-thirds majority of the P-members of the technical committee or the subcommittee voting may be deemed sufficient for the committee draft to be accepted for registration as an enquiry draft; however, every attempt shall be made to resolve negative votes.[33]

The enquiry draft is then circulated to all members for a 5 months vote. The draft is approved if no more than one-quarter of the total of number votes cast is negative: abstentions and negative votes which are not accompanied by technical reasons are excluded.[34] Only if no negative votes at all are cast may the enquiry draft be published as an international standard. Otherwise, the competent TC/SC must get back to the drawing board and make 'every attempt to resolve negative votes.'[35] The revised draft is then circulated among the national members for a 2 month vote, with identical requirements to the enquiry stage. Unless an appeal is still pending, the

[30] ISO/IEC Statement on *Consumer Participation in Standardization Work*, November 2001.
[31] Article 2.3.5, ISO/IEC Directives Part 1: Procedures, 4th edn, 2001.
[32] Above, Article 2.5.5.
[33] Above, Article 2.5.6.
[34] Above, Article 2.6.3. There must also be a repeat of the two-thirds majority of the P-members of the relevant committee.
[35] Above, Article 2.6.5.

standard can proceed to the publication stage. National members may appeal against decisions of ISO-bodies at all levels in a cascade process leading up to the Council Board whose decision is final.[36] Appeals on decisions concerning new work items, committee drafts, enquiry drafts and final drafts, however, are only allowed when 'matters of principle' are involved or when the contents of a draft 'may be detrimental to the reputation of ISO.'[37] P-members, and only P-members, may appeal against 'any action or inaction' of the TC/SC they consider to be contrary to ISO's statutes, rules of procedure or directives or, intriguingly, 'not in the best interests of international trade and commerce, or such public factors as safety, health or environment.'[38]

There is no obligation on members, regardless of their participation in the development of the standard or of their voting, to adopt ISO standards. Unlike European standards, ISO standards exist as such and can be used without any need for transposition by national standards bodies. National standards bodies wishing to use international standards can either adopt them as they are, transpose them with the addition of clearly identified permitted technical deviations, or modify and amend them at will. Only the first two options, however, are considered by ISO to be 'adoptions' of international standards.[39]

2.1.4 Defining an 'International Standard'

The TBT Agreement fails to explain what an 'international standard' is. The ISO and its electrotechnical counterpart, the IEC, are not mentioned at all in the Agreement itself, and feature in the Code of Good Practice only as the bodies that receive notification of acceptance of the Code by other standards bodies. A 'standard' is defined as follows:

> Document approved by a recognized body, that provides, for common and repeated use, rules guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory.[40]

As the explanatory note to the definition underlines, this differs in two respects from the ISO definition.[41] First, it only covers voluntary documents. Second:

[36] Above, Article 5.1.1.
[37] Above, Article 5.1.3.
[38] Above, Article 5.1.2.
[39] See ISO/IEC Guide 21. ISO would like standards bodies to identify standards clearly as IDT (Identical), MOD (Modified) or NEQ (Not Equivalent) to ISO standards.
[40] Annex 1 to the TBT Agreement, Terms and Their Definitions for the Purpose of This Agreement.
[41] See Section 3.2, ISO/IEC Guide 2. Cf Article 1 (4), Directive 98/34/EC, (1998) OJ L 204/37.

> Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

An 'international' body or system is further defined as a one 'whose membership is open to the relevant bodies of at least all Members'. These scant elements form the background of a heated transatlantic debate on what exactly should be understood as an 'international standard,' or rather, whether it is appropriate to endow ISO with the same functions under the TBT Agreement as the ones discharged by the Codex under the SPS Agreement.[42]

Opposition to a monopoly for ISO is strongest among self-styled 'international standards bodies' in the United States. Standards developed by American bodies such as ASTM and ASME are used worldwide and are generally highly regarded. Understandably, they lobby hard to have their documents accepted as 'international standards' under the TBT Agreement. ASME's reasoning runs as follows: ASME guarantees technical consensus and procedural due process; its committees are open to qualified individuals regardless of nationality. ISO, on the other hand, is portrayed as a 'political' organisation:

> The TBT Agreement tacitly assumes that ISO standards are based on consensus. The current ISO standards development system, however, does not conform to the accepted US definition of a consensus process. The ISO process does not ensure adequate technical consensus. There are no provisions for ensuring fair opportunity of representation across the full range of affected interests. In the end, each participating country has a single vote, which as a political and purely commercial device may be appropriate. However, when standards fill both trade normalization and safety roles, this system provides no assurance that appropriate levels of technical review are achieved.[43]

ASTM's President, James Thomas, recently published his own tirade against the 'Geneva' interpretation of 'international standard':

[42] See Petersmann, 'Prevention and Settlement of International Trade Disputes between the European Union and the United States' (2000) 8 *Tulane J Int & Comp L* 233, 253 (dismissing ISO as a suitable institution for the prevention of US–EU trade disputes in one single paragraph, noting, without any support, that ISO is widely perceived to be dominated by 'industry' and by 'Europe'). Better argumentation in OECD, *Regulatory Reform and International Standardisation*, TD/TC/WP (98) 36/Final, 29 January 1999; and Werle, 'Standards and Standards Organisations in the International Free Trade Regime' (2001) 14 *Knowledge, Technology & Policy* 127. See generally Falke, *International Standards for the Elimination of Barriers to Trade—An Analysis of the Agreements and of the Discussion of Standardization Policy* (Report commissioned by the Commission for Occupational Health and Safety and Standardization (KAN), Bremen, ZERP, 2001).

[43] General Position Paper of ASME International on Standards and Technical Barriers to Trade, March 1997. Globalisation breeds odd bedfellows. See Wallach, above n 4, 833 (deploring the fact that the WTO and NAFTA 'do not mandate any procedural safeguards requiring openness or transparency', operating instead on the sole criterion of 'whether the standard is set in an international body.') Lori Wallach is with Public Citizen's Global Trade Watch, hardly an organisation ASME and its members would feel much affinity with.

> Advocating a political structure based on national delegations as the prerequisite for the development of 'recognised' voluntary international standards rejects and casts aside the United States' system and its *de facto* international standards. The principles upon which the system of consensus standards organisations in the United States are built are, in every respect, commensurate with the principles of the Agreement, as are the international standards that system produces. It meets all the criteria, and goes beyond. It is open to anyone, of any nationality. This makes it actually, not virtually, a system for all interested parties.
>
> . . .
>
> It's time to take a long, hard look at our situation and our standing in the arena of international standards politics. US principles of market-driven standardisation, open competition, and the right to choose are not appreciated in Geneva. US standards development practices, with governments acting as equals as opposed to protectors, role models, or subsidisers, are not acceptable norms in Geneva. International standards developed by US organisations that do not ascribe to national delegations are discredited in Geneva. US voluntary consensus international standardisation practices are dismissed in Geneva—not because they are not in accordance with good standards practices, not because they aren't open, transparent and impartial, not because they aren't part of the most successful economy on the face of the earth, not because they aren't less likely to erect unnecessary barriers to trade—but because they are different.[44]

The American stance has consistently been to privilege both market acceptance and technological excellence over what is perceived as the 'political' compromise that produces ISO standards.[45] In its official communications, the federal government has prompted the WTO Trade Committee to 'clarify' the relationship of Members' obligations arising out of the TBT Agreement to 'standards that are outdated, scientifically or technically flawed, or the result of 'unfair (non-transparent, non-consensus) procedures', a barely concealed stab at ISO. Moreover, it notes that 'arguably, bodies which operate with open and transparent procedures which afford an opportunity for consensus among all interested parties

[44] Thomas, 'Time to Take Stock', *ASTM Standardization News*, 7, 8, 10 August 2000. Response in Eicher, 'Context and Perspectives on WTO/TBT and the Vienna Agreement', *ASTM Standardization News*, 24 October 2000.

[45] Actually, Japan has gone furthest along this track. See *Issues Concerning International Standards and International Standardisation Bodies*—Submission from Japan, G/TBT/W/113, 15 June 1999. There, it proposes to amend the TBT Agreement in such a fashion as to exclude from the Agreement's presumption of conformity those standards that 1) do not adequately reflect 'the status of existing technologies' and 2) 'do not have substantial share in the global market of like products in terms of consumption'. They even propose market share to be expressed in percentage points, without, however, venturing to give a number. For the stress on Japanese standards exercised by trade agreements, see Edelman, 'Japanese Product Standards as Non-Tariff Trade Barriers: When Regulatory Policy Becomes a Trade Issue' (1988) 24 *Stanford J Int L* 389.

will result in standards which are relevant on a global basis and prevent unnecessary barriers to trade', a barely concealed endorsement of American standards bodies.[46]

The European Commission has objected vigorously, and argues effectively for a monopoly of the established international standards bodies ISO and IEC. In its submissions to the TBT Committee in 1999, it made the point that 'objectivity requires that standardisation bodies cannot claim two different levels of status (national, regional or international) at the same time'. Further, it emphasised that a proliferation of competing international bodies should be avoided. Next, it argued that international standards should be the product of 'global consensus', and that participation should be open 'without discrimination on grounds of nationality', preferably 'through one delegation representing all relevant standardisation bodies in a country'.[47]

Members of the TBT Committee have taken the opportunity of the second triennial review of the Agreement to enunciate a number of core principles of international standardisation and create some more ambiguity in the process:

> In order for international standards to make a maximum contribution to the achievement of the trade facilitating objectives of the Agreement, it was important that all Members had the opportunity to participate in the elaboration and adoption of international standards. Adverse trade effects might arise from standards emanating from international bodies as defined in the Agreement which had no procedures for soliciting input from a wide range of interests. Bodies operating with open, impartial and transparent procedures, that afforded an opportunity for consensus among all interested parties in the territories of at least all Members, were seen as more likely to develop standards which were effective and relevant on a global basis and would thereby contribute to the goal of the Agreement to prevent unnecessary obstacles to trade. In order to improve the quality of international standards and to ensure the effective application of the Agreement, the Committee agreed that there was a need to develop principles concerning transparency, openness, impartiality and consensus, relevance and effectiveness, coherence and developing country interests that would clarify and strengthen the concept of international standards under the Agreement and contribute to the advancement of its objectives. In this regard, the Committee adopted a decision containing a set of principles it considered important for international standards development (Annex 4). . . . The dissemination of such principles by Members and standardizing bodies in their territories would encourage the various international bodies to clarify and strengthen their rules and pro-

[46] US Paper on the First Triennial Review, G/TBT/W/40, 25 April 1997.

[47] *On the Grounds for the Acceptance and Use of International Standards in the Context of the WTO Technical Barriers to Trade Agreement*, Note from the European Community, G/TBT/W/87/Rev 1, 30 September 1999.

> cedures on standards development, thus further contributing to the advancement of the objectives of the Agreement.[48]

By focusing on both membership of national standards bodies *and* on procedural safeguards, the Decision in Annex 4 does nothing to solve the disagreement; it merely brings it to sharper focus. Thus ANSI sees itself obliged to repeat the position that 'the determination of international standards status, and thus favoured treatment under the TBT Agreement, should be based on procedural elements of the standards development process and global relevance of the standards in question.' With dismay, it takes notice of the 'membership' criteria in Annex 4:

> This is important because experience to-date has shown that some nations and some regions have interpreted the term 'international standards' as excluding standards developed by the US voluntary consensus standards organizations that by criteria of process, quality, use, and acceptance clearly embody the other Annex 4 criteria and meet global needs. Some sectors in the US continue to be concerned that too much emphasis is being placed on the formal structure and membership of an organization, rather than the process under which a standard is developed and whether the development process is responsive to safety and regulatory considerations, global market forces, and the need for balance in technical expertise regardless of technical origin.
>
> The US private and public sectors should continue to support the principles of standards development on both a national and international level and continue to oppose attempts to exclude standards simply on the grounds of organizational name and structure.[49]

The European Commission, on the other hand, is clearly suffering from procedure-fatigue:

> The principles adopted in relation to the WTO TBT are in line with European thinking on international standards, and they are consistent with the basic principles respected by the European standards bodies and their national members. However, from a European perspective, not only the standards development process, but also the constitution of the bodies developing international standards plays an important role of public authorities were to use international standards as a basis for regulation.[50]

[48] Committee on Technical Barriers to Trade, Second Triennial Review on the Operation and Implementation of the Agreement on Technical Barriers to trade, G/TBT/9, 13 November 2000, para 20. Annex 4, Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2.5 and Annex 3 of the Agreement, is an elaborated version of the Code of Good Practice.

[49] ANSI, *Paper on International Standards Development and Use*, Approved by the Board of Directors on 30 January 2002. ANSI might take comfort from Kenneth Abbott's conclusion, largely on the basis of the Decision, that 'the international system appears to be moving towards the US position.' Or it might not. See Abbott, 'US–EU Disputes Over Technical Barriers to Trade and the "Hushkits" Dispute' in Petersmann and Pollack (eds), *Transatlantic Economic Disputes—The EU, the US and the WTO* (OUP, Oxford, 2003) 247, 258.

[50] European Commission, *European Policy Principles on International Standardisation*, G/TBT/W/170, Communication of 8 October 2001, para 16.

In the *Sardines* case, the European Communities sought and obtained a ruling on the matter from the WTO Panel and Appellate Body. At issue was the divergence between Regulation 2136/89 on marketing standards for preserved sardines and Codex Stan 94 of 1978 on canned sardines and sardine-type products. The EC argued, among a great many other things, that the Codex standard should not be considered a 'relevant international standard' since it had not been adopted by consensus as required by the TBT Committee's 2000 Decision. The Panel dismissed that Decision as a mere 'policy statement of preference,'[51] and read the explanatory note to Annex 1 as acknowledging that consensus 'may not always be achieved' and hence decided that 'international standards that were nor adopted by consensus are within the scope of the TBT Agreement.'[52] The Appellate Body endorsed the Panel's literalism and confirmed that consensus is not a requirement for standards under the TBT Agreement. However, the AB, unlike the Panel, does seem to at least recognise the problem of legitimate transnational governance. It just leaves it to be resolved by the private sphere:

> [W]e uphold the panel's conclusion [—] that the definition of a 'standard' in Annex 1.2 to the TBT Agreement does not require approval by consensus for standards adopted by a 'recognized body' of the international standardization community. We emphasize, however, that this conclusion is relevant only for purposes of the TBT Agreement. It is not intended to affect, in any way, the internal requirements that international standard-setting bodies may establish for themselves for the adoption of standards within their respective operations. In other words, the fact that we find that the TBT Agreement does not require approval by consensus for standards adopted by the international standardization community should not be interpreted to mean that we believe an international standardization body should not require consensus for the adoption of its standards. That is not for us to decide.[53]

The debate has several dimensions. On one level, the quibble over ambiguous semantics reflects fundamental disagreement over regulatory philosophy. As American commentators gladly point out, the choice is as to which model to choose for international standardisation—the European system—'monolithic, integrated, formalistic and policy-driven', or the US

[51] *European Communities—Trade Description of Sardines*, Report of the Panel of 29 May 2002, WT/DS231/R, para 7.91. Cf Marceau and Trachtmann, above n 16, 840 (describing the purpose of the system 'not to dictate to other international organizations how they should proceed but rather to encourage the participation of Members in the law making (standard setting) bodies to which the TBT seems to have lent certain quasi-legislative authority.')

[52] Above, para 7.90.

[53] *European Communities—Trade Description of Sardines*, Report of the Appellate Body of 26 September 2002, WT/DS231/AB/R, para 227. Cf the casenote by Howse, (2002) 29 *LIEI* 247.

system—'pluralistic, sometimes fragmented, *ad hoc* and market-driven'.[54] The Commission's stance transposes onto the global level the principles of the European standards system; in brief, national authorities' surrender of complete discretion in health and safety regulation should be offset by the principle of national representation in standard-setting. Both positions are framed in terms of a requirement of 'consensus'. The European Commission's insistence is undermined by the fact that European legislation does not actually require 'consensus' for standards; the Information Directive defines an 'international standard' merely as 'adopted by an international standards organisation and made available to the public.'[55] The omission is barely made up for by repeated insistence on consensus in Council resolutions.[56] The US position is undermined, perhaps even more, by the Trade Agreements Act that rather obviously views 'international standards organisations' as places where national interests are defended.[57] The Act even goes so far as to give the Secretary of Commerce the power to make 'appropriate arrangements to provide for the adequate representation of United States interests' if the US member of the international standards body does not demonstrate 'willingness and ability' to do so.[58]

Probably more important than regulatory philosophy, however, is economic convenience. ASME bluntly states that 'to discount or devalue US consensus standards from being considered as international standards within the context of the TBT disadvantages US technology and industries'.[59] The European Union, on the other hand, has good reasons to put its faith in ISO. Roughly 40 % of all CEN standards are identical with ISO standards; for CENELEC standards identical to IEC standards the figure is 70%. Though reliable data is hard to come by, the comparable figure for ANSI can safely be put well below 10%.[60] Part of this is due to the so-called

[54] Warshaw and Saunders, 'International Challenges in Defining the Public and Private Interest in Standards' in Hawkins, Mansell and Skea (eds), *Standards, Innovation and Competitiveness* (Edward Elgar, Aldershot, 1995) 67, 70.

[55] Article 1.4, Directive 98/34/EC, (1998) OJ L204/37, requires adoption by a 'recognised' body and voluntary application.

[56] Council Resolution of 28 October 1999 on the role of standardisation in Europe, (2000) OJ C 141/1, para 11: 'standardisation is a voluntary, consensus-driven activity, carried out by and for the interested parties themselves, based on openness and transparency, within independent and recognised standards organisations'. Cf Council Resolution of 18 June 1992, (1992) OJ C173/1.

[57] 19 US 2571(6) defines an 'international standards organisation' as an organisation open to '*representatives*, whether public or private, of the United States and at least all Members.' Emphasis added. The TBT, it will be recalled, works with the 'relevant bodies of at least all the Members.'

[58] 19 US 2543.

[59] ASME, Letter to the Office of the US Trade Representative, Trade Policy Staff Committee, 14 October 1998.

[60] Section 1.2.8 of the ANSI Procedures provide that 'standards developers shall take international standards into consideration and shall, if appropriate, base their standards on international standards.' In its *Global Action Report*, December 1999, p18, ANSI notes: 'Though

'Vienna Agreement' between CEN and ISO,[61] and the parallel 'Dresden Agreement' between CENELEC and IEC.[62] These agreements seek to avoid duplication of work and provide for mechanisms of mutual consultation and reciprocal representation at meetings; moreover, for some items there is even a parallel voting procedure whereby one organism accepts to submit the results of the other's technical work for voting to its members.[63] One good reason why European standards bodies are so eager to transpose ISO standards is that they dominate the standards setting process. ANSI has one vote representing the whole of the United States, CEN members all have one vote each and are regularly accused of block voting. There is a kind of *de facto* G6 in ISO, with ANSI, the Standards Council of Canada and the Japanese JISC represented both in Council and on the Technical Management Board, together with BSI, DIN and AFNOR. But CEN members hold a third of total Council votes, and almost half of the TMB votes.[64] More importantly, European experts greatly outnumber Americans, or any conceivable 'bloc' as participant members in Technical Committees and Subcommittees, where influence on the technical contents of standards can be exercised effectively.[65] Perhaps most significantly, European standards

sufficient data is not yet available to confirm a trend in increased adoption of international standards as ANS, both staff and ANSI constituents have observed that the frequency of identical or harmonized adoption of international documents of ANS appears to be increasing.' That's all very well, but it is quite safe to estimate the comparable figure to CEN's at far below 10%. A search of ANSI's database (www.nssn.org) reveals a grand total of 51 standards that are catalogued as ANSI/ISO standards, of which 13 form part of the ISO 9000 quality management series and 25 concern standards on photography, adopted by the Photographic and Imaging Manufacturers Association. Not a single ISO–identical standard is listed that was adopted by any of the major American standards bodies. Firms could, of course, use international standards regardless. But see Barrett and Yang, 'Rational Incompatibility with International Product Standards' (2001) 54 *J Int Econ* 171.

[61] Reproduced in Nicolas, *Common Standards for Enterprises* (Opoce, Luxembourg, 1995) 249 ff.

[62] Published on http://www.iec.ch/cenelec.htm

[63] Roughly one sixth of all ISO work items are covered by parallel voting mechanisms, of which one fourth are developed in CEN, as ANSI reports with some relief in its *Global Action Report*, December 1999. The Council's Resolution on 'The Role of Standardisation of Europe', 19 October 1999, (2000) OJ C 141/1, speaks of the 'exemplary nature' of the agreements and encourages Europe's trading partners to adopt 'comparable mechanism for co-operation with international standards bodies and for the transposition of international standards.'

[64] On the Council, the Big Three are joined by AENOR, DS and SIS. On the TMB, by NEN and SIS.

[65] The oldest TC in the organisation, TC 1—Screw threads, has 18 P-members, ANSI being joined by CEN members SIS (secretariat), AFNOR, BSI, CSNI, DIN, DS, NEN, ON, SNV and UNI, and further by Egyptians, Russians, Japanese, Poles, South Africans, Chinese and Australians. The newest, TC 222—Personal financial planning, has 17, ANSI (secretariat) being joined by CEN members AFNOR, BSI, DIN, ON, SIS, and SNV, and further by Malaysians, Argentines, Japanese, Koreans, South Africans, Canadians, New Zealanders, Singaporese and Turks. The most CEN-dominated TC I could find is the admittedly obscure TC 186—Cutlery and table and decorative metal hollow-ware, which has 9 participating members: BSI, AENOR, AFNOR, DIN, IPQ, SNV and UNI being joined by the Koreans and Russians.

bodies hold the vast majority of TC/SC secretariats, a crude but effective measure of influence in ISO's standardisation work. First, holding the secretariat is a good measure of the financial commitment of a member—ISO's annual operational costs of 140 million Swiss francs a year are financed for 20% out of membership fees and publications income and for 80% directly by members holding secretariats.[66] Second, the member holding the secretariat has considerable informal influence on the technical work, for example through control of the committee's agenda and by virtue of the fact that the nationality of the chairperson of the committee almost always coincides with the country of the member holding the secretariat.[67] Table 5 shows the distribution of secretariats in 2002.[68] However striking the CEN domination, it should be noted that as recently as 1986, DIN, AFNOR and BSI combined to hold close to 400 secretariats and ANSI had barely 80.[69] There has been a spectacular American catch-up operation, and ANSI is now the biggest sole provider. However, Europe's 'Big Three' are close on its heels and all CEN members combined still hold over three fifths of the total number of secretariats.

Table 5: Repartition of TC and SC Secretariats in ISO among National Standards Bodies, 2002.

CEN Members		Rest of the World	
Germany-DIN	121	US-ANSI	138
UK-BSI	104	Japan-JICS	39
France-AFNOR	84	Canada-SCC	20
Sweden-SIS	27	Australia-SAI	15
Netherlands-NEN	19	Russia-GOSTR	15
Switzerland-SNV	19	South Africa-SABS	10
Norway-NSF	18	India-BIS	8
Italy-UNI	14	China-SAC	6
Other CEN members	39	Others	25
Total	**445**	Total	**276**

Source: ISO, 2002 Annual report.

[66] *ISO in Figures*, January 2000.

[67] Chairpersons are 'nominated' by the Secretariat and appointed by the Technical Management Board. The ISO/IEC Directives Part I, 3d edn, 1995, Section 1.8.1, used to state that 'the possibility of appointing as chairman a national of a country other than that of the secretariat shall be considered.' This, however, hardly ever happened, at least in ISO. Accordingly, the phrase is now deleted from ISO/IEC Directives Part 1: Procedures, 4th edn, 2001 *juncto* ISO Supplement, 2001. Formally, of course, both the secretariat and the chairperson are to 'act in a purely international capacity, and divest themselves of a national point of view.' Articles 1.8.2 and 1.9.2, ISO/IEC Directives Part 1: Procedures, 4th edn, 2001.

[68] In the IEC, the situation is very similar. Of the 172 TCs and SCs, the United States hold 31. Japan holds 10, Canada 5, and Australia 2. France alone has 32, Germany 25, and the United Kingdom 22. EU Member States taken together hold 113.

[69] AFNOR dropped spectacularly from 140 to 80.

2.2 Diagonal Issues Concerning International Standards

2.2.1 Public Acceptance of Private International Standards

The TBT Agreement causes diagonal conflicts in the United States, in much the same way as the European arrangements cause them in Member States: ANSI is a private association and is not subjected to government control and certainly not bound by the commitments the federal government chooses to make. The US Trade Agreements Act declares:

> It is the sense of Congress that no State agency and no private person should engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States.[70]

The President 'shall take such reasonable measures as may be available to him' to 'promote' observance by State agencies and private persons of requirements equivalent to those imposed on federal agencies.[71] As regards international standards, the 1998 OMB Circular spells out these requirements as follows:

> This policy does not establish a preference between domestic and international voluntary consensus standards. However, in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications.[72]

Moreover, any sense that the commitments of both public and private regulators to avoid conflict with, or even duplication of, international standards work have any teeth in domestic law soon evaporates:

> No standards-related activity being engaged in within the United States may be stayed in any judicial or administrative proceeding on the basis that such activity is currently being considered, pursuant to the Agreement, by an international forum.[73]

[70] Section 403, Title IV, Trade Agreements Act 1979, Public Law 96–39, codified in 19 USC 2533 (a). Note that 'private person' in this context is defined as 'any corporation, association, or other legal entity organized or existing under the law of any State, whether for profit or not for profit, 19 USC 2571 (9)(B).

[71] 19 USC 2533 (b) *juncto* 2532 ('No federal agency may engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States.') Cf Section 471 of the NAFTA Implementation Act 1993, Public Law 103–182, codified in 19 USC 2576 ('Nothing in this chapter shall be construed (1) to prohibit a Federal agency from engaging in activity related to standards-related measures.')

[72] Office of Management and Budget, Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities, 2 October 1998, Section 6 h. Compare the language in 19 USC 2532 (2)(A) ('Each federal agency, in developing standards, shall take into consideration international standards and shall, if appropriate, base the standards on international standards.')

[73] 19 USC 2562.

Any suggestion by 'an appropriate international forum' that any standards-related activity in the country violates the obligations of the US under the Agreement will be 'reviewed' by an interagency organisation 'with a view to recommending appropriate action';[74] similar suggestions coming from a party to the Agreement will have to be presented to the US Trade Representative,[75] who will then enter into consultations with the 'agency or person' alleged to have engaged in violations under the Agreement and will thus 'undertake to resolve' the issues on a 'mutually satisfactory basis.'[76] Further than that, there is 'no right of action under the laws of the United States with respect to allegations that any standards-related engaged in within the United States violates the obligations of the United States under the Agreement.'[77]

Even if the international regime on private standards is diligently kept out of the national legal sphere, the Trade Agreement Act takes the representation of American interests in private international standards organisations very seriously indeed. Whichever 'private person' is recognised by the international organisation as a member is charged with the task of representing US interests.[78] In that sense, the recognition of ANSI as the US member to ISO on the part of NIST in the Memorandum of Understanding seems almost superfluous.[79] However, as noted, the Act also provides for a mechanism by which the Secretary of Commerce can make 'appropriate arrangements' to remedy a situation in which he has 'reason to believe' that US interests are 'inadequately' represented in international organizations, if need be 'through' the private member if the international organisation requires representation by that member.[80] And in that light, it does seem important that ANSI's responsibilities in the international arena are spelled out fairly comprehensively in the MoU. ANSI must ensure representation of US interests 'at all policy and technical levels' within ISO and IEC and convene 'accountable and competent

[74] 19 USC 2554.
[75] 19 USC 2552.
[76] 19 USC 2553.
[77] 19 USC 2551.
[78] 19 USC 2543 (2) provides that 'the representation of US interests before any private international standards organisation shall be carried out by the organisation member.' 19 US 2543 (1) defines 'organisation member' is the 'private person who holds membership in a private international standards organisation' and 'private international standards organisation' as 'any international standards organisation before which the interests of the United States are represented by a private person who is officially recognised by that organisation for such purpose.'
[79] Section 2.1, MOU between ANSI and NIST, signed 24 September 1998.
[80] 19 USC 2543 (3)–(5). The Secretary is to notify the US member of his misgivings; the member then has ninety days to demonstrate its 'willingness and ability to represent adequately United States interests before the private international standards organisation.' 'Appropriate arrangements through the appropriate organization member' cannot mean much different from US public officials in some way 'taking over' power in a private organisation such as ANSI.

delegations' to do so. It must 'encourage strong and effective participation by appropriate US stakeholders' in all relevant committees, subcommittees and working groups, taking account of and working with 'all affected interests' to develop and promote 'a single, coordinated US position.'[81]

In Europe, it seems to be the European public authorities that go out of their way to dampen the enthusiasm of the European standards bodies to adopt international standards. In its 1990 Green paper, the Commission made its commitment to international standards conditional upon reciprocity:

> If Europe is to promote further international standardisation, however, others must do the same. The Community expects that its leading economic partners, and particularly the United States and Japan, will be prepared to commit more resources to international standardisation in the coming years, and, equally important, to implement international standards at the national level. Unless al the parties concerned act with the same commitment as Europe has done in the past, this important mechanism cannot be properly exploited as a means of promoting international trade and economic growth.[82]

In the Follow-up two years later, the Commission even went so far as to point out that it would be 'pointless and politically unacceptable for the Community to transfer work to the international standardization bodies if only standardization bodies in Europe were to take over international results.[83] The Commission's failure to realise it was re-enacting the same stance it had spent most of the 1980s accusing national public authorities of has been noted and savagely criticised in the general wave of indignation spurred by the Green paper.[84] It still fails to appreciate the irony, however. In its 2001 *European Policy Principles on International Standardisation*, it offers two gems that may well have been taken, *mutatis mutandis*, from French or German policy principles on European standardisation 15 or so years ago: first, it notes how there is 'widespread concern among the public on the appropriateness, use and limitations of international standards for political and ethical reasons or due to cultural diversity.'[85] Second, it comes up with the barely disguised theory that international standards are especially useful if they are, well, European standards, where it claims that

[81] Section 3.1, MOU between ANSI and NIST, signed 24 September 1998.

[82] Commission Green paper, *Action for Faster Technological Integration in Europe*, COM (90) 456 final, para 60.

[83] Commission Communication, *Standardisation in the European Economy*, (1992) OJ C 96/2, para 48.

[84] See above. See also *CEN Strategy: 2010*, section 2.4 (listing as a strategic objective 'to ensure that priority is given to cooperation with ISO, provided it is timely in delivery, and that international standards meet European legislative and market requirements and that non-European global players also implement these standards.')

[85] European Commission, *European Policy Principles on International Standardisation*, G/TBT/W/170, Communication of 8 October 2001, para 10.

'the value of national and regional standards as stepping-stones to international standardisation should also be recognised.'[86]

2.2.2 Public Influence in Private International Standardisation

Much as the New Approach has enhanced the role of central standards bodies and forced Member States to centralise their standards systems, so the TBT is sparking 'national standards strategies' in the United States and in Canada.[87] ANSI has a difficult position in ISO despite all its tough talk of 'global leadership'.[88] Unlike its European centralised counterparts, it does not formulate technical opinions itself and does not send 'ANSI delegations' to technical committee meetings. Instead its participation in ISO TCs takes place by means of Technical Advisory Groups (TAGs), formed on a more or less *ad hoc* basis, consisting of interested industry representatives. ANSI tries to ensure that these represent 'the US interest' by an elaborate set of accreditation conditions and further procedural guidelines.[89] For financial reasons and organisational structure, ANSI is thus wholly dependent on sufficient industry interest for the ISO project at hand. Belinda Collins of NIST describes a history of 'hit-or-miss' participation in ISO/IEC committees: 'including not participating in a committee for several years; sending different participants to each successive committee meeting; failing to circulate documents widely enough to build consensus among affected parties; ignoring important committees, and/or feeling that these venues do not meet their standards needs.'[90] Moreover, the lack of any serious regulatory interface mechanism between ANSI and the federal government makes it difficult to develop a coherent US position in various fora. ANSI is not even mentioned in OMB Circular A-119.

The Director of NIST recently gave this testimony before Congress:

> The United States needs an effective national standards strategy if we are to compete effectively in the global market. While there has been much talk about the need for such a strategy for the past several years by the US

[86] Above, para 9.

[87] See eg Leight and Leuteritz, 'Conference Report—Toward a National Standards Strategy to Meet Global Needs' (1999) 104 *Journal of Research of the National Institute of Standards and Technology* 83 and ANSI, *National Standards Strategy for the United States*, Approved by the ANSI Board of Directors on 31 August 2000. See also National Research Council, *Standards, Conformity Assessment, and Trade: Into the 21st Century* (National Academic Press, Washington, 1995). Cf Standards Council of Canada, *Issues Paper: Towards a Canadian Standards Strategy*, June 1999; and *Canadian Standards Strategy and Implementation Proposals*, March 2000.

[88] See eg ANSI's *Global Action Report*, December 1999.

[89] See ANSI Procedures for US Participation in the International Standards Activities of the ISO, 1997.

[90] Collins, 'A Standards Infrastructure for the Future', *Mechanical Engineering Magazine*, April 2000.

> standards community, we still have not been effective in developing and implementing one. In many sectors, this lack of strategy is beginning to cause problems. Europe *does* have a strategy and it is running at full throttle. It is fair to say that European governments and industries believe that they can create a competitive advantage in world markets by strongly influencing the content of international standards.[91]

He added that the 'disparate and decentralised' US standards community needs to 'resolve our differences with one another to achieve a unified US approach to international standards setting.' The Americans have several problems in this regard. For one thing, public policy as concerns standards is dispersed over federal agencies. For another, private standards setting is even more dispersed and decentralised. The *National Standards Strategy* explicitly 'applauds' the benefits that result from the diversity of organisations developing standards in the US, 'ranging from those accredited by ANSI to special purpose industry consortia.'[92]

In their Memorandum of Understanding, NIST and ANSI try to address both problems, agreeing 'on the need for a national unified approach to develop the best possible national and international standards'.[93] The MOU is intended to 'facilitate and strengthen the recognition of ANSI as the representative of US interests at the international level by all participants; improve domestic communication and co-ordination among both public and private sector parties in the United States on voluntary standards issues; and increase the effectiveness of US Government agency participation in the national and international voluntary standards setting process.'[94]

[91] Raymond G Kammer, Director of the National Institute of Standards and Technology, before the House Committee on Science Subcommittee on Technology, 28 April 1998; emphasis in original.

[92] ANSI, *National Standards Strategy for the United States*, 2000, 8. Cf Mattli, 'International Governance for Voluntary Standards: a Game-Theoretic Perspective' in Bermann, Herdegen and Lindseth (eds), *Transatlantic Regulatory Co-operation—Legal Problems and Political Prospects* (OUP, Oxford, 2000) 337, 338 (noting how ANSI's status in international standardization 'is not fully accepted by major players in the US standards community, and a number of organizations continue to act independently in their dealings with other national standards organizations.')

[93] Section 1.2, Memorandum of Understanding between the American National Standards Institute and the National institute of Standards and Technology, 25 September 1998 (www.nist.gov).

[94] Section 1.4, Memorandum of Understanding between the American National Standards Institute and the National institute of Standards and Technology, 25 September 1998 (www.nist.gov). See also Memorandum of Understanding between the Occupational Safety and Health Administration and the American National Standards Institute, 19 January 2001 ('As the US member body to ISO, PASC, COPANT, and IEC, ANSI will be encouraged to participate in the safety and health-related policy-making groups and committees of these organizations. ANSI will provide OSHA with proposed draft international safety and health standards from these organizations. OSHA will provide ANSI with comments on the proposed international standards, and ANSI will provide these comments to the Technical Advisory Group developing the US position on these standards.')

In its 1996 Communication on external trade policy and standards, the Commission expressed its unease with the fact that, because of the TBT Agreement, 'in several fields it has become difficult to deviate from internationally developed rules and standards even where there may be technical reasons for doing so.' And so,

> it would be desirable to consider whether, and in which circumstances, the Community should be involved more closely in the work of such international bodies, so as to ensure continued consistency between internationally established rules and standards, Community rule-making and our WTO obligations.[95]

It is an extraordinary spectacle to see the Commission, the architect of the New Approach, getting so nervous at the idea of private transnational governance. The Council slapped the Commission's wrists in 1997,[96] and in its 1999 Resolution came up with the softer solution to the diagonal problem:

> [the Council] stresses the need, while respecting the independence of national standards bodies, to ensure that interests defined at European level be presented coherently in both international standards bodies and intergovernmental fora, and that to this end appropriate mechanisms for the exchange of relevant information and preparatory consultations be foreseen by the Commission, the Member States and the European standards bodies.[97]

The need for a unitary voice in international standardisation has also put a stop to the Commission's toying with the idea of a proliferation of European standards bodies. As noted, this still looked like an attractive idea to speed up the standards setting process in 1990.[98] In its 1998 discussion paper, however, the Commission acknowledged:

> Efficiency is not likely to be enhanced by the recognition of new standards bodies. New organisations would have to cope with the same tension

[95] Commission Communication on Community External Trade Policy in the Field of Standards and Conformity Assessment, COM (96) 564 final, para 19.

[96] Council Conclusions of 26 June 1997 on the Communication on Community External Trade Policy in the Field of Standards and Conformity Assessment, belatedly published in (2001) OJ C 8/1 ('When considering whether, and in which circumstances, the Community should be more closely involved in the work of international rulemaking/standards bodies, the Council invites the Commission to study the practical impact from the angle of the division of competencies between national and European bodies.')

[97] Council Resolution of 28 October 1999 on 'The Role of Standardisation in Europe', para 37. Cf European Commission, *European Policy Principles on International Standardisation*, G/TBT/W/170, Communication of 8 October 2001, para 30 ('While representing their own constituencies in specific discussions, European actors are invited to follow the principles set out in this paper which, taken together, define the European policy in relation to international standardisation.') Cf Section 2.4, *CEN Strategy: 2010* (listing as a strategic objective to 'ensure proper coordination of national contribution on 'subjects of vital European interest.')

[98] See Green paper, COM (90) 456/final, para 46.

> between efficiency and accountability as CEN, CENELEC and ETSI. As they would not be members of the international standards organisations ISO/IEC/ITU, they would not be in a position to represent Europe's interest at the international level, which is becoming increasingly important.[99]

2.3 Co-ordinating Public and Private Rulemaking

2.3.1 Public Procurement

European public procurement law battles the use of technical prescriptions as a discriminating device by relying on European standards. Article 10 of the Public Works Directive thus provides:

> Without prejudice to the legally binding national technical rules and insofar as these are compatible with Community law, the technical specifications shall be defined by the contracting authorities by reference to national standards implementing European standards, or by reference to European technical approvals or by reference to common technical specifications.

Only absent European standards is it 'appropriate' to refer to international standards.[100] The GATT Agreement on Government Procurement (GPA), however, imposes international standards:

> Technical specifications prescribed by procuring entities shall, where appropriate:
>
> (a) be in terms of performance rather than design or descriptive characteristics; and

[99] Report from the Commission to the Council and the European Parliament, *Efficiency and Accountability in European Standardisation under the New Approach*, SEC (98) 291, para 29. Other proposals for more 'competition' among European standards bodies need to address the same issue. But they do not. See Schellberg, *Technische Harmonisierung in der EG–Ökonomie und Politik der gegenseitigen Anerkennung, Rechtsangleichung und Normung* (Peter Lang, Frankfurt, 1992); Ladeur, 'Towards a Legal Concept of the Network in European Standard-Setting' in Joerges and Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart Publishing, Oxford, 1999) 151.

[100] Article 10, Council Directive 93/37/EEC concerning the coordination of procedures for the award of public works contracts, (1993) OJ L 199/54. Cf Article 8, Council Directive 93/36/EEC coordinating procedures for the award of public supply contracts, (1993) OJ L 199/1. French law imposes French standards or other standards applicable in France 'en vertu d'accords internationaux.' See Article 13, Décret 84–74 *fixant le statut de la normalisation*, JO 1 February 1984, p 490, as amended by Décret 90–653, JO 25 July 1990, p 8904, Décret JO France 'en vertu d'accords internationaux.' See Article 13, Décret 84–74 fixant le statut de la normalisation, JO 1 February 1984, p 490, as amended by Décret 90–653, JO 25 July 1990, p 8904, Décret 91–283 JO 20 March 1991, p 3873 and Décret 93 1235 JO 17 November 1993, p 15850, *juncto* Article 6, Décret 2001–210 *portant code des marchés publics*, JO 8 March 2001, p 37003. Cf Roussel, 'L'incidence de Non–Respect des Normes Techniques dans les Marchés Publics' (2003) 59 *AJDA* 1696.

(b) be based on international standards, where such exist; otherwise, on national technical regulations, recognised national standards, or building codes.[101]

The European Union refuses to abandon its privileging of European standards, and actively pursues a policy of mandated work to CEN and CENELEC to make sure an adequate body of harmonised standards exists.[102] Significantly then, it is left to the co-operation mechanisms between the European and international standards bodies to ease away the obvious tension between the two sets of requirements.[103]

2.3.2 Pressure Equipment

ASME has a lot to be concerned about regarding international standards on pressure equipment. Its Boiler and Pressure Vessel Code is recognised and used world wide; it is also incorporated in state and local regulations throughout the United States and Canada. European standards in this sector are currently being issued by CEN under Commission mandates in the framework of the Pressure Equipment Directive.[104] Consider the rhetoric in the following statements made by the opposite parties in the debate during a CEN-sponsored conference on the matter in September 1999; first, an ASME representative gently dismisses CEN standards as 'regulatory' standards:

> The underlying philosophy of standards development under CEN concerns many in the US. People familiar with US standards development are disturbed by inability to participate in standards development in Europe. As discussed below, we understand this is a function of the different structure and apparent underlying rationale of standards development between the US and Europe. The US observation is that European standards development is largely a function of implementing EC regulations. Consequently, non-European interests are excluded from direct participation on CEN standards committees. . . .

[101] Article VI (2), GPA. See generally Arrowsmith, *Government Procurement in the WTO* (Kluwer, London, 2003).

[102] The Directives were amended in light of the GPA; see European Parliament and Council Directive 97/52/EC amending Directives 92/50/EEC, 93/36/EEC and 93/37/EEC concerning the coordination of procedures for the award of public service contracts, public supply contracts and public works contracts respectively, (1997) OJ L 328/1. The amendments do not touch the provisions on technical specifications. The same holds for the new overhaul. See Common Position 33/2003 on public works, public supplies and public services, (2003) OJ 147 E/1 and Common Position 34/2003 on utilities, (2003) OJ C 147E/137.

[103] See eg Eeckhout, *The European Internal Market and International Trade* (OUP, Oxford, 1994) 324.

[104] European Parliament and Council Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment, (1997) OJ L 181/1. The Commission has mandated 772 standards; more than 400 standards have been ratified, but so far the references of only 10 standards have been recognised. Cf (1999) OJ C 227.

> As a private sector standards developer, ASME is committed to welcoming qualified participants, regardless of their nationality. ASME's procedures require balance of affected interests on technical consensus committees, but do not discriminate based on citizenship.... This approach reflects a fundamental, important difference between private sector standards and those developed under a regional regulatory scheme. ASME is obviously interested in promoting the use of its standards as an acceptable means of meeting regulatory requirements as well as a basis for facilitating international trade. However, we believe meeting this goal is embodied in the end product, supported by a process which assures free access, transparency and due process.[105]

Here is an excerpt of what CEN has posted as the Conference Summary:

> It is acknowledged that the new CEN standards are designed to meet the specific needs of the European Community since they are based mainly on traditional European practices as exemplified in our own individual national standards. However, the strength of the CEN standards is that the technical quality is high since they have been developed in partnership by experts from the various member states, who are in touch with other experts across the world. Therefore one can imagine that our CEN standards will make an impact on a much wider front than Europe. Although other standards will still have a place and a role to play it is to be hoped that the economic advantage of using CEN standards will minimise the need and the use of other standards.[106]

As can be readily appreciated, international agreement on pressure equipment standards has long been impossible to find, due to vested economic interests and deeply rooted technical differences. What's more, agreement has not been sought: the relevant technical committee in ISO, TC 11, has been dormant for over twenty years.

A solution has now been found, one which could have profound consequences for the way international standardisation is conceived of in other areas as well. Acting on a mandate defining the scope of its work not just as 'standardisation' of certain goods but, in addition, and uniquely so, as 'international co-ordination,'[107] TC 11 has now published ISO/TS 16528:

[105] Feigel, 'US View of the PED and CEN Standards and Future Development of US Pressure Equipment Standards', reproduced in *Mechanical Engineering Magazine*, November 1999.

[106] Spence, 'Summary of the Conference', (www.cenorm.be).

[107] See OECD Trade Committee, *Standardisation and Regulatory Reform: Selected Cases*, TD/TC/WP (99) 47/Final, 24 February 2000. Cf Eicher, 'Standards Wars Past, Present and Future—Can the Free Market Rationalize and Regulate Itself?' in DiBernardo, *et al*, (eds), *NIST Centennial Standards Symposium: Standards in the Global Economy: Past, Present, and Future,* NIST Special Publications 974,Gaithersburg MD, 2002, 14, 16. See also the Note submitted by New Zealand to the TBT Committee, 'Equivalency of Standards: An Interim Measure to Facilitate Trade in the Absence of International Standards', G/TBT/W/88, 15 September 1998 (describing Joint Australian/New Zealand Standard AS/NZS 1200: 1994–Pressure Equipment as an 'umbrella standard' which recognises compliance with both the ASME code and EN 286.)

2002, *Boilers and pressure vessels—Registration of codes and standards to promote international recognition.* This is explicitly an 'umbrella standard' spelling out core performance requirements and involving a system of recognising national or regional standards as fulfilling those essential requirements.[108]

TC 11 has thus explicitly become something of a forum for what Hawkins calls 'technological diplomacy':

> Standards-making is now not so much a process of coming to consensus about how existing or future practices should be codified, it is more an organic process of determining whether the basis for consensus exists at all, or if it can be built, and with respect to which elements.[109]

It could well be argued that this is just the stuff of politics. The analogy between the 'umbrella standard' and the concept of 'essential requirements' as employed in the New Approach is lost on no one. Transferring the model of 'essential requirements' to the global level is, on the face of it, attractive. Those who propose it, however, generally envisage a clear separation of political from 'technical' decision–making. Alan Sykes would like to see high-level *officials* hammering out a deal on 'essential safety requirements'; it would then be up to technical experts to draft the standards to meet those requirements *and* to issue an opinion on whether existing national standards meet those requirements already.[110]

The dilemma is always the same; on the one hand, it is questionable whether industry standards can come up with a set of core guidelines that will be acceptable to regulators; on the other, it is questionable whether regulators can work out a set of relatively precise requirements under which standards can be drafted that are acceptable to the market. Efforts to separate 'political' decision making from 'technical' decision-making are unlikely to solve it.[111]

[108] Power distribution in TC 11 reflects its status; the secretariat is run by ANSI, the chairman is American, the Working Group convenor is Japanese—all of this to balance the fact that 10 out of 28 participating members are CEN members: AENOR, AFNOR, BSI, DIN, DS, ON, MSZT, SIS, SNV and UNI Romanian ASRO, a CEN affiliate, also participates, as do the Standards Council of Canada, Standards Australia International, and Standard New Zealand.

[109] Hawkins, 'Standards-Making as Technological Diplomacy: Assessing Objectives and Methodologies in Standards Institutions' in Hawkins, Mansell and Skea (eds), above n 54, 157.

[110] Sykes, above n 3, 132. His off-hand proposal that such could be done 'under the auspices of the ISO or GATT, for example' is, perhaps, just a little bit careless. Cf Falke, *International Standards for the Elimination of Barriers to Trade—An Analysis of the Agreements and of the Discussion of Standardization Policy* (Report commissioned by the Commission for Occupational Health and Safety and Standardization (KAN), Bremen, ZERP, 2001) 80 ff.

[111] Sykes sees at least half the problem in as much as he recommends more systematic participation by regulators in ISO technical work. See A Sykes, above n 3, 131.

2.3.3 Environmental Management Systems

The regulation of environmental management and audit systems represents perhaps the most illustrative example of the intricacies related to the intersection of private and public initiatives on different levels of governance.[112] In the general context of greater environmental awareness (and increased danger of stringent government regulation), industry interest in a voluntary standard along the lines of ISO's 9000 series on quality management started to grow earnestly in the late 1980s. The International Chamber of Commerce published a 'position paper' on environmental auditing in 1990. BSI published its 'specification for environmental management systems' BS 7750 in 1992. And then the Council of Ministers adopted the EMAS Regulation in 1993.[113] The regulation provides for the possibility for companies to be registered under a Community environmental management and audit scheme, consisting of a detailed framework of requirements whose fulfilment is checked by independent verifiers. As a voluntary scheme, it was recognised as being in potential competition with management standards. The regulation devises a system of incorporation of standards into the regulation. Article 12 reads:

> Companies implementing national, European or international standards for environmental management systems and audits and certified, according to appropriate certification procedures, as complying with these standards shall be considered as meeting the corresponding requirements of this regulation, provided that:
>
> (a) the standards and procedures are recognized by the Commission acting in accordance with the procedure laid down in Article 19;
> (b) the certification is undertaken by a body whose accreditation is recognized in the member State where the site is located.

In the course of 1993 it became evident that ISO's effort to draft an 'environmental management' standard met with world wide support, especially from non-European countries. The Commission reacted in October by sending an official mandate to CEN to follow the work in ISO. From the moment CEN accepted the mandate, its members were bound by the standstill obligations imposed by CEN's internal regulations. However, by that time BSI had already put in a request for recognition of its BS 7750

[112] See generally Coglianese and Nash, 'Environmental Management Systems and the New Policy Agenda' in Coglianese and Nash (eds), *Regulating from the Inside: Can Environmental Management Systems Achieve Policy Goals?* (Resources for the Future Press, Washington, 2001) 1.

[113] Council Regulation 1836/93/EEC allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit scheme, (1993) OJ L 168/1. See generally Falke, '"Umwelt–Audit"–Verordnung' (1995) 1 *ZUR* 4.

standard under the regulation; more controversially, in a bid to compete with the British standard, NSAI and AENOR did the same, the latter for a standard of which it was not all clear it had been adopted in time.[114]

The requests thus ended up in the Article 19 Committee where no sufficient majority was found;[115] when pushed up to Council level, they met with the same lack of endorsement. Under the regulatory procedure, the Commission then took it upon itself to grant the requests and published its three decisions in February 1996.[116] The recognition, however, extended only to certain parts of the regulation and, most importantly, did not include the standards' certification procedures, making it commercially almost worthless. All three decisions further featured the following bitter Article 2:

> This Decision is without prejudice to the elaboration of requirements for environmental management and audit systems in any future European standard and does not constitute a dispensation from the obligation to transpose European standards as national standards without change, and to withdraw conflicting national standards in due time.

The German-led opposition was mounted on two sets of familiar arguments: first, it was maintained that EMAS contained self-explanatory requirements and hence that there was no need for further guidance by way of standards. In this case, however, standards were not so much needed to explicate legislative requirements as they were recognised as

[114] A rather complicated issue. The problem lay in the determination of two dates; when exactly the Spanish standard was 'adopted', and when exactly the standstill obligations begun. The standard was adopted by AENOR's Standardisation Council on 11 October 1994. However, Spanish standards law at the time obliged AENOR to publish a monthly list of adopted standards in the *Boletín Oficial* 'con lo cual pasarán a ser normas españolas'. Article 8 (2), Real decreto 1614/85, *Ordenación de actividades de normalización y de certificación*, (1985) BOE (219), 4529 (the sentence does not feature in the relevant Article 8 f of the new *Reglamento de la Infrastructura para la Calidad y la Seguridad Industrial*, approved by Real decreto 2200/1995, (1996) BOE (32) 3929). The official date of the standard as a Spanish standard was hence the date of the publication of its title and number in the official journal, which was 14 December. However, the Commission accepted AENOR's argument that the procedure leading up to publication in the official journal was of a purely administrative nature without possibility of amending the standard. Even with the date of 11 October, however, the problem was not yet solved. CEN's internal regulations provide that standstill starts 'no later than the date of agreement in principle by the Technical Board.' Article 6.3, CEN/CENELEC Internal regulations, Part 2: Common Rules for Standards Work. In this case, the TB decided by written procedure. In one instance, CEN maintained that the relevant date was the last day NSO's could cast their votes—6 October. In a letter to AENOR, however, CEN mentioned the day the TB's notified its decision to accept the mandate, 31 October. The Commission in the end decided to grant AENOR's request and accept 31 October, albeit with reservations concerning both AENOR's good faith in the matter and CEN's desultory dealings.

[115] Cf Töller, 'The "Article 19 Committee": The Regulation of the Environmental Management and Audit Scheme' in Van Schendelen (ed), *EC Committees as Influential Policymakers* (Ashgate, Aldershot, 1998) 179, 189 ff.

[116] Commission Decisions 96/149/EC (Irish Standard IS 310); 96/150/EC (British Standard BS 7750: 1994); and 96/151/EC (Spanish Standard UNE 77-801(2)-94), (1996) OJ L 34/42, 44, 46.

simply being on the market prior to the EMAS regulation; especially for small and medium sized enterprises, it would be unnecessarily burdensome to go through two sets of partially identical procedures.[117] Second, it was argued that the market-integrating objective of EMAS would be undermined by the recognition of purely national standards. In the end, it was just a matter of the geographical scope of industry standardisation lagging behind the Community's timetable to push through an environmental regulatory instrument.

That soon changed: ISO published its standard 14001 in September 1996,[118] adopted by CEN as EN ISO 14001: 1996, and soon after by all CEN members as national standards.[119] The Commission recognised the new ISO/EN standard in April 1997.[120] On the level of the internal market, the new standard solved the problems of market repartition; on the international level, the problems had just begun.

'Recognition' of the ISO standard under EMAS, as was the case for the national standards, is confined to those requirements of EMAS actually covered by the standard. Extra checks are thus still necessary to verify other aspects. The differences are partly due to the fundamentally different conceptions of the two instruments.[121] ISO 14001 is a marketing instrument, which sees to organisations, and merely 'recommends' compliance with environmental regulations. EMAS is a piece of 'economised' environmental regulation, concerned with production sites, which explicitly links certification to full regulatory compliance.[122] Moreover, EMAS places great emphasis on external communication, requiring detailed environmental statements to be made public 'in a concise, comprehensible

[117] The 'whereas' considerations of the EMAS Regulation justify Article 12 in this sense.

[118] See eg Roht–Arriaza, 'Shifting the Point of Regulation: The International Organization for Standardization and Global Lawmaking on Trade and the Environment' (1995) 22 *Ecology L Q* 479; Rodgers, 'The ISO Environmental Standards Initiative' (1996) 5 *NYU Env L J* 181; Murray, 'The International Environmental Management Standard, ISO 14000: A Non-Tariff Barrier or a Step to an Emerging Global Environmental Policy?' (1997) 18 *U Penn J Int Econ L* 577; Roht-Arriaza, '"Soft Law" in a "Hybrid" Organization: The International Organization for Standardization' in Shelton (ed), *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System* (OUP, Oxford, 2000) 263.

[119] The standard has also been adopted as a National American Standard.

[120] Commission Decision 97/265/EC, (1997) OJ L 104/37.

[121] See eg Hüwels, 'Normen für das Umweltmanagement in der Ernährungsindustrie—Ein Vergleich von Umweltauditverordnung und ISO 14000' (1997) 24 *ZLR* 1; Feldhaus, 'Wettbewerb zwischen EMAS und ISO 14001' [1998] *Umwelt und Planungsrecht* 41.

[122] Even if tucked away in an annexed requirement of putting an 'environmental policy' in place which 'will aim, in addition to providing for compliance with all relevant regulatory requirements regarding the environment, at the continual improvement of environmental performance'. Annex I (3), Regulation 1836/93. A review of the burgeoning commercial eco-management literature concludes depressingly that the issue of regulatory compliance is treated, if at all, in such a way as to fear the worst for the regulation's use as a voluntary instrument of furthering compliance; see Lübbe-Wolff, 'Wegweiser und Irrgärten– Literatur zum Umweltmanagement und zur Zertifizierung nach der EG–Umweltaudit–Verordnung' [1996] *ZUR* 339.

form'.[123] ISO 14000 is much more conservative about external communication, among other reasons for American liability law.

The European Union has been under increasing pressure from global trading partners to substitute EMAS wholesale for ISO 14001. As a voluntary scheme, so goes the argument, EMAS has no claim to public justifications for diverging from international standards and merely constitutes an unnecessary barrier to enterprises used to ISO certification procedures. The counter-argument—that the 14000 series is but a toothless 'gimmick' and does not do anything to actually improve industries' environmental performance, has begun to lose its force in the face of the standard's enormous world wide success.

In 1998, the Commission responded with a proposal for an amended Regulation. In 2001, the new Regulation was adopted by Council and Parliament.[124] The Community's response has been twofold: on the one hand, the regulation is adapted considerably to ensure closer compatibility with ISO 14001 and to strengthen its use as a marketing instrument by the introduction of an EMAS logo; on the other hand, the basic philosophy of a 'mixed' instrument is retained and the regulatory use of EMAS even strengthened.

The reference to 'national standards' has been scrapped from the provision allowing for recognition of additional standards.[125] Annex I states that the system 'shall be implemented according to the requirements of' Section 4 of the EN ISO 14001:1996,' which it reproduces with the permission of CEN.[126]

Terms and definitions of the Regulation are adjusted to ensure compatibility with ISO 14000. Mostly, these are minor modifications.[127] One major if ambiguous adjustment is made to the definition of the entity to be registered. The most important overall amendment to the regulation envisaged is the scheme's extension to non-industrial organisations, including public authorities. The entity to be registered is thus changed from 'site' to 'organisation', in line with ISO's scheme. However, unlike the Commission's proposal, the Regulation holds on to EMAS being linked to the *environmental* criterion of 'site'—'a geographic location including all infrastructure, equipment and materials', rather than ISO's

[123] Article 5 (2), Regulation 1836/93.

[124] The Commission's first Proposal was published as COM (98) 622 final in October 1998; the Parliament's Opinion on first reading was delivered on 15 April 1999, (1999) OJ C 219/385; the Commission's Amended Proposal was published as COM (99) 313 final in June 1999; the Council's Common Position was adopted on 28 February 2000. On 19 March 2001, the Regulation was finally adopted as Regulation 761/2001, (2001) OJ L 114/1.

[125] Now Article 9.

[126] The Regulation calls the standard a 'national standard'; the Common Position called it a 'European standard', and the Commission's amended proposal calls it an 'international standard'.

[127] The shored up definition of 'environmental programme', for example.

economic criterion of 'organisation'-'a company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration'[128]—one of the classic objections to the 14000 series is that registered companies allegedly are allowed to flush away all kinds of waste as long as the exhaust pipe is not located on the factory floor. The Council's position now leaves the issue to the EMAS committee:

> The entity to be registered as an organisation under EMAS shall be agreed with the environmental verifier and, where appropriate, the competent bodies, taking account of Commission guidance, established in accordance with the procedure laid down in Article 14 (2), but shall not exceed the boundaries of one Member State. The smallest entity to be considered shall be a site. Under exceptional circumstances identified by the Commission in accordance with the procedure laid down in Article 14 (2), the entity to be considered for registration under EMAS may be smaller than a site, such as a sub-division with its own functions.[129]

The revised text also strengthens the regulatory use of EMAS, and hence indirectly of ISO 14000.[130] On the one hand, it is repeated dutifully that 'EMAS shall be without prejudice to (a) Community law, or (b) national laws or technical standards not covered by Community law and (c) the duties of organisations under those laws and standards regarding environmental controls.[131] On the other, the regulatory compliance requirement is fleshed out considerably and now reads:

> Organisations shall be able to demonstrate that they
>
> (a) have identified, and know the implications to the organisation of, all relevant environmental legislation;
> (b) provide for legal compliance with environmental legislation; and
> (c) have procedures in place that enable the organisation to meet these requirements on an ongoing basis.[132]

[128] Article 2 (s) and (t), Regulation 761/2001, (2001) OJ L 114/1.

[129] Article 2 (s), Regulation 761/2001, (2001) OJ L 114/1.

[130] In the United States, the EPA has published a very cautious position statement in the *Federal Register* of 12 March 1998, Vol. 63, 12094, hinting at the usefulness of ISO 14000 for improving compliance with regulatory requirements. By that time, a 'Coalition on ISO 14000 Implementation' had already been formed by General Electric and several trade associations, including various ANSI SDO's (American Iron and Steel Institute, American Petroleum Institute) to protest against *any* Government 'interference' with 'internal decisions' of organisations; regulatory requirements of conforming to the standard would 'reduce flexibility, stifle innovation, reduce international competitiveness and in some instances be considered non-tariff trade barriers.' See 'Industry Coalition Addresses Government Use of ISO 14000 Standards', Press Release, October 1997, posted on www.ansi.org. See, however, Meidinger, 'Environmental Certification Programs and US Environmental Law: Closer Than You May Think' (2001) 31 *Environmental Law Reporter* 10162 (disputing the coercive law—private certification dichotomy).

[131] Article 1 (3), Regulation 1836/93, moved to Article 10 (1) in Regulation 761/2001, (2001) OJ L 114/1.

[132] Annex I (B) (1), Regulation 761/2001, (2001) OJ L 114/1.

Moreover, Member States 'should consider' how EMAS registration 'may be taken into account' in the implementation and enforcement of environmental law 'in order to avoid unnecessary duplication of effort by both organisations and competent enforcement authorities'.[133] In order to encourage widespread participation, the Commission and national authorities should also 'consider' how registration under EMAS 'may be taken into account' in public procurement policy.[134]

3. STANDARDS AND FREE TRADE IN THE AMERICAS

3.1 The North American Free Trade Agreement

Chapter Nine of the North American Free Trade Agreement substantially overlaps with the TBT, in that parties' standards-related measures that conform to international standards shall be deemed to be consistent with the fundamental obligations of non-discrimination and of not creating 'unnecessary obstacles to trade.'[135] In several respects, however, the obligation to take international standards into account in NAFTA is less onerous than the one imposed by the TBT. First, NAFTA adds 'scientific justification or the level of protection that the Party considers appropriate' to the climatic, technological or infrastructural factors that render international standards 'ineffective or inappropriate' means to fulfil the Parties' legitimate objectives.[136] The obligation, moreover, shall not be construed to prevent parties from adopting, maintaining or applying any standards-related measure that results in 'a higher level of protection than would be achieved if the measure were based on the relevant international standard.'[137] Second, there is no equivalent Code of Practice for private bodies but merely the obligation on parties to 'seek to ensure observance' of these provisions by non-governmental standardising bodies 'through appropriate measures.'[138]

[133] Article 10 (2), Regulation 761/2001, (2001) OJ L 114/1.

[134] Article 11 (2), Regulation 761/2001, (2001) OJ L 114/1. The Commission's proposal is silent on the point.

[135] Article 905 *juncto* 904 (3) and (4). The Parties 'affirm with respect to each other their existing rights and obligations relating to standards-related measures under the GATT Agreement on Technical Barriers to Trade and all other international agreements, including environmental and conservation agreements to which those Parties are party.' Article 902 (2). Note that NAFTA works with the phrase 'standards-related measure' to cover standards, technical regulations and conformity assessment procedures. The definition of 'international standard' is taken over from the TBT, with the addition of 'including ISO, IEC, Codex, the WHO and the ITU' Article 915.

[136] Article 905 (1).

[137] Article 905 (3).

[138] Article 902 (2).

NAFTA also provides, after a fashion, for regional harmonisation and/or mutual recognition of standards:

> Without reducing the level of safety or of protection of human, animal, or plant life or health, the environment or consumers, without prejudice to the rights of any Party under this Chapter, and taking into account international standardisation activities, the Parties shall, to the greatest extent practicable, make compatible their respective standards-related measures, so as to facilitate trade in a good or service between the Parties.[139]

To 'make compatible' is defined as to 'bring different standards-related measures of the same scope approved by different standardising bodies to a level such that they are either identical, equivalent, or have the effect of permitting goods or services to be used in place of one another or fulfil the same purpose.'[140]

3.1.1 Canada

Canada has a centralised and formalised 'Nationals Standards System' with a high degree of public involvement. Set up as a Crown Corporation by Act of 1970, the Standards Council of Canada co-ordinates national standardisation and certification, accredits standards bodies, adopts standards as National Standards of Canada, and designates Canadian representatives to international standards bodies.[141] The 15 members of the Council are appointed by the Governor in Council: there are three designated seats for federal and regional governments and one for a representative of the accredited standards bodies. The other eleven members 'must be representative of a broad spectrum of interests in the private sector.'

Only standards written by accredited standards bodies are considered for adoption as National Standards of Canada;[142] the criteria for accreditation form a combination of 'the more rigorous' of the provisions of ISO/IEC Guide 59 and of the WTO Code of Good Practice.[143] The SCC reviews adherence to its procedures and hears appeals which are open to 'a party substantially concerned with the standard' on 'any action taken by a Canadian standards-writing organisation relating to the procedures used in the preparation or publication of a National Standard of

[139] Article 906 (3).

[140] Article 915.

[141] Article 4, Standards Council of Canada Act, RSC 1970, c 41 (1st Supp), last amended in 1996, c 24.

[142] Other organizations may submit standards for approval as a National Standard of Canada to the SCC. However, that standard is then assigned by the SCC to an accredited standards-writing organisation who is to put it through its normal review procedures. See Article 6.4–CAN–P–2E Criteria and Procedures for the Preparation and Approval of National Standards of Canada.

[143] See CAN–P–1D Accreditation of Standards–Development Organizations.

Canada.'[144] The procedures insist on balanced interest representation, consensus and a demonstrable attempt to 'resolve all negative votes',[145] on the 'opportunity for equal access and effective participation' for 'concerned interests directly or materially affected',[146] on public review and on mechanisms for dispute-resolution.

The Council has accredited four Standard Development Organisations. Two of these are government organisations—the federal *Canadian General Standards Board*, established in 1934, and the *Bureau de Normalisation du Québec*, set up in 1961. The other two are private non-profit organisations. *Underwriters Laboratories Canada*, dating back to 1920, affiliated in 1995 with its US namesake, occupies itself mainly with testing and certification activities. By far the most important standards body is the *Canadian Standards Association*, set up in 1919. CSA has published over 1800 standards. Under the name *CSA International* it runs a testing and certification business extending all over North America and even has an office in China. Moreover, *CSA America* is an ANSI-accredited SDO. In line with clearly defined strategic objectives, Canada is well prepared to accept the American theory of 'international standards':

> The global acceptance of many US standards and the magnitude of Canada's exports to the US require that Canada establish and maintain mechanisms for Canadian participation, monitoring and influencing of international standards development centred in the US.[147]

3.1.2 Mexico

The *Dirección General de Normas*, a directorate of the Ministry of Trade and Industrial Development, had had a monopoly in the issuing of *Normas Oficiales Mexicanas* for decades until the early 1990s. These NOMs could be either mandatory or voluntary, but they were all established by the government. It wasn't until the advent of the GATT Standards Code and NAFTA that Mexican law and policy distinguished between technical regulations and standards. Faced with the global drive towards private standardisation, it became part of the official Mexican international trade strategy to create a private standards system. This, however, according to a former General Director of Standards of the Ministry, was not easy at all:

> One problem Mexico encountered was that it did not know how to form these bodies, so help was sought from the European Union. This is a fact not

[144] Article 11, CAN–P–2E Criteria and Procedures for the Preparation and Approval of National Standards of Canada.

[145] Above, Article 5.6.

[146] See Annex 3 (normative), CAN–P–1D– Accreditation of Standards Development Organizations.

[147] Standards Council of Canada, *Canadian Standards Strategy and Implementation Proposals*, March 2000, p18.

> commonly known. We told the Europeans that if they didn't help Mexico, we were going to enter into a free trade agreement with the United States and because our standardization system was, to say the least, in shambles, most likely it would be taken over by American market forces and private sector organizations, thereby jeopardizing any meeting of the system with the European countries. Within five days the Europeans authorized a grant of $2 million in ECUs. These funds were provided in order to assist the Mexican government in strengthening this project of privatization and enhancement of its standardization system.[148]

This 'frantic race to create private bodies',[149] then, found its legislative embodiment in the 1992 *Ley Federal sobre Metrología y Normalización*.[150] The law sets up a two-tier system of technical specifications, co-ordinated by a semi-public *Comisión nacional de normalización*.[151] The category of official, mandatory Mexican standards is maintained.[152] These are based on preliminary drafts established by competent public authorities, which are then submitted to so-called *Comités consultivos de normalización*.[153] These committees, in turn, are set up by the competent public authorities and presided over by a representative of the Ministry most closely involved with the matter at hand. Currently there are 22 active consultative committees. Even if provision is made for participation of wide circles of interested parties, it is at the discretion of the public authorities, in co-ordination with the CNN, to decide who are actually to be invited.[154] Once decided upon by the committee, the entire draft standard is pub-

[148] Portal, 'Mexican Standards-Related Policy and Regulation' (2001) 9 *United States–Mexico Law Journal* 7, 10–11. For what two million Euros buys these days, see Article 19, Decision 2/2000 of the EC–Mexico Joint Council of 32 March 2000 (confirming their rights and obligations under the TBT Agreement, the Parties shall intensify bilateral co-operation in the field of standards and technical regulations 'to increase mutual awareness and understanding of their respective systems'; they shall work towards promoting the use of international standards and facilitating the adoption of their respective standards, and they set up a Special Committee on Standards and Technical Regulations whose functions include 'enhancing co-operation on the development, application and enforcement of standards, technical regulations and conformity assessment procedures.')

[149] Above, 11. Portal's history of NAFTA negotiations gets even better. He reports that the Mexicans, knowing full well that their system was 'somewhat deficient', originally proposed to 'get rid' of all standards and 'start from scratch and create uniform North American standards.' US and Canadian delegates were reportedly 'quite amused' with this proposal and quickly declined. Above, 11–12.

[150] Published in the *Diario Oficial* of 1 July 1992; last amended on 19 May 1999.

[151] Article 59. The CNN is dominated by representatives of public authorities. The only provisions the law makes for further interest representation is the possibility for the public authorities to appoint representatives of industrial and commercial chambers or associations, and the possibility to 'invite to participate' all sorts of other public and private organisations and associations (including consumer organisations and trade unions) if and when issues of their competence, special expertise or interest are being discussed.

[152] Article 52.

[153] Article 44. 'Interested persons' are free to make proposals to the public authorities for official standards, but they do need to do so at the preliminary draft stage and not directly to the Consultative committees.

[154] Article 63.

lished in the *Diario oficial* for a 60-day public review period. The committee then has 45 days to reply to comments received and to modify the standard.[155] Decisions in the committee are taken by consensus or, if such is unattainable, by simple majority. However, a standard can only be adopted if the president and at least half of all representatives of the public authorities on the committee vote in favour.[156]

The law also sets up a 'new' category of 'normal' Mexican standards of voluntary application.[157] The law establishes the fundamental conditions for a standards to be considered *normas mexicanas*: first, they have to take international standards as their basis unless these are 'inefficient or inadequate for the desired objectives' and such is 'duly justified'; second, they have to be based on the consensus of the interested circles that participate in the committee, and have to be submitted for public review via a notice in the *Diario oficial*.[158] Normally, these standards are established by *Organismos nacionales de normalización*. For accreditation as a national standards body, organisations need to adhere to the WTO Code of good practice and to have their statutes approved by the DGN, which, in turn, is conditional upon these statutes specifying that standardisation takes place through technical committees with balanced interest representation of producers, distributors, consumers, professional associations and 'general interest' organisations, 'without excluding any sector of society that could have an interest in their activities.'[159] Representatives of public authorities have the statutory right to participate in any technical committee.[160]

Currently, six national standards bodies have been accredited by the DGN. These are the unimaginatively named *Asociación Nacional de Normalización y Certificación del Sector Eléctrico* (ANCE) and *Normalización y Certificación Electrónica* (NYCE) in the electrotechnical sector; the *Organismo Nacional de Normalización y Certificación de la Construcción y Edificación* (ONNCE) in the construction sector; the *Instituto Nacional de Normalización* Textíl (INTEX) for clothing; the *Sociedad Mexicana de Normalización y Certificación* (NORMEX) for food and beverages, and the *Instituto Mexicano de Normalización y Certificación* (IMNC) for quality systems.[161] In case of standard projects not covered by competent standards bodies, *normas mexicanas* can be issued by *Comités Técnicos Nacionales de Normalización*, free floating ad hoc bodies that need accreditation by the DGN.[162]

[155] Article 47. Official Mexican standards are revised after 5 years; Article 51.

[156] Article 64.

[157] Article 51–A However, administrative and judicial authorities are to take Mexican standards as a 'reference' in civil, commercial or administrative disputes. Article 55.

[158] Article 51A.

[159] Article 65 II b.

[160] Article 66 I.

[161] The latter adopted the WTO Code in April 2000; the others between April and September 1999.

[162] The DGN reports some 35 active CTNNs. http://www.econiomia.gob.mx.

3.1.3 Harmonisation of Standards

NAFTA sets up a Committee on Standards-related measures, designed to 'facilitate' the process by which standards are to be 'made compatible.' Purely intergovernmental, the Committee may set up subcommittees or working groups that 'may' include or consult with representatives of non-governmental bodies, including standards bodies.[163] Outside the structure of NAFTA itself, ANSI, the SCC and the DGN have formed a consultative *Trilateral Standardization Forum*, designed to 'promote' harmonisation of standards.[164] By and large, however, harmonisation of standards under NAFTA is a purely 'bottom-up' process accomplished by the industry association accredited by the members of the Forum.

Unsurprisingly, bilateral compatibility of American and Canadian standards is higher on the agenda than trilateral initiatives. The logically paramount imperative for the Canadian standards community has long been to ensure compatibility of standards with American standards.[165] CSA 'endorses' hundreds of ANSI, ASTM and SAE standards, as well as ISO and IEC standards, by adopting them without modification upon review by the appropriate Technical Committee.[166] The association has also gone through an apparently rather painful process with ASME to produce a harmonised Elevator Safety Code.[167] And finally, it signed a Memorandum of Understanding with the ICC in 1999 'in recognition of

[163] Article 913. The Committee is instructed to set up subcommittees in four areas: telecommunications, land transportation, the automotive industry, and the labelling of textile and apparel goods.

[164] The Standards Council of Canada is worried about consumer representation in these efforts. Noting how, in ANEC, 'Europe' has established a 'very effective, well-funded, interjurisdictional body to ensure adequate consumer representation in European standards work' it has, as part of its Canadian Standards Strategy, announced its intention to 'explore with representatives of the US and Mexico and the standards community the possibility of establishing a similar body.' See SCC, *Canadian Standards Strategy and Implementation Proposals*, March 2000, 33.

[165] SCC, *Canadian Standards Strategy and Implementation Proposals*, March 2000, 6 ('As a country, Canada relies heavily on American standards in many areas such as health, safety and transportation, by accepting these as equivalent to our own or by directly referencing them in our legislation/regulation. Within this context, however, it is essential that Canada pursue harmonisation on a sector-by-sector basis, ensuring that these standardisation practices take account of Canadian priorities, interests and objectives.')

[166] As of April 2001, CSA had endorsed around 400 standards, the bulk of which ANSI (100), ISO (110) and IEC (170) standards.

[167] CSA, News Release of 30 March 2001, 'Harmonization gets Lift through New Elevator Code' ('Creating the harmonized document has been an intricate—and difficult—process. Although the Canadian and US Codes were becoming more similar as CSA and AMSE shared the results of their work, we had never worked in a more formal structure for harmonizing elevator safety requirements. Despite some faltering in the process, we developed a viable solution, with two national committees working towards an end result that combines the best thinking on this topic. In all, more than 200 people participated, from both sides of the border—a true joint partnership that will yield important benefits in the years to come.')

each organisation's vision towards a comprehensive and coordinated set of model codes and standards.'[168] The one trilateral effort of note is the expansion of the bilateral harmonisation program of UL and CSA to the *Asociación Nacional de Normalización y Certificación del Sector Eléctrico* (ANCE) of Mexico under the flag of CANENA, the Council for Harmonisation of Electrotechnical Standards of the Nations of the Americas.[169] Under the scheme, Technical Harmonisation Committees are set up to draft a harmonised standard. However:

> The formal approval of any standard is accomplished outside of CANENA, within and according to the procedures of the organizations involved. Accordingly, there is no formal voting on the standards within the THC or STC. Consensus as determined by the THC or STC Chair will govern the conduct and the completion of the work using the definition of consensus provided in ISO/IEC Guide 2. THCs or STCs shall not be dominated by any single member company or organisation. Membership on a THC or STC or any Subcommittee or Working Group of the THC or STC shall be open to all interested CANENA members on an equal basis.[170]

3.2 South- and Latin American Free Trade Agreements

The WTO and NAFTA Agreements have exercised a profound influence on other regional free trade arrangements. Throughout the 1990s, several of them adopted provisions on standards in some fashion. Chapter 14 of the so-called 'G3' Agreement between Mexico, Colombia and Venezuela replicates almost word for word the text of Chapter Nine of NAFTA, with the major difference that the G3 doesn't see any need to accommodate the idea that standards may be adopted by independent, self-regulatory

[168] ICC, News Release of 15 November 1999, 'CSA International and International Code Council Sign MoU' (www.intlcode.org). Negotiations with ONNCE are reported to be on their way. See Organization of American States, Trade Unit, *Provisions on Standards and Conformity Assessment in Trade and Integration Arrangements of the Western Hemisphere*, SG/TU/WGSTBT/DOC6/96/ Rev 3, 9 February 1998, V A.

[169] The acronym stems from the Spanish *Consejo de Armonización de Normas Electrotécnicas de las Naciones de America*. Based in Virginia and purportedly open to standards bodies throughout the Free Trade Area of the Americas, the organisation is currently limited to the NAFTA area. CANENA describes itself as 'industry-driven organisation' and extends membership to companies, trade associations, government agencies and individuals. It does not develop standards but does strive to 'facilitate and promote the development of harmonised standards and codes.' See Articles 1 and 2, CANENA By-laws.

[170] Article 6.5, CANENA Standardization Procedures. See generally the *Procedures for Harmonizing ANCE/CSA/UL Standards*. THCs are to give 'technical reasons' for deviating from IEC standards. Article 5.4.1. The first trinational harmonised standard, CSA C22.2 for low voltage fuse, was published in 2000. See CSA, News Release of 29 September 2000, 'CSA International announces publication of first trinational standard.' UL publishes an updated status report on binational and trinational harmonisation on its website. Results so far as not overwhelming.

private bodies.[171] In 1999, the Council of Ministers of the Central-American Common Market adopted a near-identical *Reglamento Centroamericano de Medidas de Normalización*.[172] Further standards discipline is woven throughout the area by a web of overlapping bilateral agreements of much the same tenor.[173] Two arrangements, however, take the harmonisation of standards further.

3.2.1 The Andean Community

In contrast to NAFTA's hands-off approach, the Andean Community of Bolivia, Colombia, Ecuador, Peru and Venezuela has integrated the harmonisation of standards fully into the legal and institutional framework of the free trade arrangement itself.[174] In 1995, the Commission set up the Andean System of standardisation, technical regulations and certification.[175] The whole system, including the standardisation aspect of it, is co-ordinated by an intergovernmental Committee.[176] The general obligations as regards standards are addressed to the Member States:

> In the process of adopting standards, the Member States will use international standards, regional standards or national standards of other countries as their reference. However, they will be able to develop standards of national interest.

[171] The *Tratado de Libre Commercio entre los Estados Unidos Mexicanos, la Repúblicas de Colombia y la República de Venezuela* was actually signed two years before NAFTA, in 1990. It entered into force a year later, in 1995.

[172] Resolution 37–99 (COMIECO XII). CACM brings together Costa Rica, Guatemala, El Salvador, Honduras and Nicaragua. Though the original *Tratado General de Integración Económica Centroamericano* stems from 1960, the more relevant instrument for economic integration is the so-called Guatemala Protocol of 1995.

[173] See eg Chapter Nine of the 1998 Mexico–Chile Free Trade Agreement; Chapter Eight of the 1999 Central-America–Chile Free Trade Agreement, and Chapter 15 of the 2000 Mexico–Northern Triangle Free Trade Agreement (El Salvador, Guatemala and Honduras).

[174] The *Instituto Ecuadoriano de Normalización* (INEN) and the *Comisión Venezolana de Normas Industriales* (COVENIN) are government agencies, and Peruvian standards work is carried out by a committee of the public *Instituto de Defensa de la Competencia y de la Propriedad Intelectual* (INDECOPI). The *Instituto Boliviano de Normalización y Calidad* (IBNORCA) and the *Instituto Colombiano de Normas Técnicas* (ICONTEC) are listed as private bodies by the WTO. ICONTEC is heavily regulated by the government, enlisted as it is in a national Standards System. See Decreto 2269/1993 *por el cual se organiza e Sistema Nacional de Normalización, Certificación y Metrología* and the 2000 *Reglamento del Servicio de Normalización Nacional del ICONTEC*. Article 5o of the Decree, for example, demands that ICONTEC's Management Board is composed for at least a third of representatives of the public authorities. The Decree also provides that the government can declare standards as Obligatory Official Colombian Standards. Significantly, the Government has declared as such CEN's Toy safety standards, the EN 71 series.

[175] See Comisión del Acuerdo de Cartagena, Decision 376 of 1995. The full name is *Sistema Andino de Normalización, Acreditación, Ensayos, Certificación, Reglamentos Técnicos y Metrología*. A largely ineffective System for the co-ordination of activities in the same areas had been established by Decision 180 of 1983.

[176] Article 6, Decision 376 of 1995.

> The Member States will gradually harmonise the standards in force in each country or will adopt standards of subregional interest. The result of this process will give rise to Andean Standards.[177]

The national standards bodies are organised in the Andean Standardisation Network which operates according to regulations adopted by the Committee.[178] Rather than elaborating procedures for standards work, those regulations oblige the national standards bodies to adhere to the WTO Code of Good Practice, and to apply ISO/IEC Guide 59 as well as the ISO/IEC Directives.[179] The Network as such does not actually develop standards itself. Basically, the whole system is a method of either adopting international or regional standards without ado, or, alternatively, adopting a national standard of one of the members of the network if three or more standards bodies vote in favour.[180] Notably, it is the Committee that establishes the Network's Technical Committees and that formally adopts Andean standards.[181]

3.2.2 Mercosur

The Treaty of Asunción, signed in 1991, set out to establish a *Mercado Común del Sur* by 31 December 1994, characterised by the free movement of goods, services and factors of production between Argentina, Brazil, Paraguay and Uruguay. In 1992, the *Comité Mercosur de Normalización* was established by the Common Market Group as an integral part of the institutional structure of *Mercosur*. The Committee was composed of representatives of 'governmental organizations designated by each state and representatives of the standards bodies of each state,' and was instructed to work towards developing *Mercosur* standards, preferably by adopting international or regional standards.[182] In 1995, however, it was removed from the *Mercosur* structure,[183] even though the four standards bodies

[177] Articles 10 and 12, Decision 376 of 1995.

[178] Article 14, Decision 376 of 1995.

[179] Article 9, *Reglamento de la Red Andina de Normalización*, adopted by Resolution 313 of 1995 of the Secretariat-General of the Andean Community.

[180] Above, Article 11. The order of preference is as follows: international standards such as ISO; draft international standards; regional standards, such as CEN and COPANT; standards of 'recognised international prestige' such as ASTM, SAE, API, NFPA and others; standards which are harmonised between two or more States of the Andean Community; national standards of states of the Andean Community; other documents of interest to the Andean Community. Above, Article 8.

[181] Above, Article 7.2. Resolution 503/1997 of the *Junta del Acuerdo de Cartagena* approves several ISO standards, two EN standards and the first six autonomous Normas andinas.

[182] Articles 1 and 2 of the Annex, Mercosur/GMC/Resolution 2/92, *Creación del Comité mercosur de Normalización y Comités Sectoriales de Normalización*. Cf Mercosur/GMC/Resolution 152/96, *Directrices para la elaboración y revisión de reglamentos técnicos Mercosur* (establishing guidelines for the adoption of 'Mercosur technical regulations' under strict adherence to the TBT Agreement.)

[183] By omission. See Mercosur/GMC/Resolution 2/95, Estructura del Grupo del Mercado Común.

marched on with its work.[184] The Committee's work is organised through national delegations to *Comités Sectoriales Mercosur*: the national standards bodies are to ensure adequate representation of manufacturers, consumers and 'general interests.' Preferably based on international or regional standards,[185] CSMs are to develop draft standards that are submitted to public review and national votes, and are adopted by consensus.[186] The CSM may decide, upon 'consultation' with the national standards bodies, that *Mercosur* standards will cancel and replace conflicting national standards.[187] The system was restructured in 1999, when the Committee reconstituted itself as the *Asociación Mercosur de Normalización*, a private non-profit association with its headquarters in São Paolo. The AMN is organised along the lines of CEN and ISO, with a General Assembly, a Management Board and a President and powers distributed in classic private intergovernmental fashion.[188] A new relationship with *Mercosur* was institutionalised in a Co-operation Agreement. The Agreement recognises on the one hand the importance of voluntary standards for international trade and especially for regional economic integration, and on the other emphasises the relationship between binding technical regulations and standards; from those considerations, then, it results important that AMN 'develops activities of interest for *Mercosur*.'[189] The 'co-operation agreement' is further especially noteworthy for the fact that it contains only obligations for the AMN; it is to accept the WTO Code of Good Practice and promote the adoption of its standards throughout the common market via the respective national standards bodies.[190] If and when *Mercosur* considers it appropriate, it is to allow

[184] On the national level, *IRAM—Instituto Argentino de Normalización,* the *Asociação Brasileira de Normas Técnicas* (ABNT), and the *Instituto Uruguayo de Normas Técnicas* (UNIT) all adhered to the WTO Code of Good Practice as private, if heavily regulated standards bodies. IRAM was recognised as the national standards body by Decreto 1474/1994 *por lo cual se crea el Sistema Nacional de Normas, Calidad y Certificación*. ABNT was recognised as the 'national standards forum' by the regulatory agency CONMETRO in 1992. Paraguay's *Instituto Nacional de Tecnología y Normalización* is a government agency that has as yet failed to accept the Code.

[185] The order of preference is as follows: international standards such as ISO; COPANT regional standards; CEN regional standards; national standards of *Mercosur* Member States; national standards of non-Member states; standards of 'recognised international prestige' such as ASTM, SAE, and others; other documents of interest to *Mercosur*. Article 12, CMN, *Procedimiento para la Elaboración de Normas Mercosur*, 2nd edn (1997).

[186] Articles 7, 12, and 24, CMN, *Procedimiento para la Elaboración de Normas Mercosur,* 2nd edn (1997).

[187] Article 4, CMN, *Procedimiento para la Elaboración de Normas Mercosur*, 2nd edn (1997).

[188] A category of 'collaborating' members is created for international and regional standards bodies, national standards bodies from non-*Mercosur* states, and 'scientific and technical bodies' from the *Mercosur* states. Article 2, AMN *Estatuto*, 1999.

[189] See the considerations to the *Convenio de Cooperación entre el Mercosur y la Asociación Mercosur de Normalización*, signed by the GMC on authorisation of the Council, Mercosur/CMC/Decision 12/99.

[190] News of AMN's acceptance of the Code has not yet reached Geneva. See G/TBT/CS/2/Rev.10.

representatives designated by *Mercosur* in the deliberations of its working groups. The Agreement will be without any legal effect as soon as, for whatever reason, the AMN will no longer be composed of national standards bodies of all Member States.[191] In 2000, AMN and CEN signed a protocol in which the two organisations 'agree that *Mercosur* is evolving according to the same principles prevailing in Europe, with AMN undertaking a role similar to that of CEN,' and endeavour to collaborate and to promote 'mutual understanding of the roles of each organisation in their respective regions.'[192]

3.3 Free Trade of the Americas

3.3.1 The Pan-American Standards Commission

The *Comisión Panamericana de Normas Técnicas* (COPANT) was established in 1956 by Argentina, Brazil, Chile, Colombia, Mexico, the United States, Uruguay and Venezuela to promote the establishment of national standards bodies and to improve the activities of the existing ones. Largely financed by the *Organization of American States* for the first two decades of its existence, it found itself woefully short of resources and lacking a permanent infrastructure or secretariat in the 1980s. Its resurgence as a force is very recent indeed. The organisation is now revamped as a private non-profit association with its headquarters in Buenos Aires and has adopted brand new statutes in 2000 along very much the same general lines of ISO and CEN. National standards bodies from 27 countries are the association's 'active members',[193] who, organised in the General Assembly, elect the association's Directors and President, and have the right to be represented in all technical organs. The new Statutes announce:

[191] Articles 3 and 4, *Convenio de Cooperación entre el Mercosur y la Asociación Mercosur de Normalización*.

[192] Protocol between CEN and AMN, signed 27 September 2000. Substantively, CEN undertakes to train AMN officers 'in matters relating to jobs/tasks performed by regional organizations', and to conduct seminars 'on the basic values of European standardisation and the European New Approach.' The Commission has invited 'regions who want to further integrate' to 'take an interest in European principles'. See *European Policy Principles on International Standardisation*, G/TBT/W/170, Communication from the European Community of 8 October 2001, para 7.

[193] AMN members IRAM, ABNT, INTN and UNIT; the Andean bodies IBNORCA, ICONTEC, INEN, INDECOPI and for Venezuela not COVENIN but the newly formed private association FONDONORMA; DGN, SCC and ANSI; and further BNSI from Barbados, INTECO/ Costa Rica; NC/Cuba; INN/Chile; CONACYT/ El Salvador; COGUANOR/ Guatemala; GDBS/ Grenada; GNBS/ Guyana; COHCIT/ Honduras; JBS/ Jamaica; MIFIC/ Nicaragua; COPANIT/ Panama; DIGENOR/ Dominican Republic; SLBS/ Saint Lucia, and TTBS/ Trinidad and Tobago. AENOR, AFNOR, UNI and IPQ are the 'adherent' members.

> The object of COPANT shall be to promote the development of technical standardisation and related activities in its members' countries with the aim of promoting their commercial, industrial, scientific and technological development in benefit of the economic and commercial integration and the exchange of goods and services, while facilitating cooperation in the intellectual, scientific, economic and social spheres.

This is to be achieved by the following 'specific' objectives:

> To provide a forum to the National Standards Bodies in order to coordinate the voluntary standardisation policies and their relation with technical regulations at the national, sub-regional and regional levels;
>
> To provide mechanisms for the preparation, adoption and harmonisation of standards in the region, in accordance with what has been established by the WTO and following the hierarchy of international, regional, sub-regional and national standards, according to the needs of the sectors concerned;
>
> To provide a means for the coordination of the positions of its members in relation to the policies and technical activities of ISO and IEC. In these two organizations, COPANT shall make every possible effort to act in block in those areas of interest to the goals of the Organisation and to support those positions in which there is consensus among its members.[194]

Still in 2000, AMN and COPANT signed a cooperation agreement in light 'of the ever clearer tendency to adopt international standards as regional or subregional standards' and of 'the changes occurred in national standards systems in respect of the constant search for greater participation in international standards bodies.' The two organisations reciprocally invite each other as Observers and commit themselves to 'promote and facilitate the direct adoption of international standards.' They also agree to coordinate their participation in ISO 'with the objective of defending the interests of the region in international standards fora.' AMN commits itself to promote the diffusion of COPANT standards among 'interested public and private sectors', while AMN standards will be considered for adoption as COPANT standards if such would result in the best interest of the other members.[195]

3.3.2 The Draft Free Trade of the Americas Agreement

Much, if not all, of the new—found vigour of COPANT is due to the FTAA process that may end up turning the whole hemisphere into a free trade

[194] Article 2, COPANT Statutes. Another objective is to 'encourage' the acceptance of and compliance with the WTO Code of Good Practice. COGUANOR, COHCIT, JBS, MIFIC, COPANIT, INTN and FONDONORMA have so far failed to do so. See G/TBT/CS/2/Rev.10.

[195] *Acuerdo de Cooperación entre la Comisión Panamericana de Normas Técnicas (COPANT) y la Asociación Mercosur de Normalización*, signed 25 October 2000.

area.[196] Through successive drafts, the Chapter on standards has sometimes incorporated the NAFTA model, sometimes remained faithful to the TBT model, and sometimes shown reflections of other models here discussed—the purely 'public' approach taken by the G3 and others, the more integrated 'public' Andean model and the 'private' *Mercosur* model. The latest draft limits itself largely to implementing the TBT Agreement.[197] Parties are required to 'favour' the adoption of international standards, and to 'endeavour to increase their effective participation' in international standardisation.[198] An 'international standard' is defined as a standard developed according to the principles set out in the TBT Committee Decision ignored by the WTO Dispute Settlement Body.[199] That procedural limit to the parties' duties is then flanked by a substantive limit:

> The objective of international standardisation activities, established by consensus in international standardisation organisations, is to establish technical standards that reflect the state of the art in applied knowledge, with a view to improving the organization of production and trade systems as well as objectives of security and protection of the population and the environment.[200]

Where international standards do not exist, or where they do not constitute 'an appropriate means of achieving legitimate objectives,' Parties are to favour and encourage the use of 'regional' standards, defined as COPANT standards.[201] Parties are also to encourage the cooperation of the hemisphere's standardisation bodies with bodies from other regions.[202]

4. CONCLUSION

The obvious consequence of the move towards international harmonisation of standards is a profound change in the functions of national standards

[196] See generally eg Rivas-Campo and Benke, 'FTAA Negotiations: A Short Overview' (2003) 6 *JIEL* 661.

[197] The Draft considered is Chapter XIII, FTAATNC/w/133/Rev 3 of 21 November 2003. See Article 4.2 ('The WTO TBT Agreement continues to govern the rights and obligations of the Parties in respect of matters covered by that Agreement.')

[198] See Articles 7 and 8.

[199] Article 1. See also Article 7.3 of the new Central American Free Trade Agreement (CAFTA). In Article 12, Chapter on Market Access, of the FTAA Draft of November 2002, an international standard was defined as 'a standard approved by an international standards body 'including the ISO, the IEC, the Codex Alimentarius Commission, the International Organisation for Legal Metrology, the International Commission on Radiological Units and Measures, *or any other body appointed by the Parties*.'. Emphasis added. ASTM's James Thomas was not amused. See his 'If You Say it Long Enough', *ASTM Standardization News*, February 2002. See also the letter sent to the US Trade Representative by, among others, ASME, ASTM, API, ICC, NFPA, ASE, and UL, on 2 April 2002. (posted at, for example, www.intlcode.org/government/pdf/ftaa040202.pdf).

[200] Article 7.2.

[201] Articles 7.1 and 9.3.

[202] Article 7.4.

bodies: they are no longer engaged so much in standard-setting, but in communicating national concerns and preferences to the global level and, in adopting international standards, communicating global concerns and preferences back to the national level. The need to mobilise and organise the necessary resources to participate effectively in this new system has led to standards bodies being privatised on the national level and seeking alliances among each other on the regional level. The abdication of public power in the international field of standardisation is compensated for by States' asserting tighter control over their standards bodies on the national and regional level. All of this is familiar from the European experience.

The debates about the status of international standards are, in the end, debates about the nature of legitimate transnational private governance. Normative concerns about self-regulation in the context of congruent borders of state and market can just about be solved by corporatism, by 'reflexive' law and arm's length regulation, and more or less credible threats of government intervention. The formulation of political 'essential' requirements and legal 'hinge clauses' can just about manage to relegate technical standards to an innocent sphere of 'technology.' Even in the European Community such fictions can be upheld. But where there is no public authority capable of giving political cover, and where there is no legal system in which to subjugate norms, self-regulation stands tall and naked, at the same time terribly impressive and terribly vulnerable.

The knee-jerk response of international trade law is to try very hard to insulate transnational governance from what could be called 'politics.' The SPS Agreement tries to do this rather transparently and pathetically by elevating the standards developed by Codex to the status of 'scientific truth.' It is science, then, that has to separate 'legitimate' regulatory measures from 'unnecessary' obstacles to trade. It should come as no surprise that this leads to a debasement of both science and politics. The TBT Agreement, on the other hand, is utterly clueless as to why it accords privileged status to 'international standards.' It doesn't even know what 'international standards' are. The general idea seems to be that national health and safety regulations need to be rationalised, on the one hand by juridifying the regime of derogations on the basis of politically motivated 'legitimate objectives' and on the other, by weeding out 'merely' technical differences through the mechanism of international standards. It should come as no surprise that this leads to both a 'technologisation' of politics and a politicisation of technology.

'Private inter-governmentalism', as practiced in CEN and in ISO, attempts to solve the legitimacy problem by counting on national delegations. These are to mobilise national expertise and provoke meaningful discussions among interested circles on the national level, which are then 'channelled' into the standardisation process on international level. ISO's chosen method of pretending to be an institution for 'technical' rather than

'political' governance is to leave the messy job of connecting technology to political choice and back in the messy realities of nation-states. This, naturally, is hardly conducive to meaningful deliberation on the international level. The American theory of 'international standards' is to circumvent 'politics' by exalting both 'the market' and 'science' over what is considered 'political' compromise between divergent national delegations. The paradox is, of course, that the mechanism through which to achieve this is, well, politics. Due process, transparency, openness, and balanced interest representation are norms for structuring meaningful social deliberation. They are not obviously the appropriate vehicles for revealing scientific 'truth' or for allowing room for the invisible hand.

The increased importance of standards on the international level has at the very least encouraged the wider participation of civil society—professional organisations, trade associations, consumer organisations—in international politics, in the determination of what is 'legitimate' and what is 'unnecessary' in international law. It has accomplished this by the simple shift from public to private. This is by no means a small achievement. The real challenge still lies ahead, however: the redefinition of politics without the state. Probably the worst possible way of going about this is to pretend that standardisation is not politics at all, and look for ways to legitimise standards-setting through the lazy mechanism of re-nationalising politics, through 'science' or through 'the market.'

7

Private Regulation in European Public Law

1. INTRODUCTION

COMMUNITY LAW'S RELIANCE on private standards, especially in the New Approach, has attracted severe constitutional criticism from the small, and predominantly German, group of Community lawyers who have shown an interest in the phenomenon. The tone is set by perhaps the most authoritative amongst them, Ernst Steindorff:

> In the area of product safety it has long been shown that the Community is forced to delegate functions of standardisation and certification and to limit itself to the formulation of essential safety requirements. With standards bodies (CEN and Cenelec), and the participation of consumer organisations to their work, either on European on national level, regulatory bodies have come into existence whose activities largely escape legal control and accountability and the effectiveness of which can hardly be verified. Whether all relevant interests are being taken into account by them is impossible to see. The producer who objects to standards because they alter the terms of competition has no legal protection. Surely, the planned new order is contrary to the rule of law (*rechtsstaatswidrig*).[1]

This line of argument has considerable force, not just in terms of legal correctness, but in terms of the wider conditions for legitimate private governance. The fact that the Court has accepted the 'New Approach' without giving it much thought is by no means reason to dismiss it.[2]

[1] Steindorff, '*Quo Vadis* Europa? Freiheiten, Regulierung und Soziale Grundrechte nach den Erweiterten Zielen der EG-Verfassung' in Forschungsinstitut für Wirtschaftsverfassung und Wettbewerb, *Weiterentwicklung der Europäischen Gemeinschaften und der Marktwirtschaft* (FIW, Köln, 1992) 11, 45. Translation mine.

[2] If doubts remained after Case 815/79 *Cremonini and Vrankovich* [1980] ECR 3583 (Member States' duty to presume conformity with essential requirements for products manufactured in compliance with harmonised standards can only be lifted by recourse to safeguard procedure), they are discarded after Case C–112/97 *Commission v Italy* [1999] ECR I–1821 (Italy failed to fulfil duties under Gas Burner Directive by prohibiting heating installations that

The basic thinking behind the allegations of unconstitutional 'delegation' under the New Approach is straightforward. Compliance with standards gives a presumption of conformity. Even if standards are hence formally voluntary for manufacturers,[3] they are binding on Member States. Moreover, given the costs involved with additional testing and conformity controls in case products do not comply with standards, the standards are *de facto* also binding on economic operators.[4] The Court of Justice has circumscribed the conditions for lawful delegation in its 1958 *Meroni* rulings.[5] There, the Court stated that the possibility entrusting certain tasks to private law bodies with distinct legal personality and with powers of their own could, in principle, be allowed, provided that

> the Commission does not delegate other powers that those it enjoys itself;
> the Commission delegates only 'strictly executive powers' and no 'discretionary powers';
> the exercise of delegated powers is subjected to the same conditions as if they had been exercised directly by the Commission, in particular the obligation to state reasons and the judicial control of decisions;
> the delegated powers remain subject to conditions determined by the Commission and subject to its continuing supervision, and
> the 'institutional balance' between the EC institutions is not distorted.[6]

comply with harmonised standards); Case C–100/00 *Commission v Italy* [2001] ECR I–2785 (Italy failed to fulfil duties under Low Voltage Directive by requiring water heaters to cut off electric supply at 100 C in stead of 130 C as established by harmonised standard); and Case C–103/01 *Commission v Germany* [2003] ECR I–5369 (Germany failed to fulfil its obligations under the Personal Protective Equipment Directive by subjecting equipment for use by fire brigade to additional requirements). No better measure of the poverty of official legal thought on the matter than the one footnote dedicated to it in Lenaerts, 'Regulating the Regulatory Process: "Delegation of Powers" in the European Community' (1993) 18 *ELR* 23, n 91 ('it could be argued' that the Community legislature exercises 'implicit political control' over the standards bodies since it 'always has the right to overturn the regulatory output of an agency.')

[3] Whatever else the merits of this formal voluntary status, it does at least keep harmonised standards out of the *Muñoz*-doctrine. See Case C–253/00 *Antonio Muñoz v Frumar* [2002] ECR I–7289 (holding that binding agricultural quality standards laid down in several Council Regulations can be enforced by means of civil proceedings between private parties.) Cf the note by Biondi, (2003) 40 *C M L Rev* 1241.

[4] Roßnagel, 'Europäische Techniknormen im Lichte des Gemeinschaftsvertragrechts' (1996) 111 *Deutsches Verwaltungsblatt* 1181, 1185 hence even goes so far as to allege infringements of fundamental economic rights.

[5] Case 9/56 *Meroni* [1958] ECR 133; Case 10/56 *Meroni* [1958] ECR 157. Though decided in the context of the ECSC Treaty, the application of the *Meroni* principles to EC law seems not in doubt. *Contra*, Dehousse, 'Misfits: EU Law and the Transformation of European Governance' in Joerges and Dehousse (eds), *Good Governance in Europe's Integrated Market* (OUP, Oxford, 2002) 207, 221.

[6] For a dispiriting view of the consequences on internal market governance, see the officialdom in Lenaerts, above n 2, and Van Gerven, 'The Legal Dimension: The Constitutional Incentives for and Constraints on Bargained Administration' in Snyder (ed), *Constitutional Dimensions of European Integration* (Kluwer, Amsterdam, 1996) 75. Cf Majone, 'The Credibility Crisis of Community Regulation' (2000) 38 *JCMS* 273, 289 ('At any rate, the so-called Meroni doctrine is totally out of step with the development of European regulatory policies.')

The 'New Approach', it is widely agreed, falls far short of fulfilling these requirements.[7] The powers of the European standards bodies go far beyond 'implementation'; there is no control or supervision of the Commission or possibilities of judicial review.[8]

A persistent problem in discussion of the 'New Approach' is that the 'Model Directive' is taken to embody all of its principles, and that different Directives are taken as faithful expressions of those principles. In fact, however, the New Approach, itself born out of the need to diversify Community strategies of regulation, is much more differentiated than most commentators realise.[9] Before embarking on the wider discussion of the legality and legitimacy of standards under Community law, therefore, the legal framework and regulatory apparatus of the New Approach will be laid out.

2. GENERAL PRINCIPLES OF THE NEW APPROACH

The 'Model Directive', it will be remembered, laid down the following basic principles:[10]

[7] See eg Lauwaars, 'The "Model Directive" on Technical Harmonization' in Bieber, *et al*, (eds), *1992: One Internal Market?* (Nomos, Baden-Baden, 1988) 151; Breulmann, *Normung und Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft* (Duncker & Humblot, Berlin, 1993); Bleckmann, *Rechtsfolgeanalyse der Neuen Konzeption* (Gutachten erstellt im Auftrag des Büros für Technikfolgen-Abschätzung des Deutschen Bundestags), (Universität Münster, Münster, 1995); Rönck, *Technische Normen als Gestaltungsmittel des Europäischen Gemeinschaftsrechts* (Duncker & Humblot, Berlin, 1995); Roßnagel, 'Europäische Techniknormen im Lichte des Gemeinschaftsvertragrechts' (1996) 111 *Deutsches Verwaltungsblatt* 1181; Schulte, 'Materielle Regelungen: Umweltnormung' in Rengeling (ed), *Handbuch zum Europäischen und Deutschen Umweltrecht* (Carl Heymanns, Köln, 1998) 449. *Contra* eg Vieweg, 'Technische Normen im EG-Binnenmarkt' in Müller-Graff (ed), *Technische Normen im Binnenmarkt* (Nomos, Baden-Baden, 1991) 57; Falke and Joerges, *Rechtliche Möglichkeiten und Probleme bei der Verfolgung und Sicherung nationaler und EG-weiter Umweltschutzziele im Rahmen der europäischen Normung*, (Gutachten erstellt im Auftrag des Büros für Technikfolgen-Abschätzung des Deutschen Bundestags), (Zentrum für Europäische Rechtspolitik, Bremen, 1995) 136 ff; Bücker, *Von der Gefahrenabwehr zu Risikovorsorge und Risikomanagement im Arbeitsschutzrecht* (Duncker & Humblot, Berlin, 1997) 213 *et seq*; Falke, 'Achievements and Unresolved Problems of European Standardization: The Ingenuity of Practice and the Queries of Lawyers' in Joerges, Ladeur and Vos (eds), *Integrating Scientific Expertise into Regulatory Decisionmaking—National Traditions and European Innovations* (Nomos, Baden-Baden, 1997) 187, 220 *et seq*; Vos, *Institutional Frameworks of Community Health & Safety Regulation—Committees, Agencies and Private Bodies* (Hart Publishing, Oxford, 1999) 281 *et seq*.

[8] The consequence of fulfilling the *Meroni* conditions is that decisions taken by the private body are open to judicial review; see Joined Cases 32 and 33/58 *SNUPAT* [1959] ECR 127.

[9] The Commission speaks of 'unintentional differences' across sectoral New Approach Directives, a situation it plans to remedy by means of a 'common base Directive'. See its Communication: 'Enhancing the Implementation of the New Approach Directives', COM (2003) 240 final, 20.

[10] Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

a) Directives limit themselves to elaborating 'essential requirements' with which products must conform. These 'shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced.'[11]
b) The task of drawing up the technical specifications is left to the European standardisation bodies. Their quality is to be ensured by standardisation mandates, the execution of which must conform to the general Guidelines for Co-operation signed between the Commission and these bodies.
c) The standards remain of voluntary application.
d) Yet, Member States are obliged to recognise that products manufactured in compliance with these standards are presumed to be in conformity with the essential requirements.

Though most Directives follow this general scheme, there are some notable explicit exceptions. Furthermore, the principle of 'autonomous' legal requirements is inherently unstable.

2.1 Explicit Exceptions

2.1.1 Autonomy of Essential Requirements

Certainly the least successful piece of New Approach legislation,[12] the Construction Products Directive is perhaps also the most controversial. Unlike the other Directives, it does not allow products to be fitted with the CE mark on the basis of compliance with the essential requirements alone. The Directive's implementation thus depends on the availability of harmonised standards.[13] Ernesto Previdi opines:

> [T]his Directive has the astonishing result of directly delegating a regulatory decision-making power to private law bodies completely outside the institu-

[11] Section B (III) (1), Annex II (the 'Model Directive'), Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[12] EN 197–1: 2000 on the composition of cement had the honour of being the first ever harmonised construction standard. See Commission communication (2001) OJ C 20/5. As of June 2003, the references of 79 harmonised standards have been published in the OJ The Commission has mandated 1003 standards. A good discussion of the wildly different success rates of the Construction and Machine Directives is Wolf, 'Deliberativer Supranationalismus und unterschiedliche Umsetzungsleistung: Ein Vergleich der Normung bei der Maschinen—und der Bauproduktenrichtlinie' in Joerges and Falke (eds), *Das Ausschußwesen der Europäischen Union* (Nomos, Baden-Baden, 2000) 329.

[13] Even if the Directive provides (1) for a mechanism of recognition of national standards, and, exceptionally, (2) for a system of recognition of 'tests and inspections' carried out by approved bodies in the producing Member State. See Articles 4 (3) and 16, Directive 89/106/EEC, (1989) OJ L 40/12.

> tional processes laid down in the EU treaty, with no institutional links or framework ever having been provided for them.[14]

The Directive has been subjected to the Simpler Legislation for the Internal Market exercise; the SLIM project team has advocated amending the Directive to bring it into line with other New Approach Directives.[15] Even if the Commission has repeatedly announced plans to adapt the Directive in this sense,[16] it has not acted upon these plans.[17]

Generally regarded as an anomaly, the Construction Products Directive actually turned out to be something of a trend-setter. The new General Product Safety Directive kills off the theory of autonomous legal requirements altogether and elevate the status of the 'mandate' in much the same way.

New Approach Directives contain differentiated 'vertical' safety requirements. The only 'horizontal' safety requirement in Community law up until 1992 was the one contained in the Product Liability Directive, leaving both a void in Community product safety law as such and a hardly justifiable discrepancy between Community-wide private law regulation and residual national public product safety law.[18] A general horizontal safety requirement was established by the 1992 General Product Safety Directive.[19] The Directive had residual effect; the requirement does not apply to products covered by 'vertical' Community legislation, including New Approach Directives or at least, it applies only to those safety aspects which are left uncovered by such Directives.[20]

[14] Previdi, 'The Organization of Public and Private Responsibilities in European Risk Regulation: An Institutional Gap Between Them?' in Joerges, Ladeur and Vos (eds), above n 7, 225, 236. Ernesto Previdi, now retired, was for many years one of the Commission officials most involved in the New Approach.

[15] See Commission Report, *Simpler Legislation for the Internal Market (SLIM): A Pilot Project*, COM (1996) 204/final.

[16] See eg Action Plan for the Single Market, CSE (1997) 1/final, 5; Commission Communication, *The Competitiveness of the Construction Industry*, COM (1997) 539/final, Action plan 4; Commission Report on the Results of the Second Phase of SLIM and the Follow-up of the Implementation of the First Phase Recommendations, COM (1997) 618 final.

[17] The latest Commission offering speaks of amendment as a 'longer term aim'. See Commission Communication, *Review of SLIM: Simpler Legislation for the Internal Market*, COM (2000) 104, 8. Lack of application and uncertainty over future amendments led Belgium to refrain from implementing the Directive. The Commission, without blinking an eye, started and won infringement procedures. See case C–263/96 *Commission v Belgium* [1997] ECR I–7453.

[18] The problem is well explained in Joerges and Falke, 'Die Normung von Konsumgütern in der Europäischen Gemeinschaft und die Richtlinien-Entwurf über die allgemeine Produktsicherheit' in Müller-Graff (ed), *Technische Regeln im Binnenmarkt* (Nomos, Baden-Baden, 1991) 159, 176 ff.

[19] Directive 92/59/EEC on general product safety, (1992) OJ L 228/24.

[20] Article 1 (2), Directive 92/59/EEC on general product safety, (1992) OJ L 228/24. As admitted by the Commission, the provision is not a shining example of clarity; see Commission Report to the European Parliament and the Council on the experience Acquired in the Application of Directive 92/59/EEC on General Product Safety, COM (2000) 140/final. It is clear, however, that the other instruments provided for by the Directive, such as the

As noted earlier, the Directive as it stands mentions harmonised standards as but one way of assessing conformity, lumped together with national standards, codes of practice, the 'state of the art and technology' and reasonable consumer expectations.[21] This lack of 'status' for standards, the Commission contended in its 2000 proposal for an amended Directive, 'has weakened the credibility of the Directive as an effective instrument for ensuring harmonisation.'[22]

The 2001 General Product Safety Directive is now effectively a New Approach Directive. Products manufactured according to national standards transposing European standards, the references of which have been published in the Official Journal, are presumed to be in conformity with the general safety requirement.[23] To this end, the Directive takes over the whole machinery of the New Approach; the Commission is to establish mandates to the European standards bodies which 'shall define the objectives that the standards must meet to ensure that products conforming to such standards are in compliance with the general safety requirement of this Directive.'[24] These mandates are to be established in consultation with the 83/189 Committee. The standards 'shall be adopted by the European standardisation bodies, in accordance with the principles contained in the general guidelines for co-operation between the Commission and these bodies.'[25] The list is completed with the usual safeguard clause and a provision allowing the Commission, again after consulting the Standing Committee, to publish references of European standards adopted before entry into force of the Directive.[26]

Although presented in seamless analogy with the New Approach, the Directive's set up represents a radical departure from its main principles. It introduces a new type of regulatory reference to standards. The reference point is no longer a detailed list of requirements or even a vague 'hinge-clause', but the mandate: a contract between a private body

emergency intervention provisions and the information sharing system, apply even for harmonised sectors. Extensively, Howells, *Consumer Product Safety* (Ashgate, Aldershot, 1998) 121 ff. Cf Commission Communication, Enhancing the Implementation of New Approach Directives, COM (2003) 240, 19.

[21] Article 4 (2), Directive 92/59/EEC on general product safety, (1992) OJ L 228/24.

[22] Commission Proposal for a European Parliament and Council Directive on General Product Safety, COM (2000) 139/final, 10.

[23] Article 3 (2), Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, (2002) OJ L 11/4. Article 3 (3) is similar to Article 4 (2) of the old Directive, with the addition of those cases 'where recourse is not made' to European standards.

[24] Article 4 (1), Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, (2002) OJ L 11/4.

[25] Above, Article 4 (2), New Approach Directives refer usually to both the mandates and the guidelines for co-operation in the recitals, not in the text. Articles 4 and 7 of the Construction Directive 89/106/EEC, (1989) OJ L 40/12, are the rare exception.

[26] Above, Article 4 (3) and (4).

and the Commission effectively replaces legal requirements set by the Council.

2.1.2 Voluntary Application of Harmonised Standards

The only area where exclusive references are in use in Community law is public procurement. Article 10 of the Public Works Directive provides:

> Without prejudice to the legally binding national technical rules and insofar as these are compatible with Community law, the technical specifications shall be defined by the contracting authorities by reference to national standards implementing European standards, or by reference to European technical approvals or by reference to common technical specifications.[27]

Concerns have been raised against this clause, especially in Germany where, as noted, the use of undated exclusive references is unconstitutional.[28] For some time, the Commission has exacerbated these objections by insisting that technically equivalent solutions which were not conform to the technical specifications referring to European standards should be excluded from the procedure.[29] In the recent exercise to revise Community public procurement law, the Commission has conceded the problem.

> Application of the provisions of the Directives has led in certain cases to a situation where standards have been treated as de facto requirements; these provisions can be construed as limiting the buyer's choice to only those products which comply with the standard. Such an interpretation does not fit with the notion of a 'reference' according to which other solutions can be compared with the solution provided by the standard.[30]

The Commission's proposals for new directives hence include a clause according to which a contracting authority or entity can not reject a tender on the grounds that products and services tendered for do not comply with European standards, international standards, national standards or common technical specifications 'where the tenderer can show, by any

[27] Article 10, Directive 93/37/EEC concerning the coordination of procedures for the award of public works contracts, (1993) OJ L 199/54. See also Article 14, Directive 92/50/EEC relating to the coordination of procedures for the award of public service contracts, (1992) OJ L 209/1; Article 8, Directive 93/36/EEC coordinating procedures for the award of public supply contracts, (1993) OJ L 199/1, and Article 18, Directive 93/38/EEC coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors, (1993) OJ L 199/84.

[28] See eg Marburger and Enders, 'Technische Normen im Europäischen Gemeinschaftsrecht' (1994) 27 *JUT* 333, 362.

[29] Commission Policy Guideline of 16 December 1992 on the interpretation of the duty to refer to European standards in Public Procurement Directives, CC/92/67.

[30] Commission Proposal for a Directive on the coordination for the award of public supply contracts, public service contracts and public works contracts, (2000) COM 275 final, 11.

appropriate means, that the solutions he proposes satisfy in an equivalent manner the requirements defined by the technical specifications.'[31]

The Directive on telecommunications terminal equipment and satellite earth station explains in its recitals:

> Whereas in respect of the essential requirements relating to interworking with public telecommunications networks and, in cases where it is justified, through such networks, it is in general not possible to comply with such requirements other than by the application of a unique technical solution; whereas such solutions should therefore be mandatory.[32]

The Directive does not, however, provide for the 'blind' adoption of harmonised standards as mandatory regulations, nor does it allow for these standards to be drawn up by public officials. It chooses a mixture. Working with a Regulatory Committee, the Commission is to adopt a list of the types of equipment for which mandatory regulations are required 'with a view to its transmission to the relevant standardisation bodies'. As a second step, it shall adopt 'the corresponding harmonised standards, or parts thereof, which shall be transformed into common technical regulations, compliance with which shall be mandatory and the reference of which shall be published in the Official Journal.'[33] The possibility of deviating from the harmonised standard is left explicitly open, which in turn opens up possibilities for political disagreement in the Committee which operates on qualified majority.

2.1.3 Standards Set by Private Bodies

The *in vitro* diagnostic medical devices Directive explicitly provides for harmonised standards being set by the Medical Device Committee,[34] acting as a regulatory committee. In the wake of various blood scares, Member States were hardly willing to leave the regulation of blood-related medical devices to the private sector.[35] The Directive thus specifies

[31] Above, Article 24, and Article 34, Commission Proposal for a Directive coordinating the procurement procedures of entities operating in the water, energy, and transport sectors, (2000) COM 276. Cf Article 23 of the Common Position on public works, public supplies and public service contracts, (2003) OJ C 147 E/1.

[32] Recital 18, Directive 98/13/EC, (1998) OJ L 74/1.

[33] Articles 7 (2) and 18 (2), Directive 98/13/EC, (1998) OJ L 74/1. The procedure was already in place with the original Telecommunications Terminal Equipment Directive 91/263/EEC, (1991) OJ L 128/1.

[34] The Committee was set up by the Implantable Medical Device Directive 90/385/EEC, (1990) OJ L 189/17.

[35] The original Commission proposal, COM (1996) 130/final, was for a 'regular' New Approach Directive. The mechanism under discussion was introduced by the Council's Common Position, (1996) OJ C 178/7. On bloodscares and the free movement of goods, see generally Hermitte, *Le Sang et le Droit– Essai sur la Transfusion Sanguine* (Seuil, Paris, 1996) 165 ff.

that for reagents used to determine HIV and hepatitis,[36] 'common technical specifications' are to be drawn up by the Committee and published in the Official Journal.[37] Compliance with these specifications carries with it a presumption of conformity with the essential requirements. As regards their legal status, the Directive is less than clear:

> Manufacturers shall as a general rule be required to comply with the common technical specifications; if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto.[38]

The Directive thus adopts the mirror image solution of the Terminal Equipment Directive; where in the latter standards are in principle set by private bodies and declared mandatory, here the standards are set by public authorities and manufacturers are, even if with a heavier burden of proof than normally, allowed to deviate from them.

2.2 Inherent Exceptions

The essential requirements, again, are to be 'worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced.'[39] Now, as noted, this theory of the autonomy of legal requirements is laid to rest indefinitely with the coming of the new GPSD. But even before that it was largely fictional in practice,[40] and necessarily so.[41] The Directives are full of such requirements as to eliminate hazards 'as far as reasonably practicable',[42] to avoid, 'as far as possible,' the risk of accidental electric shock,[43] and to provide, 'where necessary', additional means of protection.[44] Moreover, the essential requirements are defined, underpinned, and circumscribed by 'hinge clauses'. And these are not exactly employed in any systematic fashion. In the Medical Devices Directives, the 'generally acknowledged state of the art' is used to *define* an essential requirement:

[36] The procedure is to be used for reagents and reagent products for the determination of blood groups as well. See List A, Annex II, Directive 98/79/EC, (1998) OJ L 331/1.

[37] Published in their entirety, that is. See Commission Decision 2002/364/EC on common technical specifications for in vitro-diagnostic medical devices, (2002) OJ L 131/17.

[38] Article 5, Directive 98/79/EC, (1998) OJ L 331/1.

[39] Section B (III) (1), Annex II (the 'Model Directive'), Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[40] See eg Previdi, above n 14, 228.

[41] Cf Breuer, 'Die Internationale Orientierung von Umwelt– und Technikstandards im Deutschen und Europäischen Recht' (1989) 9 *JUT* 43, 109 ff.

[42] Annex I, 1.2, Pressure Equipment Directive 97/23/EC, (1997) OJ L 181/1.

[43] Annex I, 6.3, In vitro Diagnostic Medical Devices Directive 98/79/EC, (1998) OJ L 331/1.

[44] Annex II, 1.2.5, Directive 94/9/EC on Protective Systems intended for use in potentially explosive atmospheres, (1994) OJ L 100/1.

> The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.[45]

In the Pressure Equipment Directive, the 'state of the art' is equated with 'current practice' and used as an *interpretative guideline* for essential requirements:

> The essential requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as to technical and economic considerations which are consistent with a high degree of health and safety protection.[46]

In the Machinery and Lifts Directives, the essential requirements are presented as setting higher objectives that attainable in the present 'state of the art':

> The essential health and safety requirements laid down in this Directive are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In this case, the machinery must as far as possible be designed and constructed with the purpose of approaching those objectives.[47]

The fact that the 'essential requirements' are not self-executing and autonomous does not end the discussion of delegation either way: it merely removes a cloud of legal formalism from the discussion and opens up the real debate. That debate should start with an overview with the manifold regulatory tools at the public authorities' disposal.

3. INSTRUMENTS OF REGULATION ON COMMUNITY LEVEL

Broadly, regulatory instruments available to the European Commission and the Member States fall into two categories. The first comprises those instruments that oversee the link between standards and the legal requirements laid down in the Directives. The second concerns general procedural requirements on the standards bodies. Again, the Directives are far from uniform.

[45] Annex I, 6, Implantable Medical Devices Directive 90/385/EEC (1990) OJ L 189/17, Annex I, 2, Medical Devices Directive 93/42/EEC, (1993) OJ L 169/1.

[46] Annex I, 4th preliminary remark, Pressure Equipment Directive 97/23/EC, (1997) OJ L 181/1.

[47] Annex I, 2nd preliminary observation, Machinery Directive 98/37/EC, (1998) OJ L 207/1, Annex I, 2nd preliminary observation, Lifts Directive 95/16/EC, (1995) OJ L 213/1. Cf Bücker, 'A Turn to Precaution in Technical Safety—The Case of European Machinery Safety Legislation' in Joerges, Ladeur and Vos (eds), above n 7, 243.

3.1 Verifying Compatibility with Legal Requirements

3.1.1 Publication of Standards' References by the Commission

The Low Voltage Directive innocently announced that references to harmonised standards were to be published in the Official Journal 'for purposes of information'.[48] New Approach Directives, however, lend the presumption of conformity to harmonised standards 'the references of which have been published in the Official Journal'.[49] It is by now accepted that publication in the OJ is a necessary condition for the presumption of conformity to take effect, even if the contrasting opinions on the subject of two (ex-) Commission officials closely involved in the debates at the time of conceiving of the modalities of the New Approach is a good measure of just how little systematic legal thinking played a part in the whole exercise.[50] The Commission does not engage in any technical verification of the standards and publishes their references 'blindly'.

3.1.2 The Safeguard Procedure

The Directives do provide for a mechanism of technical verification *after* the standard's references have been published upon complaints from either Member States or indeed the Commission itself. The safeguard procedure clause in its most common form is drafted as follows:

> Where a Member State or the Commission considers that the harmonised standards . . . do not entirely meet the essential requirements . . ., the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor.

[48] Article 5, Low Voltage Directive 73/23/EEC, (1973) OJ L 77/29.

[49] In accordance with the Model Directive; see Annex II (V) (1) (a), Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[50] See Anselmann, 'Die Bezugnahme auf Harmonisierte Technische Regeln im Rahmen der Rechtsangleichung' in Müller-Graff (ed), above n 18,101, 107; Anselmann, *Technische Vorschriften und Normen in Europa: Harmonisierung und gegenseitige Anerkennung* (Economica, Bonn, 1991) 39 ('constitutive'); Previdi, above n 14, 234–35 ('informative'). A relatively minor matter that still causes confusion is whether publication by Member States of the references to national standards transposing European standards is an additional necessary condition, and if so, *how many* member states should publish them. Most Directives merely state that 'Member States shall publish the reference numbers to those standards'; see eg Article 5 (1) (a), Gas burners Directive 90/396/EEC, (1990) OJ L 196/15; Article 5 (2) Machinery Directive 98/37/EC, (1998) OJ L 207/1. The Hot Water Boilers Directive, however, grants presumption of conformity to standards 'the reference numbers of which have been published in the Official Journal and for which the Member States have published the reference number of the national standards transposing those harmonised standards.' See Article 7 (1), Directive 92/42/EC, (1992) OJ L 167/17. Since 'European' standards as such do not exist, and presumption of conformity is granted to products complying with 'national standards transposing harmonised standards', publication of at least one transposing national standard is necessary.

> The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall inform the Member State whether or not it is necessary to withdraw those standards from publication.[51]

In light of the Court's rulings, the safeguard procedure is the *only* mechanism which allows national authorities to deny the presumption of conformity of products manufactured in conformity with harmonised standards.[52] It is, however, far from clear what the procedure exactly entails. Instead of outright withdrawal of the standard's references, some Directives speak vaguely of 'measures to be taken' with regard to the standard in question and the publication of its references.[53] References to the standards bodies are rare. Only the Toy Safety Directive openly states the obvious:

> 'The Commission shall inform the European standardisation body concerned and, if necessary, issue a new standardisation brief.'[54]

While stopping short of mentioning ETSI, the new Telecommunications Terminal Equipment and Earth Satellite Station Equipment Directive is even bolder and instructs the Commission to 'take the necessary steps to correct the shortcomings noted in the standards.'[55]

[51] See eg Article 6, Simple Pressure Vessels Directive 87/404/EEC, (1987) OJ L 220/48; Article 6 (1), Personal Protective Equipment Directive 89/686/EEC, (1989) OJ L 399/18; Article 6 (1), Gas Burners Directive 90/396/EEC, (1990) OJ L 196/15. The Committee is urged to deliver 'an urgent opinion' or deliver one 'as a matter of urgency' in some Directives. See eg Article 6, Recreational Craft Directive 94/25/EC, (1994) OJ L 164/15; and Article 6, Toy Safety Directive 88/378/EEC, (1988) OJ L 187/1. The Commission is to take action 'upon receipt' of the opinion in, for example, Article 6, Lifts Directive 95/16/EC, (1995) OJ L 213/1, and 'taking into account' the opinion in Article 6, Pressure Equipment Directive 97/23/EC, (1997) OJ L 181/1. Article 9, Low Voltage Directive 73/23/EEC, (1973) OJ L 77/29, demands a Commission Decision only in case one of the other Member States objects to a notified unilateral measure by a Member State prohibiting the placing of equipment of the market. The Commission, complaining of its own 'lack of specialised technical expertise', has floated the idea of extending that principle across the board. See the Commission Communication, Enhancing the Implementation of New Approach Directives, COM (2003) 240, 18.

[52] See *Cremonini*, above n 2, para 11 (Article 9 'precludes any action by the judicial authority as such') and para 14 ('since a judicial authority is not empowered, where there is a presumption of conformity, to adopt any measure restricting the free movement of goods, such a step may be taken only in the context of the procedure of Article 9 of the Directive by a national administrative authority acting on behalf on the Member State and empowered to participate in that procedure'). Cf *Commission v Italy*, above n 2, paras 54 *et seq* (recourse to Article 30 EC is precluded since essential requirements are completely harmonised and Community procedures are provided for in case of emergencies).

[53] See Article 5 (2), In Vitro Diagnostic Medical Devices Directive 98/79/EC, (1998) OJ L 331/1; Article 5, Explosives for Civil Use Directive 93/15/EEC, (1993) OJ L 121/20.

[54] Article 6 (2), Toy Safety Directive 88/378/EEC, (1988) OJ L 187/1.

[55] Article 8, Telecommunications Terminal Equipment and Satellite Earth Station Equipment Directive 98/13/EC, (1998) OJ L 74/1. Even if it applies to 'normal' harmonised standards as well, the phrase should be seen in the light of the particular regulatory scheme of that Directive which allows the Commission to adopt these standards as mandatory technical specifications. The same goes for the particularity that the procedure is opened up for standards that *exceed* the essential requirements.

As an *ex post* emergency mechanism to deal with shortcomings in harmonised standards whose references have already been published, the safeguard procedure has produced little, but significant, Commission action. The only instance where the presumption of conformity has been withdrawn altogether so far is a 2000 Decision concerning a safety standard for silage cutters taken upon Italian complaints of, *sic*, 'many fatal accidents.'[56] On two other occasions, the Commission decided to withdraw the presumption of conformity partially, once by publishing an Opinion to the effect that a standard under the Low Voltage Directive should not be taken to address particular risks,[57] and once by taking a Decision republishing the reference to a standard under the Machinery Directive with a warning excluding the presumption of conformity from specific portions of the standard.[58]

Significantly, the procedure has been triggered on several occasions *before* the publication of the references of harmonised standards—thus potentially turning the whole mechanism into an appeal mechanism available for disgruntled and outvoted national standards bodies and unhappy Member States. In one case, France objected to EN 692 on mechanical presses after adoption in CEN, where AFNOR had voted against, but before publication in the OJ. After much discussion, a compromise was reached and the Commission published a Decision wherein it acknowledged that the standard had defects and that a new mandate was to be given to CEN. It did go through with publication, however, accompanied by a warning to the effect that presumption of conformity was denied to certain presses referred to in the standard.[59] The most obvious consecration

[56] See Commission Decision 2000/693/EC on withdrawing the references of standard EN 703 'Agricultural machinery—Silage cutters—Safety' from the list of references in the framework of implementing Directive 98/37/EC, (2000) OJ L 286/40. As noted in the Decision, CEN/TC 144 had agreed to start work on revising the standard but concluded it would take 'several years' before the revised standard could be ratified.

[57] Commission Opinion on EN 60335, (2000) OJ C 104/8, obliging manufacturers to address the risk of high non-working surface temperatures. The reference to EN 60335 was published in (1999) OJ C 268/1.

[58] Commission Decision 2003/224/EC on the publication of the reference of standard EN 1495, (2003) OJ L 83/70. Outright rejections of Member State complaints are a little more common. See Commission Decision 2002/1002/EC on the publication of the reference of standard EN 848–3 (machinery), (2002) OJ L 349/103; Commission Decision 2003/189/EC on the publication of the reference of standard EN 613 (gas burners), (2003) OJ L 74/26; Commission Decision 2003/190/EC on the publication of the reference of standard EN 521 (gas burners), (2003) OJ L 74/28; and Commission Decision 2003/312/EC on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks (construction), (2003) OJ L 114/50.

[59] Commission Decision 98/100/EC on the publication of the reference standard EN 692 'Mechanical presses—safety' in accordance with Council Directive 89/392/EEC, (1998) OJ L 23/34. References to EN 692 were published in (1998) OJ C 183. See Frichet-Thirion, 'Quels Recours en cas de Normes Défectueuses?' (1998) 18 *Les Petites Affiches* 35. The exercise was repeated with respect to two European standards concerning the safety of industrial trucks. See Commission Decision 2000/361/EC on publication the references to standards EN 1459:1999 'Safety of industrial trucks—Self-propelled variable reach trucks' and EN

of the safeguard procedure as a pre-publication filter is a 2001 Decision on standards under the packaging waste Directive which led to the publication of references to two standards accompanied by warnings and of the reference to three other standards not being published at all.[60]

With precedent set, the safeguard procedure has thus been transformed *de facto* from an instrument dealing with emergency situations and market surveillance to an extra layer of administrative verification of the technical contents of standards. The drafting of the safeguard clause in the new Directive on radio equipment acknowledges the new state of affairs and provides explicitly for the possibility of the Commission publishing 'guidelines on the interpretation of harmonised standards or the conditions under which compliance with that standard raises a presumption of conformity.'[61] On the other hand, the Council's 1999 resolution tries to relocate the issue in the European standards bodies, calling on them 'to adopt procedures to resolve, in cooperation with the public authorities, problems which might otherwise lead to the application of the safeguard procedure.'[62] The Commission is clearly getting nervous about the procedure:

> [T]he Commission is confronted with difficulty in managing the safeguard clause procedure as currently designed in most of the New Approach directives. The Commission is given the task of managing highly complex, technical cases, on the basis of decisions taken at national level by technically specialised national authorities or agencies, and (in certain cases) to perform a risk analysis. Due to the technical nature of such cases, specialised technical expertise, rarely available within the administration, is required. To procure specialised expertise makes the procedures longer and compromises their effectiveness in terms of free circulation.[63]

1726–1:1999 'Safety of industrial trucks—Self-propelled trucks up to and including 10000 kg capacity and industrial tractors with a drawbar pull up to and including 20000 N–Part 1: general requirements', (2000) OJ L 129/30. This time the references were published in an Annex to the decision itself, with a warning to the effect that the standard does not cover the risks that operators are exposed to 'in the event of the truck accidentally topping over.' Commission Decision 2001/570/EC on the publication of the reference of standard EN 71, (2001) OJ L 205/39, published the reference to EN 71 accompanied by a note to the effect that a certain clause will confer the presumption of conformity only as from a certain date.

[60] Commission Decision relating to the publication of references for standards EN 13428, EN 13429, EN 13430, EN 13431, and EN 13432, (2001) OJ L 190/21.

[61] Article 5 (3), Directive 99/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, (1999) OJ L 91/10.

[62] Consideration 21, Council Resolution of 28 October 1999 on the role of standardisation in Europe, (2000) OJ L 141/1.

[63] Commission Communication, 'Enhancing the Implementation of the New Approach Directives', COM (2003) 240 final, 18. The Commission's concern is largely due to the sudden surge in notifications in recent years. In 2001, it received 530 such notifications, 428 of whom under the Low Voltage Directive. Above, Annex III, Table 1.

The Commission thus proposes to 'outsource' operations to a body 'staffed by technically competent experts,' to speed up the procedure.[64]

3.1.3 Commission Mandates

The new 'standardisation brief' the Toy Directive envisages in case of a standard that does not satisfy the essential requirements has its roots in the Information Directive. There a procedure is established whereby the Commission, upon consultation of the Standing Committee, may 'request' the European standards bodies to draw up a European standard within a given time limit.[65] It is well established, and repeated in all Directives' recitals, that employment of this procedure is a necessary condition for the status of 'harmonised' standard. Its purpose is also clear: it serves as a mechanism to ensure that harmonised standards satisfy the 'essential requirements'. The Model Directive speaks of 'standardisation mandates' which must ensure the 'quality' of harmonised standards.[66] It is, on the other hand, very unclear what the exact nature of the document is. From the Directives themselves no clarification can be expected. Only the Pressure Equipment Directive uses the word 'request'.[67] Several Directives speak of standards adopted on the basis of a 'remit' from the Commission.'[68] Other Directives envisage standards adopted 'at the prompting'[69] or 'at the instigation'[70] of the Commission. Contrary to this co-operative language, the Implantable Medical Devices Directive clearly speaks in hierarchical terms of a Commission 'instruction'.[71] The Model Directive's term 'mandate', however, has the most currency.[72] The Commission has tried to clarify the nature of the document by stating that 'rather than focusing on terminology, it is important to consider that standardisation activities must be based on a formal invitation of the Commission.'[73]

[64] Commission Communication, 'Enhancing the Implementation of the New Approach Directives', COM (2003) 240 final, 21.

[65] Article 6 (3) and 6 (4) (e), Directive 98/34/EC, (1998) OJ L 204/37.

[66] Annex II, Introduction, Council Resolution on a new approach to technical harmonisation and standards, (1985) OJ L 136/1.

[67] Recital 17, Pressure Equipment Directive 97/23/EC, (1997) OJ L 181/1.

[68] See eg Recital 6, Simple Pressure Vessels Directive 87/404/EEC, (1987) OJ L 220/48; Toy Safety Directive 88/378/EEC, (1988) OJ L 187/1; and Recital 17, Machinery Directive 98/37/EC, (1998) OJ L 207/1.

[69] Recital 6, Recreational Craft Directive 94/25/EC, (1994) OJ L 164/15; and Recital 12, Directive 94/9/EC on Equipment for use in explosive atmospheres, (1994) OJ L 100/1.

[70] Recital 8, Personal Protective Equipment Directive 89/686/EEC, (1989) OJ L 399/18.

[71] Recital 7, Directive 90/385/EEC, (1990) OJ L 189/17. The Commission's Green Paper—*Action for faster technological integration in Europe*, COM (1990) 456/final, featured an Annex with a list of mandates now called 'order vouchers'.

[72] See eg Recital 6, Directive 93/15/EEC on Explosives for Civil use, (1993) OJ L 121/20 ('under a mandate'); Recital 13, Medical Devices Directive 93/42/EEC, (1993) OJ L 169/1 ('on a mandate'); Recital 7, Lifts Directive 95/16/EC, (1995) OJ L 213/1 ('on the basis of a mandate').

[73] Commission, *Guide to the implementation of Directives based on the New Approach and the Global Approach*, (Opoce, Luxembourg, 2000) 29, n 77.

The 'mandate' in practice is part contract—fixing target dates, arranging financial modalities and so forth, and part technical elaboration of the essential requirements. For mandates given outside the scope of the New Approach, they effectively replace the essential requirements as the sole legal requirement set on standards. Before issuing one, the Commission must 'consult' the 83/189 Standing Committee as well as, where applicable, the 'vertical' committee set up by the Directive in question. Even if the Commission insists that it seeks 'consensus' from sectoral national public authorities,[74] it is under no obligation to heed to objections. Only the Construction Directive provides for a mechanism whereby Member States can challenge the mandate; that particular mechanism, however, seems rather useless as the Commission is to take a decision upon consulting the same Committee that was to be consulted before issuing the mandate in the first place.[75] Legally, the mandate is a contract, and cannot be imposed by the Commission on the standards bodies: the Technical Board of CEN can freely decide whether or not to accept the terms of the mandate.[76] To avoid problems at a later stage, it is practice to involve experts from the relevant TC early on in the process of drafting.[77]

3.1.4 Guidelines for Co-operation

The Commission and CEN signed 'General Guidelines for Co-operation' in November 1984.[78] New Approach Directives refer to the document in that CEN and Cenelec are considered 'competent bodies to adopt harmonised standards in accordance with' these Guidelines.[79] In it, the

[74] Above, 29.

[75] Article 5 *juncto* Article 7, Construction Directive 89/106/EEC, (1989) OJ L 40/12. The Commission has accused Member States of seeking to cramp so much technical detail in the mandates that it might as well have adopted Directives for every single family of products. See Commission Report on the Construction Products Directive, COM (1996) 202 final, 4. The European Parliament similarly accused Member States of an 'obstructive attitude' in the Committee which it considered 'one of the main causes of the delay' in the implementation of the Directive. See Resolution on the Commission report on the CPD, (1997) OJ C 371/219. Another good measure of the lack of co-operative atmosphere in the CPD Committee is Case C–263/95 *Germany v Commission* [1998] ECR I–441 (Commission decision annulled for procedural defect consisting of failing to send the German representatives a draft in German until the eve of the relevant meeting).

[76] In the standards bodies' internal regulations, mandates are treated the same way as any other 'proposal for standards work'. Article 4.1.3, CEN/CENELEC Internal Regulations, Part II: Common Rules for Standards Work, 1996.

[77] Astonishingly, the Commission has proposed to 'outsource' the drafting of mandates to the same body of technical experts that would deal with the safeguard procedure. Commission Communication, 'Enhancing the Implementation of the New Approach Directives', COM (2003) 240 final, 43.

[78] The document is reproduced in Nicolas, *Common Standards for Enterprises* (Opoce, Luxembourg, 1995) Appendix 4.

[79] See eg Recital 7, Implantable Medical Devices Directive 90/385/EEC, (1990) OJ L 189/17.

Commission basically grants a monopoly to CEN and CENELEC for 'assigned' preparation of European standards; the standards bodies pledge 'to ensure that the standards drawn up satisfy the essential requirements for the protection of citizens (safety, health . . .) set either by the Directives to which the standardisation mandates are related, or by the standardisation mandates themselves'. Curiously, that phrase has been dropped in the revamped 2003 Guidelines, which merely speaks of an 'expectation' that the European standards bodies take 'a consistent approach' in accepting and executing or rejecting mandates, and ensure that rules in decision-making procedures 'continue to preserve accountability to the European Community, EFTA members and the economic and social partners concerned in work undertaken under a mandate.'[80]

3.1.5 CEN 'Consultants'

The Council has called upon the Commission 'to ensure that standardisation activities covered by mandates are subject to thorough monitoring.'[81] In practice, the only way of doing so is through the good offices of the 'CEN consultants'. To ensure the compatibility of standards with the essential requirements, CEN and the Commission agreed from the early 1990s onwards to have independent 'experts' follow the work on harmonised standards from an early stage onwards. They are recruited by CEN in close collaboration with the Commission and the EFTA secretariat, financed by the Commission via separate budget lines. Often closely involved with the original drafting of the Directive concerned, it is their job to clarify the terms of the essential requirements and/or mandates and to make sure that these are taken account of in every step of the process.

The role of the 'consultant' is a very delicate matter in the relationship between the regulator and the standards body.[82] The general guidelines on their role explicitly state that it is not their job to 'control' the technical work or to participate in the drafting process, but merely to signal 'incoherence' between draft standards and the legal requirements. Consultants are hierarchically subordinated to the CEN General Secretariat even if allowed to have direct contact with Commission services.[83]

[80] Section 4, *General Guidelines for the Co-operation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association*, (2003) OJ C 91/7.

[81] Council Resolution on the role of standardisation in Europe, (2000) OJ L 141/1, recital 25.

[82] Gambelli situates unease primarily east of France. See Gambelli, *Aspects Juridiques de la Normalisation et de la Réglementation Technique Européenne* (Eyrolles, Paris, 1994) 101 ('Certains experts allemands perçoivent très mal cette intervention d'un consultant dans les travaux de normaisation. Ils dénoncent la paralysie, la bureaucratie et l'arbitraire crées par cette "tutelle"'.)

[83] *Dispositions générales régissant le rôle des experts techniques vis-à-vis du CEN et de la Commission*, annexed to all CEN/CEC contracts regarding consultants. On file with author.

CEN's Technical Board adopted a Standing Resolution in 1993 wherein it expressed 'appreciation' for the important work of these consultants, but also stressed their 'advisory role' and noted that the whole set-up was in line with the principle that TCs and, ultimately, the TB itself are the responsible bodies for the ENs.[84]

3.2 Procedural Requirements on Private Standard-Setting

3.2.1 Recognition of European Standards Bodies

The Council, in its 1992 resolution, has established several guiding principles for standardisation. It reiterated the importance of 'a cohesive system of European standards, organised by and for the parties concerned, based on transparency, openness, consensus, independence of vested interests, efficiency and decision-taking on the basis of national representation'.[85] Now, the Commission used to have the power to amend the Annex of the Information Directive and hence to recognise standards bodies as either 'European standards bodies' or 'national standards bodies' for purposes of Community policy. For CEN and CENELEC, featuring in the very first version of the Directive in 1983[86] and explicitly recognised in the Model Directive as the 'competent bodies to adopt European harmonised standards',[87] the Commission obviously had no way of making such recognition conditional upon adherence to these principles. ETSI, established in 1988, was officially 'recognised' by the Commission only in 1992, after long debates over the institute's internal regulations.[88] Even if that decision was taken one month after the adoption of the resolution, no mention of the latter was made.

The idea that the 'recognition' of standards bodies is more than a merely administrative exercise was strengthened by the 1994 amendment to the Information Directive. Changes to the list of national standards bodies were left to the Commission, acting 'on the basis of communications from

[84] CEN/BT Standing Resolution BT 149/1993, 'Role of the "experts" in the execution of mandates—Procedure.'

[85] Recital 8, Council resolution on the role of European standardisation in the European economy, (1992) OJ C 173/1.

[86] Directive 83/189, (1983) OJ L 109/8, operated with a rather mystifying List 1, 'standards institutions' which included CEN and CENELEC and their members, and List 2, 'National standards institutions', which is exactly the same except for CEN and CENELEC.

[87] Annex II, Council resolution on a new approach to technical harmonisation and standards, (1985) OJ C 136/1.

[88] Commission Decision 92/400 amending the list of standards institutions annexed to Council Directive 83/189/EEC, (1992) OJ L 221/55. In its 1990 Green Paper, the Commission expressed concern over ETSI's adhering to the 'basic principles of standardisation, such as transparency and independence of particular interests'. See Green Paper, *Action for faster technological integration in Europe*, COM (1990) 456 final, para 24.

Member States'. The power to amend the list of European standards bodies, on the other hand, was shifted to the Council acting on the basis of a proposal from the Commission.[89]

The Commission finally introduced the principles of the Council's resolution in a 1996 decision recognising ETSI's 'National Standards Organisations' in as far as these do not coincide with CEN or Cenelec members.[90]

Ex post facto as it is, the idea of officially recognising standards bodies subject to some sort of test of adherence to politically agreed general principles of standardisation work is attractive both intrinsically and for its resonance with some national policies of 'accreditation' and similar mechanisms of administrative approval.

3.2.2 Public Involvement in Standards Work

As stipulated in the Guidelines for Cooperation, CEN and Cenelec have opened up the possibility for Commission representatives, and representatives of the EFTA Secretariat, attending meetings of the Technical Board and of Technical Committees. They may do so as observers, without voting rights.[91] In practice, the Commission has the expertise, the resources nor the willingness to do so in any significant way.

3.2.3 Voting Arrangements

The Commission has been successful in progressively convincing the European standards bodies to modify their internal regulations to allow for a system of qualified majority voting as provided for by Article 205 EC.[92] In a first stage, the standards bodies gave up on unanimity and introduced weighted voting, but insisted on a maximum of 3 member bodies casting a negative vote. That clause has now been deleted much to the satisfaction of the Commission.[93] At the same time, an amendment was introduced to put the standards bodies from EEA countries on the same footing as those from EU Member States. As it stands now, an EN can be

[89] Article 1 (2), Directive 94/10/EC, (1994) OJ L 100/30.

[90] Commission Decision 96/139 amending the list of national standardisation bodies in Annex II to Council Directive 83/189/EEC, (1996) OJ L 32/31. In its answer to question P–2522/01 of MEP Weiler ('How does the Commission ensure that the standardisation process is democratic and transparent?'), the Commission states that 'compliance with the conditions for accountability is linked to the recognition of bodies as European standards bodies under Directive 98/34/EC'. (2002) C 40 E/246.

[91] Section 2.1.3 and 2.3.5, CEN/Cenelec Internal Regulations Part 2: Common Rules for Standards Work, 1996.

[92] The Internal Regulations still insist that 'every effort shall be made to reach unanimity.' Above, Section 5.1.5.

[93] The Commission noted in its Green Paper, COM (90) 456/final, para 18, that it had been asking, 'so far unsuccessfully', for this condition to be removed.

adopted with a majority of 71% of the weighted votes of CEN's members which belong to the EEA.[94]

Voting runs counter to the deeply engrained cultural practice of seeking consensus in the standardisation community, especially at technical committee level. Even if the Council has reiterated its preference for 'more frequent recourse to indicative voting at an earlier stage in the standardisation process',[95] the standards bodies' internal regulations instruct TC chairmen to 'do everything possible to obtain a unanimous decision of the technical Committee. If unanimity on a subject is not possible, the chairman should try to seek consensus rather than rely simply on a majority decision.'[96]

3.2.4 Involvement of Interested Circles

The Commission has been far less successful in its attempts to convince the standards bodies to involve consumers, workers and environmental interests in the process. In the 1984 Guidelines for Co-operation, the following was agreed:

> In order to establish the grounds for a large recognition of the importance of European Standards, CEN and Cenelec will ensure that the interested circles, especially public authorities, manufacturers, users, consumers, trade unions, can, if they so wish, be effectively associated in the drawing-up of European Standards: the Commission will, should the case arise, help in the definition of the appropriate modalities.

The primacy of national delegations as an organisational principle in the European standards bodies stands in the way of effective representation of diffuse interests. At several occasions the Commission has urged CEN and Cenelec to open up their structures both at technical level and at the level of governing bodies. In its Green paper it held it to be 'inappropriate' that manufacturers and industrial users had the opportunity to be involved in the technical work whereas consumers and trade unions were effectively excluded; it thus pleaded for direct representation of major interest groups.[97] If reluctantly, CEN agreed in 1992 to create the category of 'associated members'.[98] Three major diffuse interests groups are now

[94] Section 5.1.5, CEN/Cenelec Internal Regulations, Part 2: Common Rules for Standards Work. 71% is proportional to 62 out of 87 votes as in Article 205 EC.

[95] Council Resolution on the role of standardisation in Europe, (2000) OJ L 141/1, recital 23.

[96] Section 2.3.3, CEN/Cenelec Internal Regulations, Part 2: Common Rules for Standards Work.

[97] Green Paper, COM (1990) 456/final, para 28 *et seq*. The Commission repeated the point in the Follow-up, (1992) OJ C 96/2, para 32 *et seq*.

[98] Article 6.3, CEN Statutes as amended and published in the *Moniteur Belge* of 18 March 1993.

represented with financial assistance of the Commission: the European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC);[99] the European Office for Crafts, Trade and Small and Medium-sized Enterprises for Standardisation (NORMAPME) and the European Trade Union Technical Bureau for Health and Safety (TUTB).[100] CEN recently announced it was ready to welcome a European coordinating structure for European environmental NGO's.[101] Notwithstanding these improvements, the Council insisted in its 1999 resolution on Consumer policy,

> [T]he development of European standards can be of great benefit to consumers, in particular with regard to their health and safety; . . . it is generally agreed that consumer representatives should be more closely involved in the standardisation process and have sufficient access to the necessary expertise in order to play their full role in this process.[102]

The 2003 Guidelines, moreover, stipulate that 'further efforts' should be made to increase the participation of diffuse interests in the drafting of standards and 'in ensuring their views are adequately taken into account.'[103]

The integration of European wide interest groups in European standardisation conflicts with the cardinal organisational principle of national delegations. Associated members are thus formally excluded from voting and have mere 'observer' status. The Council has recently again called upon the standards bodies to 'improve existing mechanisms, supplementing consensus at national level, allowing them to give broad consideration to the positions expressed by the various interest groups during the standardisation process.'[104]

[99] Farquhar, 'Consumer Representation in Standardisation' (1995) 3 *Consumer L J* 56, provides a good history and overview. Cf Howells, 'Consumer Safety and Standardisation—Protection Through Representation?' in Krämer, Micklitz and Tonner (eds), *Law and Diffuse Interests in the European Legal Order—Liber Amicorum Norbert Reich* (Nomos, Baden-Baden, 1997) 755.

[100] The other associated members are the European Chemical Industry Council (CEFIC); the European Confederation of Medical Devices Associations (EUCOMED), and the European Construction Industry Federation (FIEC).

[101] CEN, Press Release, 9 June 2000, 'CEN is open to a balanced representation of environmental interests', www.cenorm.be.

[102] Recital 10, Council Resolution of 28 June 1999 on Community consumer policy 1999 to 2001, (1999) OJ C 206/1. Compare the different reactions to the Commission's Report, *Efficiency and Accountability in European Standardisation Under the New Approach*, COM (98) 291 final: ANEC, *Efficiency and Accountability of European Standardisation*, Brussels, May 1998, ANEC98/GA/36, and CEN, 'Efficiency of European Standardisation—CEN Contribution', published in (1998) 77 DIN Mitteilungen 656.

[103] Section 4, General Guidelines for the Co-operation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association, (2003) OJ C 91/7. Cf Howells and Wilhelmsson, 'EC Consumer Law: Has it Come of Age?' (2003) 28 *ELR* 370, 387 (describing the experience under the new approach as 'relatively encouraging.')

[104] Council Resolution on the role of standardisation in Europe, (2000) OJ L 141/1, recital 24. In its 2002 Conclusions on standardisation, (2002) OJ C 66/1, the Council 'stresses the importance it attaches to the ability of all relevant interested parties to participate effectively

The consequence of CEN's structure is that consumer—and worker interests should be included in the process via the national standards bodies. Several Directives contain a clause obliging Member States to ensure that 'appropriate measures are taken to enable both sides of industry to have an influence at national level on the process of preparing and monitoring the harmonised standards.'[105]

3.3 Conclusion

The formal defence against assertions of 'delegation' is easily made. Conformity with standards lends but a *presumption* of compliance with legal requirements: Member States are free to challenge that presumption through the safeguard procedure. Compliance with standards is *voluntary*: the only mandatory requirements imposed on manufacturers and producers are the 'essential requirements' embodied in legislative texts.[106]

In practice, the New Approach has moved far beyond these formal arguments and has developed a rather sophisticated arsenal of regulatory mechanisms seeing both to the link between legal requirements and technical standards and to the internal procedural legitimacy of the standardisation process itself.

4. PROPOSALS FOR THE JURIDIFICATION OF STANDARDISATION

And yet, consensus among lawyers has it that all of this is far from sufficient, that improvements are necessary, and thus, that juridification of the standardisation process is necessary. Some cannot even resist the temptation of wanting to turn the standardisation system into a

in standardisation, requests that national standards bodies ensure the involvement of such parties in the process at national level, and invites the European standards bodies to foster the exchange of information with the relevant interested parties at European level.' See also ANEC, Press Release, 1 October 1997, 'ANEC calls on the standards bodies to involve consumers more closely in their work', and TUTB, 'Trade union participation in European standardisation work: TUTB network sounds alarm', (1996) (2) *TUTB Newsletter*. In the Preamble to its *Strategy*: *2010*, CEN notes that 'genuine European interests are expected to be increasingly represented within CEN's decision-making process, provided they demonstrate their legitimacy to the extent the current CEN membership does.'

[105] Article 5 (3), Lifts Directive 95/16/EC, (1995) OJ L 213/1; see further Article 5 (5), PPE Directive 89/686, (1989) OJ L 399/18; Article 5 (3), Pressure Equipment Directive 97/23/EC, (1997) OJ L 181/1. Other Directives speak of 'social partners'; see Article 5 (3), Directive 94/9/EC on protective equipment for use in explosive atmospheres, (1994) OJ L 100/1; Article 5 (3), Machinery Directive 98/37/EC, (1998) OJ L 207/1.

[106] See Majone, *Regulating Europe* (Routledge, London, 1996) 25 (delegation critics 'assume a distinction between the public and private sector, which in the area of standards setting is far from clear-cut. . . . [I]n the area of technical standards, the important distinction is not between public and private, but between mandatory and voluntary standards.')

Community agency, coupled with the subjugation of standards in the hierarchy of norms.[107] Even the European Parliament expressed itself in this sense where it obscurely stated that it considered it 'necessary to continue working towards a proposal for a statute of a Community agency for the European standardisation bodies'.[108]

Albert Bleckmann demands the complete subordination of European standardisation to the machinery of Community administrative lawmaking. On a rather wild juridification spree, he demands

a) a legal obligation for the Commission to send representatives to meetings of committees of the standards bodies, and voting rights for those representatives, including a right of veto to block the adoption of a standard for the time it takes the Standing Committee to make a final recommendation on the standard's compatibility with the essential requirements; the final decision of the Commission should be open to judicial review;[109]
b) a Regulation establishing the procedures for standardisation to open the standards bodies themselves up for judicial review.[110] Since the Community does not have the competence to adopt such a regulation, a new Community organ should be established by an act of the Council.[111]

For the majority of commentators, such measures seem to deny the reasons why the Community legislator relies on standards in the first place. Their preferred solution is to ensure legitimacy by making legislative assemblies out of standards bodies themselves. A longstanding tradition in German legal thought,[112] the idea is that the legislator should not rely

[107] See eg Previdi, above n 14, 241, fondly supported by Majone, above n 6, 275 (singling out the inability to transform the present institutional framework of standardisation into an agency as an example of the 'tendency to evade clear institutional choices in favour of stopgap measures', the price of which 'shortsighted strategy' is a credibility crisis in Community regulation.)

[108] See the Resolution on the Commission Communication on the Broader use of Standardisation in Community Policy, (1996) OJ C 320/208, Recital 23. How exactly the Parliament envisages this 'statute' is a bit of a mystery in light of Recital 2, where it considers 'that any dependence of standardisation on authorities or institutions closely associated with authorities should continue to be avoided in the future.'

[109] Bleckmann, above n 7, 95.

[110] Above, 99–100.

[111] Above, 105. Also pleading for a Regulation, Führ, *Reform der Europäischen Normungsverfahren* (Gutachten erstellt im Auftrag des Büros für Technikfolgen-Abschätzung des Deutschen Bundestags) (Fachhochschule Darmstadt, Darmstadt, 1995). Roßnagel, above n 5, 1187, demands some unspecified legal act recognising and formalising the European standard organisations' role in Community legislation.

[112] The classics are Marburger, *Die Regeln der Technik im Recht* (Carl Heymanns, Köln, 1979); Denninger, *Verfassungsrechtliche Anforderungen an die Normsetzung im Umwelt—und Technikrecht* (Nomos, Baden-Baden, 1990).

on private standards unless these are set according to certain guarantees of interest-representation, fair procedure, and expertise.[113]

In this vein, Josef Falke suggests to adopt a Standardisation Directive circumscribing the conditions under which the Community legislator is allowed to take recourse to standards. He proposes the following text:

> For the purpose of giving concrete form to the requirements laid down in its legal acts concerning products, processes and installations, the Community may assign the task of elaborating technical specifications to the European standards bodies under the following conditions:
>
> The Community legislator must lay down as precisely as possible the essential requirements that products or processes must satisfy to ensure a high level of protection of safety and health, the environment and other non-economic interests;
>
> The technical specifications must satisfy these essential requirements; must have no legally binding force whatsoever and must be reviewed regularly;
>
> The relevant expertise must be fully represented in the standardisation committees;
>
> Interested parties, in particular public authorities, industry, users, consumers, trade unions, environmental protection organisations as well as a representative of the Commission must be able to participate in the elaboration of the technical specifications; the public must have the right to express its opinion on draft specifications;
>
> Drafts and final technical specifications must be easily accessible to all interested parties.[114]

Seemingly less intrusive still, but probably much more disastrous in practice, are calls to formalise standardisation procedures along the lines of the US Administrative Procedure Act.[115]

[113] See eg Lübbe-Wolff, 'Verfassungsrechtliche Fragen der Normsetzung und Normkonkretisierung im Umweltrecht' (1991) 6 *Zeitschrift für Gesetzgebung* 219; Führ, 'Technische Normen in demokratischer Gesellschaft' (1993) *ZUR* 99; Roßnagel, 'Rechtspolitische Anforderungen an die verbandliche Technikstеuerung' in Kubicek and Seegers (eds), *Perspektive Techniksteuerung* (Sigma, Berlin, 1993) 169; Marburger and Enders, above n 28; Führ, above n 111; Falke and Joerges, above n 7; Roßnagel, above n 4; Falke, above n 7, 220 *et seq*; Schmidt-Preuß, 'Normierung und Selbstnormierung aus der Sicht des öffentlichen Rechts' (1997) *ZLR* 249; Howells, above n 99; Vos, above n 7, 281 *et seq*. From a social science perspective, Voelzkow, *Private Regierungen in der Techniksteuerung: Eine Sozialwissenschaftliche Analyse der Technischen Normung* (Campus, Frankfurt, 1996). *Contra* Di Fabio, *Produktharmonisierung durch Normung und Selbstverwältung* (Carl Heymanns, Köln, 1996) 117 *et seq* (democratic deficit of standardisation is to be remedied by legal reception of standards, not by 'pluralisation' of the standards writing process itself).

[114] See Falke and Joerges, above n 7, 165; Falke, above n 7. A Directive to 'harmonise' procedures of national standards bodies and to 'clarify' the Community's 'expectations' as to the work of the European standards bodies was proposed by a Florentine powerhouse in Dehouse, *et al*, *Europe After 1992—New Regulatory Strategies*, EUI Working Paper Law 92/31, (European University Institute, Florence, 1992) 28.

[115] See Lübbe-Wolff, above n 113; Führ, 'Technische Normen in demokratischer Gesellschaft' [1993] *ZUR* 99; Vos, above n 7, 311. See the discussion of the APA below. Otherwise, consider Mashaw, 'Imagining the Past; Remembering the Future' [1991] *Duke L J* 711, 720 ('Judicial action is inherently conservative in its conceptual content and often

The delegation debate draws together different threads of fundamental constitutional concerns about private governance—the 'delegation' of legislative powers, the lack of administrative and judicial review of standards, the lack of public control over standards bodies and the lack of internal democracy in the standards bodies. There is, of course, a common underlying proposition: standards fulfil public functions and should thus be subordinated to some kind of 'public' control. The problem with 'delegation' debates, however, is that they tend to weave the different threads into a continuum. On one end of the scale, there is the idea that standards have legal effects and should thus be subordinated in the hierarchy of norms, locked into the constitutional frame of legitimacy, and subjugated under administrative control and judicial review. On the near end is the idea that standards setting is an inherently private activity which can be legitimately used for public purposes on the condition that it observes procedural criteria of good governance. These ideas, however, represent radically different conceptions of legitimacy. One sees the 'public' interest necessarily embodied in public institutions; the other sees the 'public' interest circumscribed by procedural criteria of good governance. What all of them have in common, however, is that, directly or indirectly, they open up the standardisation process for judicial review.

5. JUDICIAL REVIEW OF THE LEGAL RECEPTION OF STANDARDS

In Breulmann's cosmetic scheme to ward off the spectre of 'delegation', Council Directives would include an explicit conferral of implementation powers to the Commission; the latter would then formally declare standards to be conform to the essential requirements by virtue of a Decision directed to all Member States.[116] He sees this as a reform without major 'material consequences'; he doesn't even seem to contemplate the possibility of opening up standards to judicial review this way. But that, of course, would be the consequence. Now, the French authorities and French scholars alike are of the opinion that judicial review of Community law's reception of standards is open already. For them, the act of publication itself constitutes a legal act of approval of the harmonised standard, an act which, moreover, can be challenged before the Court of Justice.[117]

dysfunctional to the point of destruction with respect to legislative and administrative attempts to construct innovative regulatory policy.') Cf Wald, 'Regulation at Risk: Are Courts Part of the Solution or Most of the Problem?' (1994) 67 *S Cal L Rev* 621.

[116] Breulmann, above n 7, 262 *et seq*. To call this 'formalistic' is 'to confuse the rule of law with formalism.' Dixit. Above, 277.

[117] See the note of the French delegation, 'Normes Européennes et Règlements—Le rôle des Autorités Publiques', 14 September 1998 (on file with author); Gambelli, above n 82, 98; Brunet and Péraldi-Leneuf, 'Les Recours Juridictionnels des Utilisateurs en cas de Normes Défectueux' (1998) 18 *Petites Affiches* 39, 44. Compare Lauwaars, above n 7, 151,

Article 230 EC allows Member States and the EC institutions to instigate annulment procedures against measures 'other than recommendations and opinions' adopted by the institutions. The argument that publications of harmonised standards are merely 'recommendations' and that they are published in the C series of the Official Journal would probably not hold up. The Court has held that actions for annulment are available 'in the case of all measures adopted by the institutions whatever their nature or form, which are intended to have legal effects.'[118] The publication surely leads to 'legal effects', as Member States are to presume conformity with the 'essential requirements' as soon as the harmonised standards are published.[119]

Of course, judicial review of the Commission's decision to publish the reference to a harmonised standard is clearly at odds with the official ideology of the New Approach, which insists on a clear separation of 'public' and 'private' responsibilities and of 'legal' and 'technical' appraisals. As the Commission argues:

> The European standards organisations are responsible for identifying and elaborating harmonised standards and for presenting a list of adopted harmonised standards to the Commission. The technical contents of such standards are under the entire responsibility of the European standards organisations. Once public authorities have agreed on a mandate, the search for technical solutions should in principle be left to the interested parties. In certain areas, such as the environment and health and safety, the participation of public authorities on a technical level is important in the standardisation process. However, New Approach directives do not foresee a procedure under which public authorities would verify or approve either at Community level or national level the contents of harmonised standards, which have been adopted with the procedural guarantees of the standardisation process.[120]

Two pages later, however, that argument runs into trouble:

> The fact that the Commission and member states can challenge a harmonised standard, instead of conducting an approval procedure prior to the publica-

whose objection against the 'new approach' is concentrated precisely on the absence of judicial review; and Bleckmann, above n 7, 98.

[118] See Case 22/70 *Commission v Council* [1971] ECR 263, para 42; Case C–325/91 *France v Commission* [1993] ECR I–3283, para 9; Case C–57/95 *France v Commission* [1997] ECR I–1627, para 7.

[119] Note Roßnagel, above n 4, 1189, who, in the name of 'subsidiarity' wants to give the Member States the power to decide for themselves whether standards are compatible with the essential requirements, subject to non-specified review of the Commission to guard against 'protectionism'.

[120] Commission, *Guide to the Implementation of Directives based on the New Approach and the Global Approach*, (Opoce, Luxembourg, 2000) 28.

> tion of the standard, indicates that a systematic verification of the technical contents of harmonised standards is not provided for.[121]

Now, as noted above, the Safeguard Procedure has effectively been transformed into an instrument of administrative approval *prior* to publication of the references of the harmonised standards. *A contrario*, then, it is not hard to argue that the Commission now has taken it upon itself the duty to verify the technical contents.

If it is accepted that the publication constitutes a contestable decision, the question becomes what judicial review of it would amount to. It seems evident that review would be open for Member States only *after* they had gone through the safeguard procedure and that it would amount to no more than a review of the Commission's handling of that procedure: standards meet *Comitology*.[122]

To come to terms with the prospect, it is perhaps useful to state a hypothesis in full drama. The Council adopts a Directive with 'essential requirements'. The Commission drafts a 'mandate' after consulting the Standing Committee. The mandate is accepted by CEN. Technical Committees go to work under guidance of a 'consultant'. CEN adopts a standard. A Member State is of the opinion that the standard is not compatible with the 'essential requirements' and requests the Commission not to publish its references. The Commission consults the Standing Committee. In the Committee the objecting Member State is defeated, and the Commission decides to publish the references to the standard. The Member State goes to Court requesting annulment of the Commission's decision.

The fundamental question is, of course, whether the Court in such a scenario would be able to restrain from reviewing the standard itself, or even the standard-setting process. Judicial scrutiny of the technical merits of the standard in question would be the ultimate nightmare scenario. That, however, is excluded:

> According to the Court's caselaw, where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority

[121] Above, 30. See also Commission Report, Efficiency and Accountability in European Standardisation Under the New Approach, COM (98) 291 final, para 7 ('public authorities have committed themselves to not insisting on approving the technical content of harmonised standards; no positive decision is required by which authorities approve the standards, even if previously such technical aspects were subject of regulation.')

[122] On the role of committees in standardisation, see Vos, above n 7, 291 *et seq*; Bücker and Schlacke, 'Die Entstehung einer "Politischen Verwaltung" durch EG-Ausschüsse—Rechtstatsachen und Rechtsentwicklungen' in Joerges and Falke (eds), above n 12, 226 ff.

> concerned. Thus, in such cases, the Community judicature must restrict itself to examining the accuracy of the findings in fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion.[123]

Deference on substance, however, is compensated for by insistence on procedure:

> [W]here the Community institutions have such a power if appraisal, respect for the rights guaranteed by the Community legal order in administrative procedures is of even more fundamental importance.[124]

These 'guarantees' amount to the requirement that the Commission clearly state its reasons and, more pertinently, that it 'examine carefully and impartially all the relevant aspects of the individual case'.[125] In practice, the latter requirement comes down to an obligation of ensuring the availability of 'expertise' in the Committee. In *Technische Universität München*, the Commission admitted to following blindly the advice of the 'group of experts' it was required to consult. The Court objected not to the abdication of responsibility, but to the quality of the experts involved. Consulting 'experts' who do not possess the 'necessary technical knowledge' is to infringe the obligation to 'examine carefully and impartially all the relevant aspects of the case in point.'[126]

A lot could be said on the Court's faith in 'expertise' in its review of Community decision-making. In this particular and very limited hypothesis, the implications seem relatively clear. The Standing Committee consists of 'representatives appointed by the Member States who may call on the assistance of experts or advisers.'[127] In a hopeful reading of *Angelopharm*, the Court insists on the consultation of experts to diffuse 'naked' parochial interests and promote a 'deliberative' style of decision-

[123] Case C–120/97 *Upjohn* [1999] ECR I–223, para 34. Cf Case C–127/95 *Norbrook Laboratories* [1998] I–1531, para 90. Optimistic about the Court's concern with procedure rather than substance, Dehousse, 'Towards a Regulation of Transnational Governance? Citizen's Rights and the Reform of Comitology Procedures' in Joerges and Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart Publishing, Oxford, 1999) 109 (basing a case for the adoption of a European equivalent of the APA largely on the Court's supposed reluctance to engage in intrusive judicial review.)

[124] Case C–269/90 *Technische Universität München* [1991] ECR I–5469, para 14.

[125] Above.

[126] Above, para 22. See Joerges, 'Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures' in Joerges, Ladeur and Vos (eds), above n 7, 295; Joerges and Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 *ELJ* 273.

[127] Article 5, Directive 98/34/EC, (1998) OJ L 204/37.

making.[128] When a Member State objects to the publication of a standard's reference under the safeguard procedure, it is under an obligation to offer reasoned technical arguments for that stance, and it is entitled to have its arguments considered on the same level of discourse. What a Member State is not entitled to do is to block the publication for reasons of 'mere' national interest, and what the Commission is hence not entitled to do is to take a decision out of 'mere' political convenience.

So far, so good. Member States have lost their influence, or the possibility of influence, over the standardisation process by the Europeanisation of standards setting. The Community obliges Member States to allow products conforming to those standards on their territory. If it seems no more than reasonable to give them the possibility to challenge the Commission's decision to grant that presumption of conformity in a committee the Commission is bound to consult, it seems also reasonable to have some judicial oversight over the way that committee functions to ensure that the Commission makes a fair and reasoned decision. That, however, is as far as judicial review should go. It is one thing to have judicial review of an administrator's reception of a standard in a legal order; it is quite another to have judicial review of the standardisation process.

The problem is that it seems unlikely to prevent the mechanism extending to the standardisation process. What if a Member State objects to the Commission's publishing a reference of a standard that the 'CEN consultants' deem not to satisfy the essential requirements? Granted, the consultant has no status whatsoever in Community law. On the other hand, it seems in line with *Angelopharm* for the Court to reason that if the Commission has decided to finance these consultants for the very purpose of verifying the standards' compatibility with the essential requirements, it better have a very good reason to ignore their advice.

Moreover, if it is accepted that the act of publication constitutes a contestable measure, the question becomes whether it is just the Member States who can challenge it. For private parties, Article 230 (4) EC restricts

[128] Case C–212/91 *Angelopharm v Hamburg* [1994] ECR I–171, para 33 (holding that, in regulatory decision-making about scientific and technical matters, the Commission must, 'in the nature of things and apart from any provision laid down to that effect', be assisted by experts delegated by the Member States.) See Joerges and Neyer, above n 126. Cf Case T–13/99 *Pfizer v Council* [2002] ECR II–3305, para 262; Case T–70/99 *Alpharma v Council* [2002] ECR II–3495, para 207 (narrowing application of Angelopharm). Cf Ladeur, 'The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental and Public Health Law? Decision-making under Conditions of Complexity in Multi-level Political Systems' (2003) 40 *C M L Rev* 1455. Compare Sunstein, 'Interest Groups in American Public Law' (1985) 38 *Stanford L Rev* 29, 63, on the 'hard look' as a device to promote deliberative agency decision-making. Cf Seidenfeld, 'Cognitive Loafing, Social Conformity, and Judicial Review of Agency Rulemaking' (2002) 87 *Cornell L Rev* 486, 546 (arguing that judicial review forces agencies 'to take into account perspectives that may be held by those with different professional training and whose work might focus on different effects of the rule.')

standing to those who are 'individually concerned' by the measure in question, a phrase the Court has notoriously interpreted restrictively.[129] Thankfully, then, the prospect of having disadvantaged manufacturers challenging the publication of a harmonised standard before the ECJ seems unlikely. For the standards bodies themselves, however, things are different. They are 'individually concerned' as the decision to grant the presumption of conformity is, in effect, a judgment on the status of their national standards implementing the harmonised standard. They suffer adverse legal effects from the decision not to publish since their standards are of much less use to economic operators than they would have been otherwise. They play, moreover, a decisive role in a policy process instigated by the Commission and hence, according to the Court's caselaw, deserve certain procedural rights regarding the Commission's final decision.[130]

CEN challenging the Commission for refusing to publish the references of a standard that it feels completely complies with the terms of a mandate? AFNOR challenging the Commission for publishing the references of a standard it had voted against within CEN?

6. DELEGATION REVISITED

Implicitly at least, the Community legislator has taken to the theory that procedural guarantees fills in the gaps of the void left after the demise of the untenable 'official theory' of constitutional legitimacy. That theory is embodied in the proposition that the essential requirements are autonomous and self-executing. If, after all, standards were really voluntary and just one of many ways to find one of many 'technical' ways of complying with self-standing legal requirements, it is hard to see why one would insist so much on the 'open and transparent' nature of the process of setting standards. The thinking comes out in this titbit from the Economic and Social Committee:

[129] The tone was set in Case 25/62 *Plaumann v Commission* [1963] ECR 106. See generally eg Albors-Llorens, *Private Parties in European Community Law—Challenging Community Measures* (OUP, Oxford, 1996); Ward, *Judicial Review and the Rights of Private Parties in EC Law* (OUP, Oxford, 2000). The Court of First Instance has, however, recently opened up standing considerably in Case T–177/01 *Jégo-Quéré v Commission* [2002] ECR II–2365, largely on the grounds that an absence of legal remedy falls foul of human rights concerns. The ECJ is unimpressed. See case C–50/00 P *UPA v Council* [2002] ECR I–6677. Cf Ragolle, 'Access to Justice for Private Applicants in the Community Legal Order: Recent (R)evolutions' (2003) 28 *ELR* 90.

[130] This caselaw was developed in competition, state aids and anti-dumping cases. See eg Case 169/84 *COFAZ v Commission* [1986] ECR 391; Case C–319/90 *CIRFS v Commission* [1993] ECR I–1125. In *Greenpeace*, the Court of First Instance generalised the principle; on appeal, the Court of Justice agreed. See Case T–583/93 *Greenpeace v Commission* [1995] ECR II–2205; Case C–321/95 P *Greenpeace v Commission* [1998] I–1651.

> It must be absolutely clear that the legislator is not delegating its powers improperly to private standardisation bodies. In cases where standards are 'de facto' binding, measures must be taken to ensure that all interested parties participate in an appropriate way in the process of establishing standards.[131]

If, moreover, it would be really possible to separate the 'political' from the 'technical' and hence to maintain that only the former is in need of 'constitutional' legitimacy whilst the latter only solves 'technical questions,'[132] it is equally hard to understand why the Commission insists so much on balanced interest representation. After all, the Commission praises standardisation not for its technical accuracy, but for its capacity to 'combine the advantages of democracy with the ability to reflect the technological state of the art.'[133]

The normative problem with standardisation revolves around the structure of the argument. According to the 'official' theory, the fact that the essential requirements are *not* autonomous and self-executing constitutes an unfortunate failure of the legislature to establish an autonomous set of normative requirements. And procedural legitimacy in the standard setting process is then but compensation for the regrettable fact that political agreement could not close off the space for standardisation to be limited to the purely 'technical' which, in turn, implies that private standardisation has to decide on 'political' issues. The whole anti-delegation debate turns on a series of *Aha Erlebnisse*: Standardisation is not just about 'technology': standardisation involves normative value judgments that affect life and limb. Standardisation involves a space previously occupied by the legislator. Standardisation signifies the privatisation of public rulemaking. Hence, standardisation needs to be subjected to the rigors of constitutional hierarchy or at least to the rigours of the surrogate political process constituted by administrative procedure.

The basic structure of this argument rests, of course, on the idea that there *is* such a thing as the purely 'technical' as opposed to the inherently 'political', just as there is the purely 'private' as opposed to the irreducibly 'public'. There is a marvellous paradox underlying the official New Approach doctrine that 'law' and 'technology' occupy clearly separate spheres. If it is taken seriously, the real problem is not 'technology' encroaching into the legal sphere, but law occupying the 'technical'

[131] Opinion of the Economic and Social Committee on 'Technical Standards and Mutual Recognition', (1996) OJ C 212/7, 6.2.2.

[132] See eg Commission Report, *Efficiency and Accountability in European Standardisation Under the New Approach*, COM (1998) 291 final, para 7 ('The policy objective of the free movement of goods should not be delegated to the voluntary standardisation level, as standardisation can only solve technical questions.')

[133] Commission Communication, *Standardisation in the European Economy*, (1992) OJ C 96/2, para 73.

sphere. The 'essential requirements' are full of very detailed requirements that reflect engineering choices; the 'mandates' are sometimes indistinguishable from technical regulations. Thus, at the same time as grounding the constitutional legitimacy question on the severance of 'law' and 'technology', the New Approach is in practice one big showcase for the proposition that, in product safety, politics invariably concerns technological choices.

By the same token, standardisation necessarily involves 'political judgment', *however* carefully circumscribed the legal guidelines are. The separation of the 'technical' and the 'political' in the New Approach is not so much a constitutional necessity as it is a mechanism to enable social consensus on complicated regulatory issues, to avoid both legislative bodies being paralysed by technical detail and technical bodies being exposed to contentious 'political' questions. The crucial point is that the 'political' and the 'technical' are not separated by epistemological boundaries but by the social structure of communication in different institutions.[134] If we value standardisation for its ability to produce social consensus on product safety, the worst thing we could do is to subject the process to the paraphernalia of political and administrative rulemaking that prevented the political administrative process from producing that consensus in the first place.[135]

The other idea behind the anti-delegation doctrine is that standards are the 'private' equivalent of public law. Yet standards differ from law in more fundamental ways than their source. Law is not an adequate institution to set technical specifications that are dynamic enough to adapt to, rather than block, technological change, and flexible enough to open, rather than close off, markets. Standards depend on market mechanisms to be accepted, rather than on the threat of sanction. Standards are pro-

[134] Christian Joerges can defend himself against allegations of celebrating rampant technocracy as 'deliberative supranationalism' much better than I can; see eg Joerges, '"Deliberative Supranationalism"– Two Defences' (2002) 8 *ELJ* 133. But I do submit that Joseph Weiler is wrong to suggest that 'deliberative supranationalism' partakes in a '*Sciencefest*'. See Weiler, 'Epilogue: "Comitology" as Revolution—Infranationalism, Constitutionalism and Democracy' in Joerges and Vos (eds), above n 123, 339, 345–46. Joerges may put a lot in faith in 'experts', but that faith is grounded on the part they play in diffusing parochial concerns and exposing 'naked' political preferences in meaningful deliberation on complicated regulatory issues, not on their privileged access to 'the truth'. See especially Joerges, above n 126.

[135] Opposing administrative strategies and 'corporatist' pluralisation, Ladeur, 'Towards a Legal Concept of the Network in European Standard-Setting' in Joerges and Vos (eds), above n 123, 155. As for his positive proposals, I admit I do not quite grasp the meaning of a 'functional equivalent of experience as a common frame of reference for public and private action' which can only be seen in a 'procedural perspective which would not so much stress the substantive requirements of giving reasons but which would shift the emphasis to the transformation of the process of knowledge generation itself,' above, 159, nor can I see how to conceive of the EC as a 'decision-making unit encouraging productive processes of self-transformation in the transnational emergent network of interrelationships between Member States, which are themselves to be viewed as co-operative networks of networks', above, 166.

duced in consensus of market players, not with the backing of political will. Standards operate on the assumption that high levels of quality and safety are a marketing tool rather than an imposed obligation. From that point of view, the central problem with standardisation under the New Approach is not the privatisation of public lawmaking, but the political instrumentalisation of private rulemaking. And the normative answer to that problem is not the reinvigoration of the public, but, rather, the reinvigoration of the public-regardingness of responsive self-regulation.[136]

7. CONCLUSION

The least contentious issue in the delegation debate is, paradoxically, the identification of the fundamental principles of good governance which standardisation should adhere to. Due process, the involvement of interested parties, the reasoned consideration of relevant expertise, the subordination of narrow economic interests to the public interest—a catalogue along these lines would not be difficult to agree on among the critics of the New Approach. The contentious issue revolves around means, not ends. And the extent to which judicial review, public authorities' vetoes, enforced interest pluralisation, and other mechanisms of public decision-making can promote such socially responsive institutionalisation of deliberation in private bodies is at best doubtful. What such mechanisms would surely produce is the disruption of the social structure of communication, the politicisation of technical discourse and the perverse effects of litigation. The better path surely is what the Commission is actually doing: prompting dialogue, inventing co-operative linkage institutions, encouraging the flow of information and mutual learning and adaptation between the public and private spheres.

The ultimate paradox of the New Approach is that, in the final analysis, the best guarantees of the 'constitutionalism' of standards setting lie exactly in the *lack* of its clear legal status the critics complain so much about. 'European' standards do not exist—only national standards transposing European standards exist. And the embeddedness of standards in national legal systems makes for 'productive irritation' of the European standards system. AFNOR's mission of *service public* cannot be overridden by its contractual obligations to CEN to implement European standards.[137] The *Bundeskartellamt* will not exempt DIN standards, whatever their origin, from the rigours of German competition law unless certain

[136] See Joerges, Schepel and Vos, *The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Process: The Case of Standardisation Under the "New Approach"*, EUI Working Papers Law 99/9, (European University Institute, Florence, 1999) 24 ff.

[137] See above.

procedural guarantees are fulfilled.[138] BSI owes a private law duty of care to third parties under UK law which prevents it from 'blindly' transposing European standards.[139]

Moreover, at least one national court blissfully ignores the ECJ's dictum in *Vrankovich* that national courts cannot lift the presumption of conformity.[140] For violations of safety regulations, including the UK implementing law of the Toy Safety Directive,[141] the UK Consumer Protection Act provides that it is a defence to show that 'all due diligence' had been exercised to avoid committing the offence. The High Court has held that compliance with harmonised standards does *not* constitute 'due diligence', and that companies are not entitled to assume that British Standards comply 'with the requirements laid down by Parliament.'[142]

Such decentralised judicial review of standards coupled with contextual regulation on the European level, it is submitted, stand a much better chance of promoting thorough deliberation in the European standards bodies than does centralised administrative control.

[138] See below.

[139] See below.

[140] See *Cremonini*, above n 2, para 11 (the safeguard procedure 'precludes any action by the judicial authority as such') and para 14 ('since a judicial authority is not empowered, where there is a presumption of conformity, to adopt any measure restricting the free movement of goods, such a step may be taken only in the context of the procedure of Article 9 of the Directive by a national administrative authority acting on behalf on the Member state and empowered to participate in that procedure'). Cf Ladeur, 'The Integration of Scientific and Technological Expertise into the Process of Standard-Setting According to German Law' in Joerges, Ladeur and Vos (eds), above n 7, 77, 98–99 (arguing against the extension of the principle to the New Approach since the Low Voltage Directive was 'based on the old conception of harmonization through individual specific directives').

[141] Toy (Safety) Regulations 1989. On the UK implementation of the Directive, see generally Weatherill, 'Playing Safe: The United Kingdom's Implementation of the Toy Safety Directive' in Daintith (ed), *Implementing EC Law in the United Kingdom—Structures for Indirect Rule* (Wiley, New York, 1995) 239.

[142] *Alan Balding v Lew-Ways Ltd* [1996] ECC 417. At issue was BS 5665: 1988, the transposition of EN 71: 1988, now withdrawn and superseded. At no point in the judgment do the Justices seem to be aware of the New Approach. Keene J even went so far as to say that there was 'no evidence that the company had *any* basis for concluding that compliance with BS 5665 would mean compliance with the Toy (Safety) Regulations.' Above, 423 (emphasis added). Even commentators who should know better ignore the point. See Scott and Black, *Cranston's Consumers and the Law* (Butterworths, London, 2000) 331, 398.

8

Private Regulation in American Public Law

1. INTRODUCTION

Not once since the New Deal has the Supreme Court struck down a piece of federal legislation on the grounds of unconstitutional delegation of legislative powers. And on the rare occasion it has ever done so, it objected to delegation to private parties, not to public agencies.[1] In *Schechter Poultry*, the Court was confronted with America's very own corporatist nightmare, the National Industry Recovery Act.[2] Passed in 1933 as an emergency measure to get the country out of the Great Depression, the Act set up a system of Presidential rubberstamping of 'codes of fair competition' set up by industrial associations. Section 3 (a) of the Act read as follows:

> Upon the application to the President by one or more trade or industrial associations or groups, the President may approve a code or codes of fair competition for the trade or industry or subdivision thereof, represented by the applicant or applicants, if the President finds (1) that such associations or groups impose no inequitable restrictions on admission to membership therein and are truly representative of such trades or industries or subdivisions thereof, and (2) that such code or codes are not designed to promote monopolies or to eliminate or oppress small enterprises and will not operate to discriminate against them, and will tend to effectuate the policy of this title.

The President furthermore was given the power to impose such conditions for the protection of consumers, competitors, employees and others and in furtherance of the public interest as he felt necessary. The Court struck down the provision as a 'sweeping delegation of legislative power.' The statute, it held,

[1] See *Panama Refining Co v Ryan* 293 US 388 (1935); *ALA Schechter Poultry Co v United States* 295 US 495 (1935); *Carter v Carter Coal* 298 US 238 (1936). The *locus classicus* on New Deal corporatism, and still a guiding light on the subject of private governance, is Jaffe, 'Law Making by Private Groups' (1937) 51 *Harv L Rev* 201.

[2] Act of 16 June 1933, 48 Stat 195. See generally Brand, *Corporatism and the Rule of Law: A Study of the National Recovery Administration* (Cornell University Press, Ithaca, 1988) and the magnificent Friedman, *American Law in the 20th Century* (Yale University Press, New Haven, 2002) 151 ff.

> does not seek merely to endow voluntary trade or industrial associations or groups with privileges or immunities. It involves the coercive exercise of the lawmaking power. The codes of fair competition which the statute attempts to authorise are codes of laws.[3]
>
> . . .
>
> Could it seriously be contended that Congress could delegate its legislative authority to trade or industrial associations or groups so as to empower them to enact the laws they deem to be wise and beneficent for the rehabilitation and expansion of their trade or industries? Could trade or industrial associations or groups be constituted legislative bodies for that purpose because such associations or groups are familiar with the problems of their enterprises? . . . The answer is obvious. Such a delegation of legislative power is unknown to our law, and is utterly inconsistent with the constitutional prerogatives and duties of Congress.[4]

As the only constitutional condemnation of delegation of lawmaking powers that stands, *Schechter Poultry*'s catalogue of objections to the NRA is the starting point for any discussion of the implications of the doctrine. The Court raised four fatal points.[5] First, the Act laid down no clear statutory criteria for the approval of the 'codes', and thus set no limits to the intrusiveness of regulatory action. Second, the Court objected mightily to the scope of the delegated authority, allowing the regulation of a 'vast array of commercial and industrial activities.'[6] Third, the Act was unfavourably compared with cases where the Court had allowed delegation to agencies on the grounds of procedural safeguards the other statutes provided. An agency is 'required to act upon notice and hearing, and its orders must be supported by findings of fact which in turn are sustained by evidence.'[7] And fourth, the empowerment of private parties was unchecked by any kind of public 'filtering'.[8] For Theodore Lowi, private standards are 'indistinguishable' from NRA Codes and hence he marvels that 'there is so little suspicion as to their constitutionality that there is no particular urge to take these issues to court' under the nondelegation doctrine.[9] The obvious answer is all too obvious. Private standards that are

[3] *Schechter Poultry*, above n 1, 529.
[4] Above, 537.
[5] See Sunstein, 'Nondelegation Canons' (2000) 67 *U Chi L Rev* 315, 320.
[6] *Schechter Poultry*, above n 1, 540.
[7] Above, 541.
[8] Just months before *Schechter Poultry* was decided, the Wisconsin Supreme Court struck down one of the 'Baby NRAs', state legislation patterned on the federal 'mother'. That Court was presciently horrified about the perverse effects of *transnational* private governance. See *Gibson Auto v Finnegan* 259 NW 420, 423 (Wis 1935), ('It is conceivable at least that a code might be proposed under the terms of the act by persons not citizens of the United States, which would, when approved by the Governor, become the law of the land.')
[9] Lowi, *The End of Liberalism* (Norton, New York, 1979) 118. Lowi refers in particular to the arrangements for adopting consensus standards under the OSH Act. See below.

adopted or referred to by law are just that—law: 'manifestly, any association may adopt a 'code' but the only code that constitutes the law is a code adopted by the people through the medium of their legislatures.'[10] When 'adopted by the people', standards are locked into the constitutional framework of legitimacy. When private standards are not adopted by legislators, they are just that—private. The question is, of course, whether this dichotomy is tenable, let alone desirable.

2. THE NONDELEGATION DOCTRINE IN THE UNITED STATES: THE DEFINITION OF 'LAWMAKING'

In *Carter v Carter Coal*, the Supreme Court made an emphatic point about its stricter scrutiny of private delegation than of public delegation. Delegation of the regulation of wages and working hours to collective bargaining was held to be

> delegation in its most obnoxious form: for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business.[11]

That stance, however, was abandoned only a few years later.[12] The Court's attitude ever since has been to ignore any difference between public and private delegations,[13] and to allow the latter with as much lenience as it does the former.[14] As Lawrence puts the matter, 'private exercise of federally

[10] *Columbia Specialty Co v Breman* 90 Cal App 2d 372, 378 (1949).

[11] *Carter Coal*, above n 1, 311. The Court struck down the legislation as 'intolerable and unconstitutional interference with personal liberty and private property' under the Due Process clause of the Fifth Amendment, not as delegation of lawmaking powers.

[12] See eg *Currin v Wallace* 306 US 1 (1939); *United States v Rock-Royal Corp* 307 US 533 (1939), (upholding delegations of rate setting powers to tobacco growers and milk producers, respectively).

[13] In truth, this signified a return to the *status quo ante*. In *St Louis, Iron Mountain & Southern Railway v Taylor* 210 US 281, 287 (1908), the issue was the constitutionality of a clause in the safety appliance law which authorized the American Railway Association, a private association, 'to designate to the Interstate Commerce Commission the standard height of drawbars for freight cars.' The Court summarily dismissed objections by stating that 'nothing need be said upon this question except that it was settled adversely to the plaintiff in error in *Buttfield v Stranahan* 192 US 470 (1904), a case which, in principle, is completely in point.' Now, *Buttfield* dealt with the constitutionality of the power delegated to the Secretary of the Treasury under the Act To Prevent the Importation of Impure and Unwholesome Tea to 'fix and establish uniform standards of purity, quality, and fitness for consumption of all kinds of teas imported into the United States.' The Court had no difficulty classifying that power as 'mere executive duty.' 192 US 495.

[14] See Abramson, 'A Fifth Branch of Government: The Private Regulators and their Constitutionality' (1989) 16 *Hastings Const L Q* 165, 188 (Court ignores crucial difference in public and private accountability and hence has produced 'an incoherent approach to the constitutional evaluation of private delegations.') See also Freeman, 'The Private Role in Public Governance' (2000) 75 *NYU L Rev* 543, 583 ('Although judicial decisions reflect little on the comparative threat posed by public versus private agents, legal commentators seem

delegated power is no longer a federal constitutional issue.'[15] Only in state courts, then, do challenges to private delegations stand a chance of success.[16]

Traditionally, State courts have taken the category of 'law' seriously and have repeatedly struck down references to standards as 'unlawful delegation.' Consider the disgust of the *Crawford* court, too good not to quote in full this time:

> In our commonwealth the power to make, amend, alter, and repeal the laws is vested in the Legislature. That body may not abdicate its functions nor delegate its powers to any other body, however learned, wise, and far-sighted the latter may be. Some courts, including our own, have relaxed, or seemingly relaxed, this principle, by giving countenance to legislation enacted to punish as misdemeanours or otherwise to penalize the breach of rules promulgated afterwards by some subordinate official body created by the legislature. But none of the cases cited has ventured so far afield as to intimate that the Legislature might delegate to some unofficial organisation of private persons like the National Fire Protective Association the power to promulgate rules for the government of the people of this state, or for the management of their property, or that the legislature might prescribe punishment for breaches of these rules. We feel certain that no such judicial doctrine has ever been announced. If assent to such a doctrine could be given, a situation might arise where owners of property with considerable persistence might learn what these Code rules were, and incur the expense of making their property conform thereto, only to find that the National Fire Protective Association had reconvened in Chicago, New York, or New Orleans, and had revised the Code, and that the work and expense had to be undertaken anew. And there would be no end to such a state of affairs. Furthermore, there is no official way, indeed no practical way, for the average property owner to know what

to view private discretion as more dangerous than agency discretion, no matter how unconstrained. While the federal judiciary may decline to resurrect the nondelegation doctrine to invalidate delegations to administrative agencies, then, it might still invalidate private delegations in private cases.') Cf Metzger, 'Privatization as Delegation' (2003) 103 *Colum L Rev* 95.

[15] Lawrence, 'Private Exercise of Governmental Power' (1986) 61 *Ind L J* 647, 649. Recent signs of life of the doctrine in eg *Michigan Pork Producers Association v Campaign for Family Farms* 174 F Supp 2d 637 (WD Mich 2001), (reading the 'Pork Act' 7 USC 4801 *et seq*, as to permit and not require, the termination of the 'pork program' upon an affirmative vote in a referendum among pork producers in order to preserve the separation of powers and the political accountability intended by the Constitution.)

[16] Above, 650. The same conclusion was drawn in Note, 'The State Courts and Delegation of Public Authority to Private Groups' (1954) 67 *Harvard L Rev* 1398 (noting demise of the Supreme Court's rule in *Carter* in federal courts and its 'continuing vitality' in state courts). Cf *Gumbhir v Kansas State Board of Pharmacy* 618 P 2d 837, 841–42 (Kan 1980), (noting how the legislature may enact general provisions for regulations and grant to state agencies 'certain discretion in filling in the details' and contrasting that with the 'strict rule' which is applied when the delegation of authority 'to some outside, nongovernmental agency is attempted.'); *Boll Weevil v Lewellen* 952 SW 2d 454, 469–70 (Tex 1997), (finding it 'axiomatic' that courts 'should subject private delegations to a more searching scrutiny than their public counterparts' and contrasting the Supreme Court's willingness to uphold private delegations with state courts' practice of frequently invalidating them.)

> these Code rules are. The laws of this state to which our people owe obedience must be officially published. The people may learn what these rules are, and they are privileged to meet legislative committees and petition the legislature for amendment, improvement, and amelioration of the laws. Shall it be intimated that if these fire prevention regulations, these 'National Electrical Code' rules are oppressive, or otherwise objectionable, the property owners of this state must be referred to some voluntary and unofficial conference of underwriters and electricians which occasionally meets here, there, or anywhere in North America for redress of grievances. But the fallacy of such legislation in a free, enlightened and constitutionally governed state is so obvious that elaborate illustration or discussion of its infirmities are unnecessary. If the Legislature desires to adopt a rule of the national Electrical Code as a law of this state, it should copy that rule, and give it a title and an enacting clause, and pass it through the Senate and the House of representatives by a constitutional majority, and give the Governor a chance to approve or veto it, and then hand it over to the secretary of state for publication.[17]

In 1958, the Oregon Supreme Court was similarly unimpressed with a similar provision which imposed 'substantial accord' with the NEC 'as approved by the American Standards Association':

> It is difficult to conceive of a delegation of legislative power more certain or more complete. The American Standards Association is a private organization with membership open to any industrial, commercial, technical or governmental group concerned with standardization work. No doubt its objectives are meritorious and its activities productive of much good. But the constitution does not sanction the delegation of legislative power to any private agency no matter how well qualified such agency may be.[18]

Noting how similar provisions were 'universally condemned',[19] a California Court of Appeals even went so far as to outlaw a provision according to which conformity with the NEC constituted 'prima facie evidence' of compliance with statutory requirements.[20] As confirmed in 1997, then, the law in California is that 'while the legislature can provide for and encourage the participation of private associations in the regulatory

[17] *State v Crawford* 177 P 360, 360–61 (Kan 1919), (citations omitted). Further state Supreme Court condemnation of reliance on the NEC in *City of Tucson v Stewart* 40 P 2d 72 (Ariz 1935); *People v Hall* 287 NW 361 (Mich 1939).

[18] *Hillman v Northern Wasco* 323 P 2d 664, 672–73 (Ore 1958).

[19] *Agnew v City of Culver City* 147 Cal App 2d 144, 154 (1956).

[20] Above, n 5. The whole clause read: 'All electrical installations in the City of Culver City shall be in conformity with the provisions of this ordinance, the Electrical Safety Orders of the State of California, and with approved standards for safety to life and property. In every case where no specific type or class of material, or no specific standards of installation are prescribed by the Electrical Safety Orders or by this ordinance, conformity with the regulations as laid down in the National Electrical Code, as approved by the American Standards Association, shall be prima facie evidence of conformity with approved standards for safety to life and property.'

process, it must stop short of giving such groups the power to initiate or enact rules that acquire the force of law.'[21]

There is, however, a definite trend to take the sharp edges of the doctrine.[22] In the words of a federal district court: 'The extensive adoption of privately developed standards indicates a reliance on private expertise but cannot be considered actual privatization of lawmaking.'[23] Condoning the incorporation by reference of the ASME Boiler and Pressure Vessel Code under the Kansas Boiler Safety Act, another federal district court noted that, 'as it becomes increasingly necessary for inadequately staffed and funded administrative agencies to deal with complex technical subjects, private groups often must be relied upon in preparing rules and regulations.'[24] The only requisite is 'ultimate authority to approve those standards' on the part of the agency.[25]

The last frontier of constitutional resistance to the adoption of private standards is the dynamic reference.[26] There is a clear majority for the view that a statute that attempts to incorporate future changes of another statute, standard, code or guideline constitutes delegation.[27] In *People v Mobil*, a New York district court was enraged at an ordinance adopting NFPA standards 'currently in effect, or as may be amended':

> By enacting the Association amendments, prior to their adoption, the County of Nassau has delegated to the National Fire Protection Association sovereign and legislative power. These delegated functions do not provide for power of execution or administration but delegates the power to make law, involving

[21] *International Association of Plumbing and Mechanical Officials v California Building Standards Commission* 55 Cal App 4th 245, 254 (1997).

[22] See eg Siegel, 'The Use of Legislative History in a System of Separated Powers' (2000) 53 *Vanderbilt L Rev* 1457, 1481 *et seq* (discussing cases that 'reveal widespread agreement with the intuitively obvious principle that static incorporation by reference does not even implicate, much less violate, any nondelegation doctrine.') Above, 1488. Times change. See Brabner-Smith, 'Incorporation by Reference and Delegation of Power-Validity of "Reference" Legislation' (1936) 5 *G Wash L Rev* 198.

[23] *Royal Insurance v RU-VAL Electric* 918 F Supp 647, 654 (ED NY 1996), (*In casu*, municipalities 'affirmatively' adopted the NEC, retained the authority 'to modify or repeal' ordinances and hence did not 'delegate' to the NFPA the power to set municipal law). The New York Constitution explicitly prohibits incorporation by reference. In *People v Shore Realty* 486 NYS 2d 124, 127 (1984), however, a New York District Court upheld references to NFPA standards in a local Fire Prevention Ordinance: 'Where, as here, specifically designated standards are adopted and incorporated into an ordinance by a legislative body; and such standards are possessed by said body at the time of the enactment and are on file with the legislative body for all to peruse, the ordinance is valid even if such standards are not directly inserted within the body of the ordinance.'

[24] *North American Safety Valve v Wolgast* 672 F Supp 488, 494 (D Kan 1987).

[25] 672 F Supp 488, 493–94 (D Kan 1987).

[26] See Jaffe, above n 1, 229 ('The constitutional nostril of the court begins to sniff, however, when the legislature adopts not only the existing standards of some technical or professional group, but any which it may prescribe in the future.')

[27] *McCabe v North Dakota Workers Compensation Bureau* 567 NW 2d 201, 204–5 (ND 1997), (collecting cases for the proposition). Cf Siegel, above n 22, 1481 *et seq*.

> the discretion of what can or can not be done, a violation of which becomes malum prohibitum.[28]

In *Northern Lights Motel*, the Alaska Supreme Court explained why it objected to the state's wholesale adoption of the 1955 edition of the Uniform Building Code '*and all future amendments thereto*':

> One reason for the prohibition against delegation to private groups is that when amendments are adopted by these groups the public does not necessarily receive notice of, or have an opportunity to comment on or criticize the amendments, as it does when they are adopted by under the Alaska Administrative Procedure Act.[29]

A recent decision by the New Mexico Supreme Court removes even this barrier.[30] At issue was a provision in the state Workers' Compensation Act which relied on 'the most recent edition' of a guide published by the American Medical Association. The Court held that legislative adoption of standards of private organizations 'is not always a delegation of legislative power: This is true even when the standard is subject to periodic revision by the private entity.'[31] The Court grounded its holding on a declaration of incompetence of public legislators:

> Legislatures encounter resource limitations, as well as other practical obstacles, which render them incapable of developing their own standards. Furthermore, the technical sophistication required to develop standards in certain fields has a prohibitory impact on legislative development of such standards.[32]

If reliance on private standards is legitimised in the first place by public authorities' incompetence and other 'practical' problems, one cannot very well strike down dynamic references because the 'public' did not have a chance to put in its two pennies' worth. In that sense, the Court is only coherent:

[28] *People v Mobil Oil Corporation* 422 NYS 2d 589, 592 (1979).

[29] *Northern Lights Motel v Sweaney* 561 P 2d 1176, 1181 (Ala 1977).

[30] See, however, already *Board of Trustees v City of Baltimore* 562 A 2d 720, 731 (Md App 1989), (Noting that, 'courts have sometimes upheld legislative adoption of private organizations' standards which are periodically subject to revision, in limited circumstances such as where the standards are issued by a well-recognized, independent authority, and provide guidance on technical and complex matters within the entity's area of expertise,' and collecting cases.)

[31] *Madrid v St Joseph Hospital* 928 P 2d 250, 256 (New Mex 1996). In agreement, eg *Pegs Branch Mining v Coleman* 2003 WL 1193090 (Ky 2003); *Farber v North Carolina Psychology Board* 569 SE 2d 287, 300 (NC App 2002). In a very similar case, the Supreme Court of Appeals of West Virginia recently held a *static* reference to the guidelines to be 'troublesome', but 'permissible.' It did, however, absolutely bar dynamic references: 'The distinction is that, when an existing standard is incorporated by reference, there is the presumption that a legislature is familiar with that standard in its entirety and approves of it. However, by attempting to incorporate a standard, plus any modifications it might undergo, a legislature is delegating its authority to the non-elected authors of the standard, who could then change the standard in some way not contemplated by the legislature.' *Repass v Workers' Compensation Division and USX Corp* 569 SE 2d 162 (W Va S Ct App 2002).

[32] *Madrid*, above n 31, 257.

> Periodic revisions of the standard will not transform an otherwise constitutional and non-delegatory statutory provision into an unconstitutional delegation of legislative power. Where a standard is periodically updated because of new scientific developments recognized by eminent professionals interested in maintaining high standards in science, the standard may still be adopted by the Legislature.[33]

From Kansas to New Jersey in fifty years, things had changed. Under New Jersey law, failure to perform electrical construction in conformity with the NEC constitutes grounds for suspension or revocation of a Contractor's license. The State Supreme Court found against delegation, elevating the NFPA to the status of federal government agency in the process:

> The Code is promulgated by the National Fire Protection Association and the American Standard Association through 17 panels of recognized electrical and safety experts throughout the country, who review and revise it every three years. The procedures of adoption, review and revision reflect a national consensus of manufacturers, scientific, technical and professional organizations, and governmental agencies. While the product bears no formal governmental aegis, the manner of its adoption and revision and the universality of its acceptance indicates to us that it should be accorded the same standing for present purposes as if it were adopted and revised by some non-New Jersey governmental agency.[34]

3. ADMINISTRATIVE LAW AS CONSTITUTIONAL LAW: THE FEDERAL NONDELEGATION DOCTRINE

When standards are adopted into federal law, they are not, of course, copied, passed through Congress, submitted to the President for veto or approval, and published in the federal register. They are adopted by federal agencies. The inquiry thus necessarily expands along a chain—from Congressional mandates to agencies to agency supervision of standardisation.[35]

[33] Above, 259.

[34] *Independent Electricians and Electrical Contractors' Association v New Jersey Board of Examiners of Electrical Contractors* 256 A 2d 33, 42 (NJ 1969). Delegation to federal agencies is allowed in New Jersey; see *State v Hotel Bar Foods* 112 A 2d 726 (NJ 1955). In other states, delegation to the federal government is a real issue. See eg *Taylor v Gate Pharmaceuticals* 639 NW 2d 45 (Mich App 2002), (delegation to FDA unconstitutional), overturned by *Taylor v Smithkline Beecham* 658 NW 2d 127 (Mich 2003), (legislature allowed to refer to 'findings' of non-Michigan public or private agencies if these findings are of 'independent significance').

[35] See generally eg *National Association of Regulatory Utility Commissioners v FCC* 737 F 2d 1095, 1143 fn 41 (DC Cir 1984), (allegations of unlawful delegation are 'typically presented in the context of a transfer of legislative authority from the Congress to agencies, but the difficulties sparked by such allocations are even more prevalent in the context of agency delegations to private individuals'); *Perot v Federal Election Commission* 97 F 3d 533, 559 (DC Cir 1996), ('We agree with the general proposition that when Congress has specifically vested an agency with the authority to administer a statute, it may not shift that responsibility to a private actor such as the CPD').

The exclusive concern of the delegation debate ever since *Schechter Poultry* has been the relationship between vague legislative mandates to agencies and procedural safeguards. Broad discretion for unelected bureaucrats, so goes the critics' argument, hurts the rule of law and undercuts democracy by politicians' passing 'hard' policy choices over to agencies.[36] The Supreme Court, however, has never struck down a statute for excessive delegation to agencies.[37] All it demands is for Congress to establish an 'intelligible principle' to guide administrators:[38]

> Applying this 'intelligible principle' test to congressional delegations, our jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives.[39]

Under that understanding, it has held up legislative mandates to act 'in the public interest',[40] to set 'fair and equitable prices,'[41] and to set 'just and reasonable' rates.[42] Lenience towards legislation, however, comes at the price of strict scrutiny of agencies' exercise of their discretion. In *Bowen*,

[36] The most influential delegation critics, besides Lowi, are Ely, *Democracy and Disgust* (Harvard University Press, Cambridge, 1980); Aranson, Gellhorn and Robinson, 'A Theory of Legislative Delegation' (1982) 68 *Cornell L Rev* 1; and more recently, Schoenbrod, *Power Without Responsibility: How Congress Abuses the People Through Delegation* (Yale University Press, New Haven, 1993). *Contra* eg Mashaw, 'Prodelegation: Why Administrators Should Make Political Decisions' (1985) 1 *J L Econ & Org* 81; Stewart, 'Beyond Delegation Doctrine' (1987) 36 *Am U L Rev* 323; Rubin, 'Law and Legislation in the Administrative State' (1989) 89 *Colum L Rev* 369, 389, 392 (arguing that 'the whole concept was born from a misunderstanding of the administrative state', engrafting 'premodern notions of control and accountability onto the realities of modern government'); Mashaw, *Greed, Chaos & Governance—Using Public Choice to Improve Public Law* (Yale University Press, New Haven, 1997) 131 *et seq* (arguing that the need for justice in individual cases overrides overly abstract concerns for accountability and the rule of law, and that general statutory clauses do more for Congressional accountability than overly precise language the electorate doesn't understand anyway); Sunstein, above n 5 (arguing that the Supreme Court has abandoned an unworkably general nondelegation doctrine in favour of a set of workable 'nondelegation canons' and that this is a good thing); Posner and Vermeule, 'Interring the Nondelegation Doctrine' (2002) *U Chi L Rev* 1721, 1722 (arguing that 'there just is no constitutional nondelegation rule, nor has there ever been' and dismissing *Schechter Poultry* as 'nothing more than a local aberration'). See further Symposium: 'The Phoenix Rises Again—The Nondelegation Doctrine from Constitutional and Policy Perspectives' (1999) 20 *Cardozo L Rev* 731. Louis Jaffe consigned *Schechter Poultry* with some relief to 'the museum of constitutional history' in 1947. Jaffe, 'An Essay on Delegation of Legislative Power' (1947) 47 *Colum L Rev* 561 (II), 561, 581.

[37] Cf *Federal Maritime Commission v Carolina State Ports Authority* 535 US 743, 773 (2002), (Breyer J, dissenting), ('The Court long ago laid to rest any constitutional doubts about whether the Constitution permitted Congress to delegate rulemaking and adjudicative powers to agencies.')

[38] *J W Hampton & Co v United States* 276 US 394, 409 (1928); cf eg *Touby v United States* 500 US 160, 165 (1991).

[39] *Mistretta v United States* 488 US 361, 372 (1989).

[40] *National Broadcasting Corporation v United States* 319 US 190 (1943).

[41] *Yakus v United States* 321 US 414 (1944).

[42] *FPC v Hope Natural Gas* 320 US 591 (1944).

the Supreme Court explicitly sanctioned the theory of judicial 'hard looks' at administrative action substituting for a constitutional anti-delegation doctrine:

> Our recognition of Congress' need to vest administrative agencies with ample power to assist in the difficult task of governing a vast and complex industrial Nation carries with it the correlative responsibility of the agency to explain the rationale and the factual basis for its decision, even though we show respect for the agency's judgment of both.[43]

On that rationale, it is difficult to see why private delegations would be more objectionable in principle than delegations to agencies. In Jody Freeman's words, 'just as courts and scholars once struggled mightily against broad delegations from Congress to the executive only to find that the challenges of modern industrial society required them, so the time has come to accept private delegations as a fact of life.'[44]

3.1 Administrative Law and the Nondelegation Doctrine

As soon as the 'hard look 'comes in to remedy legitimacy deficits, the constitutional issue of delegation is framed in terms of the objectives administrative law is expected to further. The source of legitimacy is then necessarily reconceptualised away from hierarchical accountability to elected legislatures towards alternative theories. In crude synthesis, the extremes on the spectrum of administrative law scholarship are occupied by the expertocratic model, which focuses on the conditions for rational and informed decision-making, and the pluralist model, which focuses on ensuring equal access to different interests.[45] The regulatory law version of civic republicanism, then, emerges as the paradigm that claims to merge the best of those worlds and leave their drawbacks behind. Recognising

[43] *Bowen v American Hospital Association* 476 US 610, 627 (1986). Cf *Burlington Truck Lines, Inc v United States* 371 US 156, 167 (1962), ('Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion.'), (Internal citations omitted).

[44] Freeman, above n 15, 585. See Rose-Ackerman, 'Consensus versus Incentives: A Skeptical Look at Regulatory Negotiation' (1994) 43 *Duke L J* 1206, 1216 (suggesting that reliance on private standards is *less* objectionable under *Schechter Poultry* principles than regulatory negotiations, in that private standards 'at least can be justified by the expertise of committee members' as opposed to 'reg neg' rules, whose defense is based on 'politics, not technical competence.') Cf Jaffe, above n 1, 249 (discussing the expertise rationale for allowing delegation in case of industrial standards and warning that 'the field of noncontroversial expertness is a narrow one' and that judgment 'will be subtly corroded by prejudice of various sorts aroused into action by the will to monopolize.')

[45] See Stewart, 'The Reformation of American Administrative Law' (1975) 88 *Harv L Rev* 1669. Recent overviews in McGarity, 'The Expanded Debate over the Future of the Regulatory State' (1996) 63 *U Chi L Rev* 1469; Croley, 'Theories of Regulation: Incorporating Administrative Process' (1998) 98 *Colum L Rev* 1.

that agency deliberations invariably involve more than merely the 'rational' and value-free analysis of 'objective' facts, it insists on extensive dialogue with interested circles. Recognising that proper decision-making entails more than the aggregation of individual preferences, it insists on deliberation, reason-giving and procedure to ensure rationality and lift the process from the muddy waters of mere interest balancing.[46] The fundamental question for the delegation doctrine, then, is in what way procedural safeguards 'compensate' for lack of political guidance by the legislative assembly.

3.2 Administrative Procedure as a Substitute for Political Mandate

In one version, administrative procedure functions as a substitute for political decision-making. In that case, agencies can derive their 'constitutional' legitimacy from outside of the constitution, in the sense that administrative procedures of 'good governance' be considered an alternative for hierarchical political accountability. Cass Sunstein argues that the delegation doctrine

> should be associated less with accountability in the abstract than with the particular constitutional goal of ensuring a deliberative democracy, one that involves not only accountability but also certain forms of bargaining and above all reflectiveness.[47]

The next step is then to realise that meaningful democratic deliberation of policy issues cannot be assumed to take place only in legislative assemblies. As Peter Schuck notes:

> Legislation is only part of the process of responsible lawmaking, and it is becoming a less important part. In some important respects, this is for the better. Today, the administrative agency is often the site where public participation in lawmaking is most accessible, most meaningful, and most effective.[48]

[46] See eg Sunstein, 'Interest Groups in American Public Law' (1985) 38 *Stanford L Rev* 29; Seidenfeld, 'A Civic Republican Justification for the Bureaucratic State' (1992) 105 *Harv L Rev* 1511; Note, 'Civic Republican Administrative Theory: Bureaucrats as Deliberative Democrats' (1994) 107 *Harv L Rev* 1401. Critical of civic republicans' focus on judicial review, Freeman, 'Collaborative Governance in the Administrative State' (1997) 45 *UCLA L Rev* 1, 21. Ayres and Braithwaite, *Responsive Regulation—Transcending the Deregulation Debate* (OUP, Oxford, 1992) explicitly subscribe to Sunstein's brand of republicanism. The father of 'responsive law' subscribes to his own version of liberal republicanism. Selznick, *The Moral Commonwealth—Social Theory and the Promise of Community* (University of California Press, Berkeley, 1992).

[47] Sunstein, above n 5, 321.

[48] Schuck, 'Delegation and Democracy: Comments on David Schoenbrod' (1999) 20 *Cardozo L Rev* 775, 781. See also Rubin, 'Getting Past Democracy' (2001) 149 *U Penn L Rev* 711, 714, 782 (arguing that our 'genuine political commitments' are embodied in 'the administrative state' and not in the concept of 'democracy', and proposing to treat 'administrative interactions', like elections, as 'a mechanism for interaction between government and society.')

If it is accepted, however, that agencies can function as pockets of democracy and derive their legitimacy not from hierarchical constitutional sources but from procedure, there seems to be no reason not to conceive of the possibility of private regimes guaranteeing 'public regarding' legislation.[49]

In the Court's version, however, procedural safeguards function not as an alternative to parliamentary deliberation, but as a substitute for legislative limits on the decision-making authority of the agency. This was already clear in *Schechter Poultry* itself. There, the Court was utterly unimpressed by the Act's requirement that the trade association not impose 'inequitable restriction on membership' and be 'truly representative'. That condition, the Court held, 'relates only to the status of the initiators of the new laws and not to the permissible scope of such laws.'[50] The Court's refusal to entertain the notion of extra-constitutional legitimacy is most dramatic in *Chevron*,[51] 'the counter-*Marbury* for the administrative state',[52] the case that more than any other seems to realise the exigencies of modern governance. In that case, the Court famously established the principle that, in cases where 'Congress has not directly spoken to the precise question at issue', courts are to defer to the agency's interpretation of the statutory provisions concerned as long as it is 'reasonable'.[53] The decision's significance comes all from this act of judicial restraint, from the recognition that judicial opinions are a far worse substitute for vague and indeterminate political mandates than are expert opinions. Perhaps the more fundamental point, however, lies in the Court's search for a countervailing principle to the democratic pedigree of clear political mandate. The relevant passage is worth quoting in full:

> In these cases the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: the regulatory scheme is technical and complex, the agency considered the matter in a detailed a reasoned fashion, and the decision involves reconciling conflicting policies. Congress intended to accommodate both interests, but did not do so itself on the level of specificity presented by these cases. Perhaps the body consciously desired the Administrator to strike the balance at this level, thinking that those with great expertise and charged with responsibility for administering the provision would be in a better position to do so; perhaps it

[49] *Contra*, eg Krent, 'Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government' (1990) 85 *Northwestern U L Rev* 62, 109–10 (discarding the 'participation' rationale of delegation to private parties on formal grounds as irreconcilable with the separation of powers doctrine and on normative grounds as reflecting at best an 'inegalitarian republicanism'). Cf Michael, 'Federal Agency Use of Audited Self-Regulation as a Regulatory Technique' (1995) 47 *Admin L Rev* 171.

[50] *Schechter Poultry,* above n 1, 538.

[51] *Chevron US v Natural Resources Defense Council, Inc* 467 US 837 (1984).

[52] Sunstein, 'Is Tobacco a Drug? Administrative Agencies as Common Law Courts' (1998) 47 *Duke L J* 1013, 1058. *Marbury v Madison* 5 US 137 (1803), of course, is the decision where the Supreme Court declared itself supreme in the exposition of the law of the Constitution.

[53] *Chevron*, above n 51, 842–3.

> simply did not consider the question at this level; and perhaps Congress was unable to forge a coalition on either side of the question, and those on each side decided to take their chances with the scheme devised by the agency. For judicial purposes, it matter not which of these things occurred.
>
> Judges are not experts in the field, and are not part of either political branch of Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges' personal policy preferences. In contrast, an agency to which Congress has delegated policymaking responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices—resolving the policy competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in the light of everyday realities.
>
> When a challenge to an agency interpretation of a statutory provision, fairly conceptualised, really centres on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges—who have no constituency—have a duty to respect legitimate policy choices made by those who do.[54]

To ground its new conceptualisation of the relationship between administrative agencies and the judiciary, the Court makes several rather fundamental moves here. First, as if it were needed, it acknowledges the difficulties inherent in the 'transmission belt' theory of agency administration, the idea that an agency's job is mere objective 'implementation' of political choice.[55] In order to ground its stance of judicial restraint, it then

[54] Above, 866. The Court limited *Chevron*-deference in *US v Mead* 533 US 218, 226–27 (2001) to instances where 'it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority. Delegation of such authority may be shown in a variety of ways, as by an agency's power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.' Justice Scalia is not amused. See his dissent in 533 US 218, 239, 241 (2001), ('The Court has largely replaced *Chevron*, in other words, with that test most beloved by a court unwilling to be held to rules (and most feared by litigants who want to know what to expect): th'ol' "totality of the circumstances" test. The Court's new doctrine is neither sound in principle nor sustainable in practice.') See eg Barron and Kagan, '*Chevron*'s Nondelegation Doctrine' [2001] *Supreme Court Review* 201; Merrill, 'The *Mead* Doctrine: Rules and Standards, Meta-Rules and Meta-Standards' (2002) 54 *Admin L Rev* 807.

[55] Stewart, above n 45, after all, is close to a 150 pages' worth of analysing the demise of that 'traditional' model of administrative law. In truth, the model was beyond rescuing much earlier. See Jaffe, above n 36, 561 ('Every student is aware that until recently, at least, the courts somnambulistically insisted that the Constitution, having placed the legislative power in the legislature, forbade the delegation of lawmaking power. Powers which produced comprehensive systems of regulation were upheld by explaining the administrative operation as a mere "filling in of the details" or "finding of the facts" pursuant to which the statute then operated. Writers quite correctly and without difficulty ridiculed this hopelessly fictional rationalization.')

allows for two distinct scenarios of legislative failure to direct administrative action and advances two distinct compensation theories for the ensuing loss of political legitimacy. Congress may simply not be able to come to a political agreement and kicks the controversy down to the level of implementation. On the other hand, Congress may simply acknowledge its own limits, and the limits of statutory law, and accept that decisions in risk regulation need to take account of highly complex and contingent factors that cannot usefully be legislated on a general level. It is indifferent which of these caused the lack of political mandate; courts should defer to the agency. That decision is legitimised in two ways. First, the agency is subject to administrative procedure which ensures decision-making which is both rational and reasonable. Second, agency directors are subject to the authority of the President. Note, however, the relationship between the two. In the gap left open by Congress, administrative decision-making subject to judicial review ensures that the agency is 'reasonable'. Once that is settled, the agency's action still needs the cover of the President. That is a constitutional point relating to the separation of powers, and simply passes the notion of accountability from the legislative branch to the executive branch; the 'transmission belt' theory is re-introduced by shifting the locus of legitimacy from legislation to implementation. The argument, of course, is impoverishing the notion of political legitimacy to a marvellous degree. The Court lets go of the unrealistic notion that all regulatory action by agencies should be traceable to political choice expressed in legislation by introducing the even more far fetched idea that presidential appointments of agency directors will ensure that agency action is 'accountable' by means of presidential elections.[56] Even in cases where Congress deliberately delegates complex policy choices to the agency on the theory that the agency is the better forum to make them, there is still the need for an abstract, meaningless hierarchical source of legitimacy.[57]

[56] For a defence of the idea, see Kagan, 'Presidential Administration' (2001) 114 *Harv L Rev* 2245.

[57] Lindseth, '"Weak Constitutionalism"? Reflections on Comitology and Transnational Governance in the European Union' (2001) 21 *OJLS* 145, 152–55, seems to take *Chevron* seriously as a normatively attractive assertion of political control over agency rulemaking, as part of a 'larger story of "normative yearning" for democratic legitimacy in the American administrative state.' That in itself is merely a very good reason not to take his own theories very seriously. Cf Lindseth, 'Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community' (1999) 99 *Colum L Rev* 628, 698 (arguing that the Community's democratic legitimacy stems from an inability to establish democratically-legitimate hierarchical supervision over supranational technocrats, and urging 'Europeans' not to ignore the American 'yearning' for ultimate responsibility). Where he uses his reading of the case to accuse Michelle Everson of misreading the American experience, and from there to dismiss her argument, it becomes downright objectionable. See Everson, 'The Constitutionalisation of European Administrative Law: Legal Oversight of a Stateless Internal Market' in Joerges and Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart Publishing, Oxford, 1999) 281 (arguing that administrative law can and should move away from state-based hierarchical sources of legitimacy to endeavour to promote alternative democratic processes.)

3.3 Expertise as a Substitute For Political Mandate

The notion of democratic accountability, if it is to be meaningful at all, presupposes policy choices to be made on the basis of 'interests' or 'preferences' which in turn presuppose a unified construction of reality—divergent cognitive frameworks can hardly produce commensurable normative preferences. In that sense, according to Jerry Mashaw,

> delegation to experts becomes a form of consensus building that, far from taking decisions out of politics, seeks to give political choice a form in which potential collective agreement can be discovered and its benefits realised.[58]

The Court, however, will not accept any theory that expertise is in some way a condition for deliberative decision-making which could substitute for constitutional legitimacy.[59] Instead, 'expertise' is to be used by the agency as an *ex ante* constraint on its own authority in 'frontiers of science' cases.

The first version of that principle was consecrated in the 1980 *Benzene* case, concerning the OSH Act.[60] That piece of legislation instructs OSHA to set those standards for toxic substances that most adequately assure, '*to the extent feasible*, on the basis of the best available evidence' that no employee will suffer damage to his health.[61] For Justice Rehnquist, concurring in the judgment striking down OSHA's standards for exposure to benzene, this section constitutes unconstitutional delegation: the standard of 'feasibility' makes meaningful judicial review impossible and is merely a reflection of Congress' habit of reaching compromise by passing the difficult issues over to agencies and hence to the judiciary.[62] Countering Rehnquist, Justice Stevens for the majority invoked the nondelegation doctrine as an instrument for statutory construction. A statute empowering OSHA to issue 'reasonable and appropriate' standards that assure workers' health 'to the extent feasible' would constitute an unlawful delegation of legislative power unless the statute is construed in such a way as

[58] Mashaw, above n 36, 156.

[59] Consider Justice Scalia's scathing dissent in *Mistretta v United States* 488 US 361, 422 (1989), ('By reason of today's decision, I anticipate that Congress will find delegation of its lawmaking powers much more attractive in the future. If rulemaking can be entirely unrelated to the exercise of judicial or executive powers, I foresee all manner of "expert" bodies, insulated from the political process, to which Congress will delegate various portions of its lawmaking responsibility. How tempting to create an expert Medical Commission (mostly MD's, with perhaps a few PhD's in moral philosophy) to dispose of such thorny, "no-win" political issues as the withholding of life-support systems in federally funded hospitals, or the use of fetal tissue for research.')

[60] *Industrial Union Department, AFL-CIO v American Petroleum Institute* 448 US 607 (1980).

[61] 29 USC 655 (b), (5). Emphasis added.

[62] 448 US 607, 671 (1980). See also Rehnquist's dissent in *American Textile Manufacturers Institute v Donovan* 452 US 490, 543 (1981).

to oblige the agency to quantify the risk sufficiently to enable it to characterise it as 'significant' before it can issue any such standard.[63]

On one level, this 'nondelegation canon' simply serves to prevent agencies from enacting utterly unreasonably absolutist standards, imposing huge costs for trivial gains.[64] On another, however, its importance goes well beyond that. It is exactly the opposite of the precautionary principle in that, absent a clear political mandate to the contrary, it demands scientific 'proof' of a risk to be offered to the court in an 'understandable way' before it will allow an agency to take action to reduce it.

The DC Circuit took this reasoning a step further in *American Trucking*.[65] At issue were air quality standards issued by the EPA acting on the Clean Air Act's mandate to set standards at a level 'requisite to protect the public health' with 'an adequate margin of safety'.[66] The Court held that to be an unlawfully broad delegation of powers, but did not strike down the Clean Air Act. Instead, it remanded to the EPA demanding that the agency find an 'intelligible principle' to bind itself:

> Where (as here) statutory language and an existing agency interpretation involve an unconstitutional delegation of power, but an interpretation without the weakness is or may be available, out response is not to strike down the statute but to give the agency an opportunity to extract a determinate standard of its own. Doing so serves at least two out of three basic rationales for the nondelegation doctrine. If the agency develops determinate, binding standards for itself, it is less likely to exercise the delegated authority arbitrarily. And such standards enhance the likelihood that meaningful judicial review will prove feasible. A remand of this sort of course does not serve the third key function of non-delegation doctrine, to 'ensure to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our government most responsive to popular will'. The agency will make the fundamental policy choices. But the remand does ensure that the courts not hold unconstitutional a statute that an agency, with the application of its special expertise, could salvage.[67]

[63] 448 US 607, 646 (1980).

[64] The problem of the 'last ten percent' rendered famous by Justice Breyer. See Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Harvard University Press, Cambridge, 1993).

[65] *American Trucking Associations v EPA* 175 F 3d 1027 (DC Cir 1999). See also *International Union, UAW v OSHA ('Lockout/Tagout I')* 938 F 2d 1310 (DC Cir 1991).

[66] 42 USC 7409 (b), (1).

[67] *American Trucking Associations v EPA* 175 F 3d 1027, 1038 (DC Cir 1999), quoting *Industrial Union Department, AFL-CIO v American Petroleum Institute* 448 US 607, 671 (1980), (Rehnquist J, dissenting).

American Trucking has been hailed as 'the *Schechter Poultry* for the new millennium',[68] and criticised for endorsing a 'science charade'.[69] One side of the story is that the DC Circuit expects agencies to put quantifiable ex ante constraints on their action and hence to deprive themselves of all possibilities to adjust their estimates, to react to new contingencies, to 'learn by doing'.[70] In *International Union, UAW v OSHA*, the Court suggested OSHA subject itself to 'cost/benefit' analysis;[71] in *American Trucking* it held that 'an agency wielding the power over American life possessed by the EPA should be capable of developing the rough equivalent of a generic unit of harm that takes into account population affected, severity and probability.'[72] Bluntly, the EPA has to make a thoroughly political decision on its objectives before it can issue standards just so that the judiciary has a criterion to which to judge the agency's action. To no great surprise, a unanimous Supreme Court has dismissed the idea:

> The idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory. The very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would itself be an exercise of the forbidden legislative authority. Whether the statute delegates legislative power is a question for the courts, and an agency's voluntary self-denial has no bearing upon the answer.[73]

[68] See Schultz Bressman, '*Schechter Poultry* at the Millennium: A Delegation Doctrine for the Administrative State' (2000) 106 *Yale L J* 1399. Lukewarm reception of the doctrine in Sunstein, 'Is the Clean Air Act Unconstitutional?' (1999) 98 *Mich L Rev* 303.

[69] See Pierce, 'The Inherent Limits of Judicial Control of Agency Discretion: The DC Circuit and the Nondelegation Doctrine' (2000) 52 *Admin L Rev* 63. More criticism in Seidenfeld and Rossi, 'The False Promise of the "New" Nondelegation Doctrine' (2000) 76 *Notre Dame L Rev* 1, and especially in McGarity, 'The Clean Air Act at a Crossroads: Statutory Interpretation and Longstanding Administrative Practice in the Shadow of the Nondelegation Doctrine' (2000) *9 NYU Env L J* 1, 4 ('An unprincipled arrogation of power to the federal judiciary, strongly reminiscent of the worst abuses of judicial power during the *Lochner* era.').

[70] In short, to kill any ambition to engage in 'democratic experimentalism'. See Dorf and Sabel, 'A Constitution of Democratic Experimentalism' (1998) 98 *Colum L Rev* 267.

[71] *International Union, UAW v OSHA ('Lockout/Tagout I')* 938 F 2d 1310, 1319 (DC Cir 1991).

[72] *American Trucking Associations v EPA* 175 F 3d 1027, 1039 (DC Cir 1999).

[73] *Whitman v American Trucking Associations* 121 SCt 903, 912 (2001). See eg Sunstein, 'Regulating Risks After *ATA*' [2002] *Supreme Court Review* 1 (classifying the Court's judgment as a 'return to normalcy' and criticising it for being 'remarkably shallow' for its lack of ambition), and the rescue operation in Schultz Bressman, 'Disciplining Delegation After *Whitman v American Trucking Associations*' (2002) 87 *Cornell L Rev* 452 (reading the case as a shift away from *constitutional* delegation review to 'hard look' *administrative* law review.)

4. A HARD LOOK AT THE ADMINISTRATIVE ADOPTION OF STANDARDS

American constitutional law operates on a clear cut distinction between 'law' and 'non-law'. The positive aspect of this dichotomy is that standards bodies themselves remain untouched by public law and hence by the paraphernalia of the 'hard look'. The question is, however, in how far this radical separation between standards-setting and legislative reception of standards can, or should, be maintained. Consider Freeman's take on the issue:

> Imposing even more constraints on private actors is one way to try to provide more accountability, increase participation, and ameliorate the risk associated with private power, even when it is supervised by a public agency. Both agency incorporation of privately set standards and agency reliance on expert panels arguably warrant greater scrutiny than agency action based solely on in-house expertise. The difficulty, of course, is distinguishing the agency's own expertise from its dependence on private parties, since private parties are so well-integrated into the traditional standard-setting process.[74]

'The greater danger', with Bardach and Kagan, is, however

> that government bureaucrats intent on ensuring that no consumer interest goes unsatisfied will encumber a private standard-setting process that has worked remarkably well with a set of time-consuming, conflict-creating formal rules and adversarial procedures that would reduce its essential advantage over government regulation.[75]

The dilemma is similar to the one in 'negotiated' rulemaking: courts could review the agency's adoption of standards under exact the same 'hard look' as they do any federal standard and renegate the standards-setting process to a form of innocuous 'advice'; alternatively, they can consider that the standards setting process itself provides pretty much the safeguards of rationality and representativeness that the APA provides for agencies. In that case, however, the milder look at the agency will be paid for by opening up the standardisation process itself for judicial review. The danger of the first option is that the notice and comment procedure under the APA becomes one huge exercise in re-enacting the standards process itself, which would effectively wipe out all the advantages of relying on standards in the first place. The drawback of the second approach is that it would subject the standardisation process with the same due process paraphernalia that have had such disastrous effects on regulatory action by public agencies.

[74] Freeman, 'Private Parties, Public Functions and the New Administrative Law' (2000) 52 *Admin L Rev* 813, 830–31.

[75] Bardach, and Kagan, *Going by the Book—The Problem of Regulatory Unreasonableness* (Temple University Press, Philadelphia, 1982) 223.

4.1 Legislative Provisions for Agency Adoption of Standards

A lot depends on the statute's wording. Take what is probably the worst case scenario, the Clean Air Act's provisions directing the EPA to promulgate 'reasonable regulations and appropriate guidance to provide, to the greatest extent practicable, for the prevention and detection of accidental releases of regulated substances and for response to such releases by the owners or operators of the sources of such releases.'[76] The Act continues:

> Any regulations promulgated pursuant to this subsection shall to the maximum extent practicable, consistent with this subsection, be consistent with the recommendations and standards established by the American Society of Mechanical Engineers (ASME), the American National Standards Institute (ANSI) or the American Society of Testing Materials (ASTM). The Administrator shall take into consideration the concerns of small business in promulgating regulations into consideration under this subsection.[77]

In a way, this is a Congressional 'non-delegation' canon; unable or unwilling to provide the EPA with workable criteria according to which to regulate accidental release of hazardous air pollutants, it lets the standards bodies do much the same what the DC Circuit expected the EPA to do itself in *American Trucking*: lay down a limit on the intrusiveness of the agency's regulatory action. But imagine the consequences. The EPA could decide that ANSI standards do not prevent release 'to the greatest extent practicable' and promulgate a stricter standard. The agency would then have to explain in court why it feels the ANSI standard is too lax. So far, reasonably good: if the agency is required anyway to resist hard looks and explain why it issues a certain standard, it can also be required to substantiate its negative judgment of the ANSI standard. But what if the EPA issues a standard that does conform to ANSI standards? In that case, the question becomes whether the standard will still be judged as any other EPA standard or whether judicial review will focus on the standards bodies themselves. Both scenarios seem absurd. Is the EPA supposed to stage a defence of ANSI's methods, procedures and findings? Is the EPA to argue that ANSI has taken 'small business concerns' into account? Alternatively, is the Court going to make a 'careful and searching' inquiry to verify whether ANSI considered the 'relevant factors' and did not make a 'clear error of judgment'?[78]

The Consumer Product Safety Act solves the dilemma by explicitly rehearsing the private standard setting process on the level of administrative notice-and-comment. The CPSC is to make a judgment on whether a

[76] 42 USC 7412 (r), (7), (B), (i), as amended by Section 301, Public Law 101–549.
[77] 42 USC 7412 (r), (7), (C).
[78] *Citizens to Preserve Overton Park, Inc v Volpe* 401 US 402 (1971).

private standard would 'eliminate or adequately reduce the risk of injury addressed' and whether it is 'likely' that there will be substantial compliance with that standard.[79] In case that determination is negative, it can propose to issue a mandatory standard. In that case, however, it is forced to include in the notice 'a discussion of the reasons' why it doesn't think a voluntary standard would 'adequately reduce' the risk at issue.[80] That reasoning stands a good chance of being challenged in court, notably by trade associations and standard developers whose standard had been judged defective. In that case, it is hard to see how 'a careful and searching inquiry' into the agency's judgment can avoid going into the merits of the voluntary standard and hence into the procedures that led up its adoption. Alternatively, the CPSC can decide that a voluntary standard fulfils the requirements. But even then:

> Before relying upon any voluntary consumer product safety standard, the Commission shall afford interested persons (including manufacturers, consumers, and consumer organisations) a reasonable opportunity to submit written comments regarding such standard. The Commission shall consider such comments in making any determination regarding reliance on the involved voluntary standard under this subsection.[81]

The administrative process is thus opened up as an appeal mechanism for the standardisation process itself. Defeated members of the standards body, competing standards bodies, and consumer organisations who feel they have not been given a voice in the standardisation process can all submit comments and hence earn the right to challenge the agency in court.

In 1999, ANSI published a *Guide for the Preparation of Standards for Use in Regulations* where it seems fully prepared to take on the challenge of fulfilling the requirements of administrative procedure. Standards Developers are urged to

(1) Respond to and address all public comments thoroughly and provide for a second public review if substantive changes are made;
(2) Produce a clear consensus record through openness and due process to facilitate any necessary application of agency administrative procedures, and
(3) Emphasise the openness and credibility of the consensus process, so that the agency administrative procedure can be eased through access to a clear consensus record.[82]

[79] 15 USC 2056 (b), (1).
[80] 15 USC 2058 (c), (3).
[81] 15 USC 2058 (b), (2).
[82] ANSI, *Guide for the Preparation of Standards for Use in Regulations,* April 1999, (http://www.ansi.org). See also the statement of Oliver R Smoot, Chairman of ANSI's Board of Directors, before the House Science Committee's Subcommittee on Technology, Environment and Standards, 28 June 2001 (adherence to the principles of ANSI's process 'goes far to meet the requirements imposed by the Administrative Procedure Act and agency statutes on which their rulemakings are based.')

4.2 Judicial Scrutiny of Agency Adoption of Standards

For many years, the stop-gap procedure whereby OSHA could, in its first years of operation, adopt 'national consensus standards' without having to go through normal rulemaking procedures constituted the only instance where federal courts had to deal with these issues. The agency was constrained by the substantive requirement that such standards should 'result in improved safety or health for specifically designated employees'. In case of divergent standards, the agency was adopt the one that offers 'the greatest protection.'[83] A further requirement results from the definition of 'national consensus standard' as

> any occupational health and safety standard or modification thereof which (1), has been adopted and promulgated by a nationally recognised standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope of provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.[84]

The arrangement, *pace* Lowi, has been challenged for unlawful delegation of legislative power several times. And every single time the issue reached an Appellate Circuit Court it has been upheld.[85] The only problem with these cases is that the Circuits do not seem to really know *why* they consider the delegation lawful. Some of them focus on the relationship between Congress and the agency. In *Blocksom*, the Seventh Circuit held the *substantive* requirements of 'improved safety' and 'greatest protection' to be evidence of Congress' having 'chosen a policy' and having 'announced general standards which guide the Secretary.'[86] In *Plum Creek*, the Ninth Circuit held that the Act's definition of 'national consensus standards' 'clearly establishes standards for the agency to follow and is well within Congress' authority.'[87] Other decisions focus on the relationship between the agency and the standards body in question. In *Noblecraft*, the same Court held that no 'undue delegation' had taken place since 'OSHA in practice did not surrender to ANSI all its standard-making function. It selected among ANSI standards with apparent discrimination.'[88] Beyond choosing among standards, however, this 'discretion' argument is

[83] 29 USC 655 (a).
[84] 29 USC 652 (9).
[85] Most recently and categorically in *Towne Construction v OSHA* 847 F 2d 1187, 1189 (6th Cir 1988).
[86] *Blocksom v Marshall* 582 F 2d 1122, 1125, 1126 (1978).
[87] *Plum Creek v Hutton* 608 F 2d 1283 (9th Cir 1979).
[88] *Noblecraft v OSHA* 614 F 2d 199, 203 (9th Cir 1980).

a dead end. As soon as the agency exercises discretion on the *contents* of specific standards, it engages in 'normal' rulemaking and should be subjected to 'normal' APA procedures. Hence, under the arrangement of adopting 'consensus standards', the agency is not allowed to 'substantively' modify a standard and 'may not impose requirements which the standard's source did not impose.'[89] Court find themselves, hence, without any substitute for constitutional legitimacy: no APA procedures to make up for wide Congressional delegation, and no discretion of the agency that could in some way be linked back to the electoral legitimacy of the President. What courts are forced to do in the end, then, is to uncover a Congressional sanctioning of the *procedural* legitimacy of national consensus standards:

> In authorizing the promulgation of standards without a public hearing or other formal proceedings, Congress reasoned that the standards had been adopted under procedures which had already given diverse views an opportunity to be considered and which indicate that interested and affected persons had reached substantial agreement on their adoption.[90]

In *Noblecraft*, the Court dismissed objections about inadequate representation on an ANSI committee summarily: 'Congress was aware of ANSI's procedures, and approved the adoption of ANSI standards as national consensus standards.'[91]

American Iron and Steel Institute v OSHA dealt with OSHA's respiratory protection standard. In 1971, OSHA had adopted an ANSI standard under the provision that allowed for bypassing the APA.[92] That standard allowed the use of respirators only when 'effective engineering controls are not feasible'; in practice, the standard disfavoured the use of (cheap) respirators and practically obliged employers to install (expensive) structural controls at possible sources of hazardous gasses, fumes, dusts and the like. When OSHA issued a new standard under the 'normal' notice-and-comment procedures in 1998, it retained that so-called 'Hierarchy-of-Controls Policy' and excluded it from the rulemaking procedure. The Court held that 'it was not unreasonable for OSHA to determine that allowing submission of evidence about the relative merits of engineering controls and respirators would have distracted attention from and clouded the essential issue before it, namely, how respirators should be used *if* they are used.'[93] The interesting comments for present purposes

[89] *Diebold v Marshall* 585 F 2d 1327, 1332 (6th Cir 1978).

[90] *Modern Drop Forge v Secretary of Labor* 683 F 2d 1105, 110 (7th Cir 1982). See also *Diebold,* above n 89, 1331 ('Notice-and-comment requirements could be dispensed with, . . . because these 'interim standards' would have already been subjected to close public scrutiny through the use of *equivalent procedures* in their original issuance.'), (emphasis mine).

[91] *Noblecraft,* above n 88, 203.

[92] 29 USC 655 (a).

[93] *American Iron and Steel Institute v OSHA* 182 F 3d 1261(11th Cir 1999), (emphasis in original).

were made in reaction to two of AISI's objections. First, the 'Hierarchy-of-Controls Policy', established by ANSI and adopted without APA safeguards, had never been subjected to public scrutiny and was thus flawed on procedural grounds. The point is invalid according to the wording of the statute and the Court quickly dismissed it; even if OSHA's authority to adopt private standards without ado lasted only two years, there is no hint in the OSH Act that OSHA was obliged to update the standard and carry it through the normal rulemaking process at any time. The Court added, however, that this 'may be undesirable from a public policy standpoint' only to qualify that point in a footnote with a reference to the procedures followed in establishing 'national consensus standards.'[94] AISI's next argument was that the 'Hierarchy-of-Controls Policy' had outlived its validity since it no longer represented a national consensus standard. This was a groundless allegation, since, as the Court quickly pointed out, the most recent ANSI standard retained the policy.[95] The question is what implications are to be drawn from the fact that OSHA policy reflects private standards. The Court concluded summarily that AISI had failed to demonstrate that OSHA had acted 'unreasonably', and then clarified in another footnote:

> If a party showed that the factual underpinning for a particular standard had evaporated, that might be relevant to the reasonableness of OSHA's decision to exclude the standard from a related proceeding; or, on the other hand, that might constitute a basis for the party to petition OSHA to modify or revoke the standard.[96]

Taken together, the two footnotes constitute something of a regulatory policy. The first strengthens the proposition advanced in the earlier cases that the procedural safeguards provided by standards bodies, subject to oversight of administrative agencies, allows for as meaningful a 'public scrutiny' as administrative procedures do. The recognition is, granted, limited to the clause in the OSH Act that explicitly allows for a derogation from all the due process constraints of 'normal rulemaking', but is significant nonetheless for being a judicial recognition of the procedures of standards-setting. The second footnote reinforces the procedural point by launching the theory that national consensus standards set substantive limits to discretion of OSHA. If the agency follows the standard, it will be given judicial latitude. If the agency decides to depart from a standard, it will be held to a tougher standard of review for 'reasonableness' and could

[94] Above, 1270, n 5.

[95] ANSI Z88.2–1992 was developed by the Lawrence Livermore National Laboratory, an ANSI-accredited standards body managed by the University of California. AISI is an ANSI-accredited standards developer as well.

[96] *American Iron and Steel Institute,* above n 93, 1270, n 8.

be forced to open up that policy decision to the process of 'normal' rulemaking.[97]

The only federal case dealing with administrative adoption of standards outside the framework of the OSH Act's peculiar arrangement is *Cellular Phone Taskforce v FCC*, a classic 'frontiers of science' case.[98] At issue was whether the FCC had been 'arbitrary and capricious' in basing its guidelines for human exposure to radiofrequency radiation partly on ANSI standards, partly on a standard issued by the Congressionally chartered National Council on Radiation Protection and Measurements (NCRP). The FCC decided to update its old guidelines, also based on an ANSI standard, when ANSI issued an updated private standard. The new, stricter, standards as well as the guidelines were tailored to take account of thermal effects of radiofrequency radiation, but declined to take aboard the theory that radiation also produces non-thermal effects. ANSI had found that no 'reliable scientific evidence exist indicating that nonthermal exposure may be meaningfully related to human health' and hence concluded that the standard 'should be safe for all'. FCC relied on this scientific assessment, and the guidelines went through notice and comment procedures unchallenged by agencies such as OSHA, the EPA and the FDA. The Court first repeated that 'in the face of conflicting evidence at the frontiers of science, courts' deference to expert determinations should be at its greatest.'[99] It then noted that 'all of the expert agencies consulted were aware of FCC's reliance on the ANSI and NCRP standards', each being advised of such evidence of non-thermal health effects as may have existed. It continued:

> Under such circumstances it was reasonable for the FCC to continue to rely on the ANSI and NCRP standards absent new evidence indicating that the fundamental scientific understanding underlying the ANSI and NCRP standards was no longer valid. At most, the newly submitted evidence established that the existence of non-thermal effects is 'controversial', and that room for

[97] In *Alabama Power Company v OSHA* 89 F 3d 740 (11th Cir 1996), OSHA based its standard on a co-operative initiative between a trade association, the Edison Electric Institute, and a trade union, the International Brotherhood of Electric Workers. When OSHA decided to diverge from the standard and impose additional requirements, the Court scrutinised the agency's rulemaking in exactly the same way as it does 'normal' rulemaking.

[98] *Cellular Phone Taskforce v FCC* 217 F 3d 72 (2nd Cir 2000). The Taskforce was joined by the 'Ad Hoc Association of Parties Concerned About the Federal Communications Commission Radio Frequency Health and Safety Rules'(!). In that light, it should perhaps not surprise that class actions against mobile phone manufacturers were brought in several state courts 'which, though couched in the language of state tort and contract law, have only one goal—to challenge in state court the validity and sufficiency of the federal regulations on radio frequency radiation from wireless phones.' *In re Wireless Telephone Radio Frequency Emissions Products Liability Litigation* 216 F Supp 2d 474 (D Md 2002). The federal district court assumed jurisdiction 'because plaintiff's suits are a disguised attack on federal law in an area of national importance,' and dismissed all claims.

[99] Above, 90, citing *Baltimore Gas & Electricity Co v Natural Resources Defense Council* 462 US 87, 103 (1983).

> disagreement exists among experts in the field. After examining the evidence, the FCC was justified in continuing to rely on the ANSI and NCRP standards.[100]

This summary substantive scrutiny of scientific validity is accompanied by a procedural requirement to keep abreast of new developments. Here as well, the Court sanctioned the FCC's reliance on the standards bodies:

> [T]he FCC satisfied itself that there was a mechanism in place for accommodating changes in scientific knowledge. It found that both the ANSI and the NCRP has 'committees that are working on revisions their respective exposure guidelines', and that 'ongoing research in a number of areas may ultimately result in changes in the fundamental understandings upon which the ANSI and the NCRP standards are based', and that it would 'consider amending its rules at any appropriate time if these groups conclude that such action is desirable.' Because the new evidence consisted of publicly available scientific papers, the FCC could reasonably expect it to be considered by the ANSI and the NCRP standing committees that were working on revising their standards.[101]

The significance of the case could easily be overstated. It almost certainly will not serve as a precedent for the proposition that an agency can withstand 'hard look' review of its APA obligations by relying on the fact that the standards body, on whose standards its rules are based, had necessarily produced 'substantial evidence' and made a 'rational' decision based on that evidence. First, this case had to do with scientific uncertainty. As noted so vividly by Shapiro, the paradox of the whole 'frontiers of science' doctrine is that deference to agencies, whose legitimacy is grounded in expertise, is greatest in those cases where the agency has to acknowledge that its expertise is insufficient.[102] Second, the case deals with 'horizontal' guidelines, cutting across the jurisdiction of several agencies. The participation of the EPA, OSHA and the FDA in the notice-and-comment procedure assured as it were a double 'filter' for regulatory reception of ANSI's findings.

5. CONCLUSION

Inconclusive as they may be, these decisions seem to point to a way out of the 'legalisation' dilemma; courts should refrain both from subjecting the

[100] Above, 90.

[101] Above, 90–91.

[102] Shapiro, 'The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science-Based Decision-Making' in Joerges and Vos (eds), *Integrating Scientific Expertise into Regulatory Decisionmaking* (Nomos, Baden-Baden, 1997) 325. Cf *Pauley v BethEnergy Mines* 501 US 680, 697 (1991), (deference to agencies all the more appropriate when the regulation 'concerns a complex and highly technical regulatory program' requiring 'significant expertise.')

standardisation process itself to all the strangling ties of the APA and from forcing the agency to re-enact all the debates that led to the standard in the private body on the level of the notice-and comment procedure. Instead, judicial review should focus on the relations between the two levels of decision-making, and differentiate between the cases where the agency follows a standard and where it substitutes its own determination for that of the standards body. In the first scenario, courts can and should demand of the agency to keep the standardisation process under review and hold the agency accountable for that review of the fairness and the scientific validity of that process. This review should emphatically far fall short of demanding that the agency subject the standards body to the same standard of review as courts impose on agencies; rather, standards bodies should be expected to discipline themselves according to a set of procedural rules, an 'internal administrative law' of sorts geared specifically to the exigencies of standardisation.[103] Standards bodies have an enormous incentive to co-operate and adjust their procedures according to such a conception of induced 'public-regardingness'; standards that are incorporated into regulatory frameworks are far more economically useful than standards that are not, and incomparably preferable to public standards. Agencies are then to limit themselves to procedural review and satisfy themselves that the standards body has adopted the standard in accordance with its own internal rules. In the latter case, courts should subject agencies to 'normal' review and demand an explanation of the reasons why they decided to depart from the national consensus standard. 'Normal' review, however, should be far less intrusive and paralysing than current practice and should certainly not amount to making it practically impossible to substitute a public standard for a private one. Whatever residual credibility threats of imposing 'public' regulation rather than relying on private standards has, it should be used to full advantage. Courts should accept the proposition that the credibility of that threat could be a productive factor in ensuring public-regardingness of private standards-setting.

[103] See Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990) 211 *et seq* (discussing standardisation procedures and concluding, at 220, that 'public and private systems look practically alike in the language of administrative procedure'); Freeman, above n 14, 642 (describing ASTM as a 'pseudo-agency' in the light of its 'balanced' committees, procedures and appeal mechanism). Compare Mashaw, *Bureaucratic Justice: Administrative Law From an Internal Perspective* (Yale University Press, New Haven, 1983), (discussing the concept of 'internal administrative law' in the context of the administration of social security and arguing for judicial deference).

9

Politics and the Economy: Linking Institutions in Competition Law

1. INTRODUCTION

Standards bodies are organisations dominated by manufacturers who agree on product specifications. Agreements on specifications necessarily limit product differentiation and hence restrict competition. Moreover, conformity to standards gives economic advantages to economic operators; the whole purpose of a standard is to allow those manufacturers that comply with them to distinguish themselves from those who do not, be it for reasons of compatibility with other products, or for reasons of presumed quality and safety.

Despite the rather obvious antitrust implications of standards, courts and competition authorities in the European Union have only very seldom shown any interest in standards bodies; consequently, standards bodies are blessedly unworried about antitrust.[1] The general novelty of rigorous competition law in Europe is one obvious reason for this state of affairs; only fairly recently, under the impetus of EC law, has the antitrust revolution spread beyond Germany.[2] More specifically and more importantly, however, is the fact that standards bodies in Europe have not generally been considered market players; they have traditionally been heavily regulated and closely tied to public authorities.

[1] See generally Falke and Schepel (eds), *Legal Aspects of Standardisation in the Member States of the EC and EFTA—Volume 2: Country Reports* (Opoce, Luxembourg, 2000). The telecommunications sector is an obvious exception. See eg Kampmann, *Wettbewerbsanalyse der Normung der Telekommunikation in Europa* (Peter Lang, Frankfurt, 1993). Related in particular to the problem of the incorporation of intellectual property rights in compatibility standards, the issue falls outside the scope of the present analysis. Cf Commission, *Intellectual Property Rights and Standardisation*, COM (92) 445/final, 24ff.; Lemley, 'Intellectual Property Rights and Standard Setting Organizations' (2002) 90 *Cal L Rev* 1889; Teece and Sherry, 'Standards Setting and Antitrust' (2003) 87 *Minn L Rev* 1913.

[2] For an overview, see the magnificent Gerber, *Law and Competition in Twentieth Century Europe* (Clarendon Press, Oxford, 1998).

In both respects, the United States constitutes the exact opposite. Caselaw is abundant, and Ross Cheit reports that the fear of antitrust scrutiny exerts considerable influence on standard setters.[3] Most of that fear stems from two high-profile cases from the 1980s, where the Supreme Court rendered sweeping condemnations of standardisation. In *Allied Tube*, the Court held that 'agreement on a product standard is, after all, implicitly an agreement not to manufacture, distribute or purchase certain types of products.'[4] In *ASME v Hydrolevel* the Court considered that 'a standard-setting organization like ASME can be rife with opportunities for anticompetitive activity.'[5] In response to the antitrust threat hanging over standards developers on the one hand, and the growing importance of private standards in federal regulatory policy on the other, Congress went so far as to pass the Standards Development Organizations Advancement Act of 2003.[6] The Act grants antitrust relief to voluntary consensus standards developers by precluding courts from finding standards development per se illegal and by limiting recovery to actual, not treble, damages.[7]

As Cheit is the first to note, the fear has generally been unfounded,[8] and United States courts have actually always been very lenient to standards bodies.[9] Standards have generally been subject to a rule of reason analysis, and hence held to a yardstick of 'unreasonable' restraint of trade. As the First Circuit reiterated in 1999, 'merely to say that the standards are disputable or have some market effects' is not enough to consider them unreasonable under the Sherman Act; 'something else or more extreme' is needed to render standard-setting 'unreasonable'.[10]

[3] Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990) 189.

[4] *Allied Tube & Conduit Corp v Indian Head, Inc* 486 US 492, 500 (1988).

[5] *American Society of Mechanical Engineers v Hydrolevel Corp* 456 US 556, 571 (1982).

[6] 108th Cong US HR 1086, passed by the House on 10 June 2003, passed by the Senate as S 1799 on 2 April 2004.

[7] Such is achieved by giving standards bodies the same treatment as joint ventures under the National Cooperative Research and Production Act of 1993. See the amendments to 15 USC 4302 (rule of reason) and 4303 (limitation on recovery).

[8] Cheit, above n 3, 189.

[9] See Gerla, 'Federal Antitrust Law and Trade and Professional Association Standards and Certification' (1994) 19 *U Dayton L Rev* 471, 503 ('Antitrust courts generally have been favorably disposed toward trade and professional association standards'); Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, Pittsburgh, 1997) 130 (noting an 'extreme unwillingness of the courts to intervene in standard setting.')

[10] *DM Research v College of American Pathologists and National College for Clinical Laboratory Standards* 170 F 3d 53, 57 (1st Cir 1999). This leniency is extended to efforts to influence the standardisation process. See eg *Heary Bros v Lightning Protection Institute* 287 F Supp 2d 1038, 1048 (D Ariz 2003), ('Only *improper* manipulation of the standard-setting process constitutes an unreasonable restraint of trade', and 'mere speech on behalf of or against a proposed standard cannot be held to be improper or unreasonable.'), (emphasis added).

This chapter will first discuss the cases where 'something more extreme' is most easily found: around the edges of the actual process of standardisation. These cases involve not the setting of standards but their use—either in certification or in unfair practices related to standards. Antitrust liability for abuse of standards and standards bodies constitutes minimum contextual regulation of standardisation. Next, I will discuss the possibilities of procedural regulation of the core—the standardisation process itself. Starting from different angles but struggling with basically the same dilemmas, competition law in both the European Union and the United States demand *procedural* guarantees to satisfy antitrust requirements. In Europe, this starts from an attempt to find a functional equivalent to the 'public interest' as embodied by public regulation; in the United States it stems from courts' compensating their deference to expertise. In both, this procedural turn is a bid to solve two dilemmas. The first is how to disentangle market aspects of standards from their regulatory aspects; the second is how to fit 'public interest' criteria of health and safety into the economic analysis to which competition law confines reasoning.

2. CERTIFICATION AND ABUSE: THE UNITED STATES

'Something else or more extreme' certainly took place in *ASME v Hydrolevel*.[11] The vice-president of a company wrote a letter to ASME inquiring whether a product marketed by a competitor, *Hydrolevel*, met a certain standard. He then changed hats and, as vice chairman of the relevant subcommittee, wrote an 'unofficial' interpretation with predictable conclusions in response to his own inquiry and had it signed by the committee chairman. Thanks to the publicity given to this interpretation to *Hydrolevel*'s customers, the latter suffered badly. The Supreme Court took the dramatic step to hold ASME liable for the conduct of not only its employees, but also of voluntary individual standardisers under a theory of 'apparent authority'. First, in light of the fact that ASME's codes were routinely adopted by local an state regulations, it harked back to *Fashion Originators* and classified the standard-setting organisation as an 'extra-governmental agency, which prescribes rules for the regulation and constraint of interstate commerce.'[12] It then proceeded to condemn standard-setting generally:

> Furthermore, a standard-setting organization like ASME can be rife with opportunities for anticompetitive activity. Many of ASME's officials are asso-

[11] *American Society of Mechanical Engineers*, above n 5.

[12] 456 US 556, 571 (1982). Cf *Fashion Originators' Guild of America, Inc v Federal Trade Commission* 312 US 457, 465 (1941). That case concerned a trade association's boycott of 'pirate' products.

> ciated with members of the industries regulated by ASME's codes. Although, undoubtedly, most serve ASME without concern for the interests of their corporate employers, some may well view their positions with ASME, at least in part, as an opportunity to benefit their employers. When the great influence of ASME's reputation is placed at their disposal, the less altruistic of ASME's agents have an opportunity to harm their employers' competitors through manipulation of ASME's codes.[13]

Antitrust liability is then construed as an incentive for ASME to clean up its act:

> Only ASME can take systematic steps to make improper conduct on the part of all its agents unlikely, and the possibility of civil liability will inevitably be a powerful incentive for ASME to take those steps.[14]

The 2003 Act directly overturns *ASME v Hydrolevel* by taking treble damages out of the sphere of the theory of 'apparent authority.' This does explicitly not affect the liability of volunteers on standards committees, in whatever capacity, who are 'engaged in a line of commerce that is likely to benefit directly from the operation of the standards development activity with respect to which any violation of the antitrust laws is found.'[15]

'Something else or more extreme' is alleged to have happened most often in denials of certification to standards rather than in the drafting and adoption of standards themselves. A footnote in *Allied Tube* warned that 'concerted efforts to enforce (rather than just agree upon) private product standards face more rigorous antitrust scrutiny'.[16] Conspired refusal to certify a competitor's product to private standards is subject to *per se* analysis. The *locus classicus* here is an angry Supreme Court's opinion in *Radiant Burners*.[17] In that case, a company's heater was refused a seal of approval by the American Gas Association, a standard-setting trade association of gas suppliers and equipment producers. That refusal closed off the market immediately as gas suppliers—members of the AGA—refused to hook up the product in question to their lines, forcing purchasers to go to *Radiant*'s competitors—members of the AGA. Under the rule of reason analysis of the Appellate Court, the AGA was not found liable. The Supreme Court reversed, and the AGA settled with Radiant before the case came back to the Seventh Circuit for decision on the merits.[18] It seems settled, on the other hand, that private certification programs that certify compliance with federal safety standards fall under the Rule of Reason. In

[13] *American Society of Mechanical Engineers,* above n 5, 571.
[14] Above, 572.
[15] Section 5, Standards Development Organizations Advancement Act of 2003, 108th Cong US HR 1086, amending 15 USC 4303.
[16] *Allied Tube*, above n 4, 501.
[17] *Radiant Burners v People's Gas Co* 364 US 656, 659 (1961). Cf *Northwest Stationers v Pacific Stationery* 472 US 284 (1985).
[18] Krislov, above n 9, 131.

Moore,[19] the Seventh Circuit held two marine industry trade associations liable under the *per se* rule for refusing to certify a type of boat trailer lamps. At issue, however, was the lamp's compliance with federal safety standards promulgated by the National Highway Traffic Safety Administration. After the decision to subject the program to *per se* analysis had been vacated on other grounds,[20] the Court came back on its ways and held that 'there is no justification for applying a per se analysis' to the 'commendable effort' to promote compliance with federal safety standards.[21]

Generally, Appellate Courts have been almost as lenient towards certification schemes as towards standard setting proper: 'it is not intrinsically an antitrust violation for an organization to limit its endorsement to those who meet its published standard.'[22] The Sixth Circuit specified the conditions for *per se* analysis in *Eliasen*:

> Where the alleged boycott arises from standard-making or even industry self-regulation, the plaintiff must show either that it was barred from obtaining approval of its products on a discriminatory basis from its competitors, or that the conduct as a whole was manifestly anti-competitive.[23]

The First Circuit even went so far as to give the American Petroleum Institute some leeway in its decisions whether or not to approve certain products:

> [I]t is not enough . . . that the plaintiff was harmed because the defendant refused without justification to promote, approve, or buy the plaintiff's product. Neither anti-competitive animus nor the other elements of a Section 1 claim can be inferred solely from the incorrectness of single business decision of a standard-setting trade association. . . . An individual business decision that is negligent or based on insufficient facts or illogical conclusions is not a sound basis for antitrust liability.[24]

3. CERTIFICATION AND ABUSE: THE EUROPEAN COMMUNITY

On two occasions, the European Courts upheld Commission decisions finding an infringement of Article 81 (1) by certification bodies. In *IAZ*,[25]

[19] *Moore v Boating Industry Associations* 754 F 2d 698 (7th Cir 1985).

[20] *Boating Industry Associations v Moore* 474 US 895 (1987). The Supreme Court remanded for further consideration in the light of *Northwest Stationers*, above n 17, on the issue of whether the absence of fair procedures warrants *per se* analysis for self-regulation. See below.

[21] *Moore v Boating Industry Associations* 819 F 2d 693, 695, 711 (7th Cir 1987).

[22] *DM Research*, above n 10, 58.

[23] *Eliasen Corp v National Sanitation Foundation* 614 F 2d 126, 129 (6th Cir 1980).

[24] *Consolidated Metal Products, Inc v American Petroleum Institute* 846 F 2d 284, 297 (5th Cir 1988).

[25] Joined Cases 96 to 102, 104, 105, 108 and 110/82 *IAZ and others v Commission* [1983] ECR 3369, an action against Commission Decision No IV/29.995– NAVEWA–ANSEAU, (1982) OJ L 1657/39.

the Court of Justice was confronted with facts very similar to those in *Radiant Burners*. The *Communauté de l'Electricité* (CEG) and other Belgian trade associations of manufacturers and sole importers of dishwashers and washing machines concluded an agreement with the National Association of Water Suppliers (ANSEAU) to monitor compliance with Belgian regulations of water quality. That legislation provided that only appliances equipped with certain devices and complying with Belgian standards were to be connected to the water supply system. To that end, they set up a mechanism whereby CEG issued conformity labels and ANSEAU ensured that only machines bearing that label were put in commercial distribution.

> The Agreement was implemented in such a way that the CEG, which alone was authorised to issue the labels, supplied them only to official manufacturers and importers and requested dealers wishing to obtain the labels either to produce proof of their status as sole importers or to appoint a sole importer in Belgium. For its part, ANSEAU played an active part in supervising the affixing of labels and drew the attention of dealers and consumers to the possible consequences of failure to affix them.[26]

The Court read this case as a private attempt to re-compartmentalise the internal market by restricting parallel imports, and showed it as little tolerance as it does to plain exclusive distribution agreements.[27]

In a more recent case, the Court of First Instance was faced with the *Stichting Certificatie Kraanverhuurbedrijf,* a certification body set up by Dutch firms hiring out mobile cranes.[28] The SCK certified companies to compliance with a range of statutory and other requirements, both regarding the management of a crane-hire firm and the use and maintenance of the cranes themselves. The aspect of the scheme the Commission took issue with was the clause in the SCK's rules prohibiting certified firms from sub-contracting non-certified firms. In a sector where hiring cranes from sub-contractors is essential to be able to meet demand, this restricted the freedom of affiliated firms and competition between them and impeded access to the market by firms based in other Member States.

The Court of First Instance had to deal with the same basic dilemma American courts faced. Any certification system by its very nature confers competitive advantages on those it certifies in relation to those it does not. By giving a stamp of approval to some and not to others, it necessarily makes it harder for the latter to compete with the former; and this is true regardless of whether certification sees to statutory requirements or

[26] Above, para 5.

[27] The *locus classicus* for the use of competition law as a complement to the free movement of goods is Joined Cases 46 and 58/65 *Consten and Grundig v Commission* [1966] ECR 299.

[28] Joined Cases T–213/95 and T–18/96 *SCK and FNK v Commission* [1997] ECR II–1739, an action against Commission Decision IV/34.179– SCK and FNK, (1995) OJ L 312/79.

private standards. Yet a certification system also increases market transparency by allowing the quality and safety of products or services to be assessed. Unless every refusal to grant a certificate is thus to be held in breach of Article 81 (1) save for judicial approval of the technical grounds for that decision on a case by case basis, some distinguishing criterion must be found. Recognition by the public authorities and compliance with Commission-promoted standards is not an option:

> The fact that SCK is a certification institution recognised by the Certification Council and complies with the pertinent European standards (the EN 45 000 series) does not prevent Article 85 (1) being applicable. The fact that the SCK rules are being recognised by the Certification Council does not in any case serve as authority to act in breach of Article 85 (1).[29]

Instead, the Commission's decision came up with this:

> If associated with a certification system which is completely open, independent and transparent provides for the acceptance of equivalent guarantees from other systems, it may be argued that it has no restrictive effects on competition but is simply aimed at fully guaranteeing the quality of the certified goods or services.[30]

Since the Commission only applied the first and fourth of those conditions, the Court of First Instance was mercifully excused from discussing 'independence' as a condition for escaping the prohibition of Article 81 (1) EC. If the Commission is really serious about that condition, certification as an exercise of industry self-regulation is impossible. As it stands now, the 'openness' requirement is clear: the system must grant access on a non-discriminatory basis. The acceptance of 'equivalent guarantees', on the other hand, presents a dilemma. The Court considered the condition 'pertinent':

> The prohibition on hiring preventing certified firms from calling on the services of uncertified firms even if they provide guarantees equivalent to those of the certification system cannot be objectively justified by an interest in maintaining the quality of the products and services ensured by the certification system. On the contrary, the failure to accept equivalent guarantees offered by other systems protects certified firms from competition by uncertified firms.[31]

The policy point is obvious, and bringing it up against a regulatory authority in a case concerning the free movement of goods would have been uncontroversial. But the Court here had classified SCK as an 'undertaking' for purposes of Community competition law for the very reason that it carried out 'an economic activity which in principle may be engaged

[29] Commission Decision IV/34.179– SCK and FNK, (1995) OJ L 312/79, para 18.
[30] Above, para 23.
[31] *SCK and FNK v Commission*, above n 28, para 137.

in by a private undertaking and with a view to a profit',[32] namely 'the issue of a certificate in return for payment'.[33]

Now, certification bodies make a profit by asking money in return for a powerful marketing instrument—being readily identified as complying with strict standards of quality and safety. That marketing instrument will only be powerful if only firms actually meeting the requirements are certified, and if the certificate is the only means to demonstrate compliance. If certification bodies are obliged to accept 'equivalent guarantees', their profitability will hurt in the short run by losing clients and in the long run by losing credibility and visibility. Certification will thus lose its value as a powerful marketing instrument, and firms will have less of an incentive to seek it. They will then also lose the incentive to meet high standards of quality and safety.

The paradox at play here is fundamental, and will come up again and again. Superficially, it consists of the Court's using competition law to force the organisation to behave in such a way as to make it immune from competition law. More fundamentally, the Court uses competition law to force the organisation to behave as a regulatory authority and aim at the improvement of health and safety at the expense of economic considerations when those economic considerations are what makes private certification such a useful instrument in the regulation of health and safety in the first place.

Both certification cases dealt with private systems monitoring compliance with statutory requirements. Unlike the Court of Justice in *IAZ*, the Court of First Instance in *SCK* was forced to deal with some fundamental issues arising from this connection with the public sphere. These came up in the review of the Commission's decision not to grant SCK an exemption under Article 81 (3) EC, rejecting SCK's arguments about the benefits of the system. SCK argued that that the public system of monitoring compliance with statutory requirements was far less effective than its own scheme. The Court held on this point:

> It must be borne in mind that it is in principle the task of the public authorities and not of private bodies to ensure that statutory requirements are complied with. An exception to that rule may be allowed where the public authorities have, of their own will, decided to entrust the monitoring of compliance with statutory requirements to a private body. In this case, however, SCK set up a monitoring system parallel to the monitoring carried out by the public authorities without there being any transfer to SCK of the monitoring powers exercised by the public authorities.[34]

[32] The formula was first floated in Case C–41/90 *Höfner v Macroton* [1991] ECR I–1979, para 21.

[33] *SCK and FNK v Commission*, above n 28, para 117.

[34] Above, para 194. Further down in the same paragraph, the Court even suggested that public failure is as good as official delegation where it notes SCK's failure to show 'that there were gaps in the monitoring of the statutory requirements carried out by the public authorities which could have made it necessary to set up a private monitoring system.'

This is, however, a dangerous statement to make in light of the 'Global approach'. The Commission's decision had held firm:

> The fact that the Commission's policy on certification allows scope for private-law certification systems that are designed to provide supplementary monitoring of compliance with statutory provisions cannot detract from the principle that the details of such systems must conform to the competition rules laid down in the Treaty. Restrictions on competition that are caught by Article 85 (1) cannot therefore be justified solely on the grounds that the introduction of a certification system necessarily fits in with the Commission's certification system.[35]

SCK argued furthermore that benefits of higher levels of quality and safety accrued from its imposing requirements over and above those stipulated by the legislator. The Court rejected the point for SCK, but seemed to accept the general principle:

> The added value of a certification system does not derive merely from the fact that it imposes obligations not laid down by law. SCK's certification system could have real added value only if the conditions imposed by it were appropriate for the purpose of the attaining the objective pursued, which is to guarantee clients' increased safety.[36]

4. ANTITRUST IMMUNITY: THE UNITED STATES

4.1 Introduction

The Congressional findings for the Standards Development Organizations Advancement Act of 2003 neatly sum up the policy issues involved with the judicial treatment of standards bodies under the antitrust laws:

> Standards developed by government entities generally are not subject to challenge under the antitrust laws.
>
> Private developers of the technical standards that are used as Government standards are often not similarly protected, leaving such developers vulnerable of being named as co-defendants in lawsuits even though the likelihood of their being held liable is remote in most cases, and they generally have limited resources to defend themselves in such lawsuits.
>
> Standards development organizations do not stand to benefit from any antitrust violations that might occur in the voluntary consensus standards development process. . . .
>
> [I]f relief from the threat of liability under the antitrust laws is not granted to voluntary consensus standards bodies, both regarding the development of new standards and efforts to keep existing standards current, such bodies

[35] Commission Decision IV/34.179– SCK and FNK, (1995) OJ L 312/79, para 38.
[36] *SCK and FNK v Commission*, above n 28, para 202.

> could be forced to cut back on standards development activities at great financial cost both to the Government and to the national economy.[37]

On the theory that the Sherman Act regulates business, not politics, the Supreme Court has enunciated two doctrines to protect the political process from antitrust scrutiny. The state action doctrine, first established in *Parker*, immunises government;[38] the doctrine of 'petitioning immunity', established in *Noerr*, protects citizens' involvement in politics.[39] The dichotomy works fine for simple cases: *Parker* protects public regulation, however anti-competitive, on the theory that the political process should be left to determine what is best for the 'public interest'; *Noerr* recognises that the political process needs the input of citizens and interest groups and hence immunises lobbying even if its purpose is to eliminate competition.[40]

Both doctrines are premised on a neat public/private distinction hard to reconcile with the messy realities of self-regulation in general and standardisation in particular. Does *Parker* immunity extend to private parties' exercise of regulatory functions? Does *Noerr* protect efforts to influence the decision-making of those private parties?

Parker immunity is certainly not granted on the grounds of the public interest served by private actions. The Supreme Court has narrowed down what it is prepared to classify as 'state action' to those actions that are 'traditionally exclusively the prerogative of the State'.[41]

Nor does status as a public law body necessarily offer protection. In *Goldfarb*, the Virginia State Bar was told that the fact that it was a 'state agency for some limited purposes' did not create an 'antitrust shield that allows it to foster anti-competitive practices for the benefits of its mem-

[37] Section 2, Standards Development Organizations Advancement Act of 2003, 108th Cong US HR 1086 and S1799. See also the testimony of David L Karmol, Vice President of Public Policy and Government Affairs, ANSI, before the Taskforce on Antitrust of the House Judiciary Committee, 9 April 2003 ('As a result of the increasing number of laws passed by the Congress since the early 1990's mandating government adoption and use of standards, and participation in private standards development, the standards community actually is performing some critical development functions that were previously the exclusive province of government agencies. As standards developers take on the role of government in formulating consensus standards, they arguably deserve some of the exemptions from liability that the government has traditionally enjoyed, such as relief from potentially onerous antitrust liability exposure.')

[38] *Parker v Brown* 317 US 341 (1943).

[39] *Eastern Railroad Presidents Conference v Noerr Motor Freights* 365 US 127 (1961).

[40] See *United Mine Workers v Pennington* 381 US 657, 670 (1965), ('Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act').

[41] *Jackson v Metropolitan Edison Co* 419 US 345, 353 (1974). This excludes, for example, utilities and schools. The 'government function' doctrine was developed to decide whether infringements of Fifth and Fourteenth Amendment rights could be attributed to the State. The Fourth Circuit applied the test to the antitrust state action doctrine in *United Auto Workers v Gaston Festivals* 43 F 3d 902 (4th Cir 1995).

bers'; only if it had been *compelled* by state legislation to violate the Sherman Act could immunity have been available.[42]

Under *Parker*, immunity is granted only to the state 'acting as sovereign.'[43] For principles of federalism, the Supreme Court abstains from second-guessing motives and consequences of anti-competitive state legislation, nor will it analyse whether the restraint is proportional to the objectives pursued. It only demands that the policy and the ensuing restraints on competition be a product of conscious political choice. In 1980, the Court in *Midcal* articulated a two-prong test for this condition to be satisfied: first; the restraint on competition must be 'clearly articulated and affirmatively expressed as state policy', and second, the policy must be 'actively supervised.'[44] In 1985, it clarified the *Midcal* test in two respects. First, in *Hallie v Eau Claire* it held that the 'active supervision' only applies where private parties carry out the anti-competitive conduct. It grounded that holding thus:

> Where a private party is engaged in the anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interests of the State. Where the actor is a municipality, there is little or no danger that it is involved in a private price-fixing arrangement.[45]

Second, it accepted the mirror-image of *Midcal* in *Southern Motor Carriers*: if passing the two tests protects the public authorities from the consequences of authorising or enforcing anti-competitive conduct by private parties, that same private conduct must be immunised as well. Otherwise, the Parker doctrine 'would stand for little more than the proposition that Porter Brown sued the wrong parties.'[46]

Southern Motor Carriers also retracted the 'compulsion' requirement under the first test: immunity is now available for private parties where state policy 'expressly permits' violations of the Sherman Act.[47] That leniency is compensated for by the Court's strict requirements under the 'active supervision' test: unsupervised collusion that advances the policy at issue or is directed at ensuring compliance of statutory requirements

[42] *Goldfarb v Virginia State Bar* 421 US 773, 791 (state agency), 789 (compulsion), (1975).
[43] Above, 790.
[44] *California Liquor Dealers v Midcal Aluminium* 445 US 97, 105 (1980).
[45] *Hallie v Eau Claire* 471 US 34, 47 (1985).
[46] *Southern Motor Carriers Rate Conference v US* 471 US 48, 57 (1985).
[47] 471 US 48, 61 (1985). In *Hallie*, above n 45, 42, the Court watered down the first test as applied to municipalities to the restraint being the 'foreseeable result'. The Ninth Circuit now explicitly extends that test to private parties. See *Nuggett Hydroelectric v Pacific Gas and Electric* 981 F 2d 429 (9th Cir 1992); *Columbia Steel Casting v Portland General Electric* 60 F 3d 1390 (9th Cir 1995). Though the Supreme Court has yet to pronounce itself on the issue, it seems unlikely to agree. In *Hallie*, it grounded the relaxation of *Goldfarb*'s 'compulsion' test explicitly on the proposition that 'we may assume that the municipality acts in the public interest. A private party, on the other hand, may be presumed to be acting primarily on his or its own behalf'. 471 US 34, 45 (1985).

receives antitrust condemnation.[48] In *Midcal* itself, the Court had no patience for California's policy of rubber-stamping winegrowers' price-fixing:

> The state simply authorises price setting and enforces the prices set by private parties. The state neither established prices nor reviews the reasonableness of the price schedules. . . . The national policy in favour of competition cannot be thwarted by casting such a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement.[49]

The Court specified later the 'mere presence of some state involvement or monitoring does not suffice', and that the test requires that 'state officials have *and exercise* power to review particular anti-competitive acts by private parties.'[50] Specifically,

> [w]here prices or rates are set as an initial mater by private parties, subject only to a veto if the state chooses to exercise it, the party claiming the immunity must show that state officials have undertaken the necessary steps to determine the specifics of the price fixing or ratesetting scheme. The mere potential for state supervision is not an adequate substitute for a decision by the state.[51]

The state action doctrine is widely seen as an unsatisfactory attempt to reconcile a conflict between 'the national policy in favour of competition' and the democratically legitimated autonomy of state legislatures to decide to displace the market with a regulatory structure to further objectives of socio-economic policy. The Court renounces both substantive legality tests and close scrutiny of decision-making processes in favour of a demand of clear allocation of responsibility. The problem of a possible substantive standard is, of course, that antitrust law hardly allows any other public interest criterion than 'efficiency'.[52] Absent a judicial catalogue of 'legitimate' substantive public interests overriding the objective of undistorted competition, the only way to avoid either such *Lochnerism* or absolute deference to whatever public authorities claim to be in the public interest is to scrutinise the decision-making process. And such a move would bring good governance concepts of administrative law into antitrust analysis. Mashaw's demand for 'public-regarding' legislation is a combination of substantive and process concerns. He would only

[48] *FTC v Indiana Federation of Dentists* 476 US 447 (1986).

[49] *California Liquor*, above n 44, 105–6.

[50] *Patrick v Burget* 486 US 94, 101 (1988), (emphasis added).

[51] *FTC v Ticor Title Insurance* 504 US 621 (1992).

[52] Which is more than enough to justify an end to the 'inverse preemption' of the state action doctrine for Easterbrook, 'Antitrust and the Economics of Federalism' (1983) 26 *J L & Econ* 23. Inman and Rubinfeld, 'Making Sense of the Antitrust State Action Doctrine: Balancing Political Participation and Economic Efficiency in Regulatory Federalism' (1997) 75 *Texas L Rev* 1203 seek to reconcile the conflict under principles of federalism; by supplementing Midcal with a 'significant spillover' test, they would deny exemption to state regulations which have a significant impact on interstate trade.

exempt legislation that can make 'a coherent and plausible claim to serve some public, rather than a merely private, interest'.[53] Courts should look

> for a combination of substantive and decision-process 'danger signals' that together would suggest that legislation is essentially private-regarding—that it benefits some group in ways that cannot convincingly be explained in terms of a broad range of possible public purposes, or in terms of a well-functioning democratic process.[54]

The problem with such an approach inspired by interest group-theory and capture concerns is the same problem inherent in public choice work in general. The combination of outcome and process makes it impossible to establish a standard in the one independent of the other: outcome is judged in terms of process, and process in terms of outcome. A state measure that benefits a certain group will be struck down if there is evidence that that particular group has exercised political pressure. A political decision-making process will be considered flawed if the outcome of that process favours a certain participant in that process over another. The fundamental flaw of these schemes is that judicial review will amount to second-guessing legislative motive. In *Omni Outdoor Advertising*, Justice Scalia for the Court rejected any such reasoning. A 'conspiracy' exception to *Parker* would 'virtually swallow up the *Parker* rule' since it is 'both inevitable and desirable that public officials often agree to do what one or another group of private citizens urges upon them.'[55]

> Few governmental actions are immune from the charge that they are 'not in the public interest' or in some sense 'corrupt'. . . . The fact is that virtually all regulation benefits some segments of society and harms others; and that is not universally considered contrary to the public good if the net economic loss to the losers exceeds the net economic gain to the winners. Parker was not written in ignorance of the reality that the determination of 'the public interest' in the manifold areas of government regulation entails not merely economic and mathematical analysis but value judgment, and it was not meant to shift that judgment from elected officials to judges and juries.[56]

If the public authorities are thus protected from adopting as policy what private interests urge them to do for their private interests, the next possibility would be to conceive of a 'conspiracy' exception to *Noerr* and hold at least those private parties liable. The Court, however, rejected that theory as well emphasising the internal coherence between the two doctrines:

[53] Mashaw, 'Constitutional Deregulation: Notes Toward a Public, Public Law' (1980) 54 *Tulane L Rev* 849, 867.

[54] Above, 875. Cf WiIey, 'A Capture Theory of Antitrust Federalism' (1986) 99 *Harv L Rev* 713, 743 (state regulation to be struck down if it does not respond to a substantial market failure and if it is the product of 'capture' in the sense that that it originated from the decisive political efforts of producers who stand to profit from the compeitive restraint).

[55] *Columbia v Omni Outdoor Advertising* 499 US 365, 375 (1991).

[56] Above, 377.

> The *Noerr*-invalidating conspiracy alleged here is just the *Parker*-invalidating conspiracy viewed from the standpoint of the private sector participants, rather than the governmental participants. The same factors which make it impracticable or beyond the purpose of the antitrust laws to identify and invalidate lawmaking that has been infected with private interests likewise makes it impracticable or beyond that scope to identify and invalidate lobbying that has produced selfishly motivated agreement with public officials.[57]

For the same reasons he objects to more intrusive administrative judicial review on the basis of interest-group theory,[58] Einer Elhauge expels from his reconstruction of both the state action doctrine and the petitioning immunity doctrine any consideration as regards the substance of the restraint or the motives behind it. The Court, he argues, implicitly employs a 'functional process view' of how to separate the political process from competitive market processes. The focus is exclusively on finding an objective standard in the decision-making process:

> Antitrust law does not stand for the proposition that all economically inefficient restraints of market competition are against the public interest. Rather, antitrust stands for the more limited proposition that those who stand to profit financially from restraints of trade cannot be trusted to determine which restraints are in the public interest and which are not.[59]

Hence, immunity is granted to state regulation whenever 'financially disinterested and politically accountable persons' make and take control over the decision restraining competition.[60] *Noerr*-immunity derives from this basic model: 'if the decision-making process is thus sufficiently reliable to merit antitrust immunity, the petitioning that provided the input to that decision-making process should also be immune.'[61] Protected by the umbrella of the political arena, conduct is immunised by *Noerr* even if its sole purpose is to eliminate competition and its methods are deceptive or unethical.[62] In *Noerr* itself, the Court suggested that immunity would be granted for any 'genuine effort to influence legislation'.[63]

[57] Above, 383.

[58] Elhauge, 'Does Interest Group Theory Justify More Intrusive Judicial Review?' (1991) 101 *Yale L J* 31.

[59] Elhauge, 'The Scope of the Antitrust Process' (1991) 104 *Harv L Rev* 667, 672.

[60] Above, 671.

[61] Elhauge, 'Making Sense of Antitrust Petitioning Immunity' (1992) 80 *Cal L Rev* 1177, 1199. The two doctrines do not always coincide. Elhauge argues that petitioning immunity may apply where the state action doctrine does not (merely urging financially interested officials to fix prices) and vice versa (organising a boycott to convince financially disinterested officials to fix prices).

[62] *Noerr*, above n 39, 139.

[63] Above, 144. The 'genuine effort' was coined to fence off the only exception to the doctrine officially allowed, the 'sham' exception for situations where conduct 'is a mere sham to cover up what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor'.

4.2 Standards Bodies as Political Institutions

Allied Tube v Indian Head dealt with the National Fire Protection Association, an ANSI-accredited standards developer whose Electric Code is adopted nation wide by local and state regulators. A standard adopted on committee level would allow the use of PVC in electric conduit and not, as before, only steel. Fearing the competition, Allied Tube, the nation's biggest steel conduit producer, agreed with other producers, sales agents and other members of the industry to pack the NFPA's General Assembly and vote the standard down.[64] Allied sought *Noerr*-immunity on the basis of two theories. The first is the flip side of basic state action immunity. Rejecting the argument that the NFPA was in effect a governmental agency, the Court held:

> [T]he Association cannot be treated as a 'quasi-legislative' body simply because legislatures routinely adopt the Code the Association publishes. Whatever de facto authority the Association enjoys, no official authority has been conferred on it by any government, and the decision-making body of the Association is composed, at least in part, of persons with economic incentives to restrain trade. 'We may presume, absent a showing to the contrary, that a government acts in the public interest. A private party, on the other hand, may be presumed to be acting primarily on his or its own behalf.'[65] The dividing line between restraints resulting from governmental action and those resulting from private action may not always be obvious. But where, as here, the restraint is imposed by persons unaccountable to the public and without official authority, many of whom have personal financial interests in restraining competition, we have no difficulty concluding that the restraint has resulted from private action.[66]

There thus seem to be three conditions to be fulfilled by decision-making bodies to qualify for state action immunity; official authority, political accountability, and financial disinterest. The first condition, however, seems unduly formalistic and, more importantly, in flat contradiction to the holding in *Goldfarb* that being a 'state agency' does not provide an

[64] This involved Allied itself arranging for 155 persons—including employees, sales agents, agents' employees, company executives and the wife of the national sales director to register as voting members and attend the meeting, all at the company's considerable expense. With another 75 votes arranged in similar fashion by other steel interests, Allied managed to get the proposal defeated by a 394–390 vote. See *Indian Head, Inc v Allied Tube & Conduit Corp* 817 F 2d 938, 940 (2nd Cir 1987).

[65] The quote is from *Hallie*, above n 45, 45.

[66] *Allied Tube*, above n 4, 501. Allied's argument was bolstered by the fact that its complaints against a competitor's obstructive dealings within the NFPA were dismissed on the same grounds in *Wheeling-Pittsburgh Steel Corp v Allied Tube & Conduit Corp* 573 F Supp 833, 842 (ND Ill 1983), (granting *Noerr*-immunity on the basis that the NFPA should be considered a 'quasi-legislative' body). Cf *Rush-Hampton Industries v Home Ventilating Institute* 419 F Supp 19 (MD Fla 1976), (granting *Noerr*-immunity on the basis that BOCA, ICBO and the SBCCI should be considered 'quasi-administrative' bodies).

antitrust shield.[67] Political accountability presents more problems. It seems relatively clear that is not a sufficient condition; Elhauge is adamant that political accountability does not and should not save a restraint imposed by financially interested actors.[68] The open question is whether financial disinterest is sufficient to immunise a restraint brought about by unaccountable actors who do not exercise official authority.[69]

In the wake of *Allied Tube*, the Supreme Court vacated and remanded a Ninth Circuit decision granting *Noerr* immunity to efforts to influence a standard set by the Western Fire Chiefs Association.[70] The WFCA is responsible for the Uniform Fire Code, which is adopted into municipal law by many local governments; even where it is not, local officials generally enforce it by refusing to issue permits for products or processes that are not in conformity.

Membership of the WFCA as a whole and of the UFC Committee is limited to public officials; representatives of private industry and others can only sit on subcommittee level. The president of Joor, a manufacturer of steel tanks designed for underground storage of hazardous fluids, sat on such a subcommittee. His business under threat from Sessions's much cheaper technique for 'lining' leaking tanks by opening them up, coating them with epoxy, and sealing them up again, he managed to persuade all levels of the standards body to effectively ban the tank lining process from the standard.

On remand,[71] the Ninth Circuit felt barred from founding antitrust immunity on the basis of the WFCA's members being accountable public officials with no financial interests in the restraint, presumably on the basis of the Supreme Court's reference to 'official authority'.[72] The question is still far from settled, however. The Supreme Court added an ambiguous footnote to *Allied* suggesting not only that 'official authority' was not necessary but even that 'financial disinterest' was the only criterion:

> Our holding is expressly limited to cases where an economically interested party exercises decision-making authority in formulating a product standard for a private association that comprises market participants. . . .[73]

[67] *Goldfarb*, above n 42, 791. Cf *Continental Ore v Union Carbide* 370 US 690 (1962), (denying immunity to an agent of the Canadian government). See Elhauge, above n 59, 690 (the 'clearest lesson' from these two cases is that 'conferring "official" authority on otherwise "private" actors does not render their exercise of that authority "state action" immune from antitrust review;' the Court's reference to the lack of official authority in *Allied Tube* is thus 'unnecessary to its reasoning').

[68] Elhauge, above n 59, 712 ff.

[69] Above, 738 ff.

[70] *Sessions Tank Liners v Joor* 487 US 1213 (1988), vacating *Sessions Tank Liners v Joor* 827 F 2d 458 (9th Cir 1987).

[71] The case came back on appeal of the District Court's condemnation of Joor; *Sessions Tank Liners v Joor* 786 F Supp 1518 (CD Cal 1991).

[72] *Sessions Tank Liners v Joor* 17 F 3d 295 (9th Cir 1994).

[73] *Allied Tube*, above n 4, 510 n 13.

The Court then denied that this description encompasses all private standards bodies, and under direct reference to *Sessions*, asserted that 'many such associations are composed of members with expertise but no economic interest in suppressing competition.'[74]

For its second theory, Allied cast the net further in search of protective state involvement. Local and state legislatures, lacking expertise and resources to second-guess the Code, adopt it without ado. Participation in the standards body, then, is, if not the only, certainly the most effective way of influencing legislation. At issue, then, was not the effort to influence decision-making in the Association but the effort to influence that legislation. And there can be no doubt that state and local regulations adopting the Code are protected by the state action doctrine. To reject this argument, the Court had to be explicit in holding that the *Noerr* doctrine does not immunise every concerted effort that is 'genuinely intended to influence government action'; immunity now depends not only on the activity's impact, but also on the 'context and nature of the activity'.[75] The activity at issue, then,

> did not take place in the open political arena, where partisanship is the hallmark of decision-making, but within the confines of a private standards-setting process. The validity of conduct within that process has long been defined and circumscribed by the antitrust laws without regard to whether the private standards are likely to be adopted into law. Indeed, because private standard-setting by associations comprising firms with horizontal and vertical business relations is permitted at all under the antitrust laws only on the understanding that it will be conducted in a nonpartisan manner offering pro-competitive benefits, the standards of conduct in this context are, at least in some respects, more rigorous that the standards of conduct prevailing in the partisan political arena or in the adversarial process of adjudication. . . .
>
> Although one could reason backwards from the legislative impact of the Code to the conclusion that the conduct at issue here is 'political', we think that, given the context and nature of the conduct, it can more aptly be characterized as commercial activity with a political impact. Just as the antitrust laws should not regulate political activities simply because those activities have a commercial impact, so the antitrust laws should not necessarily immunize what are in essence commercial activities simply because they have a political impact.[76]

Having *Sessions Tank Liners v Joor* back before it in 1994, the Ninth Circuit Court gave another twist to the public/private distinction. It being established that the legislative impact of the Code in itself was not enough

[74] Above. In a case brought against pre-consensus IAPMO, a federal District Court granted *Noerr* immunity on the basis that model code decisions were made by 'a disinterested group of government representatives'. *Solahart Industries v IAPMO* 1996 WL 765978 (SD Cal 1996), affirmed in *Solahart Industries v IAPMO* 141 F 3d 1179 (9th Cir 1998).

[75] *Allied Tube*, above n 4, 503, 504.

[76] *Allied Tube*, above n 4, 507.

to render the standards body 'public', the Court now applied *Noerr* immunity not on the basis of the nature of the decision-making process but on the basis of the source of the damages suffered. Whereas Allied Tube lost market force from the stigma of having its product banned from the standard, Sessions failed to show any damages resulting from anything else than from permit denials by public authorities applying the Uniform Fire Code. The injuries thus suffered 'flowed directly from government action',[77] and not, as the phrase in *Allied* went, 'from the effect the standard has of its own force in the marketplace.'[78] On that basis, the Court found the case to be 'entirely out of the realm of *Allied*.'[79]

What the circuit Court does here is in effect 'reason backwards' from the enforcement of the Code by public officials to its commercial impact. Restraints imposed by public officials are protected by *Parker*; efforts to influence the grounds on which public officials restrain competition are protected by *Noerr*.

> Unlike private actors acting in combination, disinterested governmental decision-makers who take measures to inhibit competition are accountable politically and procedurally to those affected by the anti-competitive measures. The policies underlying the Sherman Act do not obtain in this context. To rule otherwise and hold Joor liable for injuries flowing from governmental decision-makers' imposition of an anti-competitive restraint, we would have to find that the restraint was imposed because of Joor's petitioning efforts. Proof of causation would entail deconstructing the decision-making process to ascertain what factors prompted the various governmental bodies to erect the anti-competitive barriers at issue. This inquiry runs foul of the principles guiding the Parker and Noerr decisions.[80]

The Court's resolve to do away with an untenably formalistic public/private distinction in the analysis of the *process* of standards-setting, however, may have led it to replace it with an untenable public/private distinction in the analysis of the *application* of standards. Disentangling 'pure' market effects of a standard from effects resulting from government codification or use of standards relies on a straightforward state-market distinction in the diffusion of standards.[81] Problems with that model are not hard to imagine. Most obviously, there is a difference between geographical spread of market—and political enforcement. If insurer Y relies on a standard X both in state A and state B, and public officials use standards only in state A, does

[77] *Sessions Tank Liners,* above n 72.
[78] *Allied Tube,* above n 4, 510.
[79] *Sessions Tank Liners,* above n 72.
[80] Above. Cf *Santana Products v Bobrick Washroom Equipment* 249 F Supp 2d 463 (MD Pa 2003). The Court makes references to *Parker v Brown,* above n 38, 352, and Elhauge, above n 61, 1240–43.
[81] See Spruyt, *Actors and Institutions in the Historical Evolution of Standard Setting,* Paper presented at the Conference 'The Political Economy of Standard Setting' (EUI, Florence, June 1998), (discussing different 'diffusion' models).

a product's ban from X in B produce damages 'from the effect the standard has of its own force in the marketplace'?

Second, the model needs some sort of criterion to distinguish 'political' from 'economic' government action. If public purchasers apply a standard and private purchasers decide to follow that course, does that standard have an 'effect of its own force in the marketplace'?

Parker and *Noerr* operate on the separation of the political and economic spheres; the only way for standards bodies to find refuge is thus to find a link with political decision-making.

Under such a formal institutional conception of the public interest, no amount of procedural guarantees and claims of 'objective expertise' will grant standards bodies the immunity reserved to public authorities. This is the fundamental choice of American antitrust law.

4.3 From 'Reasonable' Restraints to Legitimate Governance

Standards are subjected to antitrust analysis and will be saved only if they constitute 'reasonable' restraints of competition. It is clear from *Allied* and *ASME v Hydrolevel* that abuse and manipulation will render standardisation 'unreasonable': the anti-competitiveness of the conduct in those cases was never in question.

Standards inevitably restrict competition. The Supreme Court recognised as much in *Allied Tube*, where it noted that 'agreement on a product standard is, after all, implicitly an agreement not to manufacture, distribute or purchase certain types of products.'[82] They are not liable to *per se* condemnation because courts recognise that they may have important benefits. This is then-Circuit Judge Breyer's endorsement of standardisation in *Clamp-All*:

> On its face, the joint development and promulgation of the specification would seem to save money by providing information to makers and to buyers less expensively and more effectively than without the standard. It may also help to assure product quality. If such activity, in and of itself, were to hurt Clamp-All by making it more difficult for Clamp-All to compete, Clamp-All would suffer injury only as a result of the defendants' joint efforts having lowered information costs or created a better product. And *that* kind of harm is not 'unreasonably anticompetitive'. It brings about the very benefits the antitrust laws seek to promote. That is to say, activity that harms competitors because it lowers production or distribution costs or provides a better product carries with it an overriding justification.[83]

[82] *Allied Tube*, above n 4, 500.

[83] *Clamp-All Corp v Cast Iron Soil Pipe Institute* 851 F 2d 478, 487 (1st Cir 1988), (emphasis in original, internal citations omitted). See also *ECOS Electronics v Underwriters Laboratories* 743 F 2d 498 (7th Cir 1984).

The issue then becomes how to distinguish good standardisation from bad—or as Breyer had it, from standard setting that 'serves no legitimate purpose' or is 'unnecessarily harmful'.[84] The obvious answer is to scrutinise the contents of the standard at issue. Advocated by antitrust lawyers, this solution, however, rests on a reified vision of standards. Gates maintains that product standards rest on 'objective criteria' and are thus 'more amenable to judicial oversight than are many other standards': '"Second-guessing" objective criteria is much less offensive than examining the subjective conclusions of "the experts"'.[85] Appellate courts have hinted at the possibility of standards being 'so unreasonable that their net effect would be to injure competition'[86] and have suggested that certification schemes could run foul of antitrust laws if the standard 'is shown to be anti-competitive in purpose or effect.'[87] Not one single decision, however, has actually struck down a standard on its merits. In *Consolidated Metal*, the Fifth Circuit explicitly held that 'a technical debate among engineers' could not be construed as an antitrust claim:[88]

> Not only would this tax the abilities of federal courts, but fear of treble damages and judicial second-guessing would discourage the establishment of useful industry standards. Under such a regime, the antitrust laws would stifle, not protect, the competitive market.[89]

In *DM Research*, the First Circuit explicitly make a policy decision against intrusive review: 'Without some kind of protective screen for treble damage liability, there would be few standards set since most involve disputable judgment calls'.[90] What courts concentrate on is what they feel most comfortable with: procedure.[91] And so it is expertise, and not politics, that brings principles of good governance back into the equation. The Supreme Court's faith in due process was expressed most clearly in *Allied Tube*:

[84] Above. Cf *Jessup v American Kennel Club* 61 F Supp 2d 5, 12 (SD NY 1999), (refusing an antitrust claim against height standards for Labrador retrievers set by the AKC on the theory that '*any* standards inevitably provide competitive advantages to dogs that meet the standards and corresponding disadvantages to dogs that do not meet the standards', and demanding evidence beyond 'mere speculation' that said standard 'was the result of an anti-competitive agreement rather than a legitimate exercise of the permissible function that defendants are authorized to perform in setting uniform breed standards.')

[85] Gates, 'Standards, Innovation and Antitrust: Integrating Innovation Concerns Into the Analysis of Collaborative Standard-Setting' (1998) 47 *Emory L J* 681, 707.

[86] *Eliasen*, above n 23, 130, n 6.

[87] *DM Research*, above n 10, 58.

[88] *Consolidated Metal*, above n 24, 295.

[89] Above, 297.

[90] *DM Research*, above n 10.

[91] Anton and Yao, 'Standard Setting Consortia, Antitrust, and High-Technology Industries' (1995) 64 *Antitrust L J* 247, 248 ('procedural considerations have played a primary role in the antitrust analysis of standard setting').

> When . . . private associations promulgate safety standards based on the merits of objective expert judgments and through procedures that prevent the standard setting process from being biased by members with economic interests in stifling product competition . . ., those private standards can have significant procompetitive advantages.[92]

The finding seems paradoxical. After having denied that the standards body, in the absence of 'official authority', could qualify as a 'quasi-legislative body' in order to have the restraints it imposes taken out of the realm of the Sherman Act altogether, the Court now holds out the prospect of holding the body's decisions not to be a restraint at all as long as it endows itself with the hallmarks of regulatory decision-making. Procedural requirements under antitrust analysis thus in effect replace the requirements of state involvement under *Parker*. The Court admits as much:

> Thus in this case the context and nature of petitioner's efforts to influence the Code persuade us that the validity of those efforts must, despite their political impact, be evaluated under the standards of conduct set forth by the antitrust laws that govern the private standard-setting process. The antitrust validity of these efforts is not established, without more, by petitioner's literal compliance with the rules of the Association, for the hope of procompetitive benefits depends upon the existence of sufficient safeguards to prevent the standard-setting process from being biased by members with economic interests in restraining competition. An association cannot validate the anticompetitive activities of is members simply by adopting rules that fail to provide such safeguards. The issue of immunity in this case thus collapses into the issue of antitrust liability.[93]

4.4 Antitrust as Private Administrative Law

Antitrust law is thus posited as the functional equivalent of administrative law as applied to private governance. This use of antitrust law to proceduralise the regulation of self-regulation, however, is far from evident under the Court's own precedent. For one thing, it is unclear how *Allied Tube* relates to the Court's caselaw on the relevance of procedural safeguards in antitrust analysis. Until 1985, courts generally relied on *Silver* for the proposition that self-regulatory arrangements could escape *per se* antitrust scrutiny if and when accompanied by fair procedures.[94] In *Northwest Stationers*, however, the Court narrowed *Silver*'s application to instances of an 'important national policy' of promoting industry self-regulation and allowed the Sherman Act to be narrowed 'only to the extent necessary to effectuate that policy'. It then added:

[92] *Allied Tube*, above n 4, 501.
[93] Above, 509.
[94] *Silver v New York Stock Exchange* 373 US 341, 364 (1963).

> In any event, the absence of procedural safeguards can in no sense determine the antitrust analysis. If the challenged concerted activity of Northwest's members would amount to a per se violation of 1 of the Sherman Act, no amount of procedural protection would save it. If the challenged action would not amount to a violation of 1, no lack of procedural protections would convert it into a per se violation because the antitrust laws do not themselves impose on joint ventures a requirement of process.[95]

There is an obvious tension with *Allied Tube* here. Just as it precludes *per se* condemnation on the sole basis of the complete absence of fair procedures,[96] *Northwest* precludes the theory that self-regulation be treated under the rule of reason on the basis of procedural guarantees. On the other hand, standard-setting is analysed under a rule of reason analysis because standards could be pro-competitive, and that very pro-competitiveness, the Court held in *Allied Tube*, depends precisely on the procedural safeguards the standard-setting process allows for.

The more fundamental limit of competition law as a regulatory instrument is the scope of reasoning it confines courts to. Analysis under the rule of reason is confined to economic parameters. The Court made an act of neoliberal faith in *National Society of Engineers* that precludes consideration of any policy objective but competition:

> It is this restraint that must be justified under the Rule of Reason, and petitioner's attempt to do so on the basis of the potential threat that competition poses on the public safety and the ethics of its profession is nothing less than a frontal assault on the basic policy of the Sherman Act. . . .
>
> The Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services. . . . The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.[97]

The lesson of *National Society of Engineers* seems to be, therefore, that courts must construe benefits to health and safety as side-effects of enhanced competition. On the other hand, the Court added a curious footnote to the opinion suggesting that restraints 'related to the safety of a product' may have 'no anticompetitive effect'.[98] Amidst the confusion, Gerla claims that courts and authorities are 'likely' to recognise a 'narrow and difficult-to-prove' health and safety defence for standards bodies if they can establish a plausible link between the standard and the promo-

[95] *Northwest Stationers,* above n 17, 293.

[96] See *Moore v Boating Industry Associations* 754 F 2d 698 (7th Cir 1985), vacated and remanded by *Boating Industry Associations v Moore* 474 US 895 (1987); and *Moore v Boating Industry Associations* 819 F 2d 693, 695, 711 (7th Cir 1987).

[97] *National Society of Professional Engineers v US* 435 US 679, 695 (1978).

[98] Above, 696 (n 22).

tion of health and safety and if the health and safety objectives at issue cannot be attained in ways less injurious to competition.[99]

The use of competition law as administrative law for standards bodies seems to depend on a whole set of problematic assumptions concerning the relationships between expertise, due process, competition and the benefits that flow from these to health and safety. First, consider Elhauge's bemusement over *Allied Tube*:

> Although one can readily see how the lack of financial bias would make the standard-setting process more reliable and desirable, it is hard to see in what sense the disinterest made the product standard 'procompetitive'.[100]

He seems to miss the point twice. First, it is not at all obvious that procedures that prevent economically interested parties from exercising decision-making power produce better standards. Justice White's dissent in *Allied* is an evergreen in the standardisation community:

> Insisting that organizations like the NFPA conduct themselves like courts of law will have perverse effects. Legislatures are willing to rely on such organizations precisely because their standards are being set by those who possess an expert understanding of the products and their uses, which are primarily if not entirely those who design, manufacture, sell, and distribute them. Sanitizing such bodies by discouraging the active participation of those with economic interests in the subject matter undermines their utility.[101]

The problem lies not just in an unfortunate coincidence of the expertise needed to draft useful standards residing with those who have a financial interest in stifling competition. There is a more fundamental dilemma at work in the effort to transplant worries about 'capture' and financial bias from the public sphere into the private sphere. Standard setting does not involve a group of individuals contributing to the public good *despite* their financial interest: standard setting involves a group of individuals contributing to the public good *because* of their financial interests. In a very real sense, the benefits of standards flow directly from their being used to hurt competitors. A standard's very aim is to convey a message to consumers and users that the products that do not comply with it are inferior to those that do. Quality and safety are not objectives of standardisation; selling more products is the objective of standardisation. The only reason why quality and safety are promoted by standardisation is because standard-setters believe they will sell more products if their products are, and are widely recognised to be, safer and of better quality than other products.

[99] Gerla, above n 9, 483–84. His claim is based in large part on the 'quality of care' defense in *Wilk v American Medical Association* 895 F 2d 352 (7th Cir 1990).

[100] Elhauge, above n 59, 741.

[101] *Allied Tube*, above n 4, 515, (Justice White dissenting, joined by Justice O'Connor).

Even more problematic is the proposition that antitrust law can secure 'objective expert judgment'. Try as they may to avoid it, it seems inevitable that courts *and juries* will have to engage in a review of the technical basis of standards. If it is accepted, first, that standards always restrict competition to an extent but also that, second, the benefits to safety and quality 'carry with it an overriding justification',[102] it seems hard to avoid inquiring whether the objective base of that standard actually does anything to further those objectives. The courts' solution to this dilemma is the same as their solution to problems of expertise in administrative law: instead of judges behaving like technical experts, standard-setting bodies are now supposed to behave like courts. 'Petitioner remains free', says the Court in *Allied Tube*, 'to take advantage of the forum provided by the standard-setting process by presenting and vigorously arguing accurate scientific evidence before a non-partisan private standard-setting body.'[103] Courts' reluctance to be drawn into technical debates on the contents of the standard will thus be paid for by their having to decide whether a sub-committee member's successful arguing the hazards of a competitor's product should count as offering 'accurate scientific evidence' or, rather, as dressed-up self-interest.[104] And it is hard to see how that decision will not necessarily have to be followed by a decision on the merits of the final standard's reflecting or not that 'accurate scientific evidence'. And finally, it is very hard to see how that inquiry will not pose a striking resemblance to a 'hard look'. The leading proposal in this regard comes from Dennis Yao, a former FTC commissioner. He advocates that courts and enforcement agencies scrutinise standards for a 'substantive reasonable basis'.[105] This examination of whether the standard can be 'reasonably' supported on the merits would involve a review of much of what the 'hard look' has accustomed regulators to: whether the standard is based on information that is 'credible' to experts, whether arguments of the opponents to the standards have been given due consideration, etc. It would also produce much of what the 'hard look' has produced in regulatory agencies: lots of lawyers, lots of record keeping, clogged up appeals mechanisms, paralysis and conservatism. Courts looking hard in administrative law is one thing, moreover; juries looking hard in antitrust law is quite another.[106]

[102] *Clamp-All*, above n 83, 487 (1st Cir 1988).

[103] *Allied Tube*, above n 4, 510.

[104] Cf *Allied Tube*, above n 4, 515, (Justice White dissenting, joined by Justice O'Connor).

[105] Anton and Yao, above n 91, 252–53. Cf Goldenberg, 'Standards, Public Welfare Defenses, and the Antitrust Laws' (1987) 42 *Business Lawyer* 629, 650 ('The courts should approach the issue in much the same way as they review administrative regulations. They should seek to determine whether the standard organisation's decision is reasonably supported by the available evidence.')

[106] See *Allied Tube*, above n 4, 514–15 (1988), (Justice White dissenting, joined by Justice O'Connor), ('In this case, for example, even if Allied had not resorted to the tactics it employed, but had done no more than successfully argue in good faith the hazards of using respondent's products, it would have inflicted the same damage on respondent and would

It is true, of course, that ANSI and other standards bodies have greatly improved their procedures in the wake of *ASME v Hydrolevel* and *Allied Tube*. The principles of openness, balance of interests, consensus, public review and the availability of appeals mechanisms have been laid down and enforced in no small measure thanks to the Court's decisions. The question is if the price to pay is not too high. Cheit notes with dismay that this due process revolution has clogged up several standards bodies to the point where delays and adversary appeals proceedings are close to taking away the vital advantages private standards setting has over public regulation:

> The antitrust influence threatens to burden the private sector with perhaps the worst aspect of public regulation: the judicial second-guessing that follows on the heels on most standards.[107]

American competition law functions on a whole series of weary public/private distinctions. It refuses immunity to private governance regimes on the theory that public officials can be trusted to act in the public interest, whereas private actors can be assumed to further their own. Standards bodies can find relief from that implausible distinction between 'political' and 'economic' institutions by relying on another one: immunity will be granted if the damage stems from the 'political' application of standards rather than the standard's 'force in the market'. If that doesn't work, the organisation is definitely to be classified an 'economic' institution and is subjected to the rigour of antitrust law. And once within the orbit of the Sherman Act, it can only save itself by showing that it is, after all, a 'political' institution.

5. ANTITRUST IMMUNITY: THE EUROPEAN COMMUNITY

5.1 Introduction

Article 81 (1) EC prohibits 'all agreements between undertakings, decisions by associations of undertakings and concerted practices which affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition.' There can be no doubt that *de facto* standards fall squarely within the orbit of this prohibition. For recognised standards, the picture is anything but clear. Neither

have risked the same antitrust suit, with a jury ultimately deciding the health and safety implications of the products at stake').

[107] Cheit, above n 3, 233.

Commission or Court have ever had to pronounce themselves on the subject in proceedings and both have actively avoided the issue.[108]

In a 1986 decision, the Commission had to do with *Belasco*, an association of Belgian roofing felt manufacturers, whose main function it was to assist in the establishment of IBN standards. The Commission took issue with an agreement that included, *inter alia*, price fixing and market sharing.[109] The product market concerned fell into two categories; products certified with the 'Benor' mark manufactured in accordance with IBN standards, and 'new' products for which no IBN standards were available. For the latter products, the agreement included a provision for joint agreement on specifications.[110] Embedded as it was in a flagrantly anti-competitive overall agreement, the Commission found 'reason to believe' that this clause was intended to restrict members' freedom to differentiate their products. It added: 'The members' participation in the establishment of IBN standards is not at issue here in this case.'[111] *Belasco* appealed to the Court of Justice claiming, among other things, a contradiction in the Commission's reasoning. Standards, it argued, are by definition designed to remove differences between products. Since IBN standards presuppose that standardised products have been on the market for several years, *Belasco* argued that the Commission's distinction between participation in IBN standardisation and the association's drafting of technical specifications was false. The Court dealt with the argument as laconically as the Commission had done:

> The measures designed to achieve product uniformity were taken under the 1979 agreement and served to reinforce its restrictive purpose. Their purpose was not therefore to enable IBN standards to be established.[112]

Understandably, the Commission and the Court had every desire to stay clear of making a decision on IBN standards' status under the competition law regime. IBN is heavily regulated by the Belgian state and an integral part of the European standardisation system. Given the Community legislator's reliance on European standards, policy reasons

[108] Part of the dearth of caselaw on the matter is due to the exemption of the obligation to notify agreements under Article 4 (2)a of the 'old' Regulation 17/62 if they had as their 'sole object' the development or application of uniform standards or types.

[109] Commission Decision 86/399/EEC, (1986) OJ L 232/15. The agreement was enforced by a system of penalties and a guarantee fund.

[110] These dealt mainly with concentrations of plastic substances in the material.

[111] Para 73 (vi), Commission Decision 86/399/EEC, (1986) OJ L 232/15. In its recent Guidelines, the Commission elevates *Belasco*-type agreements to the *only* type of inherently objectionable use of standards. See Commission Notice—Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements, (2001) OJ C 3/2, para 165 ('Agreements that use a standard as a means amongst other parts of a broader restrictive agreement aimed at excluding actual or potential competitors will almost always be caught by Article 81 (1).')

[112] Case 246/86, *Belasco v Commission* [1989] ECR 2117, para 49.

indicate that some sort of protection from antitrust scrutiny be found for recognised standards.

Standards, however, inevitably distort competition to an extent, whether they are set by recognised standards bodies or set by a group of collaborating manufacturers. The Commission has thus long insisted that standards fall under the competition regime, be they set by national associations or by the European standard bodies.[113] In 1995 it warned that

> Standards should not limit the freedom of the marketplace by excluding products—particularly innovative products—that do not conform to them. They should not be misused to preserve or create a dominant market position to the detriment of free competition by formalising in an officially recognised document the solution adopted by a single major supplier unless appropriate measures are taken to make the relevant technology available to other interested suppliers. . . .
>
> Nor should it be used to confer an undue advantage to certain interested parties by bypassing the process of democratic decision-making and creating de facto market conditions which will be extremely difficult for the legislator to reverse due to the severe economic penalties that might then have to be incurred.[114]

The stakes have been raised, moreover, by the Court's recent 'privatisation' of the *Francovich* regime on State liability for breach of EC law.[115] In *Courage v Crehan*, the Court obliged national courts to open the possibility for 'any individual' to claim damages for loss caused by behaviour of the type prohibited by Article 81 (1) EC.[116] Unless, then, courts are prepared to scrutinise standards on their technical merits and their impact on the market in all individual cases where competitors and consumers claim damages, the only option available is to detect something in the nature or activity of recognised standards bodies generally that warrants antitrust immunity.

The structure of EC competition law, however, prevents any easy answers. Agreements prohibited by Article 81 (1) EC are automatically void.[117] The Treaty allows only two exceptions. First, the Commission can declare Article 81 (1) EC inapplicable under Article 81 (3) EC if all the conditions listed there are fulfilled; the conduct at issue must yield

[113] See eg the Commission Notice concerning agreements, decisions and concerted practices in the field of co-operation between enterprises, (1968) OJ C 75/3, and more recently, the Commission's answer to Question E–1883/94 by Sir Jack Stewart-Clark, (1994) OJ C 24/45.

[114] Commission, *On the Broader Use of Standardisation in Community Policy*, COM (95) 412/final, 6.

[115] Joined Cases C–6 and 9/90 *Francovich and Bonifaci v Italy* [1991] ECR I–5357.

[116] Case C–453/99 *Courage v Crehan* [2001] ECR I–6297, para 26. Controversially, 'any individual' includes parties to the illegal agreement. The roots for the sensible part of the holding lie in AG Van Gerven's Opinion in Case C–182/92 *Banks v British Coal* [1994] ECR I–1209.

[117] Article 81 (2) EC.

contributions to improving the distribution of goods or to promoting technical or economic progress, consumers should be allowed a 'fair share' of the resulting benefits, the restraints imposed must be 'indispensable' to the attainment of those objectives, and competition must not be 'eliminated'. Second, under Article 86 (2) EC, 'undertakings entrusted with services of general economic interest' are exempted from the competition rules in as far as their application would obstruct the performance, in law or in fact, of the particular tasks assigned to them.

In its recent 'Guidelines on the applicability of Article 81 to horizontal co-operation agreements' the Commission dedicates a chapter to standardisation where it finds not one but several grounds for protecting recognised standards bodies. In its enthusiasm, however, it does seem to get carried away. First, it laconically classifies recognised bodies under Article 86 (2):

> Agreements to set standards may be either concluded between private undertakings or set under the aegis of public bodies or bodies having been entrusted with the operation of services of general economic interest, such as the standards bodies recognised under Directive 98/34/EC. The involvement of such bodies is subject to the obligations of the Member States regarding the preservation of non-distorted competition in the Community.[118]

Second, it considers that the conditions for an exemption under Article 81 (3) EC will be met almost automatically by recognised standards. For economic benefits to materialise an 'appreciable proportion of the industry must be involved in the setting of the standard in a transparent manner.'[119] Whether the resulting restrictions on competition imposed are 'indispensable' for the attainment of those benefits is a matter of procedure as well:

> All competitors in the market(s) affected by the standard should have the possibility of being involved in discussions. Therefore, participation in standard setting should be open to all, unless the parties demonstrate important inefficiencies in such participation or unless recognised procedures are foreseen for the collective representation of interests, as in formal standards bodies.[120]

[118] Commission Notice—Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements, (2001) OJ C 3/2, para 162. Cf Section 1, *General Guidelines for the Co-operation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association*, (2003) OJ C 91/7, (the Commission, EFTA and the European standards bodies 'take note that because of the public recognition of the organisations that issue them, and by compliance with specific procedures, including a public enquiry and a vote, standards (ENs) thus adopted are distinct from other technical specifications established on a voluntary basis.')

[119] Above, para 169.

[120] Above, para 172.

Finally, it renders all these considerations superfluous by denying that recognised standards restrict competition at all:

> Where participation in standard-setting is unrestricted and transparent, standardisation agreements as defined above, which set no obligation to comply with the standard or which are parts of a wider agreement to ensure compatibility of products, do not restrict competition. This normally applies to standards adopted by the recognised standards bodies which are based on non-discriminatory, open and transparent procedures.[121]

The Commission's generosity towards standards bodies comes at the price of coherence, probably best explained by its desire to accommodate different national conceptions of standardisation. Roughly, immunity founded on state involvement corresponds to the status of AFNOR as being entrusted with a mission of *service public*. Immunity on the grounds of voluntary application and wide interest representation corresponds to DIN's treatment under German competition law. Accommodating different national regulatory frameworks under Community competition law, however, is not likely to lead to a coherent Community-wide conception of standardisation, applicable to both national and European standards bodies.

5.2 Standards Bodies as Political Institutions

AFNOR is, as noted, entrusted by the Conseil d'Etat with a *mission de service public* and enjoys *prérogatives de puissance public*;[122] as recently confirmed by the Conseil de la concurrence, the association enjoys immunity from competition law.[123] From, of all things, a staff case, the French have argued to have found a similar endorsement of CEN by the Court of First Instance. The case was brought by the present director of DG Enterprise, Evangelos Vardakas, upon his move to the Commission from his former job as Secretary General of CEN. He objected to the Commission's refusal to give him an expatriation allowance. His claim hinged on the interpretation of 'international organisation', a category the Commission wished to limit to 'organisations created by States or by an organisation which itself was created by States'. The CFI held:

> Although admittedly, the CEN was not created by States or by international organisations themselves created by States, it has been recognised by States

[121] Above, para 163.

[122] Conseil d'Etat, 14 October 1991, *Conchyliculture*, No 90260; Conseil d'Etat, 17 February 1992, *Textron*, No 73220, both published in (1992) *La semaine juridique (JCP)*, ed G, 428.

[123] Conseil de la concurrence, Décision 03–D–13 du 11 mars 2003, *Produits Industriels Lorrains (PIL)*, para 49 (declining, on the basis of *Conchyliculture*, above n 122, jurisdiction over AFNOR's adoption of and certification to standards since these actions are not 'activités de production, de distribution et de services' for purposes of Article L 410–1 of the *Code du commerce*.)

> and by international organisations created by States, such as the European Communities, and has been entrusted with tasks in the public interest.[124]

From a technical concept of administrative law, the notion of *service public* has evolved into a key element of French political philosophy and an icon of national identity.[125] At its core lies the predominance of politics over the market. The political process defines the 'general interest'; efforts to further it are to be shielded from market forces by law. Entrusting organisations with a public service mission serves both to legitimise and to limit their exercise of public powers. The fundamental point is that such bodies are to be regulated by 'public' administrative law and not subjected to 'private' competition law.[126]

To transplant that argument onto Community level, two possible theories are open. It could be argued that such bodies are not 'undertakings' at all for purposes of Community law. Such a theory presents the Court of Justice with a problem: if Member States are allowed to determine the scope of competition law unilaterally, both the unity of Community law and the system of undistorted competition would suffer badly. The Court has thus rejected the notion that national legal designations and regulatory frameworks define what constitutes an 'undertaking'.[127] Instead, it has fashioned 'deep' functional criteria to establish what kinds of activities can and should be subjected to the discipline of the market. Thus, in *Höfner* it classified a government agency as an 'undertaking' because it engaged in an activity 'that has not always been, and is not necessarily, carried out by public authorities.'[128] Conversely, it shielded a private company from the competition rules in *Diego Calì*, since it exercised powers 'which are typically those of a public authority'.[129] The concept of an 'undertaking',

[124] Case T–4/92 *Evangelos Vardakas v Commission* [1993] ECR II–357, para 47.

[125] See eg Chevallier, 'Regards sur une évolution' [1997] *AJDA* 8 ('Le service public apparaît en France comme un véritable mythe, c'est-à-dire une de ces images fondatrices, polarisant les croyances et condensant les affects, sur lesquelles prend appui l'identité collective'); Truchet, 'Etat et Marché' (1995) 40 *Archives de philosophie du droit* 314 (defining the very 'State' as the 'ensemble complexe de missions de service public et de prérogatives de service public orienté vers l'intérêt général'). See further eg Jourdan, 'La formation du concept de Service Public' (1987) *Revue de droit public* 89; Pontier, 'Sur la conception Française du Service Public' (1996) *Recueil Dalloz* 9.

[126] See the analysis in Cohen-Tanugi, *Le Droit Sans l'Etat* (PUF, Paris, 1985) 124 ff. (*Service public* is the expression of an ideological split between public and private spheres; the institutional incarnation of the 'general interest' in the State prevents law from having a 'responsibilising' role in the market.) Cf Caillosse, 'Le Droit Administratif Français Saisi par la Concurrence?' [2000] *AJDA* 99; Linotte and Romi, *Services Publics et Droit Public Économique*, 5th edn (Litec, Paris, 2003).

[127] See eg Case 118/85 *Commission v Italy* [1987] ECR 2599, para 11 ('having recourse to Member States' domestic law in order to limit the scope of Community law undermines the unity and effectiveness of that law and cannot, therefore, be accepted.')

[128] *Höfner*, above n 32, para 22 (employment placement agency).

[129] Case C–343/95 *Diego Calì e Figli v SEPG* [1996] ECR I–1547, para 23 (cleaning up polluted harbours).

then, 'encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way it is financed.'[130]

In *Eurocontrol*, the Court found an international organisation carrying out 'tasks in the public interest' on behalf of the States that had set it up.[131] It held that powers related to air navigation control were 'typically those of a public authority' and 'not of an economic nature justifying the application of the Treaty rules of competition'.[132] Despite French flirtations with the idea of establishing an analogy with CEN on the grounds of 'tasks in the public interest', it seems out of the question that standardisation would be classified either as 'not of an economic nature' nor as an activity involving exercise of powers 'typically of a public authority'.[133]

The Court's resistance to the notion of service public has elicited much anger in French circles:

> L'idéologie d'un grand marché ouvert s'est rapidement dotée d'armes juridiques efficaces qui peu à peu se sont révélées de véritables machines de guerre contre les entreprises investies d'une mission de service public.[134]

Concentrating on Article 86 (2), however, the French secured a political victory by the insertion of Article 16 EC in the Amsterdam Treaty. That provision, of dubious legal value, emphasises the place of services of general economic interest in the 'shared values of the Union' as well as their role in promoting 'territorial and social cohesion.' The Community and the Member States, in their respective spheres of action, are hence to ensure that they operate 'on the basis of principles and conditions that enable them to fulfil their mission'.[135]

[130] *Höfner*, above n 32; see further eg Joined Cases C–159 and 160/91 *Poucet et Pistre* [1993] ECR I–637; Case C–244/94 *Fédération Française des Sociétés d'Assurance* [1995] ECR I–4013 (French social security schemes). See eg Slot, 'The Concept of Undertaking in EC Competition Law' in Due, Lutter and Schwarze (eds), *Festschrift für Ulrich Everling* (Nomos, Baden-Baden, 1995) vol II, 1413; Maillo González-Orús, 'Beyond the Scope of Article 90 of the EC Treaty: Activities Excluded From the EC Competition Rules' (1999) 5 *EPL* 387; Louri, '"Undertaking" as a Jurisdictional Element for the Application of EC Competition Rules' (2002) 29 *LIEI* 143.

[131] Case C–364/92 *SAT Fluggesellschaft v Eurocontrol* [1994] ECR I–45, para 27.

[132] Above, para 30.

[133] Délégation française, *Normes européennes et règlements—le rôle des Autorités publiques*, Memorandum transmitted to the Council on 14 September 1998, 23.

[134] Belloubet-Frier, 'Service Public et Droit Communautaire' [1994] *AJDA* 270. See further Kovar, 'Droit Communautaire et Service Public: Esprit d'Orthodoxie ou Pensée Laïcisée' (1996) 32 *RTDE* 215, 493; Delacour, 'Services Publics et Concurrence Communautaire—Aspects Juridiques' [1996] *RMCUE* 501.

[135] For early debate, see eg Commission, *Services of general interest in Europe*, COM (96) 443/final; 'Public Service Obligations: A Blessing or a Liability?' (1996) 33 *C M L Rev* 395. On the legal significance of the provision, see eg Rodrigues, 'Les Services Publics et le Traité d'Amsterdam: Genèse et Portée Juridique du Projet de Nouvel Article 16 du Traité CE' [1998] *RMCUE* 37; Ross, 'Article 16 and Services of General Interest: From Derogation to Obligation?' (2000) 25 *ELR* 22.

Article 86 (2) EC is the one provision deferring to Member States' political decisions to insulate certain activities from the market. In the Court's interpretation of the derogation, it does not seek to establish a deep catalogue of intrinsic public interests; indeed, the Court has never attempted to offer any definition of 'services of general economic interest'. The Court has granted Member States considerable leeway in defining the interest to be protected and has even gone so far as to concede that they may exclude all competition in their effort to protect it. The price of such tolerance is the demand for a convincing argument as to why, and how much, restriction of competition is necessary for the interest to be protected.[136] More importantly still for present purposes, the Court also demands an act of the public authorities granting the exclusive rights in question. The exact extent of the latter requirement is not clear. The Court first articulated it in 1974 when it excluded from the scope of Article 86 (2) those undertakings 'to which the state has not assigned any task and which manages private interests.'[137] Later, the Court has specified that the specific undertakings must be named in that act, and that general descriptions of the conditions and rules applying to undertakings wishing to avail themselves of special rights are insufficient.[138] Later yet, it demanded close monitoring on the part of the public authorities and full transparency as regards the special needs concerned as well as the impact on the market of the fulfilment of those needs.[139] Recently, the Court has been lenient as regards the form of the act concerned, not necessarily insisting on a legislative measure or regulation but contenting itself with a the grant of a concession governed by public law.[140] That tolerance, however, does not detract from the requirements on the contents of the act nor of the 'active supervision' test.

National standards bodies operating under standards laws, like AFNOR, could hence easily avail themselves of Article 86 (2);[141] it is more than doubtful, however, whether organisations linked to the State by contracts and/or memoranda of understanding would qualify. Different national standards bodies, even when they implement exactly the same

[136] See Case C–320/91 *Paul Corbeau* [1993] ECR I–2533; Case C–393/92 *Almelo v IJsselmij* [1994] ECR I–1477. The criteria have arguably been softened in Case C–154/94 *Commission v Netherlands* [1997] ECR I–5699. Cf Case C–340/99 *TNT Traco v Poste Italiane* [2001] ECR I–4109; Case C–475/99 *Ambulanz Glöckner* [2001] ECR I–8089. See generally Moral Soriano, 'How Proportionate Should Anti-competitive State Intervention Be?' (2003) 28 *ELR* 112.

[137] Case 127/73 *BRT v SABAM* [1974] ECR 313, para 23.

[138] Case 7/82 *GVL v Commission* [1983] ECR 483, paras 31–32.

[139] Case 66/86 *Ahmed Saeed* [1989] ECR 803, paras 55–56.

[140] Case C–159/94 *Commission v France* [1997] ECR I–5815, para 55.

[141] See Gambelli, *Aspects Juridiques de la Normalisation et de la Réglementation Technique Européenne* (Eyrolles, Paris, 1994) 154 ('La normalisition rentre aisément dans ce cadre'). Before the publication of the Commission's guidelines, Article 86 (2) EC was never considered by authors outside of France analysing standardisation under competition law. See eg Stuurmans, *Technische Normen en het Recht* (Kluwer, Deventer, 1995) 297 ff; Schießl, *EG-Kartellrechtliche Anforderungen an die Europäischen Normungsorganisationen CEN, CENELEC und ETSI* (Peter Lang, Frankfurt, 1995).

European standards, would thus be accorded different treatment under EC competition law. The Commission's attempt to avoid this is to suggest that CEN, CENELEC and the national standards bodies have been 'entrusted' with the operation of services of general economic interest for purposes of Article 86 (2) EC by the Information Directive. That argument seems weak on formal grounds: the Information Directive 'entrusts' the standards bodies with nothing but the running of a notification system. More importantly, the argument seeks to protect standards bodies by virtue of a public interest mission that depends on state involvement in standardisation. That is at odds with general Community standardisation policy.[142] It will not do to deny administrative 'delegation' of regulatory tasks on the one hand on the grounds that standards bodies are independent private organisations, and argue for antitrust immunity on the other hand on the grounds that they have been 'entrusted with services of general economic interest'.

5.3 From 'Reasonable' Restraints to Legitimate Governance

One way to escape the requirements of a legal act and state supervision under Article 86 (2) EC would be grant an exemption to bodies that can make no claim of being 'entrusted' with public interest services under Article 81 (3) EC. The Commission has tried this once. That was also the first and only time it saw a clearance struck down by the Court of First Instance.[143]

> [B]y using in this case as a criterion for granting exemption from the rules of Article 85 (1) of the Treaty fulfilment of a particular public mission defined essentially by reference to the mission of operating services of general economic interest referred to in Article 90 (2) EC of the Treaty, the Commission based its reasoning on a misinterpretation of Article 85 (3) of the Treaty.[144]

The Court's reasoning seems to preclude any possibility of using the public interest as an independent criterion under the exemption provision. The Court admitted that the Commission, 'in the context of an overall assessment, is entitled to base itself on considerations connected with the

[142] See, for instance, the European Parliament's Resolution on the communication from the Commission on a broader use of standardisation in Community policy, (1996) OJ C 320/208 ('any dependence of standardisation on authorities or institutions closely associated with public authorities should continue to be avoided in the future').

[143] Joined Cases T–528, T–542, T–543 and T–546/93 *Metropole télévision et al v Commission* [1996] ECR II–649, an action against Commission Decision 93/403/EC, (1993) OJ L 179/23, an exemption for the statutes of the European Broadcast Union.

[144] Above, para 123. See however Wesseling, *The Modernisation of EC Antitrust Law* (Hart Publishing, Oxford, 2000) 94 ff, 105 ff (showing that the Commission, in the wide discretion the Court allows it under Article 81 (3) EC, routinely bases its decisions on non-competition concerns). Cf Monti, 'Article 81 EC and Public Policy' (2002) 39 *C M L Rev* 1057.

pursuit of the public interest in order to grant exemption under Article 81 (3) of the Treaty', but such an analysis necessarily would have to include 'other justification', a review of 'economic data', and a rigid proportionality test.[145] The protection of health and safety by private agreements restricting competition can thus never be justified under the provision on the strength of public interest objectives alone. Economic analysis of pro- and anti-competitive effects of standards is required.[146]

Even if now of only academic concern, there used to be procedural concerns confounding the substantive difficulties under Article 81 (3); until recently, application of the provision was a Commission monopoly.[147] Administering a regime whereby all standards are to be notified separately and evaluated for pro-competitive effects would clearly overload the Commission. A block-exemption would remedy the procedural problem. In *Wouters*, the Court explicitly rejected German concerns about notifications paralysing the regulatory activity of professional associations on the grounds that 'it is always open to the Commission *inter alia* to issue a block exemption.'[148] Such a measure, however, would presuppose a generalised judgment on the pro-competitive effects of standards. Such general immunity on grounds of benefits to the economy, however, is hardly defensible given the very different economic effects of different standards.[149] Authors who favour this solution do so grudgingly, for reasons of 'legal security'.[150] Even the Commission's well willing Guidelines require certain baseline economic conditions to be fulfilled which are so flexible and sometimes even contradictory that individual evaluation of particular standards seems indispensable. Standards must not limit innovation and yet may not trigger 'unduly rapid obsolescence' of existing products.[151] Moreover:

[145] Joined Cases T–528, T–542, T–543 and T–546/93 *Metropole télévision et al v Commission* [1996] ECR II–649, para 117–120.

[146] See also the Guideline on *Trade Associations, Professions and Self-Regulating Bodies*, OFT 408, issued by the UK Office of Fair Trading, concerning exemption under Section 9 of the Competition Act 1998, identical to Article 81 (3) EC, para 4.5: 'Technical standards can help to promote safety and protect consumers and are therefore likely to be candidates for exemption. The benefits would, however, have to be assessed against any effects on competition in deciding whether exemption would be ultimately justified.'

[147] Article 9 (1), Council Regulation No 17 implementing Articles 85 and 86 of the Treaty, (1962) OJ L 13/204. See however Regulation 2003/1 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, (2003) OJ L 1/1.

[148] Case C–309/99 *Wouters v Nederlandse Orde van Advocaten* [2002] ECR I–1577, para 69.

[149] Denying grounds for general exemption, Schießl, above n 140, 46 ff. With similar reservations, Racine, 'Normalisation, Certification et Droit de la Concurrence' [1998] *RIDE* 147, 160 ff.

[150] See Stuurmans, above n 141, 353. Characteristically unconcerned, Gambelli, above n 141, 153 ('les objectifs et les 'enteintes' techniques élaborées par la normalisation ont essentiellement pour but le progrès technique et économique. Il est normal que la normalisation bénéficie d'une présomption favorable au regard du droit de la concurrence.')

[151] Commission Notice—Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements, (2001) OJ C 3/2, para 170. The Commission explicitly states that effects on innovation must be analysed 'on a case-by-case basis.'

> By their nature, standards will not include all possible specifications or technologies. In some cases, it would be necessary for the benefit of the consumers or the economy at large to have only one technological solution. However, this standard must be set on a non-discriminatory basis. Ideally, standards should be technology neutral. In any event, it must be justifiable why one standard is chosen over another.[152]

The Commission's way out consists of the suggestion that recognised standards bodies with 'recognised procedures for collective interest representation' will guarantee that 'all competitors affected by the standard' have the possibility of 'being involved in discussions'.[153] This approval of collectively determining 'economic benefits' and the 'indispensability' of measures to attain those benefits, however, seems at odds with the grounds underlying European administrative authorisation of anti-competitive agreements. On the theory that decisions under Article 81 (3) EC entail important Community policy decisions, the Commission has until very recently refused to allow decentralisation of its application.[154] If even allowing national courts and enforcement agencies the power to engage in a policy analysis of pros and cons of anti-competitive measures raises such difficulties for the coherence of Community competition policy,[155] it is hard to see why the Commission would feel so ready to entrust such decisions to a proceduralised conception of market democracy.

The idea of generally exempting standardisation from antitrust review on grounds of wide interest representation is put into practice by German competition law.[156] The *Gesetz gegen Wettbewerbsbeschränkungen* (GWB) declares the general prohibition of restricting competition inapplicable to agreements and decisions that 'merely' have 'the uniform application of standards and types' as their object, as long as the benefits resulting from the 'rationalisation' are proportionate to the resulting restriction of competition.[157] Such agreements are to be notified to the *Kartellamt* which carries out that proportionality analysis. Issuing a standard is to be construed as a recommendation for uniform application of the technical

[152] Above, para 171.

[153] Above, para 172. For an attempt to find 'pure' competition justifications for wide industry participation, see Dolmans, 'A Standard for Standards' (2002) 26 *Fordham Int L J* 163, 171 *et seq*.

[154] The Commission announced its readiness to give up the monopoly in its *White Paper on the Modernisation of the Rules Implementing Article 85 and 86 of the EC Treaty*, Commission programme No 99/27, 28 April 1999. Cf Regulation 2003/1 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, (2003) OJ L 1/1. See generally eg Idot, 'Le Nouveau Système Communautaire de Mise en Oeuvre des Articles 81 et 82 CE' [2003] *CDE* 283; Venit, 'Brave New World: The Modernization and Decentralization of Enforcement under Articles 81 and 82 of the EC Treaty' (2003) 40 *C M L Rev* 545.

[155] See generally Wesseling, above n 144.

[156] See generally Falke, *Rechtliche Aspekte der Normung in der Bundesrepublik Deutschland* (Opoce, Luxembourg, 2000) 215 ff.

[157] Article 5, GWB.

specifications contained in it.[158] Such recommendations are allowed if they are explicitly classified as voluntary, and their compliance is not forced upon undertakings by 'economic, social or other pressure'. They all have to be notified. Standards bodies have a privileged status, in that they are exempted from the duty to notify and from the duty to designate standards explicitly as 'non-binding'.[159] That privilege, in turn, is conditional upon their status as 'rationalisation associations', which the GWB defines as associations whose statutory purpose it is to set standards in such a way that suppliers and users affected by the standard are 'appropriately represented'.[160] The privilege, however, is subject to residual review for abuse and continued compliance with the requirement of interest representation by the enforcement agencies.

DIN, with the approval of the *Bundeskartellamt*, published a checklist in 1976 in which it specified the requirements the GWB puts on German standards. This *Merkblatt* also faces the consequences of European standards' status under German law. DIN is hence to refrain from transposing European standards unless it is convinced, after careful review, that they fulfil the same requirements as those, which German standards have to comply with in order to survive antitrust scrutiny.[161]

5.4 Antitrust as Private Administrative Law

Given the confines of reasoning under Article 81 (3) EC, equivalent privilege on conditions of equivalent procedural guarantees under Community law will have to be found under Article 81 (1) EC itself.[162] The final solution offered by the Commission's Guidelines does exactly that. Voluntary standards set in recognised standards bodies with 'non-discriminatory, open and transparent procedures' are held not to restrict competition.[163] In this case there is no public interest *justification* for distortions of competition; instead, there is antitrust *immunity* for private parties on the basis of procedural public interest guarantees. This is certainly a new theory under EC competition law, and one can wonder how much thought the Commission has actually put into it. It is one thing to say that standards

[158] Unlike Community competition law, the GWB does not treat 'recommendations' as agreements or decisions. See *IAZ and others*, above n 25, para 20 ('a recommendation, even if it has no binding effect, cannot escape Article 85 (1) where compliance with the recommendation by the undertakings to which it is addressed has an appreciable influence on competition on the market in question.')

[159] Article 38 (2) 2, GWB.

[160] Article 5 (2) GWB.

[161] Merkblatt für DIN–Normen als Normen– und Typenempfehlungen nach § 38 Abs 2 Nr 2 des GWB, 5 October 1976, reproduced in DIN Normenheft 10, 399–413.

[162] This is the thesis of Schießl, above n 141.

[163] Commission Notice—Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements, (2001) OJ C 3/2, para 163.

benefit health and safety and should be immune from competition law on the grounds that these concerns outweigh injury to competition—a substantive public interest test. It is another thing to say that political decisions by public authorities to restrain competition by relying on private standards bodies should be immune from competition law on the grounds that antitrust regulates economics, not politics—the institutional public interest test of the state action doctrine. But it is a yet different thing altogether to say that standards set by private parties in a fair and transparent decision-making process are immune from competition law—a procedural public interest test.

It is argued here that the theory finds support in the *effet utile* doctrine concerning anti-competitive state measures.[164] At first sight, the Court's caselaw seems to preclude any possibility for such a procedural conception of the 'public interest'. On the one hand, the Court insists on an institutional norm of 'official character' of legislation and condemns delegation of regulatory powers to private parties whatever the substantive effects of the private agreements concerned. On the other hand, the Court insists on a substantive competitiveness norm and condemns anti-competitive agreements whatever the amount of public involvement and whatever the legal classification given to those agreements. It is submitted here that the separate substantive and institutional norms are in contradiction with each other and ultimately dissolve into one procedural norm.

Articles 81 and 82 EC are, in themselves, concerned solely with the conduct of undertakings and not with laws or regulations adopted by Member States.[165] Under Article 10 EC, however, Member States are to 'abstain from any measure which could jeopardise the attainment of the objectives of the Treaty', one of which, according to Article 3 (g) EC, is the establishment of 'a system ensuring that competition in the internal market is not distorted.' Starting with the 1977 case of *INNO v ATAB*, the European Court of Justice has long read all these provisions together to fashion what is known as the *effet utile* doctrine, according to which Member States are required not to introduce or maintain in force measures which may render the competition rules ineffective.[166] Such would be the case, the Court clarified in *Van Eycke*,

> where a Member State requires or favours the adoption of agreements, decisions or concerted practices contrary to Article 85 or reinforces its effects, or deprives its own legislation of its official character by delegating to private parties responsibility for taking decisions affecting the economic sphere.[167]

[164] Here and in Schepel, 'Delegation of Regulatory Powers to Private Powers under EC Competition Law: Towards a Procedural Public Interest Test' (2002) 39 *C M L Rev* 31.

[165] See Joined Cases 177 and 178/82 *Van de Haar* [1984] ECR 1797, para 24 and more recently eg Case 22/98 *Jean Claude Becu et al* [1999] ECR I–5665, para 31.

[166] Case 13/77 *INNO v ATAB* [1977] ECR 2115, paras 28–31.

[167] Case 267/86 *Van Eycke v ASPA* [1988] ECR 4769, para 16.

The meaning of the delegation test is highly controversial. On any plain understanding of the wording of the doctrine as a whole, 'delegation' is a separate prohibition from the norm prohibiting requiring, favouring or reinforcing private infringements of Article 81 (1) EC. But in that case the test seems either over-intrusive or over-deferential. On the one hand it seems to imply the possibility of the ECJ scrutinising national regulatory frameworks for anti-competitive effects without any evidence of objectionable private behaviour. On the other extreme, it might also be thought to imply that sufficient State involvement can immunise otherwise objectionable private agreements. Neither understanding of the test is tenable. Taken together, one undercuts the premise of the other. Taken separately, they both fail to strike an acceptable balance between Member State autonomy and Community law. The Court has duly dismissed them. The fundamental problem with the Court's rescue operation is, however, that it seems to have rejected each proposition by resurrecting the other. The intrusive substantive norm has been rejected relying on a deferential institutional norm: whatever the anti-competitive effects, legislation is now saved as soon as it is 'official'. The deferential institutional norm has been rejected relying on an intrusive substantive norm: anti-competitive agreements are prohibited regardless of the 'official' authority bestowed on them. This does not solve anything: the two separate tests of *effet utile* still contradict each other, and taken together they still do not strike an acceptable balance between substantive intrusiveness and institutional deference.

One understanding of the test conceives of delegation as objectionable State action that undermines the objective of a system of undistorted competition even in the absence of any connection with private parties' engaging in the kind of behaviour prohibited by Article 81 (1) EC. This is the solution best supported by the plain wording of the *effet utile* doctrine as a whole. Member States can infringe the combined norm of Articles 10 and 81 EC either by sanctioning private collusion prohibited by Article 81 EC *or* by delegating regulatory powers to private powers. If the prohibition of delegation were conditional upon anti-competitive behaviour by the private parties endowed with regulatory responsibilities, it would not make sense to conceive of delegation as a separate instance of objectionable state action. In that case, after all, the State would inevitably require, favour or reinforce such behaviour. Moreover, the history and application of the delegation test reinforce this interpretation. First, there is little doubt that the Court formalised the test in *Van Eycke* as a restatement of a principle it had articulated in two earlier cases that dealt with scenarios where private collusion was rendered superfluous by state legislation.[168] In *INNO v ATAB*, a supermarket objected to Belgian legislation making the price of tobacco set unilaterally by producers or importers compulsory. With minimum

[168] See eg AG Darmon in Case C–185/91 *Reiff* [1993] ECR I–4796, para 47 of the Opinion.

prices thus fixed unilaterally, the tobacco retailers' association had no reason to form a cartel. To add to concern, the legislative initiative was attributable to a Member of Parliament who also happened to be the secretary of an association of retailers that had much to gain by warding off being undercut by supermarkets. The Court held as a matter of principle that Member States may not enact measures 'enabling undertakings to escape from the constraints' imposed by the competition rules.[169] In *Au blé vert* the Court had to deal with French legislation that obliged publishers and importers to fix prices for books and prohibited retailers from undercutting that price by more than 5 per cent. The Court noted that the arrangement did not require any behaviour contrary to Article 81 (1) EC on the part of the parties involved, and added ominously:

> Accordingly, the question arises as to whether national legislation which render corporate behaviour of the type prohibited by Article 85 (1) superfluous, by making the book publisher or importer responsible for freely fixing binding retail prices, detracts from the effectiveness of Article 85 and is therefore contrary to the second paragraph of Article 5 of the Treaty.[170]

Second, the Court applies the two branches of the *Van Eycke* restatement cumulatively. Granted, in *Van Eycke* itself the Court's findings under the first test were inconclusive.[171] In later cases, however, the Court has consistently applied the delegation test even where it found no signs of favouring, requiring or reinforcing private anti-competitive behaviour under the first test.[172]

This understanding of the test has something to commend it, and has found considerable and influential support in the literature. It would conform to classic notions of pre-emption; it would ensure that different regulatory structures, be they corporatist or purely legislative, would be measured to the same substantive norm.[173] More controversially, it would lend considerable weight to efforts to ensure deregulation across the board.[174] On the other hand, it would put the Court in the politically

[169] *INNO v ATAB*, above n 166, para 33.

[170] Case 229/83 *Leclerc v Au blé vert* [1985] ECR 1, para 15.

[171] *Van Eycke*, above n 167, paras 17–18 (referring back to the national court).

[172] See eg Case C–332/89 *Marchandise* [1991] ECR I– 1027; Case C–245/91 *OHRA Schadeverzekeringen* [1993] ECR I–5851; *Reiff*, above n 168; Joined Case C–401 and 402/92 *Tankstation 't Heuske* [1994] ECR I–2199; Case C–153/93 *Delta* [1995] ECR I–2517; Case C–96/94 *Spediporto v Spedizioni Maritimma del Golfo* [1995] ECR I–2883; Joined Cases C–140–142/94 *DIP v Bassano del Grappa and Chioggia* [1995] ECR I–3257; Case C–266/96 *Corsica Ferries v Antichi Ormeggiatori* [1998] ECR I–3949; and Case C–38/97 *Librandi v Cuttica* [1998] ECR I–5955.

[173] See eg Gyselen, 'Anti-Competitive State Measures under the EC Treaty: Towards a Substantive Legality Standard' (1994) 19 *ELR* –CC 55.

[174] For *Ordoliberal* enthusiasm, see eg Van der Esch, 'Die Artikel 5, 3f, 85/86 und 90 EWG als Grundlage der Wettbewerbsrechtlichen Verpflichtungen der Mitgliedstaaten' (1991) 155 *ZHR* 274; Mestmäcker, 'Zur Anwendbarkeit der Wettbewerbsregeln auf die Mitgliedstaaten und die Europäischen Gemeinschaften' in Baur, Müller-Graff and Zuleeg (eds), *Europarecht, Energierecht Wirtschaftsrecht– Festschrift für Bodo Börner* (Carl Heymanns, Köln, 1992)

uncomfortable position of having to decide on a potentially infinite number of national instruments of national economic policy and having to fashion substantive public interest exceptions.[175]

Even if there is, hence, a solid case for thinking that State legislation can be struck down under the delegation test even in the absence of an infringement of Article 81 (1) EC by private parties, the Court has never actually done so. In *INNO v ATAB*, it took refuge in the regime regulating the free movement of goods.[176] In *Au blé vert*, it came up with a pre-emption argument.[177] And in the one case where it found delegation, it found that the State required an agreement contrary to Article 81 (1) EC as well.[178] Perhaps more importantly, there is a conceptual problem with the theory after the Court's judgment in *Meng*.[179] That case dealt with German legislation prohibiting insurance agents from passing on the commission they receive from insurance companies upon concluding a contract. The anti-competitive effects of this legislation seem identical to the ones in *Au blé vert* and *INNO v ATAB*: it prohibits economic agents from competing on price by sacrificing profit margins. The legislation logically does not favour, require or reinforce private anti-competitive behaviour, since such behaviour is superfluous. The legislation has exactly the same effect that a cartel between insurance agents would have. This time the Court squarely addressed the issue. In what must be interpreted as a major statement of principle, it held that Articles 10 and 81 EC do not apply to State legislation 'in the absence of any link with conduct on the part of undertakings of the kind referred to in Article 85 (1) of the Treaty.'[180] And yet, the Court let the delegation test stand in *Meng* and applied it even after it had already concluded that no such private conduct could be deduced from the legislation at issue.[181]

277; Möschel, 'Hoheitliche Maßnahmen und die Wettbewerbsvorschriften des Gemeinschaftsrechts' in Forschungsinstitut für Wirtschaftsverfassung und Wettbewerb, *Weiterentwicklung der Europäischen Gemeinschaften und der Marktwirtschaft* (FIW, Köln, 1992) 89; Bach, *Wettbewerbsrechtliche Schranken für staatliche Maßnahmen nach Europäischem Gemeinschaftsrecht* (Mohr, Tübingen, 1992).

[175] See eg Marenco, 'Le Traité CEE Interdit-il aux Etats Membres de Restreindre la Concurrence?' (1986) 22 *CDE* 285; Slot, 'The Application of Articles 3 (f), 5 and 85 to 94 EEC' (1987) 12 *ELR* 179. For an authoritative account of judicial discomfort, see Everling, 'Wirtschaftsverfassung und Richterrecht in der Europäischen Gemeinschaft' in Immenga, Möschel and Reuter (eds), *Festschrift für Ernst-Joachim Mestmäcker* (Nomos, Baden-Baden, 1996) 365, 375.

[176] *INNO v ATAB*, above n 166, para 35 (holding that, 'in any case', such measures will be generally be incompatible with the regime on the free movement of goods).

[177] *Leclerc v Au blé vert*, above n 170, para 20 (holding that, 'as Community law stands', the norm resulting from the combined application of Articles 10 and 81 EC is not 'specific enough' to preclude Member States from enacting legislation such as the one at issue).

[178] Case C–35/96 *Commission v Italy* [1998] ECR I–3851.

[179] Case C–2/91 *Wolf W Meng* [1993] ECR I–5751.

[180] The Court attached such importance to the matter that it asked Member States to intervene by sending out a number of questions. See the Report of the Hearing in Case C–2/91 *Wolf W Meng* [1993] ECR I–5751.

[181] *Meng*, above n 179, para 10.

What could be objectionable about *Au blé vert*-type situations are hence not the anti-competitive effects of the arrangement, but merely the relinquishing of official powers to private traders. The conclusion must be that the delegation test is not an effects-based substantive norm looking for a regulatory equivalent of the kind of behaviour prohibited by Article 81 (1) EC, but an independent institutional norm, looking for 'official status' of public legislation. And here lies the often overlooked perversity of *Meng*: the case is readily acknowledged for putting forward the major deferential proposition that 'official' legislation is immune from antitrust whatever its anti-competitive effects.[182] It is much less widely credited for the intrusive proposition that logically follows from the radical separation of the two tests: that a Member State falls foul of the *effet utile* norm if it delegates regulatory powers to private parties even if those parties do not infringe Article 81 (1) EC.[183]

An obvious solution would be to turn the whole doctrine into an institutional norm requiring official status rather than a substantive norm requiring undistorted competition. If depriving legislation of its official status renders state action objectionable, logic suggests that a cloak of 'official status' will render private behaviour unobjectionable. The delegation test would then be interpreted as a *Midcal* test, and the cumulative application of the two branches could be explained as a filter.[184] The Court first examines whether an infringement of Article 81 (1) EC can be inferred from the legislation at issue. If it does find a restrictive concertation of undertakings, the measures could still be saved if they 'are taken in pursuit of a legitimate and clearly defined public interest objective and where Member States actively supervise that concertation.'[185]

This solution, however, has much the same drawbacks as the first proposition. The Court, first, has never used it. In each case it found no delegation, it found no anti-competitive conduct either.[186] Second, it would be wildly inconsistent with its own caselaw. In the 1985 case of *BNIC v Clair*, the Court had to consider a price-fixing agreement adopted

[182] Suffice it to refer to Reich, 'The "November Revolution" of the European Court of Justice: *Keck*, *Meng* and *Audi* Revisited' (1994) 31 *C M L Rev* 459. Advocates-General Jacobs and Léger have recently expressed their dissatisfaction with *Meng*'s requirement of a 'link'. See their Opinions in Joined Cases C–180 to 184/98 *Pavel Pavlov* [2000] ECR I–6451, and Case C–35/99 *Manuele Arduino* [2002] ECR I–1529, respectively.

[183] *Meng*, above n 179, para 18 of AG Tesauro's Opinion (no need for link with private anti-competitive behaviour under delegation test 'precisely because, and to the extent to which, the Member State *deprives its own legislation of its official character*.') (Emphasis in original).

[184] See eg Gyselen, above n 173; Marenco, 'Government Action and Antitrust in the United States: What Lessons for Community Law?' (1987) 14 *LIEI* 1.

[185] This is AG Jacobs's test as proposed in *Pavlov*, above n 182, para 163.

[186] See eg *Marchandise*, above n 172; *OHRA*, above n 172; *Reiff*, above n 168; *Tankstation 't Heuske*, above n 172; *Delta*, above n 172; *Spediporto*, above n 172; *DIP*, above n 172; *Corsica Ferries v Antichi Ormeggiatori*, above n 172; and *Librandi*, above n 172.

by the *Bureau national interprofessionnel du cognac*.[187] The case presented perfect material for the establishment of a state action doctrine. BNIC was financed by para-fiscal levies, its members were appointed by the Minister, it was entrusted with a public service mission by law, and its decisions were made binding by ministerial decree. The Court was unimpressed. First, even if appointed by the Minister, the Bureau's members were proposed for appointment by trade organisations and must, according to the Court, consequently 'be regarded as in fact representing the those organisations'.[188] Second, the fact that the *Bureau*'s decisions were only recommendations made binding by decree of the public authorities was held to be irrelevant.

> It must be pointed out that for the purposes of Article 85 (1) it is unnecessary to take account of the actual effects of an agreement where its object is to restrict, prevent or distort competition. By its very nature, an agreement fixing a minimum price for a product which is submitted to the public authorities for the purpose of obtaining approval for that minimum price, so that it becomes binding on all traders on the market in question, is intended to distort competition on that market.[189]

Agreements and decisions restricting competition are thus prohibited *per se*, even if the body concerned is entrusted with a mission of *service public* and makes decisions according to procedures approved by law:

> [T]he legal framework within which such agreements are made and such decisions are taken and the classification given to that framework by the various national legal systems are irrelevant as far as the applicability of the Community rules on competition and in particular Article 85 of the Treaty are concerned.[190]

Two years later, the Court drew the consequences. In *BNIC v Aubert*, this time dealing with the adoption of an agreement fixing market shares, the Court condemned France for making the agreement generally binding.[191]

The implication must be that no amount of state involvement can save an arrangement that infringes Article 81 (1) EC. This conclusion, moreover, conforms to the structure of Article 81 EC. Infringements of Article 81 (1) EC are automatically void under Article 81 (2) EC, save for exemp-

[187] Case 123/83 *BNIC v Clair* [1985] ECR 391. In the extraordinarily weakly reasoned judgment in *Arduino*, above n 182, the Court could be argued to apply a State action test. In para 43, it denied delegation on the grounds that the State retained final discretion and found, *for those very same reasons*, that the Italian State was not 'open to criticism that it requires or encourages the adoption of agreements, decisions or concerted practices contrary to Article 81 of the Treaty.' Cf Thunström, Carle, and Lindeborg, 'State Liability under the EC Treaty Arising From Anti-Competitive State Measures' (2002) 25 *World Competition* 515.

[188] Above, para 19.

[189] Above, para 22. Note that AG Léger in *Arduino,* above n 182, para 78, considers these principles 'too strict'.

[190] Above, para 17.

[191] Case 136/86 *BNIC v Aubert* [1987] ECR 4789, para 24.

tions granted by the Commission under Article 81 (3) EC on strictly economic grounds. The provision simply does not allow for public interest justifications once an infringement has been found.[192] It also confirms the general principles of Community law. Institutional deference to national public authorities' conception of how best to further the public interest, regardless of the anti-competitive consequences of their actions, would be to let Member States determine the scope of EC competition law unilaterally, a consequence the Court has stated to be unacceptable.[193]

But if this analysis is correct, we now still have two branches of *effet utile* that fundamentally contradict each other. Under the first, the Court objects to anti-competitive agreements whatever the amount of official authority bestowed on the arrangement. Under the second, the Court objects to lack of official authority whatever the anti-competitive effects of the arrangement. If it wants to save an arrangement, the Court has to find *both* a reason not to classify it as anti-competitive independent from public involvement *and* a reason to deny delegation independent from the objectives the arrangement pursues, the interests it protects, or the procedural guarantees it provides. If it finds one but not the other, it has to condemn the arrangement. But it never does find one but not the other. It always finds both or neither.

On the same day as *Meng*, the Court decided *Reiff*.[194] The facts of that case were strikingly similar to those in the *BNIC* cases. In accordance with the *Güterkraftverkehrsgesetz* (GüKG), prices for road haulage were set by a tariff board, whose members were appointed by the Minister upon the suggestion of undertakings and associations operating in the sector. Decisions of the board were routinely made binding by the Minister. Yet to the disgust of many, the Court saved the arrangement.[195] First, it found

[192] In the one string of cases where the Court decided to defer to the 'public interest', it held that collective labour agreements, by virtue of their status in the Treaty, fall outside the scope of Article 81 EC altogether. See Case C–67/96 *Albany International* [1999] ECR I–5751; Joined Cases C–115 to 117 and 219/97 *Brentjens Handelsonderneming* [1999] ECR I–6025; Case C–219/97 *Drijvende Bokken* [1999] ECR I– 6121; Case C–222/98 *Van der Woude* [2000] ECR I–7111. This exemption, however, applies explicitly only to public interest objectives recognised in the Treaty. See Case T–144/99 *Institute of Professional Representatives before the European Patent Office* [2001] ECR II–1087, para 67 (dismissing claims that rules of professional conduct fall outside the scope of Article 81 EC on the grounds that, 'where those drafting the EC Treaty intended to remove certain activities from the ambit of competition rules or apply a specific regime to them, they did so expressly').

[193] See eg Case 118/85 *Commission v Italy* [1987] ECR 2599.

[194] *Reiff*, above n 168.

[195] See the casenotes by Möschel, 'Wird die Effet Utile Rechtssprechung des EuGH Inutile?' (1994) 47 *NJW* 1709; Bach, (1994) 31 *C M L Rev* 1357; Van der Esch 'Loyauté Fédérale et Subsidiarité' (1994) 30 *CDE* 523. The referring judge in *Delta*, above n 172, a very similar case, was asked whether he would consider retracting his reference after *Reiff* was decided. AG Darmon reports that he declined to do so 'not by reason of the differences which might exist between the problems raised by the two procedures, but because, since it disagreed with the solution adopted by the Court, it concluded, for its part, that there was a cartel'. See para 5 of the Opinion.

something in the operation of the tariff board that made it less reprehensible than decisions taken by the *Bureau*:

> The Tariff Boards provided for by the GüKG are made up of tariff experts from the relevant sectors of the road haulage industry who are not bound by orders or instructions from the undertakings or associations which proposed them to the federal Minister of Transport for appointment. Those boards cannot therefore be regarded as meetings of representatives of undertakings in the industry concerned.
>
> Moreover, the GüKG does not allow the tariff Boards to fix the tariffs solely by reference to the interests of undertakings or associations of undertakings engaged in transport but requires them to take account of the interests of the agricultural sector and of medium-sized undertakings or regions which are economically weak or have inadequate transport facilities. Furthermore, the tariffs are fixed only after compulsory consultation of an advisory committee made up of representatives of the users of the services.[196]

Next, the Court also found that the German public authorities' rubberstamping of the tariffs carried more 'official authority' than the French enforcement of BNIC's price-fixing:

> [T]he Federal Minister not only has the power to establish the Tariff Boards and advisory committees, and to decide on their composition and structure but many also personally attend their meetings or be represented at them or delegate that right to agents of the *Bundesanstalt*. Furthermore, if the tariffs decided on by a Tariff Board are inimical to the public interest, the Federal Minister of Transport may, by agreement with the Federal Minister for Economic Affairs, fix the tariffs himself in the stead of the Tariff Board.[197]

Both of the Court's findings are implausible on the facts. The *Bureau* was subject to extensive state involvement and regulated by administrative law due to its status as having a *mission de service public*. It is hard to see how these factors are any less relevant for the antitrust analysis than the statutory classification as 'experts' and the formal obligation to take the 'general interest' into account. It is also hard to see how the German Minister's prerogatives provide any safeguards against 'delegation' that were absent in BNIC. The *Bureau* was established by public law, its members appointed by the Minister, its decisions open to judicial review in administrative court, and its meetings attended by a *Commissaire du Gouvernement*. The Minister, moreover, had every right to refuse to extend the agreements issued by the *Bureau*.

More importantly, the application of both tests in *Reiff* undercuts the doctrinal stance of *BNIC* and *Meng*. The Court could not and did not find something intrinsically pro-competitive under the first test—it saved the arrangement from Article 81 (1) EC *because of* legislative public interest

[196] *Reiff*, above n 168, paras 17–18.
[197] Above, para 22.

guarantees.[198] It could not and did not find sufficient 'official authority' in the formal and strictly theoretical possibility of the Minister's rejecting or amending the tariffs proposed—it saved the arrangement from constituting delegation *because of* the finding that the committee did not infringe the competition rules. The question remains, then: do we now have an institutional public interest test to mitigate the substantive competitiveness norm of *BNIC* and a substantive public interest test to mitigate the institutional 'official authority' norm resulting from *Meng*? Or do we have one single public interest test to determine the compatibility of self-regulation under EC competition law?

In the scheme of Article 81 (1) EC, the question of whether committee members are to be deemed 'representatives' of the undertakings concerned is a matter of the personal scope of the provision. The question is whether a particular regulatory committee is to be considered an 'association of undertakings', or, conversely, 'an arm of the State working in the public interest.'[199] In *Pavlov*, the Court recently summed up its caselaw on the matter. At issue was a decision taken by a professional association of medical specialists to set up a pension fund and apply to the public authorities to make membership of the fund compulsory for the whole profession. The Court held:

> Admittedly, a decision taken by a body with regulatory powers within a given sector might fall outside the scope of Article 81 of the Treaty where that body is composed of a majority of representatives of the public authorities and where, on taking a decision, it must observe various public-interest criteria.[200]

In so far as it gives the impression that the composition requirement is a *sine qua non*, the Court's formulation is careless. To insist on a public majority would constitute a conceptual travesty. Granting immunity to regulatory bodies on the grounds that it consists in majority of representatives of public authorities comes suspiciously close to hiding a state action doctrine in the definition of 'association of undertakings'. And the absurdity that would ensue is quite phenomenal. On the one hand, the whole point of *effet utile* is to refuse to defer to what national public authorities deem to be in the public interest. *BNIC* teaches that whatever the legal status of the body concerned, whatever the political discretion to reject or amend decisions taken by the body, whatever the possibilities of judicial

[198] The Court admits as much, and worse, in *Wouters*, above n 148, para 68. There it professes to defend para 17 of BNIC by pointing out that where a Member State granting regulatory powers to a professional association 'is careful to define the public-interest criteria and the essential principles with which its rules must comply and also retains its power to adopt decisions in the last resort', the rules adopted by that professional association 'remain State measures and are not covered by the Treaty rules applicable to undertakings.'

[199] *Arduino*, above n 182, para 39.

[200] *Pavlov*, above n 182, para 87. AG Léger takes this to be the authoritative test in *Arduino*, above n 182, para 18; and *Wouters*, above n 148, para 70 *et seq*.

review, an anti-competitive agreement infringes Article 81 (1) EC. On the other hand, *Pavlov* seems to suggest that decisions taken by a body consisting in majority of public authorities would fall outside the scope of the competition rules even if they were grossly anti-competitive and even in the absence of any possibility of political oversight or judicial review.

It would also be in flagrant contradiction with its own caselaw. The only instance where the Court found a majority of representatives of public authorities and an obligation to observe various public interest criteria was *Spediporto*, a case dealing with Italian legislation regulating tariffs for road haulage. The Court held that the proposals discussed by the committee could not be regarded as 'agreements, decisions or concerted practices between economic agents'.[201] That same piece of legislation was later amended to the effect that the public authorities had lost their majority on the committee. In *Librandi*, the Court was not at all taken aback:

> [t]he change in the majority-minority relationship within the central committee does not warrant the conclusion that a restrictive agreement within the meaning of Article 81 of the Treaty exists when, under the national legislation in question, the central committee must continue to observe, in adopting its proposals, the public-interest criteria defined by the Italian law.[202]

In the same case, the Court was forced to explain what it meant by its frequent references to the 'public' or the 'general' interest. What the term makes clear, so the Court, is 'that the interests of the collectivity had to prevail over the private interests of individual operators.'[203] It is clear, then, that the requirement of a majority of representatives of the public authorities cannot be taken to stand for the strong proposition that only public officials can be trusted to represent the public interest. It stands for the much weaker proposition that public officials can be trusted *not* to represent 'the private interests of individual operators'.

It is also clear that *Pavlov*'s second requirement, the procedural obligation 'to observe various public interest criteria', is both necessary and sufficient to meet the Court's demands. But this requirement of process stands for a proposition that goes far beyond the one underlying the composition requirement. The Court is in effect putting its faith in the idea that procedural guarantees can discipline financially interested parties to serve the public interest.

[201] *Spediporto,* above n 172, para 25.

[202] *Librandi*, above n 172, para 34.

[203] Above, para 40. For strong opinions on *Spediporto* and *Librandi*, see Leroy, 'L'intérêt Général Comme Régulateur des Marchés' (2001) 37 *RTDE* 49 (arguing that the decisions are 'without theoretical basis or legal definition' and generally in 'flagrant contradiction' with the EC Treaty). Cf Triantafyllou, 'Les Règles de la Concurrence et l'Activité étatique y Compris les Marchés Publics' (1996) 32 *RTDE* 57, 66 ('si les structures sont suffisamment imprégnées de l'intérêt général, elles acquièrent une vocation publique').

To be sure, the Court seems less than comfortable with its own radical approach. Wherever it can, it clings on to supplementary arguments. If, as in *Spediporto*, it finds a majority of public officials, it will gratefully emphasise that fact. But the public majority argument is not qualitatively different from finding that a committee merely reflects a balance of interests. In *DIP*, a case dealing with Italian regulation of municipal licenses for retailers, the Court was happy enough with a committee consisting in majority of a combination of workers' representatives, representatives of public authorities and experts appointed by the latter. The requirement to be satisfied there seemed to be merely that representatives of self-interested traders be in the minority.[204] And even that watered down composition requirement can be traded in for *status* arguments. In *Reiff*, after all, the Court had to do with a committee exclusively composed of financially interested traders. There, however, the Court seemed perfectly happy with legal provisions that provided that committee members were present as 'independent experts' and 'not bound by orders or instructions' of the undertakings that proposed them.[205] *Librandi* takes the issue one step further yet again: instead of relying on legislative provisions that instruct financially interested committee members *individually* to act as public-spirited citizens, the Court takes the leap of faith of relying on provisions that instruct the committee *collectively* to adhere to principles of good governance. The process requirement transforms antitrust into a kind of administrative law for private regulation. And what antitrust protects here is not a competitive market; what antitrust protects is democratic governance.

If *Reiff* and progeny are seriously taken to be consistent with *BNIC*, the result is absurd. Under *BNIC*, an anti-competitive agreement among financially interested traders infringes Article 81 (1) EC even if politically accountable officials acting under the constraints of the full panoply of administrative law decide that the agreement serves the public interest. Under *Reiff* and progeny, an agreement among financially interested private parties, however anti-competitive, is kept outside the scope of Article 81 (1) EC altogether as soon as these private parties obliged to 'observe the public interest' even if they are not subject to political control or judicial review. The problem is, of course, that *BNIC* severs the antitrust analysis from the delegation issue and hence does not allow for public interest

[204] *DIP*, above n 172, para 17.

[205] *Reiff*, above n 168, para 17. In *Delta*, above n 172, para 16, the Court made up for the lack of legislative provisions to the effect that committee members were 'experts' by pointing out that financially interested parties were outvoted three to five in an expanded committee by a chairman and two assessors whose independence was 'expressly underlined' in law. In *DIP*, above n 172, para 18, the Court reinforced its point about the composition of the committee by pointing out that even the members appointed or nominated by traders' organisations were 'present as experts on distribution problems and not in order to represent their own business interests.'

considerations from the delegation test to be carried over to the Article 81 (1) EC issue. Theoretically, the committees in *Reiff* and even *Librandi* would have been safe from antitrust condemnation even if the Court had found that the public authorities had delegated regulatory powers to them.

A Member State is not allowed to 'deprive its own legislation of its official character by delegating to private parties responsibility for taking decisions affecting the economic sphere'. After *Meng*, that prohibition supposedly applies regardless of whether those private parties infringe Article 81 (1) EC.

In as far as it implies that the delegation test is autonomous from the antitrust analysis, this is complete fiction. The Court applies the two independently knowing full well that they cannot possibly yield different results. It cannot condone an anti-competitive agreement on the grounds that the public authorities retain final responsibility, and it cannot condemn legislation in the absence of a link with an infringement of Article 81 (1) EC by private parties.

In the one case where it condemned an arrangement, the Court frankly admitted that the two tests are one and the same. In *Italy v Commission*, dealing with the setting of customs agents' fees, the Court found that the *Consiglio nazionale degli spedizionari doganali* constituted an 'association of undertakings' since it was composed of representatives of financially interested parties who could not possibly be categorised as 'independent experts', and since there was nothing in the legislation in question to oblige, or even encourage, the CNSD to take into account public-interest criteria. The Court then moved on to the delegation test only to note that it was clear *from these exact same considerations* that the legislation in question 'wholly relinquished to private economic operators the powers of the public authorities as regards the setting of tariffs.'[206]

The Court, however, refuses to recognise the mirror image of this reasoning. Whenever it finds that a committee is not an 'association of undertakings' it still applies the delegation test and still insists on the 'official character' of legislation. The patently absurd situation this leads to was best brought out in *DIP*. In that case the Court upheld Italian legislation regulating municipal licensing for new shops according to which a committee is set up which issues opinions on individual requests. In the normal scheme of things, the municipality draws up a 'commercial development plan' laying down criteria the mayor has to take account of when issuing his final decision. However, in case such a plan is not finalised, the mayor cannot grant any licenses without the favourable opinion of the

[206] Case C–35/96 *Commission v Italy* [1998] ECR I–3851, para 57, referring back to paras 41–44. The *Consiglio* had, of course, already been held to infringe Article 81 (1) EC by the Commission in Decision 93/438/EEC (IV/33.407–CNSD), (1993) OJ L 203/27, upheld by the CFI in Case T–513/93 *CNSD v Commission* [2000] ECR II–1807.

committee. After dutifully explaining this veto, the Court held stoically that it 'followed' that the Italian public authorities had not delegated their powers to private economic operators.[207]

The problem is, of course, that the Court *cannot* condemn a Member State for delegation if there is no anti-competitive behaviour on the part of private parties. And so it never finds delegation, even if that requires the ludicrous holding that a Member State does not 'delegate' power to private parties when it grants those parties have veto power to block the entry into the market of potential competitors. And that only begs the question: why apply the delegation test at all?

What the Court looks for under the delegation test is final responsibility on the part of the public authorities to reject or amend the proposals put forward by the committee at issue. This, however, cannot be taken to mean that the Court will defer to whatever the national public authorities choose to put a stamp of official approval on. That would go against the very core of the *effet utile* doctrine—that Community law will not defer to whatever Member States claim to be in the public interest. There are hints in the Court's caselaw that it sees the problem and understands that it should underpin the delegation test with a conception of the 'public interest' that does not depend solely on the 'official character' of legislation. Delegation was denied in *Reiff* not on the generic ground that the final responsibility for the tariffs laid with officials, but because the public authorities had to 'ensure that the boards fix their tariffs by reference to considerations of the public interest' and substitute them with their own if such was not the case.[208] In *Delta* the Court considered the Minister's status important not because he was politically accountable, but because he was, by virtue of his office, under a duty 'to safeguard the public interest'.[209] If this line of reasoning is followed, the justification for insisting that public authorities, and not private traders, take 'responsibility for taking decisions affecting the economic sphere', is that public authorities, unlike private traders, can be trusted to act in the public interest. And if this much is accepted, there was no reason to apply the delegation test in *Spediporto*: there, after all, public officials effectively determined the tariffs in the first place.[210] And if public discretion is logically equivalent to a public majority, the Court has already made clear in *Librandi* that procedural public interest obligations provide guarantees equivalent to a public majority.[211] At this point, then, the 'public interest' test under the definition of 'association of undertakings' is one and the same as the 'public interest' test in the delegation analysis. Consider the Court's treatment of consulting obligations: in *Reiff*,

[207] *DIP*, above n 172, paras 22–23.
[208] *Reiff*, above n 168, para 22.
[209] *Delta*, above n 172, para 21.
[210] The Court did so anyway, of course. *Spediporto*, above n 172, paras 27–28.
[211] *Librandi*, above n 172.

the Tariff Board was obliged to consult an advisory committee of users, which the Court took to be an element in deciding whether or not the Board constituted an 'association of undertakings.'[212] In *Spediporto* and *Librandi*, the Court held that the competent Minister's duty to consult concerned third parties was an argument against 'delegation'.[213] Both findings are implausible: consultation of concerned third parties neither protects competition nor reinforces the 'official character' of legislation; consultation of concerned third parties enhances the procedural legitimacy of decision-making.

Absent mere institutional deference, the 'public interest' under the delegation test cannot mean anything different from the Court's definition in *Librandi*: that the interests of the collectivity have to prevail over the private interests of individual operators.[214] The appropriate distinction, then, is not between private decisions and decisions endowed with 'official character' enshrined in public regulation. The appropriate distinction is between decisions taken in the advancement of the collective good and decisions taken in the pursuit of narrow private interests. The appropriate demand is for 'public-regarding' regulation, not for public regulation.[215] The 'delegation' test, then, locates the 'public interest' not in public institutions but in procedures that ensure democratic governance.

What are, then, the implications of *Reiff* for European standardisation? Those who argue most passionately for the constraints that *effet utile* imposes upon the European institutions themselves do so with explicit reference to the dangers of delegating regulatory tasks to the European standards bodies.[216] The problem is that this anti-corporatist liberalism is an empty normative claim in the field of standardisation. It drives a wedge between the two pillars of the *effet utile* doctrine that leaves only two options open, both of which are destructive of the very idea of standardisation. Either standards are to be evaluated under Article 81 (1) EC as merely private agreements, and analysed individually on their merits and their impact on the market. Alternatively, the Commission is to draft and adopt standards officially and arrogate and exercise the right to reject or amend them before doing so, relegating private stand setting to some innocuous advisory function. Both options are detrimental to what the Council has identified as the core of standardisation, 'a voluntary, consensus driven activity, carried out by and for the interested parties themselves.'[217]

[212] *Reiff*, above n 168, para 18.
[213] *Spediporto*, above n 172, para 27, and *Librandi*, above n 172, para 35.
[214] *Librandi*, above n 172, para 40.
[215] See Mashaw, above n 53.
[216] See Van der Esch, 'Dérégulation, Autorégulation et le Régime de Concurrence Non Faussée dans la CEE' (1990) 26 *CDE* 499, 517; Möschel, above n 174, 103.
[217] Council resolution on the role of standardisation in Europe, (2000) OJ C 141/1, para 11.

The least *Reiff* and progeny can be said to have done is to have expelled the monopoly of rigid and formalistic economism from the analysis of Article 81 (1) EC. There is now in EC competition law a set of procedural public interest criteria, however rudimentary, that provides at least a normative framework for the public regulation of private governance regimes. Hallmarks of public-regarding regulation, such as wide interest representation, consultation of affected outside interests, and efforts to assure economic disinterest, have been transplanted from public administrative law to competition law.

Carrying these principles over from the sphere of economic regulation to the field of social regulation, Christian Joerges and his collaborators have extrapolated constitutional implications from *Reiff* for European standards setting.[218] Joerges' fundamental point is to dissolve the 'delegation' issue by pushing it both outward and downward. In *Reiff*, the formal possibility of the public authorities imposing their own tariffs cancelled out both the fact that they never actually made use of that power and the weakness of the safeguards of public-regardingness of decision-making in the committee itself. In the area of technical standards, it is inconceivable to give such powers to the Commission. Joerges solves that problem by two related moves. First, he argues that the relevant public responsibility is detached from the process of standardisation itself. The corresponding duty of the public authorities to setting fair prices is not setting fair standards; the corresponding duty is ensuring product safety. And genuine safety interests are guaranteed by legislation—on the basis of the General Product Safety Directive and the essential safety requirements in individual New Approach Directives on the one hand, and the Product Liability Directive on the other hand—and enforced by public authorities and courts.[219] These surrounding legal structures put constraints on standards, which do not, however, compensate for direct administrative supervision. Hence, second, the demands put on the internal organisation are different than those the Court contented itself with in *Reiff*. Standards have not just economic consequences but affect the health and safety of citizens. Accordingly, the public interest requirements on private decision-making are not just negative—seeking to avoid financial bias and collusion, but

[218] The *Reiff* analogy was first introduced in standards literature by Falke and Joerges, *Rechtliche Möglichkeiten und Probleme bei der Verfolgung und Sicherung Nationaler und EG-weiter Umweltschutzziele im Rahmen der Europäischen Normung*, (Gutachten erstellt im Auftrag des Büros für Technikfolgen-Abschätzung des Deutschen Bundestags), (Zentrum für Europäische Rechtspolitik, Bremen, 1995) 147 ff. See also Joerges, '"Good Governance" Through Comitology?' in Joerges and Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart Publishing, Oxford, 1999) 311, 331 ff; Joerges, Schepel and Vos, *The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Process: The Case of Standardisation Under the "New Approach"*, EUI Working Papers Law 99/9 (European University Institute, Florence, 1999) 34 ff.

[219] Joerges, Schepel and Vos, above n 218, 56.

positive—seeking to promote knowledgeable and responsible decision-making. The difference comes to light best in the requirement for 'expertise'. In *Reiff*, being an 'expert' was construed by the Court as a signal of independence; in standardisation, being an 'expert' is a condition for adequate decision-making. In *Angelopharm*, the Court has indicated that, in matters for which the Commission and the political committees it surrounds itself with lack the necessary knowledge to make an informed decision, there is a legal obligation, 'in the nature of things and apart from any provision laid down to that effect', to seek the advice of scientific and technical experts.[220] Joerges has argued that, in standardisation, *Angelopharm* and *Reiff* converge in the obligation incumbent on the Commission to ensure that, when it makes use of private bodies for purposes of social regulation, those private bodies have and use the necessary expertise.[221]

The bite of the doctrine lies not, of course, only in the Court's listing of vague and formal conditions to be fulfilled for self-regulatory mechanisms to be excluded from the competition-law regime. The bite of the doctrine lies in the fact that the actual fulfilment of these vague and formal conditions can be reviewed by national courts. As the Court stated in *Librandi*:

> [I]t is for the national courts to determine, in the exercise of their jurisdiction, that in practice tariffs are fixed subject to observance of the public-interest criteria defined by the law and that the public authorities are not handing over their prerogatives to private economic agents.[222]

All of this however, still depends on the requirement that the public authorities do not 'deprive their legislation of its official character.' As applied by the Court now, private, unregulated standardisation finds no protection whatsoever under the *effet utile* doctrine. Even if the Court were to accept that requiring public authority to take the final decision would be foolish and counterproductive in the area of standards, it would still require *legislative* public-interest obligations to be imposed on the internal organisation of standards bodies, and administrative review of those obligations being heeded to.[223]

I have argued at improbable length why the delegation test as applied by the Court is inconsistent with its own caselaw, contrary to the basic principles of Community law, formalistic and plain wrong. As regards standardisation, it would be utterly absurd. A European standard rendered mandatory in one Member State now has a better chance escaping

[220] Case C–212/91 *Angelopharm v Hamburg* [1994] ECR I–171, para 33.
[221] Falke and Joerges, above n 218, 153–54.
[222] *Librandi*, above n 172, para 36.
[223] See Schießl, above n 141, 132 (arguing for a Regulation codifying the Model Directive wih additional interest representation guarantees to have the European standards bodies escape the sphere of application of the *effet utile* doctrine).

the confines of Article 81 (1) EC than the same standard applied voluntarily in another Member State; a European standard adopted by AFNOR would probably fulfil the Court's conditions thanks to the veto power of the French public authorities and the standards law, a standard adopted by BSI would not.

Generally, holding on to the 'delegation' test as understood now by the Court, a voluntary standard adopted by a fair process subject to wide interest representation, public review, and acknowledged expertise, would not be immunised from antitrust review on the grounds of those public interest safeguards; these public-interest criteria would only be allowed into the analysis if standard were subsequently rendered mandatory by public law. And that would have the absurd consequence that mandatory standards are subjected under a looser antitrust review than voluntary standards. Which, in turn, goes against the Commission's Guidelines, which posit voluntary application as a condition for inapplicability of Article 81 (1) EC,[224] as well as against common sense. A voluntary standard is subjected to testing by the market; a bad standard can theoretically just be ignored.

The Court has taken a bold step by introducing concepts of good governance into the analysis under Article 81 (1) EC. What it has done is collapse the issue of liability into the issue of antitrust immunity; regimes will not be held liable under Article 81 (1) EC if they are immunised by public-interest criteria. As long as the Court holds on to an institutional concept of the public interest as incarnated by the public authorities, however, it will have done nothing but hide a state action doctrine in the definition of 'association of undertakings.'

6. CONCLUSION

Both the Supreme Court and the European Court of Justice have struggled to find a way to balance the benefits to safety and health standards provide with the threat of anti-competitive collusion taking place in standards bodies. The relatively easy part of that exercise has been to come down hard on blatant instances of abuse of standards and the process of standardisation for private gain. But implicit there is already the core problem; if competition law cracks down on 'illegitimate' standardisation, it should find a way to define and police the borders of 'legitimate' standardisation. Overcoming the problem entirely would imply one of two choices: either all standard setting is regarded as a private competition—distorting activity and all standards would be subject to economic impact analysis under

[224] Commission Notice—Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements, (2001) OJ C 3/2, para 165.

antitrust law, or all standardisation is regarded as a public activity in the 'general interest' and subjected to public law review of good administration.

The hybrid nature of standard setting has compelled both legal systems to engage in messy public/private distinctions. And the comparative finding is paradoxical. The Supreme Court starts with the notion that states are free to make use of private regimes, which violate the Sherman Act as long as they do not 'delegate' their powers to those regimes. It then collapses the issue of immunity into the issue of liability, and only grants immunity if the private regime is found not to be liable under the Sherman Act. The European Court of Justice starts with the notion that Member States are only free to make use of private regimes if these do not violate Article 81 (1) EC. It then collapses the issue of liability into the issue of immunity, and only finds private regimes not liable if the public authorities have not 'delegated' their powers.

The European Court of Justice has cornered itself in an impossible situation. As its *effet utile* doctrine stands now, the Court argues in circles: there is no delegation because the private arrangement is pro-competitive, and the arrangement is pro-competitive because there is no delegation.

The Supreme Court has found an immunity doctrine within liability analysis by proceduralising its notion of 'pro-competitiveness': *Allied Tube* stands for the proposition that wide interest representation, due process, and expertise render standards compatible with the Sherman Act; only as long as these criteria for 'pro-competitiveness' are observed will standards bodies be considered to act as public bodies. In American law, a rigidly institutional concept of the 'public interest' is compensated for by stretching out competition law.

What the Court of Justice has to do is find a liability doctrine within immunity analysis by proceduralising its notion of 'delegation'. *Reiff*, properly understood, stands for the proposition that wide interest representation, due process and expertise provide safeguards of the public interest equivalent to the ones provided by public measures; only as long as these public interest criteria are observed will standards bodies not fall within the sphere of application of Article 81 (1) EC. In European law, rigid economic analysis under Article 81 (1) EC should be compensated for by stretching out the concept of the 'public interest'.

If not the reality, this chapter at least has shown the potential competition law has for subjecting private transnational governance to a more or less coherent set of procedural requirements that are cut loose from hierarchical conceptions of legitimacy. Standards bodies should be disciplined into institutionalising and enforcing these procedural requirements, subject to decentralised non-intrusive judicial review for defects and abuse.

10

Custom, Science and Law: Linking Institutions in Tort

1. INTRODUCTION

THE GENERAL DEBATE on the regulatory functions of tort law focuses on the relative institutional advantages of public and private law. At bottom an argument between the distributive superiority of public regulation and the advantages of flexibility of private law, the debate tends to cast the two systems as parallel universes which can do little but frustrate each other's objectives.[1] The US tort system is generally considered the functional equivalent of public health and safety regulation,[2] and a more effective one at that: as consumer advocates say, 'the legal system has given us the world's safest products.'[3] That American emphasis on private law litigation, then, is commonly contrasted to the paramount role of public regulation in Europe. In one such effort, Howells singles out 'the extent to which European standardisation is integrated to the legal regime' as one of the most striking differences between the two systems. In the EU, standardisation has become 'part of the corporatist state structure' which not only strengthens the regulatory regime but also leads to a 'certain degree of involvement of all interested parties', as opposed to the US where standardisation 'is still largely a private procedure' and hence of little benefit to consumer safety.[4]

[1] Compare eg Brüggemeier, *Prinzipien des Haftungsrechts* (Nomos, Baden-Baden, 1999) 22–23 (contrasting the advantages of tort law—flexibility, sensibility to context—with abstract and inflexible public regulation); and Rose-Ackerman, *Rethinking the Progressive Agenda—The Reform of the American Regulatory State* (Free Press, New York, 1992) 199 ff (arguing against the regulatory role for tort law, specially in products liability, for reasons of distributive efficiency).

[2] See generally Komesar, *Imperfect Alternatives: Choosing Institutions in Law, Economics and Public Policy* (University of Chicago Press, Chicago, 1994) ch 6.

[3] Wolfman, *Public Citizen Litigation Group*, quoted in Tomkins, 'Justice is Blind' *Financial Times* 17 July 1998, 15. Much of this alleged effectiveness of American tort law is, of course, related to generous punitive damages, contingency fees and other factors of little interest to the issues at hand here.

[4] Howells, 'The Relationship Between Product Liability and Product Safety—Understanding a Necessary Element in European Product Liability Through a Comparison with the US Position' (2000) 39 *Washburn L J* 305, 308.

However, it is important to realise, as underlined by Neil Komesar, that the matter of institutional choice does not finish with the simple choice between public regulation and private law. *Within* tort law, decision-making authority is often necessarily allocated to the political process (statutory requirements), technical knowledge (feasibility), to the market (risk/benefit), to professions (custom), or even to general social norms ('reasonable man', 'legitimate consumer expectations').[5] And the comparative inquiry into the way standards fit into this normative fabric cannot stop at the threshold issue of 'public' law versus 'private' law.

This chapter traces the role of standards in these institutional choices. In each of these, the issue revolves around the conditions under which courts are willing to lend authority to standards by constituting them as legally valid social custom, political choice, or even scientific truth. And that, in turn, leads to the potential of private law to constitute standards bodies as *loci* of legitimate decision-making.

The first section deals with negligence, and largely serves to introduce the themes that come up in the rather longer and more formal discussion of product liability law. The chapter concludes with a section on the conditions under which standards bodies themselves can be held liable for promulgating defective standards.

2. NEGLIGENCE AND THE JURIDIFICATION OF CUSTOM

In the relatively simple world of Pennsylvania in the late 1880s, the legal requirement of due care was famously held *never* to exceed social custom by the state Supreme Court:

> [T]he unbending test of negligence in methods, machinery, and appliances is the ordinary usage of business. No man is held by law to a higher degree of skill than the fair average of his profession or trade, and the standard of due care is the conduct of the average prudent man.
>
> [N]o jury can be permitted to say that the usual and ordinary way, commonly adopted by those in the same business, is a negligent way for which liability shall be imposed. Juries must necessarily determine the responsibility of individual conduct, but they cannot be allowed to set up a standard which shall, in effect, dictate the customs, or control the business, of the community.[6]

Under threat of the dangers of the industrial age, however, this 'unbending' *per se* rule soon gave way to what has been coined the 'evidentiary rule' according to which adherence to customary rules is but an indication

[5] Komesar, above n 2, 156–57.
[6] *Titus v Bradford* 136 Pa 618, 626 (Pa 1890).

of meeting the legal requirement.[7] Arguably America's two most famous jurists ever are held responsible for the negligence revolution. At the turn of the century, Oliver Wendell Holmes cut legal norms loose from custom in *Behymer*:

> What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not.[8]

Three decades on, Learned Hand expressed the rationale for the new rule thus in *The T.J. Hooper*:

> Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have lagged in the adoption of new and available devices. It may never set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.[9]

This autonomy of legal requirements from custom puts the legal system under enormous normative and cognitive strain. Admittedly, the vast increase in public health and safety regulation associated with the welfare state has relieved courts of much of the stress for a long time. But from an evolutionary perspective, the argument is easily made that under technological pressure and increasing social differentiation, the ability of public regulation to occupy the field of product safety with a comprehensive set of precise legal requirements has diminished to the point of obsolescence. In that process, old indeterminate legal concepts acquire a new sense of modernity:

> Le rythme du développement technique est devenu beaucoup plus rapide que le rythme de production des normes, ce qui fait que les anciens critères

[7] Early influential consecration of the theory in Morris, 'Custom and Negligence' (1942) 42 *Colum L Rev* 1145. A good contemporary discussion of custom in tort law is Hetcher, 'Creating Safe Social Norms in a Dangerous World' (1999) 73 *S Cal L Rev* 1.

[8] *Texas & Pacific Railway Co v Behymer* 189 US 468, 470 (1903).

[9] *The TJ Hooper* 60 F 2d 737, 740 (2nd Cir 1932). In the wake of *The TJ Hooper*, evidence of complying with ASME codes and the state Boiler Code was brushed aside in the Wisconsin Supreme Court: 'The fact that the custom of manufacturers generally was followed is evidence of due care, but it does not establish it as a matter of law. Obviously, manufacturers cannot, by concurring in a careless or dangerous method of manufacture, establish their own standard of care.' *Marsh Wood v Babcock & Wilcox Co* 240 NW 392, 396 (Wis 1932). Richard Epstein sees socialist tendencies in Hand's condemnatory rhetoric: 'He was able to make the gap between custom and negligence seem less like a fine point in the law of torts and more like an attack on industry, one that gained credibility because it was authored by a great judge whose own conservative credentials could scarcely be called into doubt. In effect, *The TJ Hooper* erected a populist manifesto for the tort law.' Epstein, 'The Path to *The TJ Hooper*: The Theory and History of Custom in the Law of Tort' (1992) 21 *J Leg S* 1, 37. For a political history of tort law, see Rustad and Koenig, 'Taming the Tort Monster: The American Civil Justice System as a Battleground of Social Theory' (2002) 68 *Brooklyn L Rev* 1.

> génériques de l'imprudence, de l'impéritie et de la négligence, en s'affranchissant du standard du bon père de famille, se replacent d'une façon tout a fait inédite au centre de la problématique de la faute.[10]

Now, armed with such vague generic legal requirements in the face of a vastly complex world, it is only logical that courts look to standards.[11] Not only do standards knit together a normative fabric the sheer quantity of which far exceeds the measly threads of public law, they also draw on a body of knowledge and expertise which is utterly unavailable to lawmakers. In 1964 the New Jersey Supreme Court admitted a code, since it was introduced

> not as substantive law, as proof of regulations or absolute standards having the force of law or of scientific truth. It is offered in connection with expert testimony which identifies it as illustrative evidence of safety practices or rules generally prevailing in the industry, and as such it provides support for the opinion of the expert concerning the proper standard of care.[12]

Other courts gradually followed suit. In 1975, the Fifth Circuit discerned a 'modern trend of cases finding national safety codes representative of a consensus of opinion carrying the approval of a significant segment of an industry' where courts had become 'increasingly appreciative' of their value, and announced with some aplomb:

> Though the law is by no means settled, this Court finds that the inherent trustworthiness of such codes and recommendations, coupled with the need for their introduction in order to impart relevant information not contained elsewhere, is sufficient to justify their admission, notwithstanding the traditional dangers of hearsay evidence.[13]

[10] Incorvati, 'Hasard et Nécessité dans les lois Scientifiques et Juridiques' in Amselek (ed), *Théorie du Droit et Science* (PUF, Paris, 1994) 105, 122. See also Brüggemeier, above n 1, 24 (the French civil code, indeterminate and open to judicial lawmaking, is 'modern again').

[11] See, however, Gusy, 'Leistungen und Grenzen Technischer Regeln—am Beispiel der Technischen Baunormen' (1988) 79 *Verwaltungsarchiv* 68, 75 ('Ist aber das Recht relativ unbestimmt, so können auch seine Erwartungen an die technische Normen nur relativ unbestimmt sein.')

[12] *McComish v DeSoi* 200 A 2nd 116, 200 (NJ 1964).

[13] *Muncie Aviation v Party Doll* 519 F 2d 1178, 1183 (5th Cir 1975). Cf eg *Frazier v Continental Oil* 568 F 2d 378, 382 (5th Cir 1978), (admitting evidence of violation of NFPA code) and *Dixon v International Harvester* 754 F 2d 573, 582 (5th Cir 1985), ('the admissibility of ANSI standards is clearly established in this circuit'). See Hoffman and Hoffman, 'Use of Standards in Products Liability Litigation' (1980) 30 *Drake L Rev* 283, 287 (noting that 'a shrinking majority of jurisdictions' would not allow standards into evidence for any purpose unless they had the force of law); Blechman, 'The Legal Significance of Voluntary Standards in the United States' in Commission Droit et Vie des Affaires (ed), *Le Droit des Normes Professionnelles et Techniques* (Bruylant, Bruxelles, 1985) 433, and the cases collected in Feld, Annotation, 'Admissibility in Evidence, On Issue of Negligence, Of Codes Or Standards of Safety Issued or Sponsored by Governmental Body or Voluntary Association' (1974–2000) 58 *Am L Rep* 148.

The threshold issue of admissibility seems well relatively well established now.[14] But that, of course, is only the beginning of the enquiry.

2.1 Non-Compliance with Standards and Breach of Legal Requirement of Due Care

The almost universal rule in civil law countries seems to be well encapsulated by Herman Cousy's phrase: compliance with standards is a necessary but not necessarily sufficient condition to be immune from negligence liability.[15] For offensive use of standards in tort, courts seem readily prepared to equate non-compliance with standards with violation of legal requirements. The French *Cour de cassation* has classified AFNOR standards as 'l'expression des règles de l'art et de sécurité minimum qui s'imposent à l'ensemble des professionnels.'[16] Non-compliance then leads to a factual presumption of negligence, rebuttable with proof that the standard was either obsolete or otherwise unsuitable.[17] In the United Kingdom, it appears that courts have more difficulty in equating non-compliance with a breach of due care. In *Ward v Ritz Hotel*, the hotel was sued for breach of care after plaintiff fell over backwards over the balustrade of a balcony. Notwithstanding the fact that it was established

[14] In *Hackley v Waldorf-Hoerner* 425 P 2d 712, 716 (Mont 1967) the Montana Supreme Court rejected American Standards Association standards in explicit disagreement with *McComish*. After an implicit rethinking of the issue in *Runkle v Burlington Northern* 613 P2d 982 (Mont 1980), *Hackley* was not explicitly overturned until the 1997 decision in *Lynch v Reed* 944 P 2d 218, 223 (Mont 1997). Noting 'some division of authority on the matter', the Court of Special Appeals of Maryland accepted the doctrine explicitly in 1995. See *Kent Village Associates v Smith* 657 A 2d 330, 337 (Md App 1995). Further State court acceptance of the doctrine in eg *Pust v Union Supply* 561 P 2d 355, 364 (Colo App 1977); *Ruffiner v Material Service Corp* 506 NE 2d 581, 584 (Ill 1987); *Hansen v Abrasive Engineering* 856 P 2d 625, 628 (Ore S Ct 1993); *Stone v United Engineering* 475 SE 2d 439, 454 (W Va S Ct App 1996); *Elledge v Richland/Lexington School District* 534 SE 2d 289, 291 (SC App 2000). The Texas Supreme Court refuses to yield, and does not admit codes that 'do not have the force of law and represent only the views of their compilers which are subject to conflicting views.' *B-R Dredging v Rodriguez* 564 SW 2d 693, 694 (Tex 1978). The Texas Court of Appeals maintained in 1985 that this was still the 'majority and prevailing view' and held it up. See *Pate v Texline Feed Mills* 689 SW 2d 238, 246 (Tex App 1985).

[15] See Cousy, 'Les Normes Techniques en Doctrine et en Jurisprudence', Commission Droit et Vie des Affaires (ed), *Le Droit des Normes Professionnelles et Techniques* (Bruylant, Bruxelles, 1985) 391, 401.

[16] Cass Civ, 4 February 1976, *Bull civ* 1976, III, No 49, 38.

[17] The issue is not all that clear though. Compare, Penneau, 'Respect de la Norme et Responsabilités Civile et Penale de l'Omme de l'Art' (1998) 18 *Petites Affiches* 28; and Champigneule-Mihaïlov, 'Les Aspects Juridiques de la Normalisation en France' in Falke and Schepel (eds), *Legal Aspects of Standardisation in the Member States of the EC and EFTA—Volume 2: Country Reports* (Opoce, Luxembourg, 2000) 231, 301. Similar reasoning applies to Belgium and Italy where non-compliance with standards is necessary to fulfil the 'diligence and prudence' and 'ordinary care' requirements of their respective civil codes. See generally, Schepel and Falke, *The Legal Status of Standardisation in the Member States of the EC and EFTA* (Opoce, Luxembourg, 2000) 231 ff.

that the balustrade was lower than permitted by BSI standards, the claim was dismissed in first instance. In the Court of Appeals, the decision was overturned two to one. In dissent, Lloyd L.J dismissed the standard as a 'mere recommendation' without statutory force the violation of which was hence 'not capable of creating a cause of action.'[18] For the majority, McCowan L.J. noted that British Standards 'represent the consensus of professional opinion and practical experience as to the sensible safety precautions,' and held the hotel in breach of its duty of care.[19]

In the US, courts are adamant that non-compliance with standards does not equal a breach of care: 'Violation of privately set guidelines, although admissible as illustrative of negligence, *does not establish negligence*.'[20] The probative value of standards depends partly on their degree of market penetration. In *Glover*, the Ninth Circuit found 'substantial evidence' of BIC's breach of the standard of care owed to consumers in expert testimony that 'no reasonable lighter manufacturer' would sell a lighter which, as did the lighter at issue, failed to meet ASTM standards for extinguishment.'[21] Better still than market penetration is adoption by public authorities: in that case, and only then, *per se* negligence is established.[22] Two issues inevitably arise. First, national standards may be adopted in one state but not another. In *Harned v Dura*, a compressed air tank exploded and severed Harned's arm. The tank was manufactured in South Dakota, where the ASME Vessel Code was not adopted, but exploded in Alaska where it was. The conflict-of-law issue as such was soon resolved, and the Supreme Court of Alaska held as a matter of law that non-compliance with the Code constituted negligence per se. It added an endorsement of the Code itself:

[18] *Ward v Ritz Hotel* [1992] PIQR 315, 320.

[19] Above, 327, with reference to *Board of Governors of the Hospitals for Sick Children v McLaughlin & Harvey* [1987] Con L R 25, 93 (Newey QC, sitting as Official Referee: 'British Standards Codes of Practice are not legal documents binding upon engineers or upon anyone else, but they reflect the knowledge and expertise of the profession at the date when they were issued. They are guides to the engineer and in my view they also provide strong evidence as to the standard of care of the competent engineer at the date when they were issued.')

[20] *Spearman v Georgia Building Authority* 482 SE 2d 463, 465 (Ga App 1997), quoting *Manley v Gwinnett Place Association* 454 SE 2d 577, 578 (Ga App 1995) and adding emphasis. Cf eg *Dunn v Wixom Bros* 493 So 2d 1356, 1359 (Ala 1986), ('customary practices and standards do not furnish a conclusive test of negligence'); *Harwood v Glacier Electric Cooperative* 949 P 2d 651, 656 (Mont 1997), ('The violation of a non-statutory standard may be used as evidence of negligence, but it is insufficient grounds on which to find the defendant negligent per se.'); *Hansen v Abrasive Engineering*, above n 14, 628 (violation of an industry custom does not constitute negligence *per se*). Legislative consecration in, for example, Colorado Revised Statutes 13–20–804 (excluding damages for negligence claims arising out of non-compliance with 'applicable building codes or industry standards.')

[21] *Glover v BIC Corp* 6 F 3d 1318, 1325 (9th Cir 1993).

[22] See eg *Lynch v Reed* 944 P 2d 218, 223 (Mont 1997). But see *Elledge v Richland/Lexington School District* above n 14, 291(proof of promulgation or adoption of national industry standards 'might be' necessary to establish negligence *per se*).

> Furthermore, we find it unnecessary to permit the superior court on remand to use its discretion to decide whether the ASME Code was too obscure, vague or arcane to serve as an appropriate standard of care. As it is both extremely precise and nationally recognised we conclude, as a matter of law, that it should be adopted as the relevant standard of care on retrial.[23]

The case came back two years later, with *Dura* advancing a new theory. Even if it didn't contest the issue of applicable law, it did argue that the fact that the Code was not adopted in South Dakota provided it with an excuse for violating Alaska law under the Restatement (Second) of Torts for instances where the defendant 'neither knows nor should know of the occasion for compliance.'[24] The Court was now practically forced to concede that per se negligence resulted from violating the Code as such, and not from violating Alaska law. Repeating that the Code was 'nationally recognised' and noting Harned's offering of proof that 'compliance with the ASME Code is possible despite the absence of a state code', the Court held that Dura's excuse was invalid:

> It would be poor public policy to allow a manufacturer's ignorance of a national safety code to excuse its negligence or to relieve it from strict liability in tort.[25]

The second issue shows the perversity of deferring to legislatures' deference to standards bodies. *Per se* negligence results from violating public regulations, even public regulations that adopt a twenty year old National Electrical Safety Code. This is true, according to the Indiana Court of Appeals, regardless of compliance with the new edition of the Code which has not yet been adopted by the state legislature.[26]

2.2 Compliance with Standards and Fulfilling the Legal Requirement of Due Care

If standards are considered to be the handiwork of a 'lagging calling', lagging behind the lag is easily condemned. If standards are considered to represent a rather nobler and rather more exigent set of norms, courts' instinct is still to regard them as requiring less than the law does or would do. To equate compliance with standards with the fulfilment of legal requirements is an altogether different matter.

Much of the importance of private law for the regulation of standard-setting lies exactly in the flexibility of the relationship between legal requirements and technical standards. Courts will review the fit between

[23] *Harned v Dura Corp* 665 P 2d 5, 14 (Alaska 1983).
[24] Restatement (Second) of Torts, s 288 (A) (2)(b).
[25] *Dura Corp v Harned* 703 P 2d 396, 410 (Alaska 1985).
[26] *Lueder v Northern Indiana Public Service Comp* 683 N E 2d 1340, 1347 (Ind App 1997).

the level of care laid down in the standard and the level of care it feels its duty to establish as a matter of law.[27] The *Bundesgerichtshof* expressed the general relationship between standards and due care thus:

> To concretise the duty of care, one can indeed draw from the rules of technology as they are laid down in the relevant standards, and, as they are drafted by committees of experts, they often offer a useful measure of the care that may be required in a given case. However, they do not always determine the ultimate care that can be expected in a particular case and do not discharge the judge from his duty to take account of the safety interests of potential victims himself. It is consistent caselaw that the duty of care is not always measured according to what is 'customary' in as far as custom does not always correspond to a comprehensive and knowledgeable evaluation of safety requirements.[28]

Hence, courts set themselves the arduous task of policing the comprehensiveness and technical up-to-dateness of standards.[29] It is, however, one thing for judges to reserve the right to apply their own review of standards' fitness for purpose; it is quite another to engage in such a review on the technical merits of the standard at issue. Courts inevitably take recourse to procedural requirements concerning the inclusion of all interested parties, and concerning mechanisms to ensure timely updating and appropriate technical sophistication.

In the United States, there is effectively a double threshold; first, standards have to fulfil the requirements of admissibility in evidence. Though many courts are satisfied with indications of what is considered 'reasonable' in a particular industry, some States demand rather more than that. The Fifth Circuit demands 'inherent trustworthiness', which it considers established for standards issued by organisations which are formed 'for the chief purpose of promoting safety.'[30] The Montana Supreme Court will allow them only if coupled with a showing of 'general acceptance in the industry concerned.'[31] In Colorado, they are admissible when intro-

[27] See generally Marburger, *Die Regeln der Technik im Recht* (Heymann, Kèoln, 1979) 341 ff. Cf Breuer, 'Gerichtliche Kontrolle der Technik als Gegenpol zu Privater Option und Administrativer Standardisierung' (1987) 4 *UTR* 91; Penneau, *Règles de l'Art et Normes Techniques* (LGDJ, Paris, 1989). For the European Community, Hans Micklitz saw the opportunity early on; see Micklitz, 'Perspectives on a European Directive on the Safety of Technical Consumer Goods' (1986) 23 *C M L Rev* 617, 625. Cf Spindler, 'Market Processes, Standardisation, and Tort Law' (1998) 4 *ELJ* 316.

[28] *Bundesgerichtshof*, 29 November 1983, (1984) NJW 801. Translation mine.

[29] See *Cour d'Appel de Bruxelles*, 14 January 1993, (1993) *L'entreprise et le droit* 136 (standards in the construction sector, taking account of the state of development of scientific knowledge at a given time, establish minimum requirements which construction professionals should fulfil; however, they are not admissible if the state of knowledge, at the time of construction, permitted better performances).

[30] *Frazier v Continental Oil* 568 F 2d 378, 382 (5th Cir 1978).

[31] *Lynch v Reed* 944 P 2d 218, 223 (Mont 1997). Cf *Sawyer v Dreis & Krump Manufacturing* 493 NE 2d 920, 925 (NY App 1986), (jury allowed to consider ANSI standards as evidence of negligence if it first found that the standards represented the general custom or usage in the industry.)

duced as 'objective safety standards generally recognised and accepted as such in the type of industry involved.'[32] But even with such a high first hurdle, courts will leave it up to the jury to decide whether compliance with standards actually satisfies the legal requirement at issue. In *Advincula*, the Illinois Supreme Court granted that evidence of compliance with 'professional standards of care' was 'indicative' of due care, but added that such evidence may be overcome by 'a sufficient showing that the prevailing professional custom or usage itself constituted negligence.'[33] In *Yampa Valley*, the Colorado Supreme Court granted that compliance with the NESC satisfied the 'minimum safety standards of the electric industry' but not that such compliance satisfied the requirement of 'good engineering practice':

> Whether Yampa Valley complied with accepted good engineering practices, or whether it exercised due care in this case, is best determined by the jury after it has examined the relevant evidence and been properly instructed concerning the effect of Yampa Valley's compliance with NESC's minimum standards.[34]

3. PRODUCT LIABILITY LAW

The ultimate answer of legal systems to the development of technology and the 'risk society' is strict liability.[35] Liability now is no longer based on reproachable behaviour but solely on the objective fact of defectiveness. If both American and European product liability law are theoretically based on strict liability, neither has the stomach to push it through. Both systems are permeated with negligence concepts.[36] The shift is, still, a real one. Courts will look for the best that could have been done, not merely what everybody does. For the use of standards, the implication is that they will have to be pushed further towards the boundaries of 'law' or 'science'.

[32] *Miller v Solaglas California* 870 P 2d 559, 567 (Colo App 1994). Cf *Briere v The Lathrop Co* 285 NE 2d 597, 604 (Ohio 1970), (affirming trial court's discretion to allow into evidence standards promulgated by private associations 'after consideration of the manner in which the rules were prepared and the extent of adherence to the rules as a custom of the trade or industry.')

[33] *Advincula v United Blood Services* 678 NE 2d 1009, 1028 (Ill 1997).

[34] *Yampa Valley Electric Association v Telecky* 862 P 2d 252, 258 (Colo 1993).

[35] But see Trumbull, *National Approaches to Consumer Protection in France and Germany, 1970–90*, (PhD Thesis, MIT, Boston, 1999) 285 ff, (explaining traditional differences between French strict liability regime and German negligence regime as to different conceptions of the consumer's role in the economy).

[36] See eg Burrows, 'Products Liability and the Control of Product Risk in the European Community' (1994) 10 *Oxford Review of Economic Policy* 68; Conk, 'Is There a Design Defect in the Restatement (Third) of Torts: Product Liability?' (2000) 109 *Yale L J* 1087. Cf Henderson, 'Why Negligence Dominates Tort' (2002) 50 *UCLA L Rev* 377.

3.1 Defectiveness: The European Community

Rules on liability for damages caused by defective products are harmonised in the European Union and beyond by the Product Liability Directive of 1985.[37] The Directive purports to impose a general regime of strict liability, and defines a defective product as follows:

> 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.[38]

Furthermore, a defect may not be deduced from the mere fact that better products are marketed subsequently.[39]

A reference to the effect that compliance with standards would exclude a 'defect' was left out of the definition of the concept on purpose lest manufacturers would be given the opportunity to be 'the masters of their own liability'.[40] The French implementing law explicitly states that manufacturers can be held liable even if they follow the *règles de l'art* or existing standards.[41] With the principle of separation thus firm in place, standards could, however, still play a significant role in helping to determine the

[37] Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 1985 OJ L210/29. See eg Goyens (ed), *Directive 85/374/EEC on Product Liability: Ten Years After* (Centre de Droit de Consommation, Louvain-la-Neuve, 1996). The Directive has been amended by Directive 99/34/EC, 1999 OJ L 141/1, cancelling the opt-out for unprocessed primary agricultural products in the wake of the BSE crisis. The Commission has launched consultations regarding the economic impact of the Directive; see its Green paper on *Liability for defective products*, COM (99) 369 final. The Community's competence to harmonise product liability law was not obvious. Denying it, eg Börner, 'Die Produkthaftung oder das Vergessene Gemeinschaftsrecht' in W Grewe, *et al*, (eds), *Europäische Geichtsbarkeit und nationale Verfassungsgerichtsbarkeit—Festschrift zum 70: Geburtstag von Hans Kutschler* (Nomos, Baden-Baden, 1981) 43. The ECJ has decided that the Directive pursues 'total harmonisation' and leaves no scope for national measures that provide for greater consumer protection. See Case C–52/00 *Commission v France* [2002] ECR I–3827; Case C–154/00 *Commission v Greece* [2002] ECR I–387; Case C–183/00 *González Sánchez v Medicina Asturiana* [2002] ECR I–3901. Cf Council Resolution of 19 December 2002 on amendment of the liability for defective products directive, (2003) OJ C 26/2. On the influence of the Directive, see generally eg Howells, Comparative Product Liability (Dartmouth, Aldershot, 1993) and OECD, Product Liability Rules in OECD Countries, 1995.

[38] Article 6 (1), Directive 85/374/EEC, (1985) OJ L 210/29.

[39] Above, Article 6 (2).

[40] Taschner, *Produkthaftung: Richtlinie des Rates vom 25 Juli 1985* (Beck, München, 1986) 80.

[41] Article 1386–10, *Code Civil*. Despite condemnation by the ECJ in Case C–293/91 *Commission v France* [1993] ECR I–1, France has waited until May 1998 to implement the Directive by inserting a new Title IV bis in Book III of the civil code. That implementation still falls short of France's obligations. See *Commission v France*, above n 37.

'safety which one is entitled to expect'. Formulated negatively, *failure* to comply with industry standards will almost automatically lead to liability.[42] Positively, 'it is hard to see how a publicly accepted mode of production, in compliance with standards and customary in the sector concerned, could fall short of legitimate safety expectations.'[43] The German government cast the issue as follows in its explanatory memorandum to the German implementing law:

> The use of standards is, next to compliance with statutory safety requirements, an important factor in the framework of legitimate safety expectations. He who uses standards strives for a product without defects. (. . .) Safety, however, is often but one aspect of standards which stands in relation to others and can be qualified by these other factors. Standards, moreover, do not always correspond to the latest technical possibilities. Therefore, compliance with standards cannot be held necessarily to mean and prove that the product in question is really without defects. If, however, the producer has manufactured the product in compliance with standards in such a way as is usual and recognised in the sector concerned regarding the product in question, and this mode of production is accepted by the public at large and by public authorities, then a presumption exists that the product corresponds to the legitimate safety expectations of the public.[44]

By making liability conditional upon a degree of social penetration of norms, strict liability is watered down at the source into a requirement of 'technically sophisticated custom'. Even if caselaw is hard to be found in Europe, it is relatively easy to see how courts will take recourse to standards.[45] Instead of verifying their technical adequacy, courts most likely will first review the scope of standards (is it intended to cover the risk at stake here?); in case of a fit, they will look at the date of the standard and the mechanism in place inside the standards body to verify its technical up-to-dateness; and then they will review both the degree of market acceptance of standards and the procedures of their elaboration. A look at American common law will perhaps shed some light on these issues.

[42] More categorical still, Reich, *Europäisches Verbraucherschutzrecht* (Nomos, Baden-Baden, 1993) 294 ('Ein fehler liegt immer dann vor, wenn das Produkt gemeinschaftsrechtliche, staatlichen oder industrieüblichen Standards nicht entspricht.') *Contra* eg Gambelli, *Aspects Juridiques de la Normalisation et de la Réglementation Technique Européenne* (Eyrolles, Paris, 1994) 209 ('le raisonnement juridique qui identifie non-conformité à la norme et défaut confère implicitement à la norme une sorte de monopole.')

[43] See Taschner, above n 40, 81. Translation mine ('Es macht Mühe zu sehen, inwiefern eine bisher von der Allgemeinheit akzeptierte produktionsweise, die normgerecht und branchenüblich war, den 'berechtigten Sicherheitsanforderungen der Allgemeinheit' widersprechen sollte.') Taschner, a high-ranking Commission official, is widely credited with drafting the directive.

[44] *Begründung des Gesetzentwurfs der Bundesregierung für ein Gesetz über die Haftung für fehlerhafte Produkte,* BT–Drs 11/2247, 19. Translation mine.

[45] Cf Snijders, *Produktveiligheid en Aansprakelijkheid* (Kluwer, Deventer, 1987) 182.

3.2 Defectiveness: the United States

Broadly in line with other 'standards policy' initiatives in the late 1970s, an early draft of a Uniform Product Liability Act suggested to create a presumption of absence of defectiveness of products that conformed to national voluntary safety standards. This status was to be given to standards in the elaboration of which consumer representatives were involved and that were considered 'more than minimum standards' at the time of their development. The initiative was abandoned due to the variance in nature and quality of standards.[46]

However, some states have persisted. The Product Liability Act of Kentucky, for example, provides for a rebuttable presumption of non-defectiveness for products that conform to 'the generally recognised and prevailing standards'.[47] Such presumptions, however, are in principle incompatible with state common law which, at least in theory, operates on a strict liability theory. They are also useless in practice, as Courts fail to see the difference between 'rebutting' presumptions and the normal burden of proof placed on the plaintiff.[48]

The Restatement (Second) on Torts of 1965 establishes liability for harm caused by 'any product in a defective condition unreasonably dangerous to the user or consumer.'[49] Though universally regarded as a strict liability rule in theory, in the thirty years since its adoption by an overwhelming majority of states, US product liability law has become an intricate meshing of different applications of different liability standards (negligence, no fault), different aspects of defectiveness (design, manufacture, warning) and tests (risk/utility, consumer expectations, alternative design), with plaintiffs usually arguing all possible combinations that would seem of use, leaving courts to struggle with picking them apart. The Restatement (Third) of 1998 might clarify some of these issues. The Restatement diverges in major respects from the EC Directive issued in 1985. It maintains strict liability only for *manufacturing* defects, leaving *design* and *warning* defects open to scrutiny under standards of negligence,

[46] See Blechman, 'The Legal Significance of Voluntary Standards in the United States' in Commission Droit et Vie des Affaires (ed), *Le Droit des Normes Professionnelles et Techniques* (Bruylant, Bruxelles, 1985) 436.

[47] Ky Rev Stat Ann s 411.310 (2). See *Owens-Corning v Golightly* 976 S W 2d 409, 411 (Ky 1998), (describing the purpose of the provision as 'not to insulate an entire industry from liability just because every member of that industry was manufacturing and distributing a product known to be inherently dangerous. We agree that if an industry adopts careless methods, it cannot be permitted to set its own uncontrolled standard. If the only test is to be that which has been done before, no industry or group will ever have any great incentive to make progress in the direction of safety').

[48] See eg *Sexton v Bell* 929 F 2d 331, 333 (4th Cir 1991), ('We can perceive no reason why the trial courts would ever have need to instruct the jury on this statutory presumption.')

[49] Restatement (Second) of Torts, s 402A.

or, as the American Law Institute prefers to call it, 'reasonableness'. Moreover, it abandons the 'legitimate consumer expectations' test in favour of a 'risk/utility' test for 'defective' products.

Even now, abstracting beyond important differences between states, true strict liability applies only to *manufacturing* defects.[50] Here, plaintiffs only have to show that the product deviates from the manufacturer's own specifications to prove that it is defective. The implications are straightforward: if a producer claims to follow standards but his product can be shown to deviate from them, he is *per se* liable. The reverse is also true, however.[51]

More complicated analyses have to be employed in the category of *design* defects. Under a theory of strict liability, it is the product that is 'unreasonably dangerous' and not the manufacturer's conduct. There is, however, widespread unease with this distinction. In many states, courts have dismissed it as unworkable and have watered down the strictness to what effectively is a negligence standard.[52] Other states, however, hold on to the theory.[53]

The consequences for the admissibility of standards in design defect cases are straightforward. Pennsylvania, a complex world in the late 1970s, maintains a stubborn and vocal loyalty to strict liability.[54] In its 1987 bellwether decision in *Lewis*, the state Supreme Court considered the matter of industry standards at some length, only to conclude categorically

[50] That is, after all, the category for which it was invented. See *Escola v Coca Cola Bottling Co* 150 P 2d 436, 441 (Cal App 1944), (Traynor J, concurring).

[51] See *Milton Lee Leverette v Louisville Ladder Company* 183 F 3d 339, 341 (5th Cir 1999), (excluding expert evidence on issue of manufacturing defect for failure to assess whether product met ANSI standards).

[52] See eg *Jones v Hutchinson*, 502 SW 2d 66, 69 (Ky 1973), (in defective design cases, 'the distinction between the so-called strict liability principle and negligence is of no practical significance'); *Feldman v Lederle Lab*, 479 A 2d 374, 385 (NJ 1984), ('when the strict liability defect consists of improper design, reasonableness of the defendant's conduct is a factor in determining liability'); *Zaza v Marquess*, 675 A 2d 620, 628 (NJ 1996), ('the ultimate question in design defect cases is whether the manufacturer acted in a reasonably prudent manner in designing and fabricating a product'); *Prentis v Yale Mfg Co*, 365 NW 2d 176, 184 (Mich, 1984), ('the underlying negligence calculus is inescapable'). For law and economics debate, see Schwartz, 'Proposals for Product Liability Reform: A Theoretical Synthesis' (1988) 97 *Yale L J* 353, 392 (arguing in favour of true strict liability offset by contributory negligence on the part of consumers); Viscusi, *Reforming Products Liability Law* (Harvard University Press, Cambridge, 1991) ch 4 (arguing for a narrow negligence standard).

[53] See eg *Barker v Lull Engineering*, 573 P 2d 443, 447 (Cal 1978), (focus on the product, not on the manufacturer's conduct); *Voss v Black & Decker*, 450 NE 2d 204, 207 (NY App 1983), (focus shifts from conduct to whether the product, as designed, was reasonably safe).

[54] See *Azzarello v Black Bros*, 391 A 2d 1020 (Pa 1978). In *Foley v Clark Equipment*, 523 A 2d 379 (Pa Super 1987), a panel of the Superior Court considered that purging negligence concepts from design defect cases was 'a futile exercise in analytical and linguistic gymnastics' and called for a rethink. Another panel 'strongly disagreed' in *Brandimarti v Caterpillar*, 527 A 2d 134, 138 (Pa Super 1987). The Third Circuit shot the *Foley* court down in *Dillinger v Caterpillar*, 959 F 2d 430, 443 (3rd Cir 1992) and *Parks v AlliedSignal*, 113 F 3d 1327, 1335 (3rd Cir 1997).

that evidence of compliance with industry standards goes to the reasonableness of the manufacturer's conduct in making the design choice and would hence 'improperly' bring negligence concepts into the equation. The ASME standards at issue were, then, irrelevant.[55] *Lewis* has been confirmed both by Pennsylvania courts federal courts.[56] It also resonates with decisions in a substantial minority in other jurisdictions.[57] In Missouri, ANSI standards are 'clearly inadmissible' in strict liability cases.[58] In *Kelley v Cairns*, the Court of Appeals of Ohio refused to admit NFPA standards:

> Admission of industrial standards may lead the trier of fact to examine a defendant-manufacturer's compliance or noncompliance with the standards. The focus of the examination is thus drawn away from the product, and whether it is inherently defective, to a focus of whether the manufacturer was at fault in failing to meet industry standards. This results in concepts of fault,

[55] *Lewis v Coffing Hoist Div, Duff-Norton*, 528 A 2d 590, 593–94 (Pa, 1987). The Court explicitly leaned on *Holloway v JB Systems*, 609 F 2d 1069, 1073 (3rd Cir 1979), ('use of trade custom as evidence of the reasonableness . . . would be permissible if the case were tried under negligence principles, but is inconsistent with the doctrine of strict liability'), but wisely ignored *Josephs v Harris Corp*, 677 F 2d 985, 990 (3rd Cir 1982), (in Pennsylvania products liability law, 'safety codes and standards may be admissible when they are prepared by organisations formed for the purpose of promoting safety.')

[56] See eg *Majdic v Cincinatti Machine Co*, 537 A 2d 334 (Pa Super 1988); *Santiago v Johnson Machine and Press Corp*, 834 F 2d 84 (3rd Cir 1987); *Habecker v Clark Equipment*, 36 F 3d 278 (3rd Cir 1994); *Shouey v Duck Head Apparel*, 49 F Supp 2d 413, 422 (MD Pa 1999).

[57] See eg *Raney v Honeywell*, 540 F 2d 932, 938 (8th Cir 1976), (applying Iowa law, upholding a refusal to instruct the jury that compliance with industry standards may be considered as evidence of due care since plaintiff is not required to prove negligence in strict liability case); *Rexrode v American Laundry Press*, 674 F 2d 826, 832 (10th Cir 1982), ('the issue of manufacturer compliance with industry standards is generally considered to be irrelevant in a strict liability case'); *Wheeler v Deere*, 935 F 2d 1090, 1099 (10th Cir 1991), ('A manufacturer's compliance with industry standards is irrelevant in a strict products liability case where the determinative question is whether a product is unreasonably dangerous'); *Lutz v National Crane Corp*, 884 P 2d 455, 465 (Mont 1994), ('even if OSHA and ANSI regulations have some tenuous relevancy in products liability cases such as this, it is not irreversible error to exclude them.'); *Jemmott v Rockwell Manufacturing*, 216 AD 2d 444 (NY 1995), ('ANSI standards are not relevant in causes of action founded in strict products liability').

[58] *Lay v P & G Health Care*, 2000 WL 1807882 (Mo App 2000) 17. The landmark case here is *Johnson v Hannibal Mower Corp*, 679 SW 2d 884, 886 (Mo App 1984), ('The introduction in evidence and consideration by the jury of this evidence of voluntary compliance with standards adopted within the power mower industry as set by ANSI must be deemed prejudicial and as having a material effect in the merits of the case. The fact that these standards were widely adopted in the industry could easily have been interpreted by the jury to mean that the product was safe and resulted in the defendant's verdict.') Cf *Lane v Armsted Industries*, 779 SW 2d 754, 758 (Mo App 1989), (admission of ANSI standards was prejudicial error). In *Lane*, however, the Court did allow evidence of standards for the issue of punitive damages. 779 SW 2d 754, 759 ('Compliance with industry standard and custom impinges to prove that the defendant acted with a nonculpable state of mind—without knowledge of a dangerous design defect—and hence to negate any inference of complete indifference or conscious disregard for the safety of others the proof of punitive damages entails.') On then issue of punitive damages, see further *Sand Hill Energy v Ford*, 83 SW 3d 483, 494 (Ky 2002).

> more associated with negligence, becoming impermissibly infused into an strict liability case.[59]

The importance of *Lewis*, however, lies not so much in the majority opinion as it does in the way the concurring and dissenting opinions bring out the issues at stake. From the concurring opinion:

> The injection of industry standards into a design defect case would be not only irrelevant and distracting, but also because of the inherently self-serving nature of 'industry standards', would be highly prejudicial to the consumer/plaintiff. By our determination today, we have made it clear that a manufacturer cannot avoid liability to its consumers that it injures or maims through its defective designs by showing that 'the other guys do it too.'[60]

The dissent, on the other hand, felt the need to 'speak out against the madness', consisting of 'a creeping consensus among us judges and lawyers that we are more capable of designing products than engineers.'

> [W]e need all the help we can get. Accordingly, I do not believe that industry standards, like the American Association of Mechanical Engineers standards at issue here, are irrelevant to the issue of whether a product was defectively designed. . . .
>
> Industry standards are written by individuals considered by their peers in industry, academia and research to be especially knowledgeable in a particular technical specialty. These standards contain their collective expert wisdom. [-] Of course, these industry standards would not be conclusive, but their relevance and competence is clear.[61]

The overwhelming majority of courts agree.[62] To avoid liability for design defects, 'manufacturers are required to design products that meet

[59] *Kelley v Cairns & Brothers, Inc*, 626 NE 2d 986, 995 (Ohio App 1993). See also *Bailey v V & O Press*, 770 F 2d 601, 607 (6th Cir 1985), (applying Ohio law, holding up a district court's refusal to instruct the jury that the defendant may be held strictly liable for failing to comply with industry standards).

[60] *Lewis*, above n 55, 595 (Pa 1987), (Larsen J, concurring).

[61] Above, 596 (Pa 1987), (Hutchinson J, dissenting). See also *Majdic v Cincinatti Machine Co*, above n 56, 345 (Wienand, J, dissenting), ('The law in Pennsylvania is an anomaly.')

[62] See eg *Reed v Tiffin Motor Homes*, 697 F 2d 1192, 1196 (4th Cir 1982), (noting that 'the majority of courts have found in design defect cases, as opposed to manufacturing defect cases, that state of the art and industry standards are relevant both to show the reasonableness of the design and that the product was dangerous beyond the expectations of the ordinary consumer'); *Carter v Massey-Ferguson*, 716 F 2d 344, 350 (5th Cir 1983), (evidence of industry standards serves the same function as evidence of industry custom, which is relevant in strict liability cases); *Ruffiner v Material Service Corp*, above n 14, 584 ('standards may be relevant in a product liability action in determining whether a condition is unreasonably dangerous'); *Miller v Yazoo*, 26 F 3d 81, 83 (8th Cir 1994), (evidence of compliance with ANSI standards is relevant 'because it tends to make the existence of an unreasonably dangerous condition more or less probable that it would be without such evidence'); *Otilio Romero v Cincinatti Inc*, 171 F 3d 1091, 1095 (7th Cir 1999), (compliance with ANSI standard 'relevant, though not conclusive' in products liability case); *DiCarlo v Keller Ladders*, 211 F 3d 465, 467 (8th Cir 2000), ('evidence of compliance with ANSI standards bears on the question of whether a product contains a design defect'). For legislative agreement, see eg Michigan

prevailing safety standards at the time the product is made.'[63] What's more, both state and federal courts reject a 'bright-line rule' that *foreign* standards, as opposed to legal standards of care, are always irrelevant:[64]

> Both engineering principles and human nature transcend national boundaries, and thus under certain circumstances proof of foreign standards may be relevant and helpful to a jury in determining the issues.[65]

Failure to comply with relevant standards is a strong indication of producing an 'unreasonably dangerous' product.[66] For claims that compliance leads automatically to reasonably safe products, however, courts have devised a number of tests qualifying the rule. First, as they do in negligence cases, courts demand evidence that such standards actually constitute 'industry standards'. Now, it is one thing to ask for some evidence of general acceptance and compliance with such dominant standards as the ASME Vessel Code.[67] The test becomes complicated, however, when there are rival standards on the market. In *Anderson*, the product at issue complied with an ASTM standard but not with a more stringent ANSI standard. The Court held that the question which constituted the 'industry standard' was best left to the jury.[68] Second, the

Compiled Laws 600.2946 (1), ('It shall be admissible as evidence in a products liability action that the production of the product was in accordance with the generally recognized and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.'); Ohio Revised Code 2307.75 (B)(4), (extent to which design conformed to 'any applicable public or private product standard' is factor to be considered in determining foreseeable risks of harm associated with design of a product.)

[63] *Redman v John Brush and Value-Tique, Inc* 111 F 3d 1174, 1177 (4th Cir 1997). But see *Touch v Master Unit Die* 43 F 3d 754, 758 (1st Cir 1995), (nonconformance with a present day safety standard is 'relevant,' but 'does not *compel* the trier of fact to find the product "unreasonably dangerous".')

[64] *Slisze v Stanley-Bostitch* 979 P 2d 317, 322 (Utah 1999). Cf *Tews v Husqvarna* 390 NW 2d 363, 367 (Minn App 1986), (holding that trial court did not abuse discretion in holding that foreign legal standards are irrelevant, but 'technology available in other jurisdictions' is relevant for the determination whether a product is unreasonably dangerous).

[65] *Blevins v New Holland* 128 F Supp 2d 952, 959 (WD Va 2001). See also *Stallings v Black and Decker* 769 NE 2d 143, 149 (Ill, 2003), (finding prejudicial abuse of discretion in the exclusion of evidence of European standards for the feasibility of alternative design.)

[66] See *Christopher Moulton v The Rival Company* 116 F 3d 22 (1st Cir 1997). The case concerns burns suffered from a 'potpourri pot' which heated liquids at temperatures exceeding those prescribed by the standard. After failure to obtain listing by UL, the Rival Company had the pot certified to the same standard by a dodgy commercial testing laboratory whose testing report 'should have raised concerns on its face'. See also *Piper v Bear Medical Systems* 883 P 2d 407, 414 (Ariz App 1993), (evidence of violation of ANSI standard 'sufficient evidence' from which the jury could find design defect). The standard at issue must, however, be more than a 'mere truism' such as the ANSI standard that requires that a ladder be designed 'to withstand its rated load.' *Crawford v Sears Roebuck* 295 F 3d 884, 885 (8th Cir 2002).

[67] See *Betts v Robertshaw* 1992 WL 302288 (Del Super 1992), (demanding evidence of industry-wide compliance with the Code).

[68] *Anderson v Hedstrom Corp* 76 F Supp 2d 422, 450 (SD NY 1999). The case concerned a failure to warn claim, for which New York views negligence and strict liability 'equivalent'. 76 F Supp 2d 422, 439. At issue were warnings on the dangers on trampoline-jumping.

'industry' standard at issue must be applicable both to the product involved and to the context in which it was used.[69] Once those hurdles are taken, the inquiry into the *T.J. Hooper*—problem begins. As articulated by the Eleventh Circuit:

> We do not, naturally, dismiss a manufacturer's compliance with industry standards, but we must also remember that those standards may sometimes merely reflect an industry's laxness, inefficiency, or inattention to innovation.[70]

Which leads to the *Lewis*-dissent problem. Again, as formulated by the Eleventh Circuit in *Elliott*:

> In our view, it is difficult to articulate a rule that categorises, in consistent fashion, those occasions when a court should defer to a manufacturer's compliance with industry standards and those occasions when a court should fashion new guidelines as to what those standards should be.[71]

Three general approaches to the problem of 'fitting' standards to legal safety requirements can be discerned. The first is to validate standards as 'objective' expert opinion. This is what the Eleventh Circuit did in *Elliott*. After being injured by a pleasure boat's rotating propeller, young Miss Elliott claimed that the boat's manufacturer should be held liable for not installing a propeller guard. Neither federal regulations nor industry standards, however, required such a device. Going through the expert testimony, the Court concluded that the current industry standards 'simply reflect the consensus of experts that the industry's adoption of propeller guards at this point would not only be infeasible, but unwise, unsafe and unfortunate.'[72]

The second test effectively analyses whether industry standards 'keep up' with society, and consists of an independent 'consumer expectations' test.[73] The social function of this hinge clause is made clear beautifully by the Fourth Circuit:

> Requiring manufacturers to meet reasonable consumer expectations ensures that their products are required to meet minimum standards deemed

[69] See eg *Ruffiner v Material Service Corp,* above n 14, 584 (refusing to apply ANSI standards for fixed ladders in land-based industrial facilities to a ladder on a towboat); *Carrizales v Rheem Manufacturing* 589 NE 2d 569, 586 (Ill App 1992), (declining to 'apply the standards of one trade or industry to a different trade or industry'); *Simon v Simon* 924 P 2d 1255, 1261 (Kan 1996), (denying that standards apply 'to everyone', and holding instead that they are 'geared heavily toward regulating the manufacture of equipment designed for industrial uses.')

[70] *Elliott v Brunswick Corp* 903 F 2d 1505, 1508 (11th Cir 1990).

[71] Above, 1508–9.

[72] *Elliott v Brunswick Corp* 903 F 2d 1505, 1509 (11th Cir 1990).

[73] *Alevromagiros v Hechinger Co* 993 F 2d 417, 420 (4th Cir 1993), (claim for failure to meet consumer expectations open to plaintiff even when he has failed to show that the product did not meet government or industry standards).

> appropriate by society, even when those societal standards demand safer products than government or industry standards.[74]

In effect, the method implies a sociological investigation into prevailing practice, knowledge and attitudes at the time of test manufacture. The test requires 'a factual determination of what society demanded or expected from a product,' which may be proved 'from evidence of actual industry practices, knowledge at the time of other injuries, knowledge of dangers, the existence of published literature, and from direct evidence of what reasonable purchasers considered defective at the time.'[75]

The third test consists of a procedural probe to guard against private interests being served by the promulgation of standards. A Ninth Circuit case involving contaminated blood brings the point home:

> The possibility that industry standards may fall short of reasonable care is particularly acute, we believe, in a situation such as this where the entire industry is comprised of only four manufacturers. Here, the individual manufacturers have a far greater influence and control over 'industry' standards than do members of industries with greater numbers of participants.[76]

If followed to its logical conclusion, this inquiry leads to an examination of the procedural legitimacy of standards. Ultimately, it seems reasonable to expect this test to eclipse the other two, as 'procedure' is law's chosen, if not only, method of validating 'scientific truth' or 'society's expectations'.

A good starting point for a policy discussion of the role of American liability law on standard setting, and vice versa, is what Ross Cheit identifies as the two major necessary changes in liability law to improve standard setting. These would 'probably have a larger impact on private standards-setting than any aspect of the various 'standards policies' offered in the last ten years'.[77] First, he argues that, in assessing the reasonableness of the risks attendant to a product or process, 'the law should consider overall effects, not just specific incidents. In other words, the law should not impose liability when overall social benefits clearly outweigh specific adverse effects.'[78] Currently, 'unreasonableness' is subject either to a legitimate consumer expectation test or a risk/utility analysis, or both, or some

[74] *Redman,* above n 63. Compare *Falk v Keene Corp* 782 P 2d 974, 981 (Wash 1989), ('It may be unreasonable for a consumer to expect product design to depart from legislative or administrative regulatory standards, even if to do so would result in a safer product'); *Soproni v Polygon Apartment Partners* 971 P 2d 500, 505 (Wash 1999), (although conformity with NFPA Codes and the UBC '*may* satisfy consumer expectations, evidence of compliance with codes should not foreclose plaintiff's claims.'), (emphasis in original).

[75] *Sexton v Bell*, abobe n 48, 337.

[76] *Doe v Cutter Biological, Inc* 971 F 2d 375 (9th Cir 1992).

[77] Cheit, *Setting Safety Standards—Regulation in the Public and Private Sectors* (University of California Press, Berkeley, 1990) 232.

[78] Above.

combination of the two.[79] In another rupture with EC law, the Third Restatement drops the 'consumer expectations test' and adopts the risk/benefit test wholesale under the theory that the former is usually nothing more than a 'clumsy circumlocution' of the latter.[80] It is in line with practice in most states,[81] for the same reason why strict liability theories are generally considered to be unrealistic. The 'consumer expectations test', after all, is 'product-based, not conduct-based.' Risk/utility analysis, on the other hand, is 'the functional equivalent' of traditional negligence analysis.[82]

Standards play different roles in this analysis.[83] In one scenario, courts consider the existence and use of certain standards as evidence of utility. Standards then come in as evidence of practices accepted in the market place which in turn attests to the value consumers attach to these practices. Judge Easterbrook on the Seventh Circuit recently on his own initiative dug up an ANSI standard setting the minimum temperature of coffee from home coffee makers at 170 degrees F to dismiss a claim of defective design of a coffee maker which produced coffee at 180 degrees F. Absent plaintiffs' evidence to the contrary, he held consumers' love of hot coffee established, a value that outweighs the risks of burns.[84] Standards here are taken at face value. In less clear-cut cases, a risk/utility analysis of a product designed in compliance with standards easily transforms into a substantive test of the risk/utility analysis used in the standard itself. In *Tannebaum*, the plaintiff argued that a certain type of forklifts should be fitted with a rear door, despite the fact that OSHA regulations and ANSI standards did not require such devices. It was undisputed that a rear door would inevitably increase the size of the machines and hence would measurably diminish its functional utility in narrow-aisle environments. For the risk analysis, the court effectively deferred to ANSI:

[79] In *Carter v Massey-Ferguson*, above n 62, 348, the Fifth Circuit held that, under Texas law, 'evidence of consumer's expectations is relevant to the risk/utility determination.' In *Potter v Chicago Pneumatic Tool Company* 694 A 2d 1319, 1334 (Conn 1997), the Connecticut Supreme Court announced the adoption of a 'risk-utility balancing component to our consumer expectation test.'

[80] Henderson and Twerski, 'The Politics of the Products Liability Restatement' (1998) 26 *Hofstra L Rev* 667, 671. The test is the feasibility of a safer alternative. For debate, see Kysar, 'The Expectations of Consumers' (2003) 103 *Colum L Rev* 1700; Henderson and Twerski, 'Consumer Expectations' Last Hope: A Response to Professor Kysar' (2003) 103 *Colum L Rev* 1791.

[81] See Judge Calabresi's learned overview in *Castro v QMV Network* 139 F 3d 114 (2nd Cir 1998).

[82] *Denny v Ford* 662 NE 2d 730, 735 (NY App 1995). Note, however, that the Third Circuit, in absence of a certification procedure, has ventured to 'predict' that the Pennsylvania Supreme Court would employ risk/utility analysis in its very strict liability jurisprudence. *Surace v Caterpillar* 111 F 3d 1039, 1044–47 (3rd Cir 1997).

[83] Compare *Carter v Massey-Ferguson*, above n 62, 350 (Garwood, Circuit Judge, concurring), (discussing the role of custom in risk/utility analysis, finding it to show, first, the collective judgment of the industry on the subject, and second, general user experience with and expectations of product handling or performance).

[84] *McMahon v Bunn-o-Matic Corp* 150 F 3d 651 (7th Cir 1998).

> Most significantly, despite what appears to have been a vigorous campaign by Tannebaum's expert to persuade the professionals on the ANSI committee to do so, ANSI has twice rejected the idea that a rear door be required as standard equipment on such forklifts. This is compelling evidence, even if it is not conclusive evidence, that engineering professionals have assessed the risk of rearward ejectment from stand-up forklifts as not unreasonably high.[85]

In *Metzgar*, a case of a child's death by choking on a Playskool building block, the Third Circuit effectively held that the relevant standard itself was badly designed:

> We note that although the purple half-column was in technical compliance with CPSC and ASTM standards, the block only minimally met the required standards by protruding in length slightly beyond the ASTM test cylinder. The block's width, however, was slightly narrower than the test cylinder. It appears that a slight modification to the block design could virtually eliminate the choking potential without detracting from the block's utility. We do not believe, therefore, that the risk of a reasonably foreseeable user choking on the block is so relatively small—measured against the block's decreased utility by modifying its present design—as to permit summary judgment for the defendants on the basis of a risk/utility analysis.[86]

Cheit's other argument leads to more difficulties. His claim is that improvements made in a standard should not be admissible in cases concerning mishaps *prior* to the improvement.[87] The concern here is that improved safety standards cast a shadow backwards to products manufactured according to older standards. With a new standard that deals with the defect at issue, the argument could be made that the older product was 'unreasonably dangerous' or at least that the harm the defect caused was 'foreseeable' at the time. The consequence could be that the industry has a stake in stalling innovation and safety improvements, and hence that no better standards are promulgated.

Trial courts overwhelmingly exclude *ex post* manufacture standards, and *a fortiori* standards promulgated after the incident happened, for lack of relevance. Under the broad discretion they enjoy on issues of admissibility of evidence, reviewing courts usually agree.[88] The substantive rationale for exclusion seems rather straightforward:

[85] *Tannebaum v Yale Materials Handling Corp* 38 F Supp 2d 425, 432 (1999).

[86] *Metzgar v Playskool and K Mart* 30 F 3d 459 (3rd Cir 1994).

[87] Cheit, above n 77, 232.

[88] See eg *Lambertson v Cincinatti Corp* 257 NW 2d 679, 683 (Minn 1977), (consistent admission of contemporary standards and exclusion of ex post standards not 'so clearly wrong' as to constitute abuse of discretion); *Rexrode v American Laundry* 674 F 2d 826, 832 (10th Cir 1982), (trial court properly excluded ex post manufacture standards since 'any relevance which the 1972 ANSI standard might have had to prove the technological infeasibility within the industry to comply with the 1941 ANSI standard in 1959 was at best remote'); *Benford v Richards* 792 F 2d 1537, 1540 (11th Cir 1986), (trial court's exclusion of ex post manufacture industry

> We agree that a safety code or regulation in effect at the time of alleged negligence may be admissible in some circumstances, even if not technically applicable to the situation in question, because it gives some indication of the standard of care at the time of the alleged negligence. In contrast, codes and regulations enacted after the alleged negligence may result from research conducted, information obtained, impracticalities eliminated or mitigated, or even a consensus formed, after the alleged negligence. As a result, such codes and regulations do not in themselves ordinarily give a similar indication of the duty of care years before their enactment.[89]

And even where courts might allow for the possibility that subsequently published standards could have some relevance, the problem lies in the instruction to be given to the jury on the subject. In *Vroman*, the Sixth Circuit had to review an instruction that told the jury it was only to consider the ex post manufacture ASA standards admitted in evidence 'if you find as a matter of fact, from the evidence, that such standards were circulated and known to the defendants, or could have been known by them in the exercise of due care at and before the time this particular mower was designed and manufactured.' Nothing wrong with that as a statement of the law;

> However, it failed, in our view, to provide an adequate instruction (if, indeed, such is possible, which is subject to doubt) concerning a publication promulgated subject to sale. A corollary vice exists in the difficulty (again, if not the impossibility) of eliminating from the minds of the jurors the persuasive weight of these documents in published form, in which they possess all of the attributes of impressive scientific treatises.[90]

The exclusion rule, however, is not steadfast. Perhaps the best way to approach the issue is to start from *Murphy*, a 1977 case where the Illinois Supreme Court objected to admission of a BOCA Building Code adopted in 1963 as relevant on the issue of whether or not handrails should be installed on stairs built in 1952. The Court had no indication that the Code reflected construction industry standards at the time, nor was it able to conclude that the Code was intended to eliminate existing hazards.[91]

standards not an abuse of discretion); *Walsh v Emergency One* 26 F 3d 1417, 1425 (7th Cir 1994), (trial court's exclusion of ex post manufacture NFPA standards no abuse of discretion); *Smith v Black & Decker* 650 NE 2d 1108, 1115 (Ill App 1995), (trial court's exclusion of ex post manufacture UL standards not an abuse of discretion); *Vannucci v Raymond* 258 AD 2d 198, 201 (NY 1999), (evidence of violating *ex-post* ASME standards is not a 'triable issue which would indicate that defendants breached a duty of reasonable care'); *Enfield v AB Chance Co* 182 F 3d 931 (10th Cir 1999), (upholding the following jury instruction: 'A standard that was issued and became effective after the date of manufacture is not relevant and should not be considered by you on the question of whether defendant exercised ordinary care').

[89] *Bennett v Greeley Gas* 969 P 2d 754, 760 (Colo App 1999).

[90] *Vroman v Sears* 387 F 2d 732, 738 (6th Cir 1968). See also *Bennett v Greeley Gas* 969 P 2d 754, 759 (Colo App 1999), ('Any marginal relevance is clearly outweighed by the potential for confusion and unfair prejudice.')

[91] *Murphy v Messerschmidt* 368 NE 2d 1299, 1302 (Ill 1977).

Several cases distinguish from *Murphy*. In *Hanlon*, the Illinois Appellate Court allowed 1981 ANSI standards because they reflected 'the basic knowledge' in 1978.[92] In *Simon*, the Kansas Supreme Court indicated that it might allow standards that 'mandate the modification of existing equipment.'[93] And in *Lievano*, the New York Supreme Court did allow ex post Building Code provisions in evidence as to whether or not handrails were placed too low:

> Although the Building Code provisions invoked by the civil engineer may not be applicable to defendant's pre-Code building, at least in the present context the Code is relevant on the issue of safety standards, *particularly absent proof from defendant that the staircase was ever in conformity with any preexisting standards*.[94]

Most significantly, the Seventh Circuit in *Ross* explicitly denied that *Murphy* established a blanket rule of exclusion. It distinguished *Murphy* as a negligence case, and held that standards are admissible on the issue of whether a product is 'unreasonably safe'.

> The fact that the standards were promulgated subsequent to manufacture goes to the weight and not to admissibility.[95]

Perhaps most significant for the standardisation process itself are the implications of participation in standard setting for manufacturers. The dissent in *Vroman* argued that the standards should have been admitted because of the manufacturer's expression of 'extreme interest' in the proposed safety code, the repeated and repeatedly declined invitations to attend committee meetings, and the public review of the standard after manufacture but before the injury.[96] The issue was much clearer in *Buchanna*, a 1996 Eighth Circuit decision. Ms Buchanna had injured her hand in 1992 in an effort to clean out the sawdust from an industrial saw. She had stopped the engine and put a piece of wood in to stop the blade from spinning. When she put her hand in she came into contact with the spinning blade. Now, defendant's president chaired the relevant ANSI committee.[97] At trial, he asserted that the industrial saw his company manufactured in 1968 met all applicable safety standards. He also testified to the safety of put-in-a-piece-of-wood method and criticised electronic blade stopping devices. The latter statements were easily undermined by 1978 ANSI standards. Under these circumstances, the Court ruled that the

[92] *Hanlon v Airco Industrial Gases* 579 NE 2d 1136, 1143 (Ill App 1991).
[93] *Simon v Simon* 924 P 2d 1255, 1260 (Kan 1996).
[94] *Lievano v The Browning School* 265 AD 233 (NY 1999), (emphasis added).
[95] *Ross v Black & Decker* 977 F 2d 1178, 1184 (7th Cir 1992).
[96] *Vroman v Sears*, above n 90, 739 (Edwards, Circuit Judge, dissenting).
[97] *Diane Buchanna v Diehl Machine* 98 F 3d 366 (8th Cir 1996).

ex post manufacture standards were admissible even if it considered their relevance and prejudicial effect 'close questions.'[98]

The Court also allowed into evidence the fact that Ms Buchanna's employer had installed an interlock device in the machine after her injury. In this respect, *Buchanna* continued something of a war of the Circuits regarding Federal Rule of Evidence 407 on 'subsequent remedial measures' that sheds some light on the policy issues concerned. Until December 1997, that rule declared evidence of measures taken subsequently, which, if taken previously, would have made the injury or harm less likely to occur, inadmissible to prove 'negligence or culpable conduct.' Two issues are at stake. First, most circuits do not allow remedial measures in strict liability cases either.[99] On this issue, *Buchanna* is the Eighth Circuit's last battle cry in a lost war it waged together with the Tenth Circuit.[100] As amended in 1997, Rule 407 now extends to 'negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction', and hence to all product liability cases. *Buchanna* introduces another distinction, however. The Court argued that even if subsequent remedial actions taken by manufacturers are generally inadmissible, actions taken by *third parties* are not covered by that principle 'because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence.'[101]

3.3 The Mandatory Standards Defence: the European Community

The Directive provides for exemption from liability when the producer proves that the defect is 'due to compliance with mandatory regulations issued by the public authorities.'[102] Regulatory instruments using indirect or indicative references to standards are not 'mandatory'. On the other hand, that standards rendered mandatory by way of exclusive reference

[98] Above, 371.

[99] See eg *Werner v Upjohn Co* 628 F 2d 848, 857 (4th Cir 1980), (rule applies to both negligence and strict liability since distinction is 'hypertechnical' in suits against manufacturers); *Grenada Steel v Alabama Oxygen* 695 F 2d 883, 888 (5th Cir 1983), (the 'real question' in strict liability is whether the product was reasonably safe at the time of manufacture and hence the jury's attention should be focused there); *Causey v Zinke, In re aircrash in Bali* 871 F 2d 812, 816 (9th Cir 1989), (rule is based on policy of encouraging potential defendants to remedy hazardous conditions without fear that their actions will be used as evidence against them); *Wood v Morbark Industries* 70 F 3d 1201, 1206 (11th Cir 1995), (rule applies to strict liability for products that are defective for being 'unreasonably dangerous').

[100] Not the very last, though. See *Maurice Porchia v Design Equipment Co* 113 F 3d 877 (8th Cir 1997). Cf eg *Robbins v Farmers Union Grain Terminal Association* 552 F 2d 788, 794 (8th Cir 1977); *Herndon v Seven Bar Flying Services* 716 F 2d 1322, 1327 (10th Cir 1983).

[101] *Buchanna v Diehl*, above n 97, citing an *obiter dictum* in *O'Dell v Hercules* 904 F 2d 1194, 1204 (8th Cir, 1990). See the vigorous dissent by Beam, Circuit Judge, at 372.

[102] Article 7 (d) of Directive 85/374/EEC.

or incorporation fall under this provision seems obvious. The counter argument used by Norbert Reich, that standards never 'issue from the public authorities' is Germanocentric, simply wrong as a matter of comparative law and overly formalistic.[103] The issue is whether manufacturers are bound by law to comply with certain technical specifications, not whether those specifications were written by public officials or by private organisations. The only seriously debatable question is whether all kinds of exclusive references can trigger the exemption. One could well argue that the exemption demands at least a conscious decision of the legislator to render a certain, defined standard mandatory.[104] French law offers an intriguing constellation. The general standards law accompanies the general empowerment to render standards mandatory with a clause providing for the possibility of requesting a derogation.[105] Anne Penneau interprets the clause such that manufacturers can avail themselves of the defence only when they have requested but were denied such derogation.[106] The underlying idea is intriguing, practically forcing manufacturers to engage in a constant review of standards. She is, however, alone in making the argument,[107] which seems adventurous as a matter of French law and unduly harsh as a matter of Community law.

Another matter is that the mandatory standard-exemption does not liberate industry from good faith obligations as regards its role in setting the standard in the first place. Where, for example, mandatory standards are based on erroneous or misleading information or anti-competitive abuse of the drafting process, courts may well reserve the right to review the role of the plaintiff in these practices and decide against immunising him from liability on those grounds.[108]

The clause demands a causal relation between the mandatory standard and the defect. In that sense, it is perhaps best conceptualised not so much as a defence against liability for producing defective products, but as pro-

[103] Reich, above n 42, 295. Article 1386–1 of the French *Code Civile* replaces the French text of the Directive, 'règles impératives émanant des pouvoirs publics', with 'règles impératives d'ordre législatif ou réglementaire'.

[104] In Reich, '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' (1986) 9 *JCP* 133, 139, his argument seemed limited to dynamic references. Stuurmans, *Technische Normen en het Recht* (Kluwer, Deventer, 1995) 260 ff, argues that the only criterion is whether or not the reference results in mandatory use of the standard—hence, also dynamic references would fall within the scope of the exception. On the discussion generally, see Schepel and Falke, above n 17, 235 ff.

[105] Article 18, *Décret 84–74 fixant le statut de la normalisation*, JO 1 February 1984, 490, as amended.

[106] Penneau, above n 17, 33.

[107] Ignoring the point, Gambelli, above n 42, 210 ff; Champigneule-Mihaïlov, 'Les aspects Juridiques de la Normalisation en France' in Falke and Schepel (eds), above n 17, 231, 312.

[108] See eg Ask, 'Legal Aspects of Standardisation in Denmark' in Falke and Schepel (eds), above n 17, 135, 169, and references there.

tection against defective legislation. Mere compliance with minimum requirements will hence not relieve of liability; manufacturers are under the additional general duty to take all measures necessary to ensure safety.[109] The requirements at issue must be so precise that they leave the manufacturer no choice as regards product design and literally force them to produce an unsafe product. This will seldom be the case with performance standards.

Given the widespread trend to abandon the regulatory technique of mandatory technical standards, the clause is unlikely to be of great significance. That conclusion is reinforced by the equally widespread trend to draft technical standards in terms of performance, rather than design requirements.

3.4 The Mandatory Standards Defence: the United States

3.4.1 The Regulatory Compliance Defence

The Restatement (Third) reads as follows as regards design and warning defects:

> A product's noncompliance with an applicable safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation;
>
> A product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.[110]

The Restatement retains well-established principles in products liability law that follow the general scheme of negligence law. Non-compliance produces *per se* defectiveness,[111] whereas compliance produces indicative, but not dispositive, evidence of non-defectiveness.[112] This weak version of the regulatory compliance defence is not without its detractors. Doctrinal

[109] See eg Falke, *Rechtliche Aspekte der Normung in den EG-Mitgliedstaaten und der EFTA: Band 3—Deutschland* (Opoce, Luxembourg, 2000) 468.

[110] Restatement (Third) of Torts: Products Liability, § 4 (1998).

[111] Note, however, that the *per se* rule only applies to statutory requirements that set a substantive standard—the Fourth Circuit recently refused to impose per se liability on the manufacturer of a medical device that had failed to obtain approval of the FDA before marketing since the breach of that regulation was 'analogous to the failure to have a driver's licence.' *Tally v Danek Medical* 179 F 3d 154 (4th Cir 1999).

[112] Restatement (Second) of Torts s 288C ('Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions'). See eg *Schwartz v American Honda Motor Co* 710 F 2nd 378, 383 (7th Cir 1983), ('Under both Illinois and federal law, compliance with applicable federal standards is relevant, though not conclusive, in a products liability case').

controversy largely mirrors, naturally, general debates about the relative institutional weaknesses of *ex post* regulation by courts and juries on the one hand, and *ex ante* regulation by administrative agencies.[113] As characterised by Lars Noah,

> Just as they malign proponents of the government standards defence for idealizing agencies and caricaturing the courts as inept, opponents of the defence inappropriately idealize the judiciary and caricature the regulatory process as corrupt.[114]

The debates also reflect different evolutionary assessments of regulatory law. On the one hand, it is clear that the common law rule of non-recognition of public law dates back to pre-welfare state regulation, and is grounded on the assumption that health and safety law be limited, vague, and minimal. Proponents of the defence argue that modern regulatory programs are more complex, more sophisticated, and designed to set optimum, rather than minimum, standards.[115] By the same token, opponents argue that tort law is necessary to counter the consequences of widespread deregulation, agency capture, the increased pace of technological development and the deepened dependence of regulators on industry expertise.[116]

As long as the fundamental institutional choice is to favour *ex post* adjudication over *ex ante* standards setting, the difference between public and private regulation is a moot point.[117] Even where compliance is promoted to something more than a mere element to be considered, the issue of public control seems of little consequence. The Tennessee Products Liability Act bestows a presumption of not being 'unreasonably dangerous' to products manufactured in compliance with applicable statutes or administrative regulations.[118] The category has been held to extend without

[113] See eg Schwartz, above n 52, 389 (arguing that compliance should be *per se* exculpatory on the assumption that 'agencies are better than courts and juries at devising regulations'); Ausness, 'The Case For a "Strong" Regulatory Compliance Defence' (1996) 55 *Maryland L Rev* 1210; *contra*, Schwartz, 'Regulatory Standards and Products Liability: Striking the Right Balance Between the Two' (1997) 30 *U Mich J L Reform* 431 (approving of balance struck in the Restatement (Third)). See further the debate between Rabin, 'Reassessing Regulatory Compliance' (2000) 88 *Geo L J* 2049 (arguing against efforts to strengthen the defence); and Stewart, 'Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System' (2000) 88 *Geo L J* 2167, 2173 (arguing for the defence where 'a regulatory program is designed to optimize a risk/benefit tradeoff').

[114] Noah, 'Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability' (2000) 88 *Geo L J* 2147, 2165.

[115] See eg Dueffert, 'Note: The Role of Regulatory Compliance in Tort Actions' (1988) 26 *Harv J Leg* 175, 208; Noah, 'Reconceptualizing Federal Premption of Tort Claims as the Government Standards Defence' (1996) 37 *William & Mary L Rev* 903, 965.

[116] See Schwartz, above n 113, 443 ff.

[117] For example, Washington allows trial courts to 'consider', without any hierarchy, custom, technological feasibility, and nongovernmental standards *or* legislative regulatory standards *or* administrative regulatory standards. Washington Statutes 7.72.050 (1).

[118] Tennessee Code 29–28–104. Cf eg Kansas Statutes 60–3304 (a); Indiana Statutes 34–20–5–1; Utah Statutes 78–15–6 (3).

much ado to ASME standards referenced in the ANSI Elevator Safety Code adopted by the state Elevator Safety Board empowered to do so by the Tennessee General Assembly.[119] The North Dakota Products Liability Act takes a short cut and, 'where no government standards exist', extends the presumption directly to 'applicable industry standards.'[120]

As soon as all discretion is taken away from courts and juries and regulatory compliance exempts a manufacturer from liability, however, the origin of the privileged standards becomes a matter of constitutional significance. At issue in *Taylor v Gate Pharmaceuticals*, a 2002 Michigan Court of Appeals case,[121] was the constitutionality of the provision in the state Product Liability Act that declared drugs not defective or unreasonably dangerous, and their manufacturer or seller not liable, if they had been 'approved for safety and efficacy by the United States Food and Drug Administration.'[122] Now, the state has a coherent and very formalistic nondelegation doctrine, according to which dynamic references incorporating determinations made by anyone but 'government agencies established under Michigan law', be they foreign agencies or private parties, are outlawed.[123] And federal agencies are, for present purposes, 'foreign agencies.' After all, if the rationale is the retention of final control by 'the people' of Michigan, all rulemaking must be kept not just within the hierarchical frame of constitutional authority but also in the territorial frame of law and state. And then federalism is as much an issue as public control over private standards bodies. In *Taylor*, then, the Court struck down the provision as unconstitutional delegation of legislative authority:

> It places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a products liability action in Michigan. Regardless of the expertise the FDA possesses in the area of drug evaluation, specifically regarding safety and fitness determinations, this is unacceptable. Michigan retains no oversight of this federal agency, it cannot check the exercise of its delegated power with standards of any precision and, because of the nature of science and the FDA's processes of approval and withdrawal of

[119] *Hung v Otis Elevator Company* 1995 WL 595646 (Tenn Ct App 1996).

[120] North Dakota Statutes 28–01.3. See, however, the Fourth Circuit's puzzlement on a similar 'rebuttable presumption' in Kentucky Revised Statutes 411.310 (2) in *Sexton v Bell*, above n 48, 333 ('We can perceive no reason why the trial courts would ever have need to instruct the jury on this statutory presumption.')

[121] *Taylor v Gate Pharmaceuticals* 639 NW 2d 45 (Mich App 2002).

[122] Michigan Compiled Laws 600.2946 (5).

[123] See eg *Coffman v State Board of Examiners in Optometry* 50 NW 2d 322 (Mich 1951), (striking down as unconstitutional delegation a provision that limited the opportunity to take the state examination in optometry to graduates from schools or colleges rated by the 'international association of boards of examiners in optometry.')

> the same, an ever-evolving list of drugs will be excluded as bases of liability actions.[124]

Contrast the conditions under which the Restatement (Third) considers that courts 'may' decide that compliance renders a product not defective as a matter of law:

> Such a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair and thorough and reflected substantial expertise.[125]

What the ALI privileges is not public authority and accountability, but good governance. Under these conditions, there is no reason *in principle* why courts should privilege public legislation and not private standards. The requirements of currency and expertise, on the contrary, suggest that private standards will qualify more often and easier than public standards.

3.4.2 Federal Pre-emption as a Mandatory Standards Defence

It is thanks to principles of federal pre-emption that the defence arising out of compliance with mandatory requirements gains teeth.[126] It is well established that 'the ultimate touchstone in every pre-emption case' is 'the purpose of Congress.'[127] If that purpose can reasonably be interpreted as the creation of nationally uniform standards, state legislation on the same issue is pre-empted. Absent such express pre-emption, the Supreme Court has offered two theories of implied pre-emption; 'field pre-emption'

[124] *Taylor v Gate Pharmaceuticals* 639 NW 2d 45, 53 (Mich App 2002). The Court addressed, in a footnote, the concern that its ruling would 'destroy the well-accepted legislative practice of assimilating nationwide standards and findings, jeopardizing the constitutionality of a wide range of similar Michigan statutes.' First, it considered it 'unlikely' that challenges would be brought by aggrieved parties 'given that none of these statutes operate like the instant provision to entirely foreclose a right of action otherwise available to an individual.' Second, even if challenges were to be brought, it did not foresee major problems since most of the statutes at issue involve the acceptable adoption of static standards, 'and those that do not could at minimum be satisfactorily interpreted under the principle that courts should apply the standard in existence at the time of enactment of the Michigan statute.' 639 NW 2d 45, n 8 (Mich App 2002).

[125] Restatement (Third) of Torts: Products Liability, § 4 (1998) comment c.

[126] For an overview of the development of the doctrine generally, see eg Spence and Murray, 'The Law, Economics, and Politics of Federal Preemption Jurisprudence: A Quantitative Analysis' (1999) 87 *Cal L Rev* 1125; Owen, 'Federal Preemption of Products Liability Claims' (2003) 55 *S Carolina L Rev* 411.

[127] *Retail Clerks v Schermerhorn* 375 US 96, 103 (1963).

where Congress has 'occupied the field' and 'conflict pre-emption' where there is an actual conflict between state and federal law.[128]

In principle, it has long been established that 'state law' for pre-emption purposes includes the common law of torts.[129] Especially in matters of health and safety, however, courts have long proceeded on a presumption against pre-emption of state tort law.[130] In its 1992 decision in *Cipollone*, however, the Supreme Court seemed to discard that tradition. At issue was a clause barring State law 'requirements or prohibitions' in the Federal Cigarette Labelling and Advertising Act of 1969.[131] The Court held that common law actions were expressly pre-empted:

> The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.[132]

For all practical purposes, *Cipollone* transformed a federalist principle of division of competences into a sweeping regulatory compliance defence.[133]

[128] *English v General Electric* 496 US 72, 78–79 (1990). Cf *Crosby v National Foreign Trade Council* 530 US 363, 372 (2000).

[129] See eg *San Diego Building Trades Council v Garmon* 359 US 236, 247 (1959), ('state regulation can be exerted as effectively through an award of damages as through some form of preventive belief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.')

[130] See eg *Maryland v Louisiana* 451 US 725, 746 (1981), (presumption against pre-emption of tort law); *Hillsborough County v Automated Medical Laboratories* 471 US 707, 718 (1985), (health and safety regulation historically a matter of local concern). Cf *Medtronic v Lohr* 518 US 470, 485 (1996), ('we have long presumed that Congress does not cavalierly pre-empt state law causes of action' an approach 'consistent with both federalism concerns and the historic primacy of state regulation in matters of health and safety.')

[131] Pub L 91–222, 84 Stat 87, s 5 (b) (1969). The whole clause read: 'No requirement or prohibition based on smoking and health shall be imposed under state law with respect to the advertising or promotion of any cigarettes the packages of which are labelled in conformity with the provisions of this Act.'

[132] *Cipollone v Liggett Group* 505 US 504, 521 (1992). A majority for the decision had to be juggled together from the four-Justice plurality, Justice Blackmun, concurring in part and dissenting in part, joined by Justices Kennedy and Sauter, 505 US 504, 531, and Justice Scalia, concurring in part and dissenting in part, joined by Justice Thomas, 505 US 504, 544.

[133] See eg Noah, above n 115, 964 (courts should see preemption 'as nothing more than a decision by Congress to give companies a defence to state tort liability if they have complied with federal safety standards.'); Rabin, 'Reassessing Regulatory Compliance' (2000) 88 *Georgetown Law Journal* 2049, 2054 ('the grey area between preemption and regulatory compliance is not conceptual, but a matter of realpolitik.') The Court did take the edges off in *Medtronic v Lohr*, above n 130, 487, where it refused to read the term 'requirements' in the Medical Devices Act to encompass tort law. *Medtronic* was close: see Breyer, J, concurring, 518 US 470, 503 (*some* tort law requirements preempted) and O'Connor, J, concurring in part and dissenting in part, joined by Justices Rehnquist, Scalia and Thomas, 518 US 470, 508 (*all* tort law requirements preempted). Cf *Wilson v Bradlees* 96 F 3d 552, 556 (1st Cir 1996), ('Indeed, absent a premption clause, the general rule is that administrative approval of a practice is pertinent information for a jury but does not impliedly cut off common-law claims reflecting a higher standard of care. . . . There is some tension between this proposition and the tendency of federal courts—relying on statutory language that is less than crystal clear—to preempt state claims based on federal-agency approvals. For the moment, the Supreme Court's inclination is balanced on a knife's edge, as the divisions in *Lohr* amply confirm.')

And in this guise, the defence defers to political authority, with scant regard for the precision of the resulting requirements. For example, the Federal Railroad Safety Act requires safety rules to be 'nationally uniform the extent practicable.'[134] A program making federal funding for the installation of *adequate* warning devices on railroad crossings conditional upon an agency's approval has been held sufficient by the Supreme Court to expressly pre-empt common law claims.[135]

More importantly, there is some evidence that regulatory compliance based on preemption principles differentiates between 'traditional' public rulemaking and regulatory strategies of reliance on private standards. The crucial case here is *Wilson*, where the First Circuit refused to hold that liability claims based on garments catching fire were preempted by compliance with a standard issued under the Flammable Fabrics Act.[136] Getting nowhere with the prescribed interpretative methods of text, legislative history and policy, the Court decided to ask 'what result would make the most sense, or, more formally, how Congress would have decided the issue if Congress had squarely confronted it.'[137] And that inquiry led the Court to examine the standard at issue:

> The current flammability standard is not one adopted by the federal agency after a searching inquiry into what best serves the public interest. It is an industry devised standard that has been perpetuated by CPSC inaction in the teeth of some indications that the standard is not adequate.[138]

Form there, the step to the final salvo, complete with the obligatory reference to *The T.J. Hooper*, is but a small one:

[134] 49 USC 20106.

[135] *Northfolk Southern Rail Co v Shanklin* 529 US 344 (2000). The case is a reaction to Circuit rebellion to *CXS Transportation v Easterwood* 507 US 658 (1993), where the Court suggested that federal funding is a sufficient condition for pre-emption. Several Circuits followed this principle. See *Armijo v Atchison* 87 F 3d 1188 (10th Cir 1996); *Hester v CSX Transportation* 61 F 3d 382 (5th Cir 1995); and *Elrod v Burlington* 68 F 3d 241 (8th Cir 1995). Judge Posner disagreed strongly in *Shots v CSX Transportation* 38 F 3d 304 (7th Cir 1994). He requires an actual determination by federal officials whether certain devices are 'adequate', rather than general agreements between states and the federal agreement to improve railroad safety. The Sixth Circuit joined him in the decision reversed by the Supreme Court, *Shanklin v Northfolk Southern Rail* 173 F 3d 386 (6th Cir 1999). Justice Ginsburg, dissenting in *Northfolk*, agrees with Posner and accuses the Court of displacing state negligence law 'without any substantive federal standard to fill the void'. 529 US 344, 360. Justice Breyer, concurring in *Northfolk*, laconically suggests changing the language of the Statute from 'adequate' to 'minimum'. 529 US 344, 359. Post *Northfolk* railway crossings in *Waymire v Northfolk and Western* 218 F 3d 773 (7th Cir 2000); and *Lee v Burlington* 245 F 3d 1102 (9th Cir 2001).

[136] *Wilson v Bradlees*, above n 133, 556.

[137] *Wilson v Bradlees*, above n 133, 556 (1st Cir 1996). The preemption clause at issue provided that 'no State or political subdivision of a State may establish or continue in effect a flammability standard or other regulation' for the same fabrics and the same risks as the standards issued under the Act.

[138] Above. The 'indications' were a comment of another court that newspaper passed the standard's test with a 48 percent margin of safety. Reserving an opinion on the adequacy of this particular assessment, the Court did add that 'it does show why one needs to be careful in giving conclusive weight to an industry standard'. Above.

> Industry standards serve many useful purposes, but we do not think that Congress, if squarely asked to address the issue, would say that such a standard should extinguish a common-law claim of design defect. If the defendants want to show that they met a prevailing industry standard, fine; but this should not preclude a plaintiff from showing that industry should have done more under certain conditions. Federal regulation may be a substitute for common-law liability; industry self-regulation is not.[139]

Unsurprisingly, State courts have endorsed *Wilson* wholeheartedly as regards the flammability standard.[140] Moreover, the reasoning has been extended to the CPSC's policy of relying on standards in *Deere*.[141] At issue was a claim that a lawn mower was 'unreasonably dangerous' for not having a 'no-mow-in-reverse' device which would stop blades rotating before the machine can move into reverse. Now, the Commission had proposed a standard imposing the device, but withdrew it subsequently and opted for a reliance on ANSI standards. The Court held that, *even if* such a voluntary standard were to be classified as a standard 'in effect' under the CPSA, *Wilson* would preclude any preemptive effect of such a standard.[142]

The CPSA is one of several federal statutes complicating the pre-emption analysis considerably by making any finding that Congress had any 'purpose' whatsoever hazardous at best. Like the National Traffic and Motor Vehicle Safety Act, the Federal Boat Safety Act and the Manufactured Housing Construction and Safety Standards Act, the CPSA contains a sweeping pre-emption clause.[143] Like the others, however, the CPSA also contains a savings clause to the effect that compliance with consumer product safety standards 'shall not relieve any person from liability at common law.'[144]

Until very recently, confusion reigned supreme in the country's courtrooms. On one extreme, some federal courts ignored the savings clause and stormed on with *Cipollone*-like theories of express preemption. In *Moe*, the Eighth Circuit held that the CPSA expressly preempts 'not only positive enactments of state standards, but also common law tort actions

[139] Above, 557 (1st Cir 1996). The Court added that 'this could well have been a different case if we were dealing with a flammability standard adopted by the CPSC after an administrative inquiry and an agency decision that it was the proper standard for the future.' Above.

[140] See eg *O'Donnell v Big Yank* 696 A 2d 846 (Pa Super 1997); *Davis v New York Housing Authority* 246 AD 2d 575 (NY 1998).

[141] *Johnston v Deere* 967 F Supp 574 (D Maine 1997).

[142] Above, 577.

[143] 'Whenever a consumer product safety standard is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision or regulation . . . which are designed to deal with the same risk . . ..' 15 USC 2075 (a). Nearly identical clauses in the Motor Vehicle Safety Act, 15 USC 1392 (d), the Boat Safety Act, 46 USC 4306, and the Manufactured Housing Construction and Safety Standards Act, 42 USC 5403 (d). The latter has been amended by the 2000 overhaul by adding that 'federal preemption shall be broadly and liberally construed'.

[144] 15 USC 2074 (a); 15 USC 1392 (k); 46 USC 4311 (g), 42 USC 5409 (c).

that would have the effect of creating a state standard.'[145] As for the savings clause, it 'should not be interpreted to subvert the preemption provision and should be read to save those claims that are not expressly preempted.'[146] On the other extreme, some state courts ignored the pre-emption clause and asserted the supremacy of state common law. In *Doyle*, the Georgia Supreme Court stubbornly held that state common law permits Georgia citizens to sue automobile manufacturers regardless of their compliance with standards established under the NTMVSA:

> That is not to say that evidence of such compliance is not significant, for it is. But, instead of acting as an impenetrable shield from liability, compliance, more appropriately, is to be a piece of the evidentiary puzzle. . . . All we do today is affirm that proof of compliance with federal standards or regulations will not bar manufacturer liability for design defects as a matter of law.[147]

The majority view holds that, whereas on the one hand the savings clause precludes a theory of express pre-emption, the pre-emption provision precludes the theory that ordinary canons of implied pre-emption are to be discarded. This is the view affirmed by the Supreme Court in its 2000 decision in *Geier*.[148] That case put an end to the bitter disagreements over the pre-emption of 'no airbag' claims under the NHTSA's crash protection standard 208.[149] The standard allows manufacturers several options, including the option to forego airbags.[150] In *Harris*, the Ninth Circuit held this to be sufficient to expressly pre-empt tort law claims.[151] The great majority of federal courts held that such claims are impliedly pre-empted as long as manufacturers choose one of the options available to them, the optional scheme being 'the federal government's chosen method of achieving the Act's safety objections.'[152] Several State Supreme Courts continued to hold otherwise, relying heavily on the savings clause.[153]

For the Court, Justice Breyer held that the savings clause 'assumes that there are some significant number of common-law liability cases to be saved' and hence precluded *Cipollone*-like linguistic stretching exercises

[145] *Moe v MTD Products* 73 F 3d 179, 182 (8th Cir 1995).

[146] Above, 183.

[147] *Doyle v Volkswagen* 81 SE 2d 518, 521 (Ga 1997), on certification from *Doyle v Volkswagen* 81 F 3d 139 (11th Cir 1996), ('no lap belt' claim).

[148] *Geier v American Honda* 529 US 861 (2000).

[149] 49 CFR 571.208 (1999).

[150] Airbags are required, by implication, for cars manufactured after January 1996. In the tortured language of the standard, these cars are to meet certain frontal crash protection requirements 'by means that require no action by vehicle occupants' 49 CFR 571.208, 6.4.1.5.1 (a)(1).

[151] *Harris v Ford Motor* 110 F 3d 1410 (9th Cir 1997).

[152] Cf *Pokorny v Ford* 902 F 2d 1116 (3d Cir 1990); *Montag v Honda* 75 F 3d 1414 (10th Cir 1990); *Taylor v General Motors* 875 F 2d 816 (11th Cir 1989); *Irving v Mazda* 136 F 3d 764 (11th Cir 1998); *Wood v General Motors* 865 F 2d 395 (1st Cir 1998); *Geier v Honda* 166 F 3d 1236 (DC Cir 1999).

[153] See *Drattel v Toyota* 699 NE 2d 376 (NY 1998); *Munroe v Galati* 938 P 2d 1114 (Ariz 1997); *Minton v Honda* 684 NE 2d 648 (Ohio 1997); *Wilson v Pleasant* 660 NE 2d 327 (Ind 1995); *Tebbetts v Ford* 665 A 2d 345 (NH 1995).

over the meaning of 'requirement' or 'standard'.[154] On the other hand, he held the pre-emption provision to 'suggest an intent to avoid the conflict, uncertainty, cost and occasional risk to safety itself that too many safety-standard cooks might otherwise create.'[155] And since courts and juries can cook up safety standards just as legislatures can, 'we now conclude that the savings clause does *not* bar the ordinary working of conflict pre-emption principles.'[156] *In casu*, then, the Court held the claim to be pre-empted since the obligatory airbag rule sought by petitioners would be an 'obstacle' to the standard's objectives.[157]

At least for statutes with a savings clause, *Geier* has largely disarmed *Cipollone*.[158] The general framework seems relatively clear now. The Eighth Circuit announced in *Harris* that it read the case as 'strongly suggesting that a minimum safety standard will rarely, if ever, impliedly pre-empt more rigorous common law safety obligations.'[159] Liability claims that would only *enforce* the federal standard are not pre-empted. In practice, this means that where an agency limits itself to requiring certain *types* of safety devices to be installed, or even where it frames technical specifications for those devices in terms of performance requirements, design defect claims of those devices are allowed.[160] The implication then seems to be that industry can ward off liability claims of this kind only by federal standards that are optimum standards, or at least reflect a comprehensive regulatory policy, and that are drafted in more than 'reasonably precise' design requirements.[161]

[154] *Geier*, above n 148, 868.

[155] Above, 871.

[156] Above, 869.

[157] The four-vote dissent in *Geier* speaks of an 'unprecedented extension of the doctrine of pre-emption'. Above, 886 (Stevens, J, dissenting, joined by Justices Souter, Thomas and Ginsburg).

[158] *Geier* has been extended to all other statutes under discussion here. See *Choate v Champion Home Builders* 222 F 3d 788 (10th Cir 2000), (MHCSSA); *Lady v Glaser Marine* 228 F 3d 598 (5th Cir 2000), (FBSA); *Leipart v Guardian Industries* 234 F 3d 1063 (9th Cir 2000)(CPSA).

[159] *Harris v Great Dane Trailers* 234 F 3d 398, 401 (8th Cir 2000).

[160] *Perry v Mercedes Benz* 957 F 2d 1257 (5th Cir 1992), (defectively designed airbag). *Moe v MTD*, above n 145 (defectively designed blade/brake clutch system, a device prescribed by the CPSC).

[161] Babb, 'Note: The Deployment of Car Manufacturers Into a Sea of Liability? Recharacterizing Preemption as a Federal Regulatory Compliance Defence in Airbag Litigation' (1997) 75 *G Wash U L Q* 1677, calls for an analogy with the Supreme Court's 'government contractor defence' doctrine espoused in *Boyle v United Technologies Corp* 487 US 500, 512 (1988). There, the Court held that 'liability for design defects in military equipment cannot be imposed, pursuant to state law, when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not the United States.' Accordingly, the 'reasonably precise' performance standards for airbags in Standard 208 would suffice to ward off liability claims. The analogy is strained for several reasons, not least the equiparity between a federal 'interest' in military equipment and a federal 'interest' in uniform standards for airbags. It seems therefore reasonable to suggest that something more stringent is needed that 'reasonably precise'.

On the other hand, it seems that non-regulation pre-empts better than minimum regulation. The question here is what constitutes 'affirmative' non-regulation. In *Freightliner v Myrick*, the Supreme Court had to do with a 'no ABS' claim. Defendants claimed that the absence of a federal standard requiring ABS pre-empted the action. Now, there used to be an NHTSA standard requiring ABS, which, however, had been struck down by the Ninth Circuit in 1978 as 'arbitrary and capricious', and had remained suspended ever since.[162] The Court dismissed the pre-emption claim and held laconically that 'it is not impossible for petitioners to comply with both federal and state law because there is simply no federal standard to comply with.'[163]

Where, on the other hand, the NHTSA makes a *conscious* decision not to regulate a certain aspect or a certain class of vehicles, as opposed to judicially induced lethargy, liability claims are pre-empted.[164]

The question is, however, how easy it is to distinguish between judicially induced lethargy and conscious regulatory policy. Not only the experts on standards committees, but the Coast Guard too have come to the conclusion that propeller guards for pleasure boats are unnecessary.[165] On two occasions has this decision been held by Circuit Courts to warrant implied pre-emption under the Federal Boat Safety Act.[166] As the Fifth Circuit explains:

> An agency decision not to regulate does not always, or perhaps even usually, carry a pre-emptive effect. Yet, a federal decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left un regulated, and in that event would have as much pre-emptive force as a decision to regulate.[167]

Now, the Coast Guard decided not to impose propeller guards on the advice of the National Boat Safety Advisory Council, a committee appointed by the Secretary of Transport consisting of state officials, indus-

[162] *Paccar, Inc v NHTSA* 573 F 2d 632 (9th Cir 1978). Technically, the standard did not require ABS, but did impose stopping distances so short that they could not be complied with without ABS.

[163] *Freightliner Corp v Myrick* 514 US 280, 289 (1995). Cf *Myrick v Freuhauf* 13 F 2d 1516 (11th Cir 1994).

[164] *Nancy Gracia v Volvo Europa Truck* 112 F 3d 291 (7th Cir 1997).

[165] See *Elliott v Brunswick* 903 F 2d 1505 (11th Cir 1990), discussed above, analysing a 'no propeller guard' claim under defective product design principles. The Court suggests a theory of express pre-emption in a footnote. Above, n 2.

[166] *Lewis v Brunswick* 107 F 3d 1494 (11th Cir 1997); *Lady v Glaser Marine*, above n 158. Several courts have held out a theory of express pre-emption. See eg *Carstensen v Brunswick* 49 F 3d 430 (8th Cir 1995). Several state courts have denied pre-emption altogether. See eg *Moore v Brunswick* 889 SW 2d 246 (Tex 1994). They have now been comforted by the Supreme Court. See *Sprietsma v Mercury Marine* 123 S Ct 518 (2002).

[167] *Lady v Glaser Marine*, above n 158, 614 (emphasis in original, quotations and citations omitted). Pre-emptive non-regulation does require evidence of the Coast Guard's formally considering, evaluating and rejecting a course of action. See eg *Stanley v Bertram-Trojan* 855 F Supp 657 (SD NY 1994); *Becker v US Marine Company* 943 P 2d 700 (Wash App 1997).

try representatives, and representatives from consumer organisations.[168] The Coast Guard explained its decision by pointing out that 'the regulatory process is very structured and stringent regarding justification', that propeller guard accident data was inconclusive, and that 'the question of refitting millions of boats would certainly be a major economic consideration.'[169] Cynically, one is tempted to see the shadow of hard look administrative review cast back on the Coast Guard. If, as in *Myrick*, a standard crumbles under a hard look in court, tort law could still establish additional safety requirements. If, on the other hand, the hard look dissuades an agency to even try and promulgate a standard, that decision in itself could be enough to pre-empt any common law liability claims. The Supreme Court's decision in *Sprietsma,* however, now requires an 'authoritative' instance of non-regulation before preemption can be implied.[170]

The open question is how the pre-emption analysis will be affected by the new regulatory policy of relying on standards. For the Coast Guard is busy with a 'Regulatory Reform Initiative' and has announced its intention of 'removing or revising obsolete and unnecessary provisions and incorporating industry standards and practices,' which will 'reduce the administrative burden to the maritime industry.'[171] If *Wilson* is anything to go by,[172] it may well be that regulatory strategies of increased reliance on voluntary standards will be accompanied by an increased reluctance to lend pre-emptive weight to federal regulation.

For private standards, the main issue regarding pre-emption is straightforward enough. States are not allowed to incorporate private standards that differ from federally promulgated standards. Thus, in *Scurlock*, the City of New Haven was not allowed to impose compliance with the SSBC and the NEC on manufactured homes that complied with HUD requirements.[173] Courts and juries, on the other hand, are perfectly free to impose

[168] 46 USC 13110.

[169] *Lady v Glaser Marine*, above n 158, 606.

[170] *Sprietsma v Mercury Marine* 537 US 51, 67 (2002), ('although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an "authoritative" message of a federal policy against propeller guards. And nothing in the Coast Guard's recent regulatory activities alters this conclusion.')

[171] See Department of Transportation, Coast Guard, Adoption of Industry Standards, 61 FR 25984, 23 May 1996. The Coast Guard leans explicitly on ASTM's F–25 Committee.

[172] *Wilson v Bradlees,* above n 133.

[173] *Scurlock v City of Lynn Haven* 858 F 2d 1521 (11th Cir 1988). Imposing additional safety standards is sometimes used as a proxy for more straightforward anti-trailer park trash legislation. Politically perhaps less attractive, the latter has the advantage of being allowed under pre-emption principles. In *Texas Manufactured Housing Association v City of Nederland* 101 F 3d 1095, 1100 (5th Cir 1996), a local ordinance regulating permitting and placement of mobile homes was upheld since it sought to 'protect property values' and was 'not expressly linked in any way to local safety and construction standards.' In *Georgia Manufactured Housing Association v Spalding County* 148 F 3d 1304, 1310 (11th Cir 1998), a local 'aesthetic' requirement was upheld since did not have 'any purported basis in consumer protection,' but was 'a straightforward declaration that the County does not want low-pitched roofs in its residential areas.'

compliance with private standards as long as these do not conflict with federal standards. Thus, in *Choate*, the Tenth Circuit held that a manufacturer could be held liable for not installing a battery back-up in smoke detectors, as required by the UBC, even if the HUD standards considered it unnecessary. A battery back up would not, after all, eliminate 'the chosen federal method for providing smoke detection in mobile homes. It would simply increase the effectiveness of that method.'[174]

3.5 The State of the Art Defence: the European Community

Easily the most controversial clause of the Product Liability Directive, Article 7 states:

> The producer shall not be liable as a result of this Directive if he proves (. . .)
>
> (e) 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 principle, generally known as the 'state of the art' defence but notorious in the European Community as the 'development risk' defence, is a compromise between the theory and ideology of strict liability and obvious industry interests.[175] The UK Consumer Protection Act 1987 declares it 'a defence to show that the state of scientific and technological knowledge was not such that a producer might be expected to have discovered the defect.'[176] The Commission took issue with this implementation, considering it to convert the Directive's scheme of strict liability into one based on mere negligence. In the Commission's view, 'the state of scientific and technical knowledge' refers to an objective fact, whereas the CPA makes the test a subjective one of 'reasonable' behaviour. The Court dismissed the Commission's application. The interesting question here is the Court's treatment of the role of industry standards. On the interpretation of 'the state of scientific and technical knowledge', Advocate General Tesauro unequivocally stated:

[174] *Choate v Champion Home Builders* 222 F 3d 788, 769 (10th Cir 2000). It is true that the HUD standard defies common sense. The smoke detector at issue did not function because of power loss. That power loss was caused by, well, a fire.

[175] See eg Stapleton, 'Products Liability Reform—Real or Illusory?' (1986) 6 *OJLS* 392, 420 (concept 'so poorly thought out' that it is debatable whether the scope of liability will be wider than a negligence regime); Howells, *Comparative Product Liability* (Dartmouth, Aldershot, 1993) 40 (finding the defence 'without logic' and arguing for it to be repealed). France tried to make the exoneration clause subject to conditions of post-market control. The ECJ did not allow it in *Commission v France*, above n 37, para 42 *et seq*.

[176] Section 4 (1) (c).

> [i]t is not concerned with the practices and safety standards in use in the industrial sector in which the producer is operating. In other words, it has no bearing on the exclusion from liability that no-one in that particular class of manufacturer takes the measures necessary to eliminate the defect or prevent it from arising if such measures are capable of being adopted on the basis of the available knowledge.[177]

The Court seems to take a milder view. It held

> First, as the Advocate General rightly observes (. . .), since that provision refers to 'scientific and technical knowledge at the time when [the producer] put the product into circulation', Article 7 (e) is not specifically directed at the practices and safety standards in use in the industrial sector in which the producer is operating, but, unreservedly, at the state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation.
>
> Second, the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed.
>
> However, it is implicit in the wording of Article 7 (e) that the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation.
>
> (. . .) On this last point, Article 7 (e) of the Directive, contrary to what the Commission seems to consider, raises difficulties of interpretation which, in the event of litigation, the national courts will have to resolve, having recourse, if necessary, to Article 177 of the EC Treaty.[178]

The difference between the CPA's 'might be expected' to know and the Court's 'is presumed to have been informed of' is rather subtle. Moreover, by changing the Advocate General's 'is not concerned with' to 'is not specifically directed at' industry standards, the Court seems to have left the possibility open for 'the state of scientific and technical knowledge' to be found embodied in standards in litigation. In that respect, it is interesting to note that Belgian standards law officially grants Belgian standards the power to confer status of conformity to 'the state of scientific and technical knowledge at the moment the products are put into

[177] Case C–300/95 *Commission v United Kingdom* [1997] ECR I–2649, para 20 of the opinion. The AG's concession was the so-called 'Manchuria' test, in that he considered it unrealistic to expect producers to be up to date with the latest research carried out in Chinese in that part of the world. Above, paras 23–24.

[178] Above, paras 17–20 of the judgment. Cf *A v National Blood Authority* [2001] All ER 289, Burton, J para 76 ('a development risk ceases to be a development risk and becomes a known risk not when the producer in question had the requisite knowledge, but if and when such knowledge were accessible anywhere in the world outside Manchuria').

circulation'.[179] Crucially, the clause was inserted by the 1986 amendment to the law, that is, after the publication of the Directive. The clause is a flagrant infringement of Community law and should be repealed.[180]

Any interpretation lending any kind of state of the art defence to compliance with technical standards without judicial review of the standards is objectionable as a matter of principle. It would be diametrically opposed to the theory of strict liability and has been overwhelmingly rejected in the literature.[181]

There is, however, something profoundly wrong with the theory of strict liability from the point of view of scientific development. The 'objective' version of the 'state of scientific and technical knowledge' embodies a profoundly acultural conception of the production of science and an amoral conception of safety. Even in consequentialist terms, however, the theory does nothing to give manufacturers an incentive to go out of their way to research and test: manufacturers have no financial reason whatsoever to reach the border between the unknown and the unknowable. In her fine book on the contaminated blood crisis in France, Marie-Angèle Hermitte disarms the dominant French resistance to the defence by constructing it as a legal obligation to push towards the frontiers of science. The consequence would be more science, not less, on condition that the defence is open only for those risks that are inaccessible to 'the mental universe' at the time of marketing despite 'solid' research.[182]

3.6 The State of the Art Defence: the United States

3.6.1 Between Custom and the Frontiers of Science

The few 'pure' strict liability jurisdictions in the United States naturally refuse to accept 'state of the art' defences. Strict liability precludes *any*

[179] Article 7, *Arrêté-Loi relatif à l'homologation ou enregistrement des normes rendues publiques par l'Institut belge de la normalisation*, MB 10 October 1976, as amended by *Arrêté royal* of 23 October 1986, MB 5 November 1986. The whole shabbily drafted clause reads: 'L'Etat et les autres personnes de droit public, les personnes de droit privé ainsi que les autres personnes concernées considèrent les normes homologuées par le Roi ainsi que les normes enregistrées par l'Institut belge de Normalisation comme des règles de savoir-faire; en outre, pour les produits, ces personnes considèrent que lesdites normes sont conformes à l'état des connaissances scientifiques et techniques au moment de la mise en circulation de ces produits.'

[180] Even if Dumortier and Godts, 'Les aspects Juridiques de la Normalisation en Belgique' in Falke and Schepel (eds), above n 17, 65, 126, do not appear too worried.

[181] See eg Taschner, above n 40, 112 ff; Schmidt-Salzer, *Kommentar EG-Richtlinie Produkthaftung, I* (Recht und Wirtschaft, Heidelberg, 1986) 683 ff; Markovits, *La directive CEE du 25 Juillet 1985 sur la Responsabilité du Fait des Produits Défectueux* (LGDJ, Paris, 1990) 218 ff.

[182] Hermitte, *Le Sang et le Droit—Essai sur la Transfusion Sanguine* (Seuil, Paris, 1996) 298–99. See also Thibierge, 'Libres Propos sur l'évolution du Droit de la Responsabilité' [1999] *RTDC* 561 (arguing that the function of liability law should and does evolve towards the generation of knowledge).

evidence as to the manufacturer's conduct or knowledge. What he 'knew or reasonably should have known' has 'absolutely no bearing on the elements of a strict products liability claim'.[183] In another contaminated blood case, the Illinois Supreme Court stated the theory in its harshest and purest form:

> To allow a defence to strict liability on the ground that there is a no way, either practical or theoretical, for a defendant to ascertain the presence of impurities in his product would be to emasculate the doctrine of strict liability and in a very real sense would signal a retreat to negligence theory.[184]

However, in a majority of states the defence is allowed, either through common law principles or by statute.[185] Much of the debate the theory causes stems from the fact that the 'state of the art' has been taken to mean anything from the frontiers of knowledge to mere custom.[186] Usually, however, the defence is assimilated to other negligence concepts, including compliance with industry standards. Having followed the 'state of the art', then, has much the same probative value as complying with standards.[187] Logically, this cuts both ways. Thus, in *Reed* the Fourth Circuit noted that a majority of courts found 'the state of the art and industry standards', *sic*, to be relevant in design defect cases.[188] And in *Santiago*, the Third Circuit held that *Lewis* barred not only industry standards in strict liability cases but the 'state of the art' as well: 'we do not believe that this difference in semantics constitutes a basis for a different result.'[189]

State legislatures struggle with the same problems. Kentucky law provides a presumption of no defect, rebuttable by preponderant evidence, for a product that conforms to 'generally recognized and prevailing

[183] *Johnson v Raybestos-Manhattan, Inc* 740 P 2d 548, 549 (Hawaii 1987).

[184] *Cunningham v MacNeal Memorial Hospital* 266 NE 2d 897, 902 (Ill 1970).

[185] See *Potter v Chicago Pneumatic Tool Comp* 694 A 2d 1319, 1346 (Conn 1997), (noting that 'the overwhelming majority of courts have held that, in design defect cases, state-of-the-art evidence is relevant to determining the adequacy of the product's design.') Cf eg *Anderson v Owens-Corning Fiberglass Corp* 810 P 2d 549 (Cal 1990); *Fell v Kewanee Farm Equipment Co* 457 NW 2d 911 (Iowa 1990); *Fibreboard Corp v Fenton* 845 P 2d 1168 (Colo 1993). For a disgusted overview of the process, see Wertheimer, 'Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back' (1992) 60 *U Cin L Rev* 1183.

[186] See generally, Wade, 'On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing' (1983) 58 *NYU L Rev* 734; Clark, *Product Liability* (Sweet & Maxwell, London, 1989) 156 *et seq*. See eg *Sturm, Ruger & Co v Day* 594 P2d 38, 44 (Alaska 1979), ('generally speaking, 'state of the art' refers to customary practice in the industry'); *Chown v USM Corp* 297 NW 2d 218, 221 (Iowa 1980), ('Custom refers to what was being done in the industry; state of the art refers to what feasibly could have been done').

[187] See *Smith v Minster Machine Comp* 669 F 2d 628, 633 (10th Cir 1982), ('If state of the art is understood to mean simply the custom and practice in an industry, and as we view it, this is a proper meaning to be attributed to it, then compliance with such standard does not constitute an absolute defence to a products liability claim. This is the rule applicable to negligence cases. A similar result would seem to be applicable in products liability cases.')

[188] *Reed v Tiffin Motor Homes* 697 F 2d 1192, 1197 (4th Cir 1982).

[189] *Santiago v Johnson Machine and Press Corp* 834 F 2d 84, 85 (3rd Cir 1987).

standards or the state of the art'.[190] Tennessee law instructs courts to take account of 'the state of scientific and technological knowledge *available* to the manufacturer.'[191] Colorado law, on the other hand, establishes a rebuttable presumption of no defect if the product 'conformed to the state of the art, *as distinguished from industry standards*.'[192] Generally speaking, then, the 'state of the art' defence falls victim to the general strict liability versus negligence debate; it sees to the manufacturer's conduct, not the objective possibility of detecting a problem. The Third Restatement sticks to that scheme. A product is defective when plaintiffs can prove the availability of a reasonable alternative design which would have prevented *foreseeable* harm. Only within those limited circumstances is the defence rejected, in the sense that a 'reasonable' alternative design includes a design 'not adopted by any manufacturer, or even considered for commercial use, at the time of sale.' Membership of a standards committee in whose meetings the hazard at issue is discussed will render an ignorance defence obviously void; moreover, 'the minutes of these meetings and correspondence between committee members are easily characterized as proper bases upon which an expert witness may rely for opinions regarding a manufacturer's knowledge of possible hazards and/or design defects.'[193] Using standards committees as reliable scientific communities has its downsides, however. Workers at Westinghouse sued Monsanto for misleading representations as concerns PCB's manufactured by the latter. One such instance was an ANSI committee report claiming that 'medical records over a nearly 40 year period' had shown that the only adverse health effects of the stuff were limited to 'occasional cases of nonchronic chloracne or other temporary skin lesions or irritations.' Shying away from the substantive question of scientific honesty, the Seventh Circuit refused to hold Monsanto responsible for the report with what could appear an excess of respect for formalities:

> ANSI is not Monsanto, and the statements of the former cannot be reasonably imputed to the latter. The committee included 10 other members, and the Foreword to the report clearly stated that 'committee approval of the standard does not imply that all committee members voted for its approval'. *Although William Papageorge, a Monsanto employee, chaired the ANSI committee and although Monsanto was the sole domestic manufacturer of PCBs*, it simply pushes matters too far to impute the ANSI committee's statement to Monsanto. No reasonable jury could find otherwise.[194]

[190] Ky Rev Stat § 411.310 (2) (1992).
[191] Tenn Code Ann §29–28–105(b) (1980).
[192] Colo Rev Stat § 13–21–403 (1)(a) (1987). Emphasis obviously mine.
[193] *Kinser v Gehl Company* 184 F 3d 1259 (10th Cir 1999). At issue was the Farm and Industrial Equipment Institute.
[194] *Johnny B Taylor et al v Monsanto Co* 150 F 3d 806, 809–10 (7th Cir 1998). Emphasis mine.

In any consequentalist theory of liability law, it seems that both pure strict liability and negligence liability fall short of giving manufacturers adequate incentive to 'produce' the necessary and desirable science. If the state of the art defence is equated with 'custom', and hence the threshold for immunity is basically doing what everybody else does, manufacturers have no reason whatsoever to engage in elaborate research and testing. As does the impossibly high threshold of strict liability, such a low threshold takes away every incentive for a manufacturer to close the gap between the known and the unknowable.[195]

3.6.2 Standards Bodies and the Constitution of 'Scientific' Evidence

Until 1993, the admission of expert evidence in American federal courts was subject to the *Frye*-test, dating from 1923,[196] according to which only scientific evidence which was 'generally accepted' in the relevant scientific community was to be admitted. The Supreme Court decided in *Daubert* that *Frye* was superseded by the Federal Rule 702 of Evidence which requires specialised knowledge, not acceptance.[197] Instead of relying on 'expert communities', the Court casts judges in the role of gatekeepers for 'good science' and demands a judiciary preliminary assessment of scientific validity. Stopping short of providing an exhaustive checklist, the Court limited itself to making some 'general observations', pointing out some of the factors judges are to bring to bear upon the inquiry. First it harks back to Popper and throws in 'falsifiability'. Then it comes up with peer review under the theory that 'submission to the scrutiny of the scientific community is a component of "good science"'. Next, the court should consider the 'rate of error', if known, of the scientific technique at hand. And finally the court may yet take 'general acceptance' into account.[198] Little if any coherent epistemological wisdom is to be gained from the Court's list. As Sheila Jasanoff notes:

[195] Wagner, 'Choosing Ignorance in the Manufacture of Toxic Products' (1997) 82 *Cornell L Rev* 773, 836, argues that common law at present puts a premium on ignorance and pleads for a state-of-the-art defence that would immunise manufacturers 'who have conducted a comprehensive battery of tests and found their product to be safe.' *Contra,* on ethical grounds, Shrader-Frechette, *Risk and Rationality—Philosophical Foundations for Populist Reforms* (University of California Press, Berkeley, 1991) 202 ff.

[196] *Frye v United States* 293 F 1013 (DC Cir 1923).

[197] *Daubert v Merrell Dow Pharmaceuticals* 509 US 579 (1993). Rule 702 reads: 'If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact at issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.'

[198] The test is a 'flexible one', 509 US 579, 594 (1993). Later, the Court made clear that it 'can neither rule in, nor rule out, for all cases and for all the time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence'. *Kumho Tire Corp v Carmichael* 526 US 137, 151 (1999).

> The deeper point about *Daubert* is the Supreme Court's role in 'world-making.' In the guise of offering guidance to lower courts, the decision perpetuated the contradictions that mark the use of science in American political life. Scientism and scepticism both found support, as the *Daubert* court paired a rhetorical deference to the universality of science with a tolerance of multiple viewpoints about how science works.[199]

The decision throws up a number of issues concerning the relationship between law and science.[200] Most conspicuously, it puts a heavy burden on federal judges. Chief Justice Rehnquist, concurring, accused the majority of imposing on them 'the obligation and the authority to become amateur scientists'.[201] Moreover, it extends that burden to the jury. Past the post of the judicial 'preliminary assessment' of scientific validity, the decision explicitly puts its faith on the legal process to distinguish between 'good' and 'bad' admissible science.

> Respondent expresses apprehension that abandonment of 'general acceptance' as the exclusive requirement for admission will result in a 'free for all' in which befuddled juries are confounded by absurd and irrational pseudo-scientific assertions. In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury and the adversarial system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are traditional and appropriate means of attacking shaky but admissible evidence. . . . These conventional devices, rather than wholesale exclusion under an uncompromising 'general acceptance' test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.[202]

[199] Jasanoff, 'Beyond Epistemology: Relativism and Engagement in the Politics of Science' (1996) 26 *SSS* 393, 407–8. For legal criticism of the Court's catholicism, Farrell, '*Daubert v Merrell Dow Pharmaceuticals Inc*: Epistemiology and Legal Process' (1994) 15 *Cardozo L Rev* 2183. See also Beyea and Berger, 'Scientific Misconceptions Among *Daubert* Gatekeepers: The Need for Reform of Expert Review Procedures' (2001) 64 *L & Contemp Prob* 327 (arguing that *Daubert* espouses two inconsistent views of science, 'process' versus 'formal logic', that should—and could—be synthesised.)

[200] The literature could fill entire libraries. See eg Symposium: 'Evidence After the Death of *Frye*' (1994) 15 *Cardozo L Rev* 1745; Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press, Cambridge, 1995); Faigman, *Legal Alchemy: The Use and Misuse of Science in the Law* (WH Freeman, New York, 1999).

[201] *Daubert,* above n 197, 601. The Ninth Circuit on remand was decidedly not amused: 'Our responsibility, then, unless we badly misread the Supreme Court's opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not 'good science', and occasionally to reject such expert testimony because it was not 'derived by the scientific method.' Mindful of our position in the hierarchy of the federal judiciary, we take a deep breath and proceed with this heady task.' See *Daubert v Merrell Dow Pharmaceuticals* 43 F 3d 1311, 1316 (9th Cir 1995). At least two State Supreme Courts have bluntly refused to abandon *Frye* and accept *Daubert*. See *Goeb v Tharaldson* 615 NW 2d 800, 814 (Minn 2000); *Logerqvuist v McVey* 1 P 3d 113, 132 (Ariz 2000).

[202] *Daubert*, above n 197, 595–96. Use of adversary court proceedings as a truth finding device has been much discussed in American literature. Peter Huber has made a career out of his tales describing how greedy incompetent 'hired gun' expert witnesses are allowed by

After *Daubert*, Circuit courts diverged on the question of whether that decision's reliability criteria applied only to 'scientific' knowledge or also to other kinds of specialised knowledge likely to be drawn upon in products liability cases. The Seventh Circuit has consistently applied *Daubert* to all expert testimony pertaining to product design defects, throwing out testimony based on engineers' 'personal observation' and experience and demanding, for example, testing before claims about the feasibility of alternative designs can be allowed in.[203] Other Courts disagreed. The Tenth Circuit in *Compton* considered the testimony of an engineer who opined, on the basis of, among other things, reports of the Society of Automotive Engineers, that the roof of a Subaru car was defectively designed. The Court held that 'the application of the *Daubert* factors is unwarranted in cases where expert testimony is based solely upon experience and training', as opposed to 'unique, untested, or controversial methodologies or techniques'. The testimony at issue, based on 'general engineering principles and concepts', then, was to be allowed.[204] The Eleventh Circuit similarly held that *Daubert* was limited to the field of 'scientific' expert testimony. In *Carmichael*, it distinguished:

> In short, a scientific expert is an expert who relies on the application of scientific principles, rather than on skill—or experience-based observation, for the basis of his opinion.[205]

The Supreme Court reversed in *Kumho*, giving Justice Breyer the opportunity to mellow down those parts of *Daubert* that smacked of excessive reification of science. First, the Court repeated what it had said earlier in *General Electric v Joiner* to the effect that appellate courts are to review district courts' decisions on expert testimony under a standard of 'abuse of discretion'.[206] More importantly, the Court rejected distinctions between different kinds of 'specialised' knowledge:

ignorant judges to expose their 'junk science' to gullible citizens chosen for jury duty. See Huber, *Galileo's Revenge: Junk Science in the Courtroom* (Basic Books, New York, 1991); Foster and Huber, *Judging Science: Scientific Knowledge and the Federal Courts* (MIT Press, Cambridge, 1997). Strong opinions elicit violent criticism. See Chesebro, 'Galileo's Retort: Peter Huber's Junk Scholarship', (1993) 24 *American U L Rev* 1637; Edmond and Mercer, 'Trashing "Junk Science"', (1998) *Stanford Tech L Rev* 3.

[203] See *Constance Deimer v Cincinatti Sub-Zero Products* 58 F 3d 341 (7th Cir 1995); *Grace Cummins v Lyle Industries* 93 F 3d 362 (7th Cir 1996). In agreement, *Peitzmeier v Hennessy Industries* 97 F 3d 293, 296–98 (8th Cir 1996); *Watkins v Telsmith* 121 F 3d 984, 990 (5th Cir 1997).

[204] *Steven Compton v Subaru and Fuji* 82 F 3d 1513, 1518–19 (10th Cir 1995).

[205] *Patrick Carmichael v Samyang Tire* 131 F 3d 1433, 1435 (11th Cir 1997).

[206] *Kumho,* above n 198, 148. Justice Scalia, concurring, was quick to point out that the discretion involved for trial courts is not the discretion to abandon the gatekeeping function, but merely the discretion 'to choose among reasonable means of excluding expertise that is *fausse* and science that is junky.' Above, 159. *Cf General Electric Co v Joiner* 522 US 136 (1997). Very close reading of *Kumho* in Edmond, 'Legal Engineering: Contested Representations of Law, Science (and Non-Science) and Society', (2002) 32 *SSS* 371.

> It would prove difficult, if not impossible, for judges to administer evidentiary rules under which a gatekeeping function depended upon a distinction between 'scientific' knowledge and 'technical' or 'other specialized' knowledge. There is no clear line that divides the one from the others. Disciplines such as engineering rest upon scientific knowledge. Pure scientific theory itself may depend for its development upon observation of properly engineered machinery. And conceptual efforts to distinguish the two are unlikely to produce clear legal lines capable of application in particular cases.[207]

The upshot is, then, that engineers are subjected to the same principles as 'scientific experts'. And the consequences entail a wonderful paradox. If anything, *Daubert* was an assertion of law's capability to distinguish valid science from 'junk' and reflected at least a growing distrust of the scientific community's own validity criteria.[208] Now, whether *Daubert* excludes more 'scientific evidence' than *Frye* is debatable and very difficult to verify. But that *Kumho* raises the barrier for the admissibility of engineering opinions in product liability cases seems beyond doubt. Prior to *Kumho*, juries were generally trusted to be able to sort out opinions based on 'general engineering principles.' Pushed under the umbrella of *Daubert*, this kind of evidence is now subject to courts' 'gatekeeping.' And whereas *Daubert* could be argued to have diminished the law's great reliance on 'scientific communities', *Kumho* has increased the law's very reluctant reliance on standards bodies.

In *Bourelle*, the Seventh Circuit excluded a mechanical engineer's testimony partly because he 'never submitted his alternative design theories to the American National Standards Institute (ANSI), despite the fact that he was aware of the organization.'[209] There is now a real trend in federal

[207] *Kumho,* above n 198, 141. See eg Sanders, '*Kumho* and How We Know' (2001) 64 *L & Contemp Prob* 373 (discussing the 'rational' as opposed to 'experiential' processing of information as the appropriate distinction, and concluding that 'the law's own epistemological needs argue for a strong preference for rational processing' and hence that *Daubert* should apply to non-scientific expertise.)

[208] This is the legal optimism at the heart of recent proposals to transplant *Daubert* to regulatory law. See Dwyer and Dwyer, '"Regulatory Daubert": A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law' (2003) 66 *Law & Contemp Prob* 7, 8, 22 (arguing that 'regulatory *Daubert*' supplies 'an ideal framework for judicial review of administrative actions', encouraging reviewing judges to be 'less deferential, and thus more probing, of agency science and related administrative justifications for regulatory action.') Cf McGarity, 'On the Prospect of "Daubertizing" Judicial Review of Risk Assessment' (2003) 66 *Law & Contemp Prob* 155, 156 ('a profoundly bad idea'); *Stewart v Potts* 996 F Supp 668, 678 n 8 (SD Texas 1998), (declining to apply Daubert to APA review of agency action on the basis that 'the Court's task under the APA is to ensure that the agency's decisions are not arbitrary or capricious; it is not to evaluate their scientific methods.')

[209] *Bourelle v Crown Equipment* 220 F 3d 532, 537 (7th Cir 2000). See also *Dhillon v Crown Controls* 269 F 3d 865 (7th Cir 2001), (excluding expert testimony on the basis that failed campaign to convince ANSI committee about the necessity of rear guards on forklift trucks shows that expert's opinion 'has never been favorably subject to peer review or generally accepted in the relevant communities.')

district courts to rely on standards bodies for indications of 'reliability' of engineering opinions.[210] In *Milanowicz*, one of them took the inquiry a step further and furnished its own *Kumho* 'checklist' for engineers' testimony in product liability cases. The list is familiar—the trilogy of law, standards and custom now makes a re-entry as 'indicia of reliability of expert testimony'. First, courts should scrutinise whether experts identify and discuss federal design standards: 'Not only do these regulations have independent legal significance, but they also represent important parameters for industrial design.' Second, courts should check whether the expert has referenced standards published by 'independent standards organizations' such as ANSI, ASME, UL and ASTM: 'While lacking the legal authority of federal regulations, they provide detailed design standards which reflect systematic testing and safety certification.' Third, courts should look for a discussion of trade literature. Finally, courts should rely on industry practice, which 'may be used as a proxy for peer review', no less.[211] This elevation of standards bodies to the status of reliable communities is not without its problems. For Judge Calabresi on the Second Circuit, the *TJ Hooper* problem in combination with the unequal distribution of knowledge in society leads to a troubled mix:

> In determining whether an expert is sufficiently knowledgeable to be admitted to testify, one of the factors that the district court ought to consider is whether other experts exist who are specifically qualified and are not in the employ of the company or the industry whose practices are being challenged. If the only experts permitted to testify inevitably represent the same side of a

[210] See eg *Garay v Missouri Pacific Railroad Comp* 60 F Supp 2d 1168, 1171–72 (D Kan 1999), (partly excluding and partly admitting evidence largely in function of reliance on 'accepted ANSI and SAE standards'); *Masters v Hesston Corp* 291 F 3d 985 (7th Cir 2002), (excluding expert testimony partly because expert's methodology was undermined by the same American Association of Agricultural Engineers standard he relied on); *Sittig v Louisville Ladder Group* 136 F Supp 2d 610 (WD La 2001); (excluding testimony of expert partly for not serving on ANSI committees and not performing any ANSI-required tests for alternative design); *Travelers Property & Casualty v General Electric* 150 F Supp 2d 360 (D Conn 2001); (admitting expert testimony for being consistent with NFPA 921, 'a peer reviewed and generally accepted standard in the fire investigation community.'); *Meineker v Hoyts Cinemas* 154 F Supp 2d 376, 379 (NDNY 2001), (excluding experts' opinions in the absence of industry standards to 'provide a foundation' for their testimony); *Chester Valley Coach Works v Fisher-Price* 2001 WL 1160012 (ED Pa 2001), (excluding expert testimony for deviating from the methodologies prescribed by NFPA 921). But, see also *Traharne v Wayne Scott Fetzer Comp* 156 F Supp 2d 717, 730 (ND Ill 2001), (exluding expert testimony on alternative design, *inter alia* on the following grounds: 'It strikes us that Mr Kaplan cannot offer an opinion on the soundness of his design without referencing the Underwriters Laboratories' Standards. His failure to do so severely lessens the validity and authenticity of his opinions.'); *Libbey v Wabash* 2003 WL 31246509 (D Me 2002), ('To disallow expert testimony because there are no industry standards applicable to the precise mechanism of injury in a given case would prevent expert testimony in any case involving an injury that had not been anticipated or otherwise addressed by the industry involved. Such an irrational outcome is not contemplated by *Daubert* or *Kumho*'.)

[211] *Milanowicz v Raymond Corp* 148 F Supp 2d 525 (D NJ 2001). Cf *Ebenhoech v Koppers Industries*, 239 F Supp 2d 455 (D NJ 2002); *McGee v Evenflo* WL 23350439 (MD Ga 2003).

> civil case, those who possess these experts can, for all practical purposes, set their own standards. And allowing an industry to do this is improper because it is very similar to what has long been held inappropriate, namely, letting the custom of an industry or trade define what is reasonable in that trade.[212]

4. LIABILITY FOR STANDARDS BODIES

4.1 The European Community

Products manufactured in compliance with technical standards can, of course, prove defective. Standard setters may well underestimate certain risks, be plainly wrong about a certain assessment or worse, have economic incentives to favour certain solution over others that outweigh safety concerns. The temptation is clear. In Spindler's words:

> If we recall that private standards play a decisive role for industry, and that technicians believe them to be equivalent to laws, there should be no discussion about the fundamental principles of liability for private organisations enacting these standards. If the pass 'bad' standards or if they do not adjust them, they should be deemed to have played a part in the chain of causation for a damage that has occurred due to a 'badly' designed product which complies nonetheless with the applicable standards. Under the regime of negligence, tort law thus could be able to formulate fundamental principles for enacting private standards. Assuming that tort law accepts such a form of liability, private organisations would have a strong incentive to avoid liability by encompassing all available knowledge in their standards.[213]

Even if it has hardly ever happened,[214] lodging liability claims against standards bodies in the EU Member States is not merely a theoretical possibility. Or at least, it is something standards bodies worry about a lot. Several of them have taken out insurance, including BSI, DS, NSF and AENOR.[215] Others line their internal regulations and conditions of sale with disclaimers. The Dutch standards bodies try to exonerate themselves from 'any direct or indirect damage caused by or in connection with the application of standards it publishes'.[216] BSI is more magnanimous, admitting to 'a duty of care' to all those who rely on its publications, either

[212] *Eleanor Stagl v Delta Airlines* 117 F 3d 76, 81 (2nd Cir 1997).

[213] Spindler, above n 27, 331.

[214] Cf Schepel and Falke, above n 17, 238.

[215] Ask, above n 108, 171; Sandvik, 'Legal Aspects of Standardisation in Norway' in Falke and Schepel (eds), above n 17, 625, 672; Gómez Acebo & Pombo, 'Legal Aspects of Standardisation in Spain', above, 717, 786; and Simmons & Simmons, 'Legal Aspects of Standardisation in the United Kingdom', above, 909, 967.

[216] Article 10.2.2, Internal Regulations of both NNI and NEC Stuurmans and Wijnands, 'Legal Aspects of Standardisation in the Netherlands' in Falke and Schepel (eds), above n 17, 557, 616, are unimpressed and consider the clause void at least as far as concerns third party liability.

directly or indirectly. Committee members are warned that, 'although standards should provide for levels of safety that protect the user, they should not be so worded as to lead the reader to believe that compliance with the standard bestows zero risk of harm.'[217] However, BSI also explicitly states that 'it remains the responsibility of users to ensure that they select standards which are in all respects appropriate to their needs and that they use them appropriately.'[218] DIN employs much the same basic reasoning. It admits to a duty of care (*Garantenstellung*), which it diffuses by publishing strict guidelines for committee members and the following directives for the users of its standards:

> Everyone capable of tort is responsible for his own actions (acts or omissions). The user of a DIN-standard is not excluded from this principle. Therefore, anyone using a DIN-standard should, in particular:
>
> —make sure he/she has the knowledge required for the use of a DIN-standard (DIN-standards are not meant for laypeople);
> —be aware that a standard is just one, and not the only, source for the determination of technically appropriate behaviour in a particular case;
> —be aware that, even if the rules for the elaboration of DIN-standards require the state of the art to be taken into account, this requirement is hard to fulfil given the rapid development of technology;
> —be aware that the result of joined efforts is not fit for the fulfilment of maximum requirements;
> —be aware that use of a DIN-standard against his/her own better judgement is prohibited (for example because the standard contains erroneous technical data, or because of infringement of others people's rights, especially intellectual property rights, or because of infringement of legal provisions).[219]

Even in those countries where a duty of care towards third parties could be established,[220] however, standards bodies would likely be successful in warding off claims if they follow certain procedures designed to gather, process and monitor as much relevant information and knowledge as possible, guard against bias, and populate their committees with recognised experts. Especially important in this regard is a monitoring mechanism after the standard has been issued, to be able to adapt standards once shortcomings have become clear. More at risk than standardisation activities is certification. AENOR and AFNOR, both administrators of their own marks, grant the right of using the mark under explicit exoneration clauses.[221]

[217] Section 6.9.1.5, BS 0:2: 1997.
[218] Section 3.3, BS 0–1: 1997.
[219] Section III, *Grundsätze für das Anwenden von DIN-Normen,* published in DIN–Normenheft 10, p 391. Translation mine.
[220] See eg Clark, 'Legal Aspects of Standardisation in Ireland' in Falke and Schepel (eds), above n 17, 469, 497.
[221] Schepel and Falke, above n 17, 237.

Where standardisation is a tightly regulated activity, the question arises whether standards bodies can avail themselves of the protection from liability claims generally accorded to public authorities. Only in Portugal are challenges to the standards body automatically challenges to the State itself.[222] Spanish standards law places the fulfilment by the standards body of its statutory duties under control of the public authorities under the explicit exclusion of the 'liability the standards body may incur from its actions.'[223] The National Standards Authority of Ireland Act 1996 declares that 'the Authority shall be a body corporate with the power to sue and be sued in its own name.'[224] In all cases but Portugal, then, the State could only be challenged for standards rendered mandatory—in which case the normal rules for civil liability of the public authorities in the exercise of their public law powers apply.

The interesting thing about French standards law is that a challenge to a standard will be decided in the light of AFNOR's public mission, and not just in the light of the standard body's duties towards single users. The decision to ratify a standard being an administrative act, AFNOR has to be challenged in administrative court.[225] The direct consequence of this is that AFNOR's decisions will be subjected to criteria of administrative discretion. In the one case brought against AFNOR, a manufacturer of pavement which proved not to resist frost was sued by the contractors who, in turn, were sued by the contracting authority, followed the chain of causation right through to AFNOR's granting of its 'NF' Mark for conformity with the relevant standards. The *Tribunal Administratif de Paris* held against plaintiff on two grounds. First, it held up AFNOR's exoneration clause for use of its 'NF' mark. Moreover, it did not hold the standards body liable for issuing the faulty standard either. The mere fact that the standard did not take frost problems into account could not be held against AFNOR since 'standardisation cannot pretend to cover every characteristic of a product'. Moreover, the standards body had taken steps to adapt the standard once it became aware of the problems involved. AFNOR had thus committed no fault in the exercise of its public mission and prerogatives of public authority.[226]

Standards bodies' private law obligations may well create problems for the regulatory framework of standards in the New Approach.

[222] Lobo, *et al*, 'Legal Aspects of Standardisation in Portugal' in Falke and Schepel (eds), above n 17, 675, 713.

[223] Article 13, *Reglamento de la Infrastructura para la calidad y la seguridad industrial,* BOE 6 February 1996, núm. 32, p 3929.

[224] Article 1(1), First Schedule.

[225] Registered and experimental standards, not subject to ratification by AFNOR's director, are to be challenged in civil court.

[226] *Tribunal Administratif de Paris*, 9 March 1993, *Société Les Grands Travaux de l'État c/ Pottier et autres*, not reported. Summary in Champigneulle-Mihailov, 'Les aspects Juridiques de la Normalisation en France' in Falke and Schepel (eds), above n 17, 231, 319.

Schematically, the set up features two sets of vertical relationships—the public leg between the Commission and Member States, and the private leg between the European standards bodies and their national members. 'Diagonal' conflicts can be readily imagined both ways.[227] BSI's duty of care has been argued to prevent the British standards body from automatically transposing European standards about which it has reservations.[228] Likewise, failure on the part of the interministerial delegate to veto the ratification of an AFNOR standard transposing a inadequate European standard has been argued to constitute a failure on the part of the State to fulfil its statutory duties.[229]

Spindler's high hopes for tort law's capacity to 'formulate fundamental principles of standardisation' depends crucially, as he readily admits, on a rather radical overhaul of fundamental principles of tort law—from the protection of private rights to the promotion of public goods.[230]

4.2 The United States

4.2.1 Strict Liability

Imposing strict liability on trade associations, that is, on parties that neither manufacture nor sell the defective product in question, is only possible on theories of 'alternative' liability. The 1973 case of *Hall v DuPont* stands for standards bodies' worst nightmare in this regard.[231] The case dealt with 18 separate accidents where children were injured by defective blasting caps. One of the problems the court faced was that, in most instances, the manufacturer of the caps was unknown. What was clear, however, was that all of them were members of the explosives industry trade association, the Institute of Makers of Explosives. What was also clear was that the IME published safety guidelines.[232] The opportunity was there, then, to establish the theory of industry-wide strict liability, or 'enterprise liability'. The Court's reasoning is worth following in some detail. First, it opted for a theory of strict liability based on the need for 'broad safety incentives' stemming from the fact 'that entire industries

[227] The term was coined by Christian Joerges to describe the limits of supremacy of Community competition law when it conflicts with private law. See Joerges, 'The Impact of European Integration on Private Law: Reductionist Perceptions, True Conflicts and a New Constitutional Perspective' (1997) 3 ELJ 378, 398. The ultimate diagonal conflict case concerns the German law on unfair competition; see Case C–41/96, *VAG-Händlerbeirat v SYD-Consult* [1997] ECR I–3123.

[228] Simmons & Simmons, 'Legal Aspects of Standardisation in the United Kingdom' in Falke and Schepel (eds), above n 17, 909, 967.

[229] Brunet and Péraldi-Leneuf, 'Les Recours Juridictionnels des Utilisateurs en cas de Normes Défectueux' (1998) 18 *Petites Affiches* 39, 45.

[230] Spindler, above n 27, 331.

[231] *Hall v DuPont de Nemours* 345 F Supp 353 (ED NY 1972).

[232] The IME is not a member of ANSI.

have been held to be below the standard of reasonable care'.[233] Second, it held that attention should focus on the activities of the industry as a group as 'the sole feasible way of anticipating costs or damages and devising practical remedies.'[234] Third, it spelled out the conditions under which this joint liability could be concentrated in the trade association where manufacturers 'delegate' safety functions to an industry-wide entity. Factors to be considered are

> the size and composition of the trade association's membership, its announced and actual objectives in the field of safety, its internal procedures of decision-making on this issue, the nature of its information-gathering system with regard to accidents, the safety program and its implementation by the association and member manufacturers, and by other activities by the association (such as legislative lobbying) with regard to safety during the time period in question.[235]

It finished off with a half-hearted attempt to sweeten the pill:

> In the event that the evidence warrants it, the imposition of joint liability on the trade association should in no way be interpreted as 'punishment' for the establishment of industry-wide organisations. Such liability would represent rather the law's traditional function of reviewing the risk and cost decisions inherent in industry –wide safety practices, whether organized or unorganized.[236]

To the relief of the standardisation community, *Hall* is 'almost universally rejected.'[237] The Ohio legislature even went so far as to enact a provision of 'precluded theories of product liability' where it explicitly liberates manufacturers from a theory of industry-wide liability, including claims concerning the joint development of product safety standards.[238] It

[233] *Hall v DuPont,* above n 231, 368, complete with a *TJ Hooper* reference.

[234] Above, 378 (it adds: 'We do not, of course, suggest that private actions are the best way to meet these problems but only that in the absence of preemptive legislation, tort principles will support a remedy.')

[235] Above, 375–76.

[236] Above, 378. The reference is, of course, to *TJ Hooper*.

[237] *Swartzbauer v Lead Industries Association* 794 F Supp 142, 145 (ED Pa 1992). See also *Cummins v Firestone & Rubber Comp* 495 A 2d 963, 971 (Pa Super 1985), ('Industry-wide liability as embodied in *Hall* has now been rejected by virtually every other jurisdiction confronted with the issue'). Cf *City of Philadelphia v Lead Industries* 994 F2d 112, 128 (3rd Cir 1993), (rejecting enterprise liability as a 'new tort principle' it refuses to articulate).

[238] Ohio Revised Code 2307.791. In relevant part, the clause reads: 'A manufacturer shall not be held liable for damages based on a product liability claim that asserts any of the following theories:

> (A) Industrywide or enterprise liability, including, but not limited to, any claim that seeks to impose liability on an entire industry or enterprise, on any members of an entire industry or enterprise, or on any trade association of an entire industry or enterprise that alleges both of the following:
>
> (1) Joint awareness of product risks;
> (2) Joint development of product safety standards or delegation of safety functions to an industry trade association or another entity.'

is safe to say, then, that standards bodies are safe from any theory of strict liability.[239]

The same is not true, however, for manufacturers' involvement in the standardisation process. In Bay Summit, a California court of appeals held that Shell could be found strictly liable for damages caused by a defective polybutylene plumbing system, notwithstanding the fact that the oil company merely supplied non-defective components to the system. The Court objected to the fact that Shell had 'actively inserted itself into the overall marketing enterprise of the final plumbing product and became a dominant player in that enterprise.'[240] Part of that effort consisted in 'an aggressive campaign to "influence and educate" the IAPMO membership,' 90% of which had voted against approving polybutylene plumbing systems for the UPC in 1980. In 1981, mysteriously, a majority voted to change the relevant standard.[241]

4.2.2 Good Samaritan Liability

Under negligence theories, however, standards bodies are increasingly subjected under a duty of care on the basis of 'Good Samaritan' liability, the theory articulated thus by Justice Cardozo in 1922: 'One who assumes to act, even gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all.'[242] The theory was formalised in section 324A of the Restatement (Second) of Torts, which provides for third party liability when one undertakes to 'render services which he should recognise as necessary for the protection of a third person or his things' if

a) his failure to exercise reasonable care increases the risk of such harm, or
b) he has undertaken to perform a duty owed by the other to the third person, or
c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

The application of the theory of Good Samaritan liability made its impact into the world of voluntary standards via its application to certification bodies. Perhaps oddly, the rationale for this is best explained in *Hanberry*, a case dealing with, of all things, the 'Good Housekeeping Seal':

[239] See eg *Harmon v National Automotive Parts Association* 720 F Supp 79 (ND Miss 1989), (NAPA 'not so directly' connected with manufacture or sale to be liable under a straightforward application of any products liability theory); *Swartzbauer*, above n 237, (dismissing complaint against LIA since the trade association neither manufactured or sold product); *Sizemore v Georgia Pacific and HPVA* 1996 WL 498410, 12 (D SC 1996), ('as a matter of law, a trade association such as HPVA cannot be held strictly liable for a product manufactured by one of its members.')

[240] *Bay Summit Community Association v Shell Oil Company* 51 Cal App 4th 762, 777 (1996).

[241] Above, 770–71.

[242] *Glanzer v Shepard* 135 NE 275, 276 (NY 1922).

> Having voluntarily involved itself into the marketing process, having in effect loaned its reputation to promote and induce the sale of a given product, the question arises whether respondent can escape liability for injury which results when the product is defective and not as represented by its endorsement. In voluntarily assuming this business relationship, we think respondent has placed itself in the position where public policy imposes upon it the duty to use ordinary care in the issuance of its seal and certification of quality so that members of the consuming public who rely on its endorsement are not unreasonably exposed to the risk of harm.[243]

In *FNS Mortgage*, a California Court of Appeals fitted IAPMO's failure to delist a defective pipe *in all three* of section 324A's categories:

> It should recognise that these services are necessary for the protection of third persons, consumers who will acquire the pipe and install it in improvements to realty. Indeed, such protection is one of IAPMO's avowed purposes. IAPMO's failure to exercise reasonable care in its undertaking increases the risk of harm to such consumers from defective pipe that otherwise would have been removed from the stream of commerce. IAPMO arguably has undertaken to perform a duty owed by local building officials to consumers (albeit one for which the officials would be afforded statutory immunity). The consumers have suffered harm because of the reliance of local building officials upon IAPMO's undertakings.[244]

Extending the theory to the promulgation of standards, however, has proven far more controversial. *FNS Mortgage* was a 'pure' certification issue, in the sense that IAPMO failed to 'delist' a pipe it knew did not meet its own standards for materials to be used. Similarly, in *US Lighting*, at issue was UL's certification of lamps that did not meet UL's own standards. The Court noted with some relief that this case was 'compelling' since it didn't require 'any second-guessing of a UL standard.'[245] In the earlier case of *Hempstead*, however, UL was held liable for certifying a defective fire extinguisher that *did* meet UL standards. And in this case, UL's negligence saw to the standards themselves: 'UL knew or should have known of the type of construction and materials which would be

[243] *Hanberry v Hearst Corp* 276 Cal App 2d 680, 684 (1969). There are limits to the theory. See *Dekens v Underwriters Laboratories* 107 Cal App 4th 1177, 1185 (2003), (excluding cancer caused by exposure to asbestos from UL's undertaking in testing and certifying small electric appliances).

[244] *FNS Mortgage Service Corp v Pacific General Group* 23 Cal App 4th 1564, 1572 (1994).

[245] *US Lighting Service v Llerrad Corp* 800 F Supp 1513, 1516 (ND Ohio 1992), (UL under duty of care, largely on basis of *Hanberry*). *Contra*, *Benco Plastics v Westinghouse* 387 F Supp 772, 786 (ED Tenn 1974), (distinguishing from *Hanberry* since the case did not involve physical injury but merely economic loss, excluding UL from the reach of 324A for its certification of outdoor signs that failed to meet UL standards. Mercifully, the Court did not validate UL's perverse argument based on its own standards. Once certified, so goes the argument, manufacturers are under a 'continuing obligation' to manufacture according to UL standards, absolving UL from any duty of care even if it continued to certify defective products. 387 F Supp 772, 778–79.)

required if the hazards involved in the use of the extinguishers were to be avoided.'[246] UL's protestation that it did not approve the 'design' of the extinguisher was then meaningless:

> Before listing a product Underwriters tests the product to see whether it meets the standards of construction and performance it has established as a pre-requisite to safety after its investigations and tests have been made. If satisfied that it does, Underwriters lists the product. If satisfied that it does not, Underwriters refuses to list the product. It is straining at words to say that Underwriters does not approve the design of a product. The design may originate with the manufacturer, but when Underwriters lists it, it thereby tacitly impresses its approval upon the design.[247]

From there it is still a step towards extending the theory to 'pure' standards setting by trade associations that merely promulgate safety standards without engaging in certification activities. In *Grinnell*, the Court distinguished the NFPA from IAPMO thus:

> [T]he NFPA does not list, inspect, certify or approve any products or materials for compliance with standards. It merely sets forth safety standards to be used as minimum guidelines that third parties may or may not choose to adopt, modify or reject.[248]

The dilemma is perhaps best brought out in a string of cases involving injuries suffered from diving into swimming pools. On several occasions, actions were brought against the National Spa and Pool Institute for promulgating inadequate standards.[249] In the mid-1980s, two courts held against a duty of care for the NSPI on the theory that the trade association had no authority over manufacturers.[250] The landmark case reversing that trend was the Alabama Supreme Court's 1990 decision in *King*. Here, the Court all but ignored the 'control' question and focused on the NSPI's 'undertaking'. The Court observed that the trade association had 'no statutorily or judicially imposed duty to formulate standards; however, it did so.'[251] The Court then noted how the standards referred to 'the needs of

[246] *Hempstead v General Fire Extinguisher Corp* 269 F Supp 109, 117 (D Del 1967).

[247] Above.

[248] *Commerce and Industry Insurance v Grinnell Corp* 1999 WL 508357, 4 (ED La 1999). Cf *NVV v American Association of Blood Banks* 75 Cal App 4th 1358, 1376 (1999), (distinguishing the AABB from IAPMO on the same grounds).

[249] The NSPI is an ANSI-accredited standards developer under the canvass-method.

[250] See *Howard v Poseidon Pools* 506 NYS 2d 523, 527 (NY 1986), (NSPI did not have the duty or the authority to control the manufacturers who did produce the product here in question); *Meyers v Donnatacci* 531 A 2d 398, 406 (NJ Super 1987), (NSPI had no authority to mandate compliance nor did it attempt to force its members to comply).

[251] *King v National Spa and Pool Institute* 570 So 2d 612, 614 (Ala 1990). The first case allowing for the application of s 324A to standard-setting proper is *Arnstein v Manufacturing Chemists Association* 414 F Supp 12, 14 (ED Pa 1976). There, the Court timidly refused to dismiss the theory on summary judgment, limiting itself to the observation that plaintiff 'should not be precluded from attempting to prove a case' under section 324A At issue was the MCA's purported negligence in setting stricter standards for exposure to vinyl chloride.

the consumer' and were presented as being based on considerations of safety. Under those conditions, 'foreseeability' as opposed to 'control' is enough to establish a duty of care:

> We find that the trade association was under a legal duty to exercise due care in promulgating the standards in question. The trade association's voluntary undertaking to promulgate minimum safety design standards for safe diving from diving boards installed in residential swimming pools (such standards being based on studies of the 'needs of the consumer' and founded on a consideration of 'safety' involved in the design and construction of such swimming pools) and to disseminate those standards to its members for the purpose of influencing their design and construction practices, made it foreseeable that harm might result to the consumer if it did not exercise that care.[252]

A decade later, *King* was followed in the Washington case of *Meneely*, where the NSPI was held 60% liable for rendering a diver quadriplegic.[253]

Another straight split over the same issue involves the contraction of HIV through blood transfusions. Standards in this sector are set by the American Association of Blood Banks, a private trade association. In a string of cases, the AABB has been accused of failing to recommend surrogate testing or other practices that could have prevented contaminated blood from being collected by blood banks. In 1996, the New Jersey Supreme Court established a duty of care in *Snyder* emphasising the AABB's longstanding and successful effort to be recognised as the leading standard setter for the sector: 'Society has not thrust on the AABB its responsibility for the safety of blood and blood products. The AABB has sought and cultivated that responsibility.'[254] *Snyder* has been followed by courts in Louisiana, New York and Virginia,[255] but explicitly rejected in 1999 by the California Court of Appeals in *NVV*.[256]

[252] Above, 616.

[253] *Meneely v Smith* 5 P 3d 49 (Wash App 2000). The total award was 11 million dollars; in order to comply with the court order, the NSPI has had to file for bankruptcy. It should be noted that the standard at issue was not approved as an American National Standard. Nonetheless, ANSI is not amused. See ANSI, 'Alert: Safety Standards on Trial', News Release, 25 June 2001, its reaction to the refusal of the State Supreme Court to hear the matter ('Although Meneely has persevered—he has completed his education and is now a stockbroker—and NSPI continues its important work, the Washington State Supreme Court decision has the potential to harm the cause of voluntary safety standards for years to come.')

[254] *Snyder v American Association of Blood Banks* 676 A 2d 1036, 1048 (NJ 1996), ('By words and conduct, the AABB invited blood banks, hospitals and patients to rely on the AABB's recommended procedures').

[255] See *Weigand v University Hospital of New York* 659 NYS 2d 395 (1997), (move to dismiss complaint on 'no duty' basis rejected); *Douglass v Alton Ochsner Medical Foundation* 696 So 2d 136 (La App 1997), (summary judgment in favour of AABB on 'no duty' basis reversed); *Jappell v American Association of Blood Banks* 162 F Supp 2d 476, 481 (ED Va, 2001), (applying Virginia law), (motion to dismiss on 'no duty' basis denied: 'when defendant undertook to ensure the safety of the nation's blood supply by issuing standards, it took on a duty to transfusion recipients to ensure those standards were drafted without negligence.')

[256] *NVV v American Association of Blood Banks*, above n 248, (granting summary judgment on 'no duty' basis in favour of AABB).

Generally speaking, then, the law as regards standard setters' duty of care is in flux, with courts coming down on either side of the issue in a fairly even split.[257] What is more, in the one case where a Federal Court of Appeals had the opportunity to address the issue, the Fourth Circuit declined to do so.[258] Courts on either side forthrightly admit to be influenced more by public policy considerations than by legal niceties.[259] The problem is that they can't seem to agree on what that policy should be, let alone how best to achieve its objectives.

There are several interrelated clusters of arguments. The first and most straightforward has already been hinted at, and sees to the nature of compliance with standards. If trade associations merely provide a forum for the promulgation of *voluntary* standards, so the argument goes in the swimming pool cases, responsibility lies squarely with individual manufacturers who are free to use or reject these standards.[260] As the *Meyers* Court said, to impose a duty 'would amount to raising NSPI to the status of a rulemaking body which the facts clearly show is unwarranted and legally unsupportable.'[261] As noted, the Alabama Supreme Court refused this reasoning in *King*:

> In our view, the fact that the standards promulgated by a trade association are based on a voluntary consensus of its members, or the fact that a trade association does not specifically control the actions of its members, does not, as a matter of law, absolve the trade association of a duty to exercise reasonable care when it undertakes to promulgate standards for the 'needs of the consumers.'[262]

[257] See generally Wellington and Camisa, 'The Trade Association and Product Safety Standards: Of Good Samaritans and Liability' (1988) 35 *Wayne L Rev* 37; Feldmeier, 'The Risk of Negligence Liability for Trade Associations Engaged in Standards Setting or Product Certification' (1999) 34 *Tort & Ins L J* 785.

[258] *Sizemore v Hardwood Plywood and Veneer Association* 114 F 3d 1177 (4th Cir 1997), (Table), 1997 WL 295644, 3 (the Court failed to see how anything the HPVA did or omitted to do had anything to do with the damage caused: 'Since it is clear that proximate cause is not present, we decline to determine whether HPVA owed a duty of care to plaintiffs.')

[259] Cf *Hanberry*, above n 243, 683 (influenced 'more by public policy than by whether such cause of action can be comfortably fitted into one of the law's traditional categories of liability'); *Benco Plastics*, above n 245, 786 ('the Court receives more guidance from practical policy considerations than whether such a claim against an endorser conveniently fits within a legal nitch'); *Meyers*, above n 250, 404–5 ('whether a duty exists is ultimately a question of fairness'); *Bailey v Hines* 719 NE 2d 178, 183 (Ill App 1999), ('public policy alone might not be reason enough to reject a duty in this case, but it does become part of the legal mix that leads us to that conclusion. However, we make no ringing policy endorsement concerning the nonexistence of a duty in all cases involving trade associations.')

[260] See *Howard*, above n 250, 527; *Meyers*, above n 250, 406. See further *Beasock v Dioguardi Enterprises* 494 NYS 2d 974, 979 (NY 1985), (Tire and Rim Institute 'neither mandates nor monitors the use of its standards by any manufacturer'); *Bailey v Hines* 719 NE 2d 178, 182 (Ill App 1999), (Truss Plate Institute 'exercised no control' over manufacturer and intended the standard at issue as a 'guide').

[261] *Meyers*, above n 250, 405.

[262] *King*, above n 251, 618.

Generally, however, courts finding a duty of care take the argument as such seriously, and seek to establish normative force of standards in one way or another.

In two blood bank cases and, as a minor concession, in *King*, courts pointed to the judicially created role standards play in establishing due care. In *Douglass*, the Court found *Snyder* supported 'by the numerous cases absolving blood banks from liability to transfusion recipients upon a showing of compliance with the guidelines of the AABB.'[263]

In *Meneely*, the court pointed to the economic realities of compliance with industry standards. Since the NSPI publishes the swimming pool and equipment industry's only comprehensive set of safety standards and members opting not to comply with them would be at a competitive disadvantage, 'members followed the standard out of economic imperative.'[264] That argument becomes complicated, however, as soon as it is realised that at least part of that 'economic imperative' stems from the (semi-)regulatory adoption of standards. In *Meneely*, the Court held the fact that NSPI's standards were incorporated into ICBO, BOCA and SBCCI Codes to be a factor adding weight to the argument.[265] In *Prudential*, action was brought against the American Plywood Association for roofing damage caused by hurricane Andrew. The APA was quick to shift the blame to the Florida Building Code. The Court was unimpressed:

> Although it is true that homebuilders must follow the requirements in the local building code, building code officials and legislators rely upon the recommendations provided by APA, which holds itself out as a research and testing agency, in adopting that code.[266]

Other courts, however, see the adoption of standards in codes and regulations as diluting, not reinforcing, the standards body's duty towards the

[263] *Douglass,* above n 255, 139. Cf *Weigand,* above n 255, 399 ('a blood bank's compliance with the industry standards of collection and testing generally constitutes proof of reasonable care on the part of the blood bank. Thus, it is clear that the care used in establishing those industry standards has tremendous impact on the manner in which blood is collected and tested.'); *King,* above n 251, 616, (noting that 'in Alabama, evidence that a defendant manufacturer complied or failed to comply with industry standards, such as the standards promulgated by the trade association in this case, is admissible as evidence of due care or the lack thereof.') This deference to standards in the blood industry is, of course, circumscribed by the *TJ Hooper* doctrine. See *Hoemke v New York Blood Center* 912 F 2d 550, 552 (2nd Cir 1990), ('[T]o find a hospital negligent, we must conclude that it failed to meet a standard of care defined in terms of the degree of care customarily exercised by physicians or hospitals in the community. Of course, if a given industry lags behind in adopting procedures that reasonable prudence would dictate be instituted, then we are free to hold a given defendant to a higher standard than that adopted by the industry.') (Citations omitted).

[264] *Meneely,* above n 253, 56–57.

[265] Above, 56.

[266] *Prudential Property and Casualty Insurance v American Plywood Association* 1994 WL 463527, 3 (SD Fla 1994). The Court relies heavily on *FNS Mortgage,* above n 244. In *FNS*, however, IAPMO's UPC *was* the 'local building code', and delisted pipes were unmarketable as building inspectors would simply refuse to sanction their use.

end user. In *Grinnell*, an insurance company held the NFPA responsible for a warehouse fire for failing sprinklers. The Court held:

> NFPA standard 231(C) is four-times removed from plaintiff's insured. NFPA standard 231(C) was incorporated by the Southern Building Code Congress International and its Standard Building Code. The City of New Orleans then adopted the Standard Building Code. The building contractor was then obliged to build and equip the warehouse in accordance with that Code. Lloyd's insured was the tenant of the building. The relationship between the NFPA and the building occupant is simply too remote to warrant the imposition of a legal duty on the facts of this case. This conclusion is buttressed by the fact that the NFPA had no control over which of its minimum standards were incorporated into municipal building codes or over any construction that purported to conform to its standards.[267]

In this line of reasoning, the attention shifts to a second cluster of arguments that sees to the processes of development of codes and standards. In *Sizemore*, another fire was blamed on the Hardwood Plywood Veneer Association. Plaintiffs considered the highly flammable plywood panelling unreasonably dangerous and accused the HPVA of misrepresenting and concealing information to make sure that the use of the material would be approved in building codes. The Court dismissed the claim in a ringing endorsement of the 'public' pre-consensus code development process:

> It is undisputed that trade associations like HPVA have a limited role in the process by which model building codes are created and amended. HPVA's building code experts made it clear that the process by which amendments to the model building codes are evaluated is extensive, thorough, and open to any interested party. All code change proposals are fully debated in a public forum. Any interested party can submit information either supporting or opposing a code change provision at any time during the process. The only persons who are eligible to vote on proposed amendments to the model building codes, however, are the public officials who are responsible for all aspects of building safety within their jurisdictions and who have no connection to any industry or other special interest. Therefore, the building codes reflect the judgment of the code officials who vote on them, not the views of any non-voting participant in the process. Because of the open nature of the code change process could, in itself, result in either the enactment or defeat of a proposed code change.[268]

Sizemore casts public officials in a role familiar to the one that courts are prone to giving them in antitrust law. They both diffuse claims of financial

[267] *Grinnell,* above n 248, 3. Not discouraged, plaintiff then brought action against UL for listing defective sprinklers. *Commerce and Industry Insurance v Grinnell* 2000 WL 6301 (ED La 2000). The Court held that 'UL's duty of ordinary care in promulgating its standards does not create a responsibility to ensure the soundness of NFPA's standards'. Above, 3.

[268] *Sizemore v Georgia-Pacific and HPVA* 1996 WL 498410, 11 (D SC 1996).

self-interest and elevate their whole association to the status of a public body.[269] As for the first problem, the *Grinnell* court found in NFPA's 'balanced' membership much the same guarantees as the *Sizemore* court found in the public domination of the rival code development associations. The Court noted how NFPA is 'not even a trade association which acts in the economic self-interest of its members':

> It is not a trade group consisting of businesses with homogeneous economic interests. Rather, it consists of insurance providers, enforcement officials, architects, engineers, fire protection manufacturers and distributors, testing laboratories, consumers and academics. It does not profit from the issuance of standards, promote the economic interests of its members, or control the activities of its members.[270]

The AABB, in contrast, was characterised in *Snyder* as 'representing its interests and those of its members. At stake for its members was a substantial financial interest in the regulation of the industry. Blood is big business.'[271]

As for the second issue, *Sizemore* is in flat disagreement with *FNS Mortgage*, where the Court found the fact that pre-ANSI-accreditation IAPMO was 'governed' by public entities and government officials not an 'appropriate basis for distinction':

> This would effectively confer on IAPMO governmental immunity, a legislative, not a judicial function.[272]

At this point the third cluster of arguments comes into play, which focuses on the relationship between private standardisation and public regulation. In *Meyers*, the Court based its public policy decision largely on a sensitivity to the 'many laudable purposes' served by trade associations, including the one of 'assisting the government in areas that it does not regulate.'[273] In *FNS Mortgage*, IAPMO argued that the public would be harmed if it owed a duty of care since it would be forced to discontinue its listing service. The Court, 'chary of indulging a conclusionary, self-serving assertion of this nature' was quick to dismiss this 'vastly overblown' claim

[269] Significantly, the Court relied on *Sessions Tank Liners v Joor* 17 F 3d 295 (9th Cir 1994), the case involving the *Noerr* doctrine for immunity from antitrust case discussed in the previous chapter, and *Ryan v Eli Lilly* 514 F Supp 1004 (D SC 1981), a case where a claim of 'civil conspiracy' to influence the FDA's approval of DES was dismissed on the strength of the FDA's 'independent review.'

[270] *Grinnell*, above n 248, 4. Cf *Meyers*, above n 250, 400, 403 (noting the diverse membership of NSPI, including the American Red Cross, officials from the public health and safety sector, coaches, physicians and teachers involved in swimming and aquatics, and noting the CPSC's involvement in the public review process.)

[271] *Snyder*, above n 254, 1050.

[272] *FNS Mortgage*, above n 244, 1574.

[273] *Meyers*, above n 250, 404.

and discerned 'no unusual or peculiar burden on IAPMO in recognising an ordinary duty of due care.'[274]

These issues come out best in the HIV cases. The *Snyder* court, as noted, grounded its imposition of a duty of care in large part on AABB's assertion of power. It also noted how the AABB *de facto* took over the regulation of blood banks. 'In 1984, the AABB was more than a trade association. It was the governing body of a significantly self-regulated industry.'[275] The AABB then argued that it did not owe a duty of care to private parties *just because* it played such a major role in public policy. The Court dismissed that claim for government immunity on a formal public/private distinction:

> Unlike government agencies, the AABB is not created by statute. It does not act pursuant to a government mandate. Nor is it accountable either to the public or to another branch of government. No matter how much power the AABB exercised, the inescapable fact is that it is not a government agency. Consequently, we need not defer to the AABB's decisions on protection of the blood supply and allocation of industry resources, as we might otherwise defer to agency determinations.[276]

It also dismissed a claim for qualified immunity—where liability would be limited to failure to act in good faith—on a slightly less formal public/private interest distinction:

> Merely because the AABB sometimes acted like a government agency does not mean it was such an agency or the functional equivalent of one. No law or government directive required the AABB to subordinate its interests to those of the public. Indeed, the record reflects the AABB's unswerving commitment to its interests and those of its members.

It then noted the absence of public scrutiny, procedural safeguards and governmental oversight to conclude against any liability immunity.[277] The parallel with *Allied Tube* is obvious, and reinforced even further by the resonance of Justice Garibaldi's dissent with that of Justice White on the Supreme Court:

> Where a private organization performs a quasi-governmental task that the state would otherwise to perform, public policy requires a grant of immunity.
> . . .
> Granting immunity to non-profit associations who have assumed some governmental duties will ensure that, undaunted by the prospect of litigation expense and potential damage awards, they will continue to perform the essential public service that they alone are well-positioned to undertake: the

[274] *FNS Mortgage*, above n 244, 1576.
[275] *Snyder*, above n 254, 1050.
[276] Above, 1050–51.
[277] Above, 1053.

> good-faith development of industry standards to protect the public health and safety.[278]

In *NVV*, the California court of appeals explicitly rejected *Snyder not* by constituting the AABB as a 'governmental agency' but by constituting the AABB as a 'scientific community.' In a familiar line of reasoning, the Court first noted the incompatibility of legal process and scientific discovery:

> To impose liability on defendant for choosing the wrong side in a scientific debate, particularly when that side represented the majority viewpoint at the time, does not further the goal of preventing future harm. The very nature of scientific debate is that the 'right' answer has not yet emerged. Imposing liability this would not aid in choosing the right side in a medical or scientific debate and might encourage rash or premature action rather than allowing a medical or scientific consensus to develop and mature.[279]

It then went on to accuse plaintiff of seeking to have the jury substitute their 'lay opinion' for that of the 'scientific and medical community.'[280] Encumbering the stand setting process with Good Samaritan liability would lead to disastrous consequences. First, the standards body's function as an 'arena' for scientific debate would be lost and researchers would digress to the 'ad hoc peer review journal process'. Second, and even worse, the result could be to leave these matters 'solely in the hands in the hands of government agencies' which would 'not further the public's interest.'[281] Agencies are subject to notice and comment, procedural safeguards and the obligation to convince courts of the 'rationality' of their decision:

> We believe imposition of liability here would have adverse consequences to the public by chilling scientific and medical debate on important issues and leaving these matters to the often slow and cumbersome processes of

[278] Above, 1058–59 (Garibaldi, J, dissenting). Garibaldi admits that complete immunity 'might encourage AABB to make negligent decisions', but maintains that no immunity 'might deter effective decision-making'. He hence calls for qualified immunity, 'the best attainable accommodation of competing values, because it simultaneously preserves both the incentive of private associations to continue developing industry rules and the right of injured parties to seek relief in extreme cases where malice or bad faith can be demonstrated.' 676 A 2d 1036, 1062. The majority was underwhelmed: 'By defending the AABB's status as a private organization free from public accountability while conferring on the AABB governmental immunity, the dissent seeks to impute to the AABB power without responsibility.' 676 A 2d 1036, 1053. The literature is likewise divided. See Todd, 'Note: *Snyder v American Association of Blood Banks*: Expansion of Trade Association Liability—Does It Reach Medical Societies?' (1997) 29 *U Toledo L Rev* 149 (a 'reasonable' test balancing policy considerations); Diegnan, 'Note: Quasi-Governmental Immunity: Should Organizations Receive Immunity For Charitable Works? *Snyder v American Association of Blood Banks*' (1998) 29 *Seton Hall L Rev* 256, 284 ('The dictates of fairness and public policy did not prevail in *Snyder*').

[279] *NVV v American Association of Blood Banks*, above n 248, 1383–84.

[280] Above, 1385.

[281] Above, 1386–87.

> government agencies or to the equally slow process of published medical journal articles and annual conferences.[282]

The Court concluded with an addendum echoing Ross Cheit's concerns about the admission in evidence of *ex post* incident standards:

> Additionally, we note that imposition of liability could hinder reconsideration of established standards. Concerns about potential liability could skew the scientific and medical debate. If the established standard had represented a consensus within the relevant community (i.e., represented the standard of care in the field) such that adherence to that standard provided a shield against liability, a professional association, because of a threat of liability, might be reluctant to recommend a new standard that was still subject to debate and would not provide the same shield to liability. Selection of a new standard could leave a professional association open to liability for not adhering to an established consensus.[283]

As the dissent notes, the problem with the majority's opinion in *NVV* is that it confuses the issue of duty with breach.[284] Courts that immunise standards bodies on a 'government function' or 'scientific community' rationale leave a worrisome regulatory void. Courts that immunise standards bodies on the basis of the voluntary nature of compliance misunderstand the realities of economic life and underestimate the normative force of private standards. They also undercut the caselaw utilising standards as codifications of custom, proxies for law or statements of 'objective' expertise in tort law. Denying a 'duty of care' is in the final analysis the denial of the regulatory potential of tort law and a declaration of incompetence of the jury system. It should not be so hard to develop principles for the 'exercise of due care' that take account of the difficulties of decision-making under conditions of scientific uncertainty, that encourage the revision of outdated safety standards,[285] and punish the pursuit of narrow private interests. These are the fundamental principles of good governance that administrative law enforces on public agencies and antitrust law imposes on private bodies.[286] They are also the principles courts resort

[282] Above, 1386.

[283] Above.

[284] Above, 1404 (Amos, J, concurring in part and dissenting in part).

[285] In *Grinnell*, above n 248, 4, the Court noted that even if the NFPA were to be subject to a legal duty of reasonable care, the association did not fail to exercise that care since it 'reviewed and revised standard on a periodic basis to keep current with new fire protection knowledge and technologies' and had procedures in place to amend standards 'to include fire safety lessons learned from significant fires or to recognize new technologies or methods.'

[286] Legal counsel for ANSI is relatively confident that adherence to ANSI Procedures renders negligence condemnation unlikely. See Smith, Bolger and Marasco, *Product Liability Claims Against Voluntary Standards Developers—An Update on Recent Developments* (ANSI, 1996); Marasco, *Standards Development: Are You At Risk?* (ANSI, 2000), (both on www.ansi.org).

to time and again in tort law, whether it is for the purpose of establishing 'due care' by manufacturers, the 'defectiveness' of products, the 'reliability' of scientific evidence or for the purpose of deciding when to defer to regulatory decisions. The exercise of 'due care' by standard setters themselves can and should be based on the same principles. This is the promise held out by *King* and *Snyder*.

5. CONCLUSION

Where legal requirements are disconnected from customary rules, standards provide an institution to re-connect them. Where tort law defers to social norms and expectations, standards provide a link. Where tort law defers to regulatory decisions, it often finds those regulatory decisions to be based on standards. Where tort law defers to science and 'technological feasibility', it finds in standards bodies social institutions for the production of expertise. None of these linkages are automatic, nor should they be. Only by maintaining its autonomy, tort law has the potential of formulating requirements and incentives that ensure that standards can play these roles in adequate fashion.

It is not at all clear that legally integrated and politically circumscribed standards fulfil these functions in a manner that leads to higher levels of consumer protection than purely 'private standards.' Perhaps more importantly, it is very doubtful indeed whether European efforts to regulate standards bodies by means of public law lead to standard-setting procedures that are in any way preferable to the ones induced by American courts' willingness to impute a duty of care on standards bodies.

The increased reliance on standards under the combined pressures of the widespread processes of deregulation and globalisation are bound to increase the importance of tort law in the regulation of standardisation. As regulatory law increasingly relies on voluntary standards, courts will cease deferring to regulatory decisions and take it upon themselves to scrutinise standards and the procedures that lead to their establishment. In this sense, tort law takes over the function of administrative law in the supervision of regulatory decision-making. And what courts look for in these instances cannot be very different from what the Restatement (Third) of Torts looks for in the determination of whether to have public law pre-empt tort actions: 'a deliberative process which is full, fair and thorough and reflected substantial expertise.'

The real challenge for private law's potential role in the regulation of standards will come from the globalisation of standard-setting. The imposition of a 'duty of care' on national standards bodies is vital in this respect. Contractual arrangements, voting patterns, political pressure and economic convenience may induce national standards bodies to transpose

international standards they know to be inadequate. A duty of care will force standards bodies to be vigilant and to insist on proper procedures in international *fora*.

But the imposition of a duty of care is only the threshold issue: the contents of that duty is the crucial matter. And that will in the end depend on law's mechanisms of recognition and criteria of validation of extra-legal norms. As elaborated in this chapter, law seems to recognise standards either as socially accepted behaviour, as politically integrated norms, or as 'science.' Of these three, only 'science' travels across borders. The challenge is, then, to resist the reification of international standards as universal 'science' and to insist on the *procedural* legitimacy of standards. The often rehearsed dichotomy between the 'social basis' of technical standards and their scientific validity is a false one on a cultural epistemological understanding of science. By the same token, however, the Europeanisation, and *a fortiori* the globalisation of standardisation will disconnect the content of standards from cultural normative and cognitive frameworks and hence lead to a disconnection between socially accepted norms and legally required behaviour. It is this space that tort law can occupy, by forcing standards bodies world wide to connect 'universal' standards to local circumstances. In this way, a 'local' duty of care translates into a duty to participate fully in international standard setting, and hence contributes to the legitimacy of international standard setting.

Conclusion
The Constitution of Private Governance

1. INTRODUCTION

THE CONSTITUTION EMBODIES and reconciles our most noble and impossible aspirations. On the one hand, it establishes a system of government of laws, not of men. At the same time it allows us to think that we are, in some meaningful way, governing ourselves.[1] The system requires that no one should be able to bind us to anything if not within the limits of the competences and according to the procedures that 'we' have established for that purpose. We should be able to trace back all laws and regulations to higher laws and regulations to yet higher ones until we arrive at the constitution itself and at the legislators we elect to represent us—that is, at ourselves. Crucially, the system requires that 'we' are able to understand, to make judgments, to choose.

We have all long accepted that the system doesn't quite work like that, basically because reality is too messy to be caught in such an elegant mould. What we have perhaps yet fully to comprehend is that it *cannot* work like that. The system assumes territorial borders—it assumes that all social life unfolds within the territory of the political community. Globalisation has shattered that assumption. The system assumes cognitive frames—it assumes that all social life is comprehensible, that all aspects of government are commensurable to political preferences. Social differentiation has shattered that assumption.

Product safety standards are hardly the stuff dreams are made of, and perhaps it is easy to accept that our constitutional aspirations do not quite capture the legitimacy of norms on such matters as propeller guards or fire door release mechanisms. And yet safety standards directly affect all of us every day of our lives. They also determine the conditions for trillions' worth of trade. Standardisation may be a small thing, but it certainly is a *res publica*.

[1] See eg Michelman, 'Law's Republic' (1988) 97 *Yale L J* 1493, 1500 ff.

2. GLOBAL LAW WITHOUT A STATE

Every single day, thousands of people gather in committees in hundreds of rooms and conference halls around the world to debate and prepare draft standards. Every single day, tens of thousands of email communications and documents make their way from one place to another, discussing, proposing, rejecting, accepting, and modifying standards. Costs and benefits are calculated, probabilities quantified, estimates adjusted, constituencies consulted, and opinions solicited; pressure is applied, reputations are put on the line, relationships solidified or endangered. People are convinced, persuaded and cajoled to vote this way or that.

The fruits of all this labour are thousand upon thousands of safety standards, some purely national or local, some imposed, coordinated, harmonised or unified in large parts of the world through intricate processes of market dynamics, organisational links, contracts and association. They largely control what we buy and whom we buy it from; they determine how safe we are at work and at play. They constitute a normative fabric far beyond the capacities of any state. Markets wouldn't exist without them. Regulators wouldn't know what to do without them. They stabilise and generalise normative expectations. In any understanding of the term but the purely positivist, they constitute law.[2]

2.1 The Making of Global Law

To speak of 'Global Bukowina,' and hark back to Ehrlich and Gurvitch to analyse modern processes of global lawmaking,[3] may well smack of 'intellectualised nostalgia' for 'the neighbourhood norms and customs of the premodern world planned out of existence by the lawmaking activities of the state', to employ Roger Cotterrell's characterisation of classic legal pluralism.[4] International standardisation is hardly a matter of spontaneous norm-formation in transnational civil society. Very little about it is spontaneous. Very little about is even decentralised. But, as Gunther Teubner points out,

> It is not so much the contrast with state law that characterizes the new social law, but its instrumentalization for purposes of political regulation, which even goes so far that politics in turn initiates artificial procedures of social norm production.[5]

[2] Suffice it to refer to Luhmann, *A Sociological Theory of Law* (Routledge, London, 1985) 73 ff.

[3] Teubner, '"Global Bukowina": Legal Pluralism in the World Society' in Teubner (ed), *Global Law Without a State* (Dartmouth, Aldershot, 1997) 3.

[4] Cotterrell, *Law's Community* (Clarendon Press, Oxford, 1995) 306–7.

[5] Teubner, 'Autopoiesis and Steering: How Politics Profit from the Normative Surplus of Capital' in In't Veld, *et al*, (eds), *Autopoiesis and Configuration Theory: New Approaches to Societal Steering* (Kluwer, Amsterdam, 1991) 127, 139.

The story of NAFTA negotiations launching the Mexican government into a 'frantic race to create private bodies' is but an example of the extent to which the diffusion and increased significance of private standardisation is a top-down process, politically sustained and institutionalised in trade agreements. The extent to which the growth in European private standardisation has been orchestrated, facilitated, financed and legally imposed on Member States by the Community institutions through the 'New Approach' is, if perhaps less glaring, the more significant example. Standardisation is being privatised throughout the developed world to facilitate the harmonisation of technical specifications. At the same time, however, standards bodies are being 'publicised': as States lose their influence in the process of harmonisation internationally, they tighten their grip on 'their' national standards bodies in an effort to regain some of the lost power. *Memoranda of understanding* flourish, in some cases replacing more direct legal and institutional instruments of control, in other cases filling a void of indifference and neglect.

National standards bodies themselves, of course, are rapidly losing power in the emerging system of private 'supranationalism.' Only the major standards bodies from the United States are able to put up a credible fight against the monopoly of the 'official' federations of standards bodies, but even that fight seems much like a rearguard battle in face of the political pressure to establish a system based on international representation of standards bodies, rather than *de facto* international use of standards. In that system, national standards bodies are not actually setting standards—they are participants in an international process of standardisation. They do much what Member States of the European Union do with respect to Community law on their own territory—they organise and develop 'national' positions to be injected into the process of standard setting itself, and then adopt and implement the results of the supranational effort on the national territory.

If, then, the process of privatisation and globalisation of standard setting is at least partly the product of political instrumentalisation, the result has still been the emergence of a relatively autonomous system of global lawmaking beyond the state. Even if adopted as national standards—and even if slightly amended or modified—a large proportion of standards used and enforced around the world for the protection of citizens' health and safety finds its origin in global processes of standardisation. Even if adopted into national law, a large portion of safety standards used in product safety regulation finds at least its basis—and more often than not, its precise technical content—in global processes of standardisation. And yet, 'we' are nowhere to be found.

2.2 Strategies of Denial

The *Crawford* court's solution to that problem was straightforward: legislators should just copy the standard, and then adopt is as law according to the procedures and through the institutions prescribed by law.[6] This solution—a simple coat of constitutional varnish to make 'us' believe that 'we' have legislated—is, of course, hopelessly inadequate, and increasingly so. And yet the same impulse is still felt across the Atlantic: deny that standards are 'private' at all by locking them into the constitutional frame of law and state. The precise manifestations of this strategy range from the merely rigid to the pathetic—adopting standards by royal decree, re-enacting the standards setting process by administrative process, constituting national standards bodies as 'public agencies,' exercise judicial review over private bodies, plant *Commissaires de gouvernement* within the organisation, or even purchase membership cards for public officials to standards bodies operating outside the jurisdiction. Even allowing for the idea that these strategies might go some distance towards bringing national private governance under public control, they are hopeless in the face of the reality of global private standardisation.

Community law is perhaps the best example of the opposite tactic: by holding on to the fiction that compliance with European standards is strictly voluntary, the strategy is to deny that standards are 'law' at all. Here, too, the manifestations of the strategy are manifold, and increasingly sophisticated. A whole array of techniques is employed in the cause of maintaining that 'the law' contains the only binding requirement—from various 'hinge clauses' to rebuttable presumptions of conformity. However refined the legal technique, however, the end result is always the same paradox: the more 'the law' defends its monopoly as the only source of mandatory commands, the more indeterminate and vague it becomes. If 'we' have decided that things must be built according to the 'acknowledged rules of technology,' or even that 'all products must be safe', we haven't really decided anything much. At best, 'we' will have decided that the judiciary is going to decide what exactly we mean with all these offerings of legislative incompetence.

3. THE LEGITIMACY OF GLOBAL PRIVATE GOVERNANCE

The alternative would be to accept international standardisation as 'law.' But the prospect of extra-constitutional law immediately raises the question of extra-constitutional legitimacy. As Gunther Teubner notes:

[6] *State v Crawford* 177 P 360, 361 (Kan 1919).

> If we abandon the old practice to obscure the de facto lawmaking in all kinds of 'private governments' and bring to light that what they are doing is producing positive law which we nolens-volens have to obey then we ask more urgently than before the question: What is this 'private legal regime's' democratic legitimation? At the same time, we see how naïve it would be to demand a formal delegatory link of private governments to the more narrow parliamentary process. Rather, we are provoked to look for new forms of democratic legitimation of private government that would bring economic, technical and professional action under public scrutiny and control. That seems to me is the liberating move that the paradox of global law without the state has actually provoked: an expansion of constitutionalism into private law production which would take into account that 'private' governments are 'public' governments.[7]

The idea of expanding constitutionalism here is not, of course, the ultimately facile effort to bring private government into the sphere of national public law.[8] The idea is, rather, to 'constitute' private governance regimes themselves as sites of legitimate lawmaking, or, in Willke's terms, the 'inner constitutionalisation' of organisations, corporative actors, and functional systems.[9] That notion, however, inevitably comes up against the objections of Jürgen Habermas. Willke's 'systems-theoretical adaptation of the Hegelian *Ständestaat*', he notes, 'takes the place of the democratic constitutional state', and even 'vitiates the idea of government by law.'[10] Habermas is, of course, not so naïve to think that the legislator can adequately regulate every single matter. Yet in his engagement with Willke's neocorporatist paradigm of law, he maintains the necessity to integrate decentralised lawmaking to the central tenets of constitutional lawmaking. His demands are high:

> When faced with political decisions relevant to the whole of society, the state must be able to perceive, and if necessary assert, public interests as it has in

[7] Teubner, 'Breaking Frames: The Global Interplay of Legal and Social Systems' (1997) 45 *Am J Comp L* 149, 159.

[8] See eg Black, 'Constitutionalising Self-Regulation' (1996) 59 *MLR* 24; Aman, 'Proposals for Reforming the Administrative Procedure Act: Globalizaton, Democracy and the Furtherance of a Global Public Interest' (1999) 6 *Ind J Glob Leg S* 397; Freeman, 'Private Parties, Public Functions and the New Administrative Law' (2000) 52 *Admin L J* 813; Aman, 'Globalization, Democracy, and the Need for a New Administrative Law' (2002) 49 *UCLA L Rev* 1687.

[9] Willke, *Ironie des Staates—Grundlinien einer Staatstheorie polyzentrischer Gesellschaft* (Suhrkamp, Frankfurt, 1992) 357 ff. He also posits the need for the constitutionalisation of the relations between organised social actors in order to, on the one hand, protect their autonomy and on the other, ensure their public-regardingness. Above, 358. See also, from a different perspective, Sabel, 'Constitutional Ordering in Historical Context' in Scharpf (ed), *Games in Hierachies and Networks—Analytical and Empirical Approaches to the Study of Governance Institutions* (Campus, Frankfurt, 1993) 65 (discussing the concept of 'constitutional orders' as distinct from markets and hierarchies).

[10] Habermas, *Between Facts and Norms—Contributions to a Discourse Theory of Law and Democracy* (Polity Press, Cambridge, 1995) 350–51.

> the past. Even when it appears in the role of an intelligent adviser or supervisor who makes procedural law available, this kind of lawmaking must remain linked to legislative programs in a transparent, comprehensible, and controllable way.[11]

His solutions, however, are desperately inadequate. As he admits,

> There is no patented recipe for this. Once again, in the final analysis, the only thing that serves as a 'palladium of liberty' against the growth of independent, illegitimate power is a suspicious, mobile, alert, and informed public sphere that affects the parliamentary complex and secures *the sources from which legitimate law can arise*.[12]

Insisting on this 'two-track' model of law and democracy thus relegates private governments to the status of, at best, an 'impulse-generating periphery.'[13]

This is hardly the place to start a general theoretical discussion of the relative merits of Habermas's insistence on the central institutions of the constitutional state and his two-track model of deliberative democracy on the one hand, and various strands of thought insisting on the institutional dispersion of the idea of constitutionalism and deliberative legitimacy on the other. What is argued here is simply, first, that there is a plausible empirical and logical case to be made that the demands placed on regulatory decision-making about complex social issues do not, in principle, demand a public institution; and second, that there is, in principle, a normatively plausible case to be made for private governance beyond the state.

3.1 The Legitimacy of 'Public' Governance

The idea that regulatory decision-making 'must remain linked to legislative programs in a transparent, comprehensible, and controllable way' is perhaps persuasive to political philosophers. Administrative lawyers and courts faced with the nitty-gritty of regulatory decision-making, however, know better. In a very real sense, administrative law is one long exercise in inventing mechanisms of control, accountability and legitimacy that provide a substitute for political mandates in legislative programs. Broad delegations of regulatory power to public agencies are accepted as a necessary fact of life in social complexity, and compensated for by administrative process. The latter involves, for example, notice and comment, procedural safeguards, and extensive consultation of relevant expertise to reach a reasoned judgment. Much as courts try to establish some link or other with a political mandates established in a legislative program, it has

[11] Above, 441.
[12] Above, 441–42. Emphasis in original.
[13] Above, 442.

become accepted, as it must be, that what is being reviewed is not so much whether the final decision can rationally be held to be the expression of the will of the central legislator but, rather, whether the administrative process itself has fulfilled the requirements of legitimate and informed decision-making.[14] Habermas himself admits that administrative rulemaking should be democratized; what he refuses to allow for, however, is the theory that rulemaking so proceduralised and democratised is a substitute for, rather than a mere complement of, constitutional democracy.[15]

Now, the problem with matters such as propeller guards for outboard motors or fire door release mechanisms is not just that they are politically minor matters; the more profound problem with them is that public authorities, let alone legislators, seldom have the expertise to make a reasoned judgment about them. Social complexity forces regulators to draw on private actors, to bargain with organised private actors, and even to rely completely on private parties' judgments.[16] It is here, on the issue of private delegations of regulatory power to 'social subsystems, large organizations, associations, and such, which, to a considerable extent, resist legal imperatives', and to 'social actors with paraconstitutional bargaining power,'[17] that Habermas firmly draws the line:

> The constitutional structure of the political system is preserved only if government officials hold out against corporate actors and bargaining partners and maintain the asymmetrical position that results from their obligation to represent the whole of an absent citizenry, whose will is embodied in the wording of the statutes. Even in attunement processes, the bonds of delegation must not tear away from actual decision-making.[18]

Private standardisation has assimilated the canons of administrative rulemaking to such an extent that it is hard to find a difference between its procedures and the procedures that sanction delegations of regulatory power to public agencies, other than that of a formal link with public power. And empirically, legislators and courts do, ultimately, allow for the theory that the procedures in place in private bodies can substitute for the mandates of legislative programs, even if courts' attempts to deny formally what they accept in practice are oftentimes strained to the point of absurdity. Even in antitrust and tort law, courts will ultimately accept private standard bodies as 'public governments.' What is more, they use

[14] See above, chs 7 and 8.

[15] Habermas, above n 11, 440 ff. He comes close where he states that 'participatory administrative practices' should be considered as 'procedures that are *ex ante* effective in legitimating decisions that, from a normative point of view, substitute for acts of legislation or adjudication.' Above, 441. For a comprehensive discussion of Habermassian proceduralisation of public regulation, see Black, 'Proceduralizing Regulation: Part I' (2000) 20 *OJLS* 597; Black, 'Proceduralizing Regulation: Part II' (2001) 21 *OJLS* 33.

[16] See eg Freeman, 'The Private Role in Public Governance' (2000) 75 *NYU L Rev* 543.

[17] Habermas, above n 11, 433.

[18] Above, 350.

traditional doctrines of antitrust and tort as doctrines of 'private administrative law', reviewing the procedural integrity and rationality of rulemaking under the guise of 'reasonable restraints' and 'duty of care.'

3.2 The Legitimacy of 'Private' Governance

Habermas insists on deliberation as the source of legitimacy of the constitutional state, rather than the mere registration of social majorities.[19] But he makes a rigid distinction between the deliberation of the public sphere, through 'networks of *noninstitutionalized* public communication' that make possible 'more or less *spontaneous* processes of opinion-formation,' and the deliberation of the central political institutions of the state who can issue binding decisions according to the procedures established by legitimate law.[20] As Dryzek dispairs, Habermas 'has turned his back on extra-constitutional agents of both democratic influence and democratic distortion.'[21]

Part of Habermas's resistance to the idea of corporatist self-government stems from his conceptualisation of cognitive and normative dimensions of rulemaking. From both viewpoints, he claims, 'it is advisable that the enlarged knowledge base of a planning and supervising administration be shaped by deliberative politics, that is, shaped by the publicly organised contest of opinions between experts and counterexperts and monitored by public opinion.'[22] 'Deliberation' among experts themselves seems, hence, inconceivable. In Habermas's conception, specialized knowledge seems clearly separated from the normative implications arising from it. As soon as expertise is implicated politically, but only then, is controversy a fact, not because of contested knowledge itself but because ethical and moral dimensions inevitably come to the fore. Politics is hence a different sphere altogether from the process of knowledge generation. What 'experts and counterexperts' have to battle out in the public arena is not the basis of their specialised knowledge, but merely the normative implications of that knowledge. Final decision-making on the basis of that knowledge, moreover, is not one, but two steps removed from the experts. The experts inform the public sphere, the public sphere informs the parliamentary complex. All this does is, in the end, is to reify and perpetuate the

[19] See the classic discussion in Manin, 'On Legitimacy and Political Deliberation' (1987) 15 *Political Theory* 338, 351–52. Cf Cohen, 'Deliberation and Democratic Legitimacy' in Hamlin and Pettit (eds), *The Good Polity—Normative Analysis of the State* (Blackwell, Oxford, 1989) 17; Cohen, 'Procedure and Substance in Deliberative Democracy' in Bohman and Rehg (eds), *Deliberative Democracy—Essays on Reason and Politics* (MIT Press, Cambridge, 1997) 407.

[20] Habermas, above n 11, 358. First emphasis added.

[21] Dryzek, *Deliberative Democracy and Beyond* (OUP, Oxford, 2000) 26. See further especially Cohen, 'Reflections on Habermas on Democracy' (1999) 12 *Ratio Juris* 385.

[22] Habermas, above n 11, 351.

dichotomy of knowledge and power.[23] And that, surely, detracts from what Bohman calls 'the best defense' of public deliberation, namely, that it improves the epistemic quality of the justifications for political decisions.[24]

John Dewey wrote of the 'machine age' that it has so 'enormously expanded, multiplied, intensified and complicated' the scope of 'indirect, extensive, enduring and serious consequences of conjoint and interacting behaviour,' that the resultant public could distinguish and identify itself.[25] He concluded that

> [t]here are too many publics and too much of public concern for our existing concerns to cope with. The problem of a democratically organised public is primarily and essentially an intellectual problem, in a degree to which the political affairs of prior ages offer no parallel.[26]

In present conditions of social complexity, Habermas's 'public' would seem completely overwhelmed. James Bohman describes the dilemma of deliberative democracy under conditions of social complexity well:

> The sheer size and complexity of society could tempt one to relegate deliberation only to representatives so much that it would be difficult to call the account democratic. An opposite error would be to underestimate complexity and locate deliberation primarily in the public sphere. Here one does not take sufficient account of the institutional requirements for such deliberation to issue in effective decisions. . . . The facts of complexity seem to present deliberative democracy with a Weberian dilemma: either decision-making institutions gain effectiveness at the cost of democratic deliberation or they retain democracy at the cost of effective decision making.[27]

In this dilemma, 'Habermas's two-track solution surrenders too much of democratic self-governance in order to achieve integration at the institutional level.'[28]

[23] For critique, see Brown, *Toward a Democratic Science—Scientific Narration and Civic Communication* (Yale University Press, New Haven, 1998) 174.

[24] Bohman, *Deliberation—Pluralism, Complexity and Democracy* (MIT Press, Cambridge, 1996) 178.

[25] Dewey, 'The Public and Its Problems' in Id, *The Later Works, 1925–1953,* Vol 2: 1925–1927 (Southern Illinois University Press, Carbondale, 1984) 235, 314.

[26] Above.

[27] Bohman, above n 24, 178.

[28] Above, 177. Cf Rubin, 'Getting Past Democracy' (2001) 149 *U Penn L Rev* 711, 745 ('It is difficult to see why rationality, or communicative action, is necessary for any of the roles that Habermas assigns to civil society other than the role of implementing Habermas's theory.') One of the ironies of Habermas's stance is to be found in the fact that David Sciulli's work on societal constitutionalism takes *exactly* the Weberian problem as its starting point, and institutionalises a procedural threshold of socially integrative governance in collegiate formations of civil society *exactly* on the basis of Habermas's ideal conditions for communicative action. See Sciulli, 'Foundations of Societal Constitutionalism: Principles from the Concepts of Communicative Action and Procedural Legality' (1988) 39 *B J Soc* 377; Sciulli, *Theory of Societal Constitutionalism: Foundations of Non-Marxist Critical Theory* (Cambridge University Press, Cambridge, 1994). Cf Frankford, 'The Critical Potential of the Common Law Tradition' (1994) 94 *Colum L Rev* 1076; Tushnet, 'The Constitution of Civil Society' (2000) 75 *Chi-Kent L Rev* 379.

4. THE CONSTITUTION OF GLOBAL PRIVATE GOVERNANCE

4.1 Representation and Deliberation

Partly out of empirical necessity, but mostly out of normative unease with the idea that legitimate governance should be limited to the central institutions of the constitutional state, theorists have begun to elaborate the idea that deliberation and procedural integrity could provide a 'stateless' alternative to the hierarchical legitimacy implicit in the unity of law and state. The idea underlies much political science work on governance.[29] The idea is central to two crucial concepts of modern legal theory. The concept of 'directly-deliberative polyarchy' combines deliberative democracy with an intensely pragmatic approach to problem-solving to come up with a radicalised theory of institutionally dispersed decision-making.[30] However national in origin, the concept has been vaunted as the blueprint for law and democracy beyond the state.[31] For all those aspirations, however, the theory remains firmly locked into local settings and is even premised on the congruence of inputs and outputs.[32] The concept of 'deliberative supranationalism' has allowed huge advances in the study of European Union governance for its capacity to dissolve the old and tired tension between intergovernmentalism and supranationalism.[33] It remains, however, in conception and normative appeal, as much a representational as a communicative account of democracy.[34]

[29] See eg Zürn, 'Democratic Governance Beyond the Nation-State: The EU and Other International Institutions' (2000) 6 *EJIR* 183, 209 (insisting on the internal democracy of 'issue networks'); Schmalz-Bruns, *Reflexive Demokratie—Die demokratische Transformation moderner Politik* (Nomos, Baden-Baden, 1995) 239 (discussing the 'microconstitutional self-organisation of societal fora.')

[30] See Cohen and Sabel, 'Directly-Deliberative Polyarchy' (1997) 3 *ELJ* 313. Cf Dorf and Sabel, 'A Constitution of Democratic Experimentalism' (1998) 98 *Colum L Rev* 267.

[31] See Gerstenberg, 'Law's Polyarchy: A Comment on Cohen and Sabel' (1997) 3 *ELJ* 343; Gerstenberg and Sabel, 'Directly-Deliberative Polyarchy: An Institutional Ideal for Europe?' in Joerges and Dehousse (eds), *Good Governance in Europe's Integrated Market* (OUP, Oxford, 2002) 289. Cf Sabel, 'Design, Deliberation and Democracy: On the New Pragmatism of Firms and Public Institutions' in Ladeur (ed), *Liberal Institutions, Economic Constitutional Rights and the Role of Organizations* (Nomos, Baden-Baden, 1997) 101 (discussing, on the basis of very little, international standard-setting as an example of democratic experimentalism).

[32] Zürn, *Regieren Jenseits des Nationalstaates* (Suhrkamp, Frankfurt, 1998) 361, regards the theory useful for locally bounded decisions in towns, neighbourhoods and countries of up to 2 million inhabitants.

[33] See Joerges and Neyer, 'Transforming Strategic Interaction into Deliberative Problem–Solving: European Comitology in the Foodstuffs Sector' (1997) 4 JEPP 609; Joerges and Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 *ELJ* 273; Joerges, '"Good Governance" Through Comitology?' in Joerges and Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart Publishing, Oxford, 1999) 311.

[34] Unperturbed by accusations of straying from deliberative correctness, Joerges, '"Deliberative Supranationalism"—Two Defences' (2002) 8 *ELJ* 133.

Perhaps more significantly, legal systems have—exclusively out of empirical necessity—begun to entertain the idea as well. A long and motley list of cases discussed in this book have dealt ultimately with the same fundamental question: under which conditions does law recognise regulations issued by private parties as constitutionally legitimate 'law'? Or rather: how does law 'constitute' private governance? And however tentatively and inconsistently, the answer that is emerging is much the same as the conditions under which the American Law Institute is prepared to have common law claims to be pre-empted by statute: when the court is confident that the deliberative process by which the safety standard was established was full, fair and thorough and reflected substantial expertise.[35] However tentatively and inconsistently, courts and legislators have shown themselves capable of recognising and validating private governance, of accepting as legitimate 'law' norms generated in private associations outside the central political institutions of the constitution and beyond the nation state.

What they require is much what 'we' require of public regulatory decision-making: due process, wide and meaningful consultation, institutionalised debate. Representation of diffuse interests is attractive in this light not because of the shallow idea that 'interests' need be 'represented' for decisions to be made 'democratically', but because it enhances deliberation, and only in the measure it does so. 'Scientific' expertise is necessary in this light not to turn the whole process into a reified exercise of political epistemology, but because it enhances the quality of deliberation. Once it is accepted that standards bodies are, in principle, useful and legitimate *loci* for the social organisation of deliberation of complicated regulatory issues, legal policy should be directed at policing the quality of that deliberation. The internal norms and procedures of standards bodies provide a useful and meaningful framework for deliberative decision-making. The legal imperative, then, is to promote the procedural integrity of autonomous private standardisation, to diversify its membership, to enhance its knowledge base, and to broaden its ethos.[36]

4.2 Centre and Periphery

As long as we keep our constitutional aspirations and our legal imagination locked in the unity of law and state, we will not only fail to understand

[35] Restatement (Third) of Torts: Products Liability, § 4 (1998), comment c.

[36] See Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, Pittsburgh, 1997) 64 ('[i]f your mission is similar to that of a government, you must be more like a polity. Since the basis of the organizational authority is not really democratic, but rather grounded in expertise and experience, more diverse internal structures based on these qualities are called for. Like a polity, standard-setting organizations must be not simple, but richly textured.')

the phenomenon of global law conceptually but also fail normatively to grasp the opportunities to enhance its legitimacy. With Gunther Teubner, what we must try and do is accept that private governments now constitute the centre, and the political regulation of the nation-state has moved out towards the edges of modern law.[37] National legal systems are but the 'impulse generating periphery' of global standardisation. That, however, is not at all a bad place to be. National legal systems may not be able to incorporate standardisation into their own constitutional hierarchy, they may not be able realistically to dismiss standardisation as mere social custom or to elevate it to the status of scientific truth, but they can exert enormous influence on the procedures and practices of national and international standards bodies. The internal administrative law of standardisation, after all, was hardly developed by a sense of civic awakening among industrial circles, or by a spontaneous due process revolution in the engineering profession. Rather, it has been the result of a long and intricate process of normative borrowing – and sometimes imposition—of norms and principles from different legal sources. French administrative review of AFNOR standards of international origin may not quite manage to bring the ISO under the control of the French state; American antitrust review of a decision by US standards developers not to adopt an international standard may not quite do the trick of bringing standardisation under the same discipline as public regulators are under the WTO. But all of these instances may—and will—provide the opportunity for courts to review and promote private deliberative decision-making. There is, of course, little in the nature of deliberation to ensure that products manufactured according to such safety standards will be safe for life and limbs. And it is for that reason, and not for a formal conception of the rule of law, that it is vital that legal requirements stay at arms' length from voluntary safety standards.

From the periphery, the public/private distinction ceases to make sense. An exclusive public law approach to standardisation assumes that the process is intrinsically political. An exclusive private law approach assumes that the process is intrinsically economic. But standard setting is inherently both and neither. It is a political process that relies on market mechanisms—standard-setters get together to write health and safety standards not moved by a civic duty but because they hope to use these standards as marketing tools and hence sell more products. It is also an economic process that relies on political principles—weeding out dangerous, inferior, and otherwise undesirable products not via the market mechanism but through structured deliberation. It is from the periphery that both public and private law mechanisms can and must contribute to the constitutionalisation of global private governance.

[37] See Teubner, 'The Two Faces of Janus: Rethinking Legal Pluralism' (1992) 13 *Cardozo L Rev* 1443.

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