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The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Processes: The Case of Standardisation under the 'New Approach'

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THE LAW'S PROBLEMS WITH THE INVOLVEMENT OF NON-GOVERNMENTAL ACTORS IN EUROPE'S LEGISLATIVE PROCESSES: THE CASE OF STANDARDISATION UNDER THE 'NEW APPROACH'[*]

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1. INTRODUCTION

The increasing reliance of the Community legislator on private standard-setting organisations poses a set of classic constitutional difficulties conveniently summed up in the catch-phrase 'delegation of regulatory competencies'. Legal debate surrounding the 'New Approach to Technical Harmonisation and Standards' employs the concept to describe and denounce the use of industrial self-regulation as an erosion of Member States' power to further social objectives of health and safety in favour of a deregulatory move by Community institutions sacrificing social objectives to the greater good of market building. This contribution sets out to demonstrate the inadequacy of this view. We believe that the world of thought lying behind 'delegation' both represents a distorted perception of constitutional problems along neat public/private and Community/Member State dichotomies and prescribes a misconceived solution to these problems – a reinvigoration of the public on the Community level. 'Delegation' does not, and cannot, take account of the specific problems posed by the inclusion of transnational private actors in the regulation of the internal market, nor can it respond in any meaningful way to the challenges posed by the globalisation of private governance structures.

While challenging the traditional perception, we insist on the constitutional importance of the governance structures established by standardisation. It is our contention that the function of 'Law' should be not so much the allocation of formal responsibility for decisions as it should be to structure the process of decision-making with a view to further procedural legitimacy. Our reinterpretation of the delegation issue will refer, analytically, to the multi-level governance approach to the study of European integration and, normatively, to 'deliberative' theories of constitutional democracy. Our suggestions will be based, first, on a reconstruction of different phases of 'conventional' perceptions of the problem in terms of 'de-regulation' and 'privatisation'. We will then deconstruct the concept of 'delegation' and, finally, try to offer – tentatively – an alternative outlook.

2. THE NEW APPROACH: 'DELEGATION' OR 'INTERVENTIONISM'? 'DEREGULATION' OR RE-REGULATION?

2.1. In Search for a New Regulatory Strategy for the Elimination of Technical Barriers to Trade

The construction of the Common Market has always been recognised to imply the removal of barriers to trade constituted

by innumerable amounts of technical product specifications incorporated in Member States' laws and administrative provisions not covered by Article 28 EC (ex Article 30 EC). The initial approach to regulate all product-specific details at the highest political level in Community directives ran into visible trouble soon after the adoption of the General Programme for the elimination of technical barriers to trade in 1969,[1] whose aim to relieve the burden on the Community's legislative process failed miserably. Over the years, Commission frustration with the slowness of the European legislative process mounted. The unanimity principle in Council decision-making coupled with the high degree of detail of the technical provisions to be agreed upon were seen as severely impeding efficient lawmaking.[2] Moreover, since technology moved faster than Council decision-making, the technical specifications which were finally produced were often obsolete by the time Directives were finally promulgated.

The 'New Approach' of 1985 marked a new phase in the establishment of the Internal Market. Led exclusively by pragmatic considerations to accelerate legislative activity, the launch of the New Approach meant a significant departure in philosophy and legislative strategy for the Community, and has

[1] OJ 1969 C 76/1.

[2] Cf e.g. J. Pelkmans, *Opheffing van technische handelsbelemmeringen*

turned out to embody a genuinely innovative regulatory technique. New Approach Directives cover entire sectors rather than single products, and limit themselves to laying down rather general 'essential requirements' of health and safety. The task of harmonising technical specifications is now left to private European standards associations. Products manufactured according to these harmonised standards enjoy a 'presumption of conformity' with the essential requirements.

The New Approach has proven an undeniable success in terms of legislative output. Where, for example, it had taken six years under the traditional approach to agree on the determination of the permissible sound level of lawnmowers,[3] under the New Approach it only took 18 months to adopt a directive on machinery.[4] Other directives were adopted for sectors ranging from construction products to telecommunications terminal equipment.[5]

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in de EG (Pilot Study in opdracht van het UNO) (Den Haag, 1985).

[3] OJ 1984 L 300/171.

[4] Directive 89/392/EEC, OJ 1989 L 183/9, since amended. A consolidated version is published as Directive 98/37/EC, OJ 1998 L 207/1.

[5] Directive 89/106/EEC, OJ 1989 L 40/12 and Directive 91/263/EEC, OJ 1991 L 128/1. Further adopted under the New Approach are Directive 87/104/EEC (simple pressure vessels), OJ 1987 L 220/48, Directive 88/378/EEC (toys), OJ 1988 L 187/1, 98/336/EEC (electromagnetic compatability), OJ 1989 L 139/19, Directive 89/686/EEC (personal protective equipment), OJ 1989 L 399/18, Directive 90/384/EEC (non-automatic weighing instruments), OJ 1990 L 189/1, Directive 90/385/EEC (implantable medical devices), OJ 1990 L 189/17, Directive 90/396/EEC

In terms of legitimacy, however, questions have been raised from the very outset about the system's admissibility under Community law. From its beginnings as an ad hoc *trovata* to speed up the process of internal market building, the history of the New Approach can be described as the Commission's continuous balancing act between accusations of 'deregulation' on the part of legal commentators and accusations of 'interventionism' on the part of the standardisation community.[6]

(gas burners), OJ 1990 L 196/15, Directive 92/42/EEC (hot-water boilers), OJ 1992 L 167/17, Directive 93/15/EEC (explosives for civil uses) OJ 1993 L 121/20, Directive 93/42/EEC (medical devices), OJ 1993 L 169/1, Directive 93/97/EEC (satellite earth equipment), OJ 1993 L 290/1 (amended together with Directive 91/263/EEC by Directive 98/13/EC, OJ 1998 L 74/1), Directive 94/9/EC (equipment and protective systems intended for use in potentially explosive atmospheres), OJ 1994 L 100/1, Directive 94/25/EC (recreational craft), OJ 1994 L 164/15, Directive 95/16/EC (lifts), OJ 1995 L 213/1, Directive 97/23/EC (pressure equipment), OJ 1997 L 181/1, and Directive 98/79/EC (in vitro diagnostic medical devices), OJ 1998 L 331/1.

[6] The complete storyline of the 'New Approach', running through *Cassis de Dijon*, the White Paper and '1992', is found in Ch. Joerges, J. Falke, H.-W. Micklitz, and G. Brüggemeier, *Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft (*Baden-Baden 1988) (English version: *European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards*, published as EUI Working Papers LAW, nos. 91/10-14, Florence, 1991; http://www.iue.it/LAW/WP-Texts/Joerges91/). More recent accounts, from different perspectives, are Falke, 'Achievements and Unresolved Problems of European Standardisation: The Ingenuity of Practice and the Queries of Lawyers' in Ch. Joerges, K.-H. Ladeur & E. Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making-National Traditions and European Innovations (*Baden-Baden 1997), 187-224; K.A. Armstrong and S.J. Bulmer, *The Governance of the Single Market* (Manchester 1998), 144 ff. and E. Vos, *Institutional Frameworks of Community Health and Safety Regulation. Committees, Agencies and*

2.2. From the Low Voltage Directive to the New Approach – From Original Sin to Innovative Regulatory Technique

The technique of referring to standards was pioneered by the Low Voltage Directive of 1973.[7] For a long time the Directive was considered by Commission officials and national administrations alike as an original sin not to be repeated, only explicable and defensible because of the peculiarities of the electrotechnical sector and the strength of the standardisation tradition in that sector. It was to gain something of a cult status afterwards, being hailed as a courageously pioneering exercise in new regulatory techniques.[8] The Directive lays down the general safety requirement of manufacture 'in accordance with good engineering practice in safety matters in force in the Community' and declares products manufactured in accordance with standards 'drawn up by common agreement' between national standards bodies to be in conformity with that requirement.

Especially in the German literature, various critiques of the technique were put forward. Röhling, for instance, viewed that this technique in substance came down to an inadmissible delegation of powers on the following grounds: the legal safety

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*Private Bodies (*Oxford 1999), 251 ff.

[7] Directive 73/23/EEC, OJ 1973 L 77/29.

[8] Cf Ch. Joerges *et al.*, above n. 6.

requirements are formulated in such vague terms as to give the standards bodies the power to decide the levels of hazard the public is exposed to. The standards bodies themselves are dominated by business interests, which makes it unlikely that the first, let alone the only thing on their agenda be safety. The delegation of powers by the Council to private standards bodies makes legislative control over these decisions all but impossible.[9] Even if the Court of Justice in *Cremonini and Vrankovich* seemed to acknowledge without much ado the compatibility of the arrangement with the Treaty,[10] these are serious objections which were to set the tone of legal debate for a decade to come. Three separate threads of the delegation-criticism are thus sewn together: first, the discretion left to private bodies by excessively vague legislative requirements, second, the lack of public control over these private bodies and third, the lack of internal democracy within these bodies.

The institutional set-up of the New Approach in many ways sought to counter these attacks. First, in 1983 the Council

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[9] E. Röhling, *Übertriebliche technische Normen als nichttarifäre Handelshemnisse im Gemeinsamen Markt* (Köln/Berlin/Bonn/München 1972), at 114 ff. Cf E. Grabitz, *Die Harmonisierung baurechtlicher Vorschriften durch die Europäischen Gemeinschaften (*Berlin 1980).

[10] Case 815/79 *Criminal proceedings against Gaetano Cremonini and Maria Luisa Vrankovich* [1980] ECR 3583. Cf Hartley, 'Consumer Safety and the Harmonisation of Technical Standards: the Low Voltage Directive', (1982) 7 *ELR* 55.

adopted the so-called Information Directive,[11] which establishes a notification procedure for national technical regulations and standards. The Directive defined 'standard' as a technical specification with which compliance is not compulsory, adopted by a 'recognised standardisation body'. The Directive further annexed a list of recognised national standards bodies and designated CEN and CENELEC as 'European standards bodies' responsible for the running of the information procedure.[12] As a

[11] Council Directive 83/189/EEC laying down a procedure for the provisions of information in the field of technical standards and regulations, OJ 1983 L 109/8, amended since. A 'consolidated' version was published as Directive 98/34/EC, OJ 1998 L 204/37. Less than a month after adoption of the consolidated version, the text was substantially amended by Directive 98/48/EC, OJ 1998 L 217/18, so as to include information society services. Especially in the field of public – mandatory – technical regulations the Directive is considered a great success. Cf Fronia and Casella, 'La procédure de contrôle des réglementations techniques prévue par la nouvelle directive 83/189/CEE', (1995) *Revue du Marché Unique Européen*, (2): 37-85; Weatherill, Compulsory Notification of Draft Technical Regulations: The Contribution of Directive 83/189 to the Management of the Internal market', (1996) 16 *YEL* 129. The importance of the directive is bound to grow by the Court's decision to render the obligation to notify draft technical regulations directly effective. Case C-194/94 *Securitel* [1996] ECR I-2230. See e.g. the casenotes by Everling, (1996) 23 *ZLR* 449, and Slot, (1996) 33 CMLR 1035; and further López Escudero, 'Efectos del incumplimiento del procedimiento de información aplicable a las reglementaciones técnicas', (1996) 23 *Revista de Instituciones Europeas* 839, and Lecrenier, 'Le contrôle des règles techniques des Etats et la sauvegarde des droits des particuliers', (1997) 5 *Journal des Tribunaux- Droit européen* 1.

[12] ETSI, the European Telecommunications Standards Institute, was set up in 1986 but was not recognised as a 'European Standardisation Body' until 1992 in Commission Decision 92/400, OJ 1992 L 221/55.

next step, the Commission signed an agreement with CEN and CENELEC in 1984.[13]

In these 'General guidelines for co-operation', the Commission confers what amounts to a monopoly of standard-setting on CEN and CENELEC and commits itself to financial assistance. CEN and CENELEC for their part commit themselves to draw up standards according to Commission mandates and satisfying the 'essential requirements' of safety and health, and to 'ensure' the 'effective association' of all interested circles in the process.

The 'New Approach' itself, then, was launched by a 1985 Council Resolution.[14] Annexed to that Resolution, a 'Model Directive' was published in which the four fundamental principles of the New Approach are laid down: legislative harmonisation is to be limited to 'essential safety requirements'; the task of drawing up technical specifications is left to the European standards bodies; these specifications are to maintain their status of voluntary standards, but, at the same time, national authorities are obliged to recognise that products manufactured in accordance with these harmonised standards are presumed to

[13] The document is published as CEN/CENELEC Memorandum 4. It can also be found in (1985) 64 *DIN-Mitteilungen* 78-79 and as Appendix 4 in F. Nicolas, *Common standards for enterprises (*Luxembourg 1994).

[14] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, OJ 1985 C 136/1.

conform to the ‘essential requirements’. This set-up would make it 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 to that Directive’.

Further, two complementary strategies are put forward to address the delegation issue. As far as the standards themselves are concerned, their quality is to be ensured by ‘standardisation mandates’ conferred by the Commission on CEN and CENELEC. Moreover, a safeguard procedure is to be put in place in each Directive allowing Member States the possibility to contest the conformity of a product or the quality of a standard. As far as the drafting of the ‘essential requirements’ is concerned, the Model Directive insists that they be ‘worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced’.

2.3. Legal Debate on the New Approach

Even if the New Approach was generally welcomed in the literature,[15] for some it still entailed a wholesale delegation of

[15] Most enthusiastically Pelkmans, ‘The New Approach to Technical

public regulatory competences to private industry-dominated bodies. For German authors, general references to standards are unconstitutional under German law.[16] In the Community context, the obligatory reference is to the European Court of Justice's case-law in *Meroni,*[17] which would allow for some degree of delegation, but under restricted conditions. Although the *Meroni* judgments related to the ECSC, their validity for the EC Treaty is generally accepted.[18] In accordance with this case-law the following conditions would apply for the admissibility of the

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Harmonisation and Standardisation', (1987) 25 *JCMS* 249. With more reservations, Bruha, 'Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft- Deregulierung durch "Neue Strategie"?', (1986) 46 *Zeitschrift für ausländisches öffentliches Recht* 1, and Falke, 'Normungspolitik der Europäischen Gemeinschaften zum Schutz von Verbrauchern und Arbeitnehmern', (1989) 3 *Jahrbuch zur Staats- und Verwaltungswissenschaft* 217. Cf Waelbroeck, 'L'harmonisation des règles et normes techniques dans la CEE', (1988) 24 *CDE* 243; Burrows, 'Harmonisation of Technical Standards: Reculer Pour Mieux Sauter?', (1990) 54 *MLR* 597, and Schreiber, 'The New Approach to Technical Harmonisation and Standards', in L. Hurwitz & Ch. Lequesne (eds.), *The State of the European Community: Policies, Institutions and Debates in the Transition Years (*Boulder 1991), 99.

[16] The *locus classicus* for German law is P. Marburger, *Die Regeln der Technik im Recht (*Köln 1979). See further e.g. Breuer, 'Die internationale Orientierung von Umwelt- und Technikstandards im deutschen und europäischen Recht', (1989) 9 *Jahrbuch des Umwelt- und Technikrechts* 43; E. Denninger, *Verfassungsrechtliche Anforderungen an die Normsetzung im Umwelt- und Technikrecht* (Baden-Baden 1990), and exhaustively J. Falke, *Rechtliche Aspekte der technischen Normung in der Bundesrepublik Deutschland* (Habilitationsschrift) (Bremen 1999).

[17] Case 9/56, *Meroni & Co. Industrie Metallurgiche S.p.A. v High Authority of the ECSC* [1958] ECR 133, Case 10/56, *Meroni & Co. Industrie Metallurgiche S.p.A. v High Authority of the ECSC* [1958] ECR 157.

[18] Cf for example, Lenaerts, 'Regulating the regulatory process: 'delegation of powers' in the European Community', (1993) 18 *ELR* 41.

transfer of sovereign powers to subordinate authorities outside of the EC institutions:

– the Commission cannot delegate broader powers than it enjoys itself;
– only strictly executive powers may be delegated;
– no discretionary powers may be delegated;
– the exercise of delegated powers cannot be exempted from the conditions to which they would have been subject if they had been directly exercised by the Commission, in particular the obligation to state reasons and judicial control of decisions;
– the delegated powers remain subject to conditions determined by the Commission and subject to its continuing oversight;
– and, the 'institutional balance' between the EC institutions must not be distorted.

The New Approach has been considered to fall short of these conditions for lawful delegation. Since compliance with harmonised standards grants a right to free movement, a delegation of powers by the Council to the private standardisation bodies is involved. This delegation would, then, not be in accordance with the *Meroni* case law since it fails to fulfil the requirement of judicial control. Since standards are not

an integral part of the Directives, they cannot be subject of an appeal for annulment nor the subject of a preliminary ruling.[19]

2.4. Europeanisation 'From Above': the 1990 Green Paper

The Commission's 1990 Green Paper[20] can be understood as an effort to address the delegation problem from another angle, this time concentrating on the status of the European standards bodies. The masterplan was to increase both effectiveness and legitimacy by imposing a fully-fledged 'Europeanised' institutional superstructure on (top) of the standard-producing community.

One of the major practical early problems the New Approach faced was the lack of standards produced to make the Directives operative. The Commission's frustration with its own lack of means to incite or force CEN and CENELEC to speed up the process led it to table a whole set of proposals ranging from new working methods and increased use of information technology to increased recourse to voting instead of the all-pervasive search

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[19] Cf Lauwaars, 'The "Model Directive" on Technical Harmonization', in R. Bieber, R. Dehousse, J. Pinder & J. H.H. Weiler (eds.), *1992: One Internal Market? A Critical Analysis of the Commission's Internal Market Strategy* (Baden-Baden 1988), 151.

[20] 'Green Paper on the Development of European Standardisation: Action for Faster Technological Integration in Europe', COM(90) 456 final.

for consensus so characteristic for standardisation. It further called for increased participation and financial commitment from European industry as well as more effective association of consumer groups and other 'interested circles' virtually blocked out of the process.

In addition the Commission suggested to create a *European Standardisation System* which would clearly define the role of all the participants at national level and European level in terms of agreed objectives and allow for greater transparency and participation of all interested circles. This system would allow for both the diversity of organisation and the autonomy of management within spectrally-based standardisation and also ensure the co-ordination, transparency and legitimacy of European standardisation by applying common rules to all standardisation bodies within this System. These rules would have to be developed by a *European Standardisation Council*. This body should provide the overall policy of European standardisation activities and be composed of representatives of industry, consumers, users, trade unions, the Commission and the EFTA secretariat. The composition of this body displays the Community concern for the need to include the participation of all the relevant interests. In addition to this body, a *European Standardisation Board* – the executive body of the Standardisation Council – would strengthen co-ordination

between the standardisation bodies. It would be composed of the officers of the European standardisation bodies and the secretary of the Standardisation Council. The European standardisation bodies would enjoy complete autonomy in the programming, financing, preparation and adoption of European standards, which would be subject to compliance with the rules of the European Standardisation System.

In the Commission's view, this System would have the benefit of increasing flexibility by providing additional sectoral organisations where industrial sectors feel the need for greater autonomy. Accordingly, the pace of production of standards would be increased since European industry would participate as associated bodies and so offer their services and expertise. Increased participation of European industry would likewise ease concerns about the long term financial stability of European standardisation, in view of the growing dependence of the standardisation bodies on public money. The Commission proposed to require the members of the European standardisation bodies to long-term financial commitment; to change the present retribution of revenue from the sales and to institute member fees for industry, participating in European standardisation (as associated bodies).

2.5. Political Resistance 'From Below'

Unsurprisingly, the Green Paper was ill-received both by industry, called upon to contribute money and expertise, and standardisation bodies, called upon to relinquish much of their power in favour of a new layer of Euro-bureaucracy and the Commission. The Commission, it was argued, had launched a 'retrograde' step towards outdated *dirigisme*. As the title of an interview published in *Enjeux* with the president of AFNOR tellingly claimed: '*Le livre vert, ou la nostalgie du réglementaire*'.[21] Particularly the proposals to create new sectoral standardisation organisations and new bureaucratic layers to supervise the activities of the existing standardisation bodies were strongly rejected by the European standardisation bodies. Other criticisms concerned the Commission's neglect of international standardisation, its sole focus on EC mandated standards, the misrepresentation of industrial involvement and the misunderstanding of operating practices in standardisation.[22] The Commission's proposals to accelerate the standardisation process by focusing on qualified majority voting in technical committees would, according to this criticism, completely ignore the core principle of consensus, characteristic for the

[21] Boulin, President of AFNOR, in (1991) 114 *Enjeux*.

[22] Cf J. Pelkmans and M. Egan, *Fixing European Standards: Moving beyond the Green Paper* (CEPS Working Document No. 65) (Brussels 1992), at 15-22.

standardisation process. '*Le livre vert ignore l'essence même de la normalisation',* an AFNOR official declared in *Le Monde*.[23]

Not much more mercy was to be expected from national administrations. The Dutch Interdepartmental Committee for Standardisation dismissed the Commission's proposals as follows:

> '[t]he cure prescribed in this instance by the Commission seems, by and large, to be worse than the ailment; the measures proposed are indicative of an almost cavalier disregard of all interests other than the Community's and of an incomplete grasp of history; they choose the wrong point of attack, they are complicated to implement and contestable in terms of Community law; they reinforce protectionist sentiments and, above all, are damaging to the credibility and therefore to the usefulness of the standardisation process'.[24]

It was clear that the Commission could not but retreat from its proposals. Abandoning most of its proposals, the Commission changed its tone considerably in its 1991 Follow-up Communication,[25] announcing its intention to:

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[23] Le Monde 27/2/1991, at 21.

[24] Position of the Dutch Interdepartmental Committee for Standardisation and Certification (ICN) on the Commission Green Paper on Standardisation, 1 May 1991, at 8.

[25] COM(91) 521 final.

> ‘assist and promote democratic self-management of standardisation by indicating the changing political context in which European standardisation takes place, the fundamental principles on which standardisation should be based and the organisational changes which may be needed to ensure that those principles are fully observed’.[26]

Although the Commission dropped the idea of radical institutional reform, it retained its idea of creating some kind of institutional structure, a *European Standardisation Forum*, which would comprise all interested parties and promote meaningful discussions on European standardisation policies. Its design would be similar to that of the proposed Standardisation Council, although with an increased membership. This body would be able to address any issue relevant to the ‘success’ of European standardisation, such as the current activity of the European standardisation bodies, the application of basic principles such as openness, participation of interested parties by the standardisation bodies, the relation between public authorities and the standardisation bodies. Even if the conclusions of the Forum could be presented in non-binding resolutions, they would in all likelihood carry considerable weight in view of the fact that the representatives of all interested parties would be on the Forum.

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[26] *Ibid*., at 7.

Even this second more moderate attempt to reform the self-regulatory process of standardisation was rejected by the standardisation bodies at the Luxembourg conference in December 1991.[27] Consequently, the Council's Resolution on the role of European standardisation in the European Economy of 18 June 1992[28] was conspicuously silent on any institutional reform of the standardisation structure, although it generally endorsed the principles set forth by the Commission in its Green Paper and Follow-up.

Unabated by the beating it has taken in the debates following the Green Paper, the Commission currently pushes through its objective of speeding up the standard-setting process by changing the structure of its financial support to CEN and CENELEC. Gradually, it is cutting back on general lump-sum subsidies and switching to project-based financing of specific items. Furthermore, it has solidified its practice of attaching 'experts' to CEN with the task of controlling the compatibility of standards with the essential requirements in the stage of drafting.[29] In 1995, the Commission issued its Communication on the Broader use of Standardisation in Community Policy, where

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[27] Cf J. Pelkmans and M. Egan, above, n. 22, at 14.

[28] OJ 1992 C 173/1.

[29] These experts are appointed in agreement with the Commission on proposal of CEN. They are subordinated to the CEN administrative hierarchy with the possibility of direct contact with relevant Commission

it announced its plans to extend the use of standardisation to other areas, including biotechnology, environmental policy and telecommunications services in the ambit of the ambitious 'Information Society' programme.[30]

Political debate on the European level concerning standards is still preoccupied with the perceived lack of efficiency of the process. At the February 1998 Cambridge Meeting of Internal Market Ministers the question was brought up again. From several sides the unfortunate idea of 'introducing' majority voting in CEN and CENELEC made a startling come-back, coupled with suggestions to open up the system and strive towards competition between European and national standards bodies.[31] The Council asked the Commission to draw up a report, the publication of which has sparked off another round of debate.[32]

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services.

[30] COM(95) 412 final.

[31] The minutes of the meeting as distributed by the Secretariat General, SI (98) 114.

[32] Efficiency and Accountability in European Standardisation under the New Approach- Report from the Commission to the Council and the European Parliament, SEC (98) 291 CEN's prompt reply 'Efficiency of European Standardisation' is published in (1998) 77 *DIN Mitteilungen*. 656.

2.6. Renewed Legal Debate on 'Delegation'

Legal debate will not leave the issue of unlawful delegation in peace.[33] Ernesto Previdi, closely involved with the New Approach during his career in the Commission, speaks, after his retirement, of the 'astonishing' delegation of regulatory decision-making powers to private-law bodies 'completely outside of the institutional processes laid down in the EU Treaty, with no institutional link or framework ever having been laid down for them'.[34] His proposal is to set up a regulatory Agency accompanied by a hierarchy of norms in Community law. Breulmann, for whom even the *Meroni* doctrine goes too far, calls for formal reception of European standards in the Community legal order by a Council act under Article 202 (3) EC (ex Article 145 (3) EC) delegating implementation powers to the Commission, and a Commission decision directed at all the Member States announcing the presumption of conformity with

[33] Recent claims of unlawful delegation include eg A. Bleckmann, *Rechtsfolgeanalyse der neuen Konzeption* (Gutachten erstellt im Auftrag des Büros für Technikfolgen-Abschätzung des Deutschen Bundestages) (Münster 1995); Roßnagel, 'Europäische Techniknormen im Lichte des Gemeinschaftsvertragsrechts', (1996) 111 *Deutsches Verwaltungsblatt* 1181, and Schulte, 'Materielle Regelungen: Umweltnormung', in H.-W. Rengeling (ed.), *Handbuch zum europäischen und deutschen Umweltrecht* (Köln 1998), 449, at 487.

[34] Previdi, 'The Organization of Public and Private Responsibilities in European Risk Regulation: An Institutional Gap Between Them?', in Ch. Joerges, K.-H. Ladeur and E. Vos (eds.), above, n. 6, 225 at 236. To be fair, his strongest language refers to the Construction Directive.

the requirements set by the directives.[35] To call this arrangement formalistic, according to him, is to confuse formalism with *Rechtsstaatlichkeit*.[36]

The debates thus far seem to have reached a dead end: on the one hand, the functioning of the Internal Market is recognised to depend largely on the self-regulatory structure of private standards-setting; on the other hand, the regulatory framework governing them is widely perceived as anarchic, unprincipled and ill-fitted with the Community legal order.

3. RESTATING THE PROBLEM: 'DELEGATION' REVISITED

The anti-delegation doctrine is instructive because it highlights two major conceptual difficulties 'the law' has with standard-setting specifically, and with transnational governance generally. Both stem from a vision of the public sphere deeply imprinted with the memory of statehood. First, there is an underlying assumption of a tidy hierarchical and territorial frame of law and private rulemaking. Second, there is an underlying assumption that the 'public interest' can be served only in hierarchical legitimisation structures. We hope that a deconstruction of the

[35] G. Breulmann, *Normung und Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft*, Berlin, 1993, 262 ff.

[36] *Ibid*., 277.

doctrine might prove insightful for a new outlook. What we argue is that the problem should not be approached as 'privatisation' of public lawmaking and the solution not to be searched for in a reinvigoration of the public. We should view the problem as political instrumentalisation of private rulemaking, and concentrate on efforts to render the private more public regarding, to invent mechanisms for publicly responsible self-regulation.

3.1. Breaking the Frame of Public Law and Private Rule-making[37]

The anti-delegation doctrine presupposes that standards-setting is inherently a public activity in need of hierarchical legitimation. The imagery behind it is that the Community in the 'New Approach' sub-contracts the very same activity it carried out itself in the 'old approach'. Private rulemaking, then, is seen as just a way to overcome the unfortunate disadvantages of the process of political decision-making. In this way of thinking, 'standards' need to be 'brought back' into the public sphere by subordination in a legal hierarchy of norms, and thus be legitimised by 'higher' law. In Community law 'technical regulations' are distinguished from 'standards' by two defining

[37] The terminology is borrowed from Teubner, 'Breaking Frames: The Global Interplay of Legal and Social Systems', (1997) 45 *American Journal of Comparative Law* 149.

elements. One sees to normative strength and distinguishes binding technical regulations from voluntary standards. The other sees to the source, and distinguishes parliamentary lawmaking from private – if 'recognised' – standard-setting.[38] Even here, the *leitmotiv* is functional equivalence. The objective seems clearly to be the substitution of detailed public technical regulations with standards, seen as an alternative to regulation.[39]

Yet, standards differ from law in more fundamental ways. One need not adhere to post-modern theories of regulatory law to understand that '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 produced in consensus of market players, not with the backing of political majority will. Standards operate on the assumption that quality, and high levels of safety, are a marketing argument rather than an imposed obligation. Perhaps most importantly, standards bodies draw from a pool of relevant

[38] Article 1, Directive 83/189/EEC OJ 1983 L 109/8.

[39] In the name of subsidiarity, for example. See Commission Communication on the Broader Use of Standardisation in Community Policy, above n. 30, at 4. On the growing importance of corporatist self-regulation under the shadow of subsidiarity, see Scharpf, 'Community and Autonomy. Multi-Level Policy-Making in the European Community', (1994) 1 *JEPP* 219.

knowledge and expertise that lawmakers can only dream of. It is in this sense that the Commission praises standardisation for 'combining the advantages of democracy with the ability to reflect the technological state of the art'.[40]

It would be a mistake, however, to assume that the interface between technology and regulation is shifted as a whole onto the European level. Technological and economic reason travels faster than regulatory cultures. In fact, how standards are incorporated in the body of law, and hence technical and economic rationality in public normative frames is highly dependent on peculiarities of scientific, administrative, and legal cultures.[41] In the United States, with its long, although contested, tradition of regulatory agencies, public and private standard-setters compete with one another.[42] In France, with its strong statist tradition featuring the ideology of 'service public', standards are 'homologated' by public authorities and incorporated in the body of administrative

[40] Commision Follow-up; above n. 25, at 16.

[41] Jasanoff, 'American Exceptionalism and the Political Acknowledgement of Risk', (1990) 199 *Daedalus* 61, explains the differences between US and European risk regulation in large part by differences in scientific culture.

[42] Cf Hamilton, 'The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health', (1978) 56 *Texas Law Review* 1329; R. Cheit, *Setting Safety Standards-Regulation in the Public and Private Sectors* (Berkeley/Los Angeles 1990); L. Salter, *Mandated Science: Science and Scientists in the Making of Standards* (Dordrecht/Boston/London 1988), and S. Krislov, *How Nations Choose Product Standards and Standards Change Nations (*Pittsburgh 1997), 104 ff.

law.[43] Generally, law incorporates technological reason by open 'rules of recognition' such as 'the state of the art', and '*règles de savoir faire'*. Especially in Germany, which has perhaps the strongest tradition of private standards-setting, this has led to a highly refined and differentiated corpus of 'hinge clauses'.[44] German legal authors, however, are the first to warn that such a system is only possible in a coherent legal cultural system with common normative frameworks.[45] However, standards-setting, under pressure of Community policy, is growing more and more into an autonomous private activity throughout Europe. Several southern Member States where standards-setting used to be a public activity have now 'privatised' their standards bodies.[46]

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[43] Décret 84-74 of 26 January 1984, JO 1/2/1984 p. 491. Cf F. Gambelli, *Aspects juridiques de la normalisation et de la réglementation* (Paris 1994).

[44] Cf Breuer, 'Direkte und indirekte Rezeption technischer Regeln durch die Rechtsordnung', (1976) 101 *Archiv des öffentlichen Rechts* 46; Breuer, above n. 16; Gusy, 'Probleme der Verrechtlichung technischer Standards', (1995) 14 *Neue Zeitschrift für Verwaltungsrecht* 105.

[45] Breuer, above, n. 16, at 71. From an economic perspective, Christel Lane argues that the high degree of penetration of technical standards in economic life in Germany as opposed to the UK is due, paradoxically, the higher degree of embeddedness of technical standards in the legal system. She thus refutes the notion that standards function as an alternative to regulation. Cf Ch. Lane, *The Role of Technical Standards in the Social Regulation of Supplier Relations in Britain and Germany* (ESRC Working Paper No. 39) (Cambridge 1996).

[46] Portugal, Spain, and Greece. Cf H. Schepel and J. Falke, *Legal Aspects of Standardisation in the Member States of the EC and of EFTA*, forthcoming. For a discussion of small countries' reactions to the European standardisation system, see Bundgaard-Pedersen, 'States and EU technical standardisation: Denmark, the Netherlands and Norway managing polycentric policy-making 1985-95', (1997) 4 *JEPP* 206.

The importance of national standards bodies has grown tremendously as a result of Community standards policy.[47] 'European' standards are now being imported into national regulatory frameworks by their transposition as national standards. These standards, it is argued, fall outside of time-honoured cultural frames holding together technology and regulation. The challenge for European law is, then, to provide those public normative frameworks on Community level in which to embed the Europeanisation of private technical normative ordering.

'Rule-making by "private governments" is subjugated under the hierarchical frame of the national constitution that represents the historical unity of law and state', writes Gunther Teubner. But now this frame has been broken:

> 'What is new is not that private governments produce their own laws. Rather it is that they evade the regulatory claims of national and international law and practice a legal sovereignty of their own'.[48]

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[47] Consider example how Elias, *UNI 1921-1991. Settant'anni al Servizio dell'Azienda Italia* (Milano 1991), at 46, discusses how UNI has liberated itself from strained relationships with the Italian state through the New Approach.

[48] Teubner, 'The King's Many Bodies: The Self-Deconstruction of Law's Hierarchy', (1997) 31 *Law & Society Review* 763, 770.

Looked at it this way, we could turn the story around: it is not so much that the Commission has abdicated public powers in favour of private bodies: the European legislator has intruded into fields of private governance and lifted these structures from their regulatory cultures. To be sure, the severance of 'law' and 'technology' is not due to autonomous functional differentiation, but is, rather, politically generated and purposefully sustained. Florence Nicolas of AFNOR describes the New Approach as

> 'making it possible better to distinguish between those aspects of Community harmonisation activities which fall in the province of technology 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'.[49]

It is submitted here that the New Approach has actually redrawn the boundaries between law and technology. The autonomy of standard-setting in Europe has now gone so far as to make it impossible adequately to incorporate technological rationality into law. Perhaps the better strategy is then to concentrate on mechanisms and procedures that would ensure the incorporation of public objectives into private rulemaking in decentralised social systems.[50]

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[49] F. Nicolas, above n. 13, at 94.

[50] Ladeur proposes the concept of 'network'. Cf Ladeur, 'Towards a

3.2. Breaking the Territorial Frame of Legal and Economic Integration

Debates in European law often seem to assume that economic integration stops at the borders of the European Union. It assumes in the case of standardisation that it can co-ordinate public and private systems of normative ordering within the neat territorial frame of the European Union. The Green Paper was attacked vigorously for 'Fortress Europe' visions of European standardisation diverging from international standardisation activities in ISO and IEC, especially from the United States. In the Follow-up, the Commission stated that

> 'where possible, the Community should have recourse to international standards rather than devise standards at the regional level'.

It then spelled out the conditions under which this could happen: the standards should be delivered within the time-scales imposed by Community legislation, the European standards bodies are to retain full contractual responsibility for delivery of the standards, and the essential requirements are to be 'taken fully into account'.[51]

Legal Concept of the Network in European Standards-Setting', in Ch. Joerges and E. Vos (eds.), *EU Committees: Social Regulation, Law and Politics* (Oxford 1999), 151 ff.

[51] Follow-up, above, n. 25, at 11. See also Communication on the

The World Trade Organisation relies more and more on standards in its efforts to open up world markets. The Agreement on Technical Barriers to Trade obliges Members to use international standards 'as basis for their technical regulations' except where these are an 'ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued'.[52] Regulations in accordance with international standards are presumed not to create unnecessary obstacles to trade.[53] Members shall take 'such reasonable measures as may be available to them' to ensure that standardisation bodies comply with the annexed Code of Good Practice for the Preparation, Adoption and Application of Standards.[54] The Code obliges standards bodies to use international standards where they exist, except in certain circumstances.[55]

ISO and IEC are dominated by the European standards bodies and their American counterparts as far as these are organised through ANSI. CEN and ISO, as well as CENELEC and IEC, have signed co-operation agreements which provides for information procedures, avoidance of duplication, co-operation in the drafting of standards by mutual representation in meetings of

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Broader use of Standardisation, above n. 30, 24-25.

[52] Article 2.4 of the Agreement on Technical Barriers to Trade (TBT).

[53] Article 2.5 TBT.

[54] Article 4.1 TBT.

[55] Article F, Annex 3 (Code of Good Practice) TBT.

TC's and the adoption of ISO standards as European standards.[56] The WTO's co-optation of ISO puts severe constraints on the ability of European standards to diverge from international standards.

The co-ordination of private and public rulemaking on a global level rehearses in several ways the same problems as it encounters on European level.[57] The WTO's instrumentalisation of standards for the exclusive purpose of market opening could well conflict with the Community's instrumentalisation of standards for purposes of social regulation. Whereas national regulatory law is under pressure from European standards, Community regulatory law is under pressure from international standards. The United States is deeply concerned, for example, about the Council Regulation concerning a Community eco-management and audit scheme,[58] since it differs slightly but significantly from the ISO 14000 series with which it is somehow in competition.[59]

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[56] The so-called 'Vienna Agreement', reproduced as Appendix 10 in F. Nicolas, above n. 13.

[57] See generally A.O. Sykes, *Product Standards for Internationally Integrated Goods Markets* (Washington D.C. 1995).

[58] Regulation 1839/93/EEC, OJ 1993 L 168/1.

[59] CEN has recently published a 'bridging document' CEN CR 12969 to explain the relationship between the two, 'The use of EN ISO 14001, ISO 14010 and ISO 14012 for EMA related purposes'. Cf Köck, 'Vollzugsaspekte des Öko-Audit Systems', in N. Reich and R. Heine-Mernik (eds.), *Umweltverfassung und nachhaltige Entwicklung in der*

The territorial frames of private and public rulemaking are thus diverging to the extent that it would be very difficult for the Community to incorporate European standardisation institutionally in its regulatory system without running into political difficulties from its international trading partners. However, the Community can exert its influence over international standardisation via its contractual arrangements with CEN to an extent its trading partners are unable to. The lack of an institutional standards-monopoly in the United States 'makes it very difficult for the United States to negotiate with international standards bodies'.[60]

3.3. Breaking the Frame of Constitutional Legitimacy

There is a seemingly strong appeal to democratic legitimacy in the anti-delegation doctrine. Law is made by politically elected, or at least publicly accountable, officials, and any delegation of rulemaking power should be traceable, in the final analysis, to that superior source of legitimacy. This must be the underlying concern of *Meroni's* prohibition for the Commission to delegate

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Europäischen Union (Baden-Baden 1997), 149-176, and Falke, '"Umwelt-Audit"-Verordnung', (1995) *Zeitschrift für Umweltrecht* 95.

[60] Kendall, Current problems in technical standardisation, (1993) 3 *EIU European Trends* 63. For a proposal for a 'global constitution' of international product safety law, cf H.-W. Micklitz, *Internationales Produktsicherheitsrecht. Zur Begründung einer Rechtsverfassung für den Handel mit risikobehafteten Produkten* (Baden-Baden 1995).

more power than it has itself, and of its distinction between 'clearly defined executive powers' and 'discretionary powers.' The world is more complicated now than it was in 1958, however. In Rubin's words, the anti-delegation doctrine 'engrafts premodern notions of control and accountability onto the realities of modern government'.[61] Modern regulatory law, then, emphasises procedural requirements of decision-making processes rather than substantive legitimation through the legal hierarchy of norms.

In European law, the two are conflated. An excursion into Community anti-trust law will clarify the point. In its case-law on anti-competitive State measures, the Court prohibits measures that render EC competition law 'ineffective'. The Court now distinguishes two major kinds of state action that would qualify: either the State 'requires or favours' concerted action or 'reinforces their effects'; or it 'deprives its own legislation of its official character by delegating to private traders responsibility

[61] Rubin, 'Law and Legislation in the Administrative State', (1989) 89 *Columbia Law Review* 369, 393. Contrast Aranson, Gellhorn and Robinson, 'A Theory of Legislative Delegation', (1983) 68 *Cornell Law Review* 1, with Mashaw, 'Prodelegation: Why Administrators Should Make Political Decisions', (1985) 1 *Journal of Law, Economics and Organization* 81. See more recently D. Schoenbrod, *Power Without Responsibility: How Congress Abuses The People Through Delegation* (New Haven 1993), and the debate between Schoenbrod and his critics in 'Symposium: The Phoenix Rises Again - The Nondelegation Doctrine from Constitutional and Policy Perspectives', (1999) 20 *Cardozo Law Review* 731. Beyond those and other debates, M.C. Dorf and C.F. Sabel, 'A Constitution of Democratic

for taking decisions affecting the economic sphere'.[62] Under the first test, the Court scrutinises whether private decision-making procedures are structured such that they yield 'public interest' measures, rather than being biased towards private interests. Since the *Reiff* case of 1993, the Court has developed a rudimentary set of procedural regulatory conditions for that purpose. The transport tariff board in that case escaped classification as a cartel because its members were to act as 'independent experts' not bound by orders or instructions from the undertakings or associations which proposed them for appointment to the Minister of Transport, and were called on by law to fix the tariffs 'on the basis of considerations of public interest'.[63] Subsequently, however, it applies the second, 'delegation' test, accumulatively, and insists on public authorities' final responsibility and discretion to substitute their own decisions for those taken by the body in question.[64]

Experimentalism', (1997) 98 *Columbia Law Review* 267.

[62] Case 267/86 *Van Eycke v ASPA* [1988] ECR 4769.

[63] Case C-185/91 *Bundesanstalt für den Güterfernverkehr v Gebrüder Reiff* [1993] ECR I-5801. Contrast Case 123/83 *BNIC v Clair* [1985]. Reiff is confirmed in Case C-153/93 *Delta Schiffahrts- und Speditionsgesellschaft* [1994] ECR I-2517, Case C-96/94 *Centro Servizi Spediporto v Spedizioni Marittima del Golfo* [1995] ECR I-2883, and Joined Cases C-140 to 142 *DIP SpA and Others v Commune di Bassano del Grappa and Commune di Chioggia* [1995] ECR I-3257; cf for a comprehensive analyis U.B. Neergaard, *Competition and competences: the tensions between European competition law and anti-competitive measures by the Member States* (Copenhagen 1998).

[64] It could well be argued that the Court insists on public responsibility in these cases due to the rather flimsy 'public interest' quality the

The two tests, however, correspond to fundamentally different conceptions. The 'delegation' doctrine corresponds to the US Supreme Court's *Midcal*[65] test and constitutes mere deference to official authority. It is institutional, assuming that public authorities have the 'public interest' at heart.[66] The Supreme Court has denied such antitrust immunity to standards bodies notwithstanding their *de facto* quasi-legislative functions. In *Allied Tube* it suggested that standard-setting could be safe from antitrust scrutiny only if 'private associations promulgate safety standards based on the merits of objective expert judgements and through procedures that prevent the standard-setting process from being biased by members with economic interests in stifling competition'.[67] Such a procedural conception would be the way forward to overcome the public/private divide in supranational decision-making. *Meroni* and the 'institutional balance of powers', it is submitted, are not the adequate instruments to do that.

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institutions at issue seemed to have. See the notes on *Reiff* by Bach (1994) 31 *CMLR* 1357, and Möschel (1994) 47 *Neue Juristische Wochenschrift* 1709. On standards bodies and EC competition law, see M. Schießl, *EG-Kartellrechtliche Anforderungen an die europäischen Normungsinstitutionen CEN, CENELEC und ETSI* (Frankfurt a.M 1994).

[65] *California Retail Liquor Dealers Association v Midcal Aluminium, Inc*., 445 US 97 (1980).

[66] For criticism, see Elhauge, 'The Scope of the Antitrust Process', (1990) 104 *Harvard Law Review* 667; on the relevance of Elhauge's views in the European context cf U.B. Neergaard, above n. 63, 275 ff.

[67] *Allied Tube & Conduit Corporation v Indian Head, Inc*., 486 US 492 (1988).

4. REINTERPRETING EUROPEAN STANDARDISATION

Our paper could stop here with a summary of our analysis. We have told the story of the New Approach as perceived by its 'Eurocrat' proponents, by the standard-setting community and by legal commentators. We have contrasted the official presentation and conventional perception with a different interpretation by a deconstruction of the (anti-)delegation doctrine; the new approach, we argued, was a *re-regulatory* move (like the internal market programme as a whole[68]), an superimposition of the Community's policy objectives onto the formerly national and international non-governmental spheres of standardisation, an effort to substitute the nationally divergent relations between standardisation and the public sphere by a pan-European policy of market building. Applying the *Meroni* doctrine to standardisation meant to establish a so far hardly visible new authority. Similarly, the following efforts of the Commission to reorganise and thereby to streamline European standardisation were a complementary interventionist move by which the Commission sought to compensate for the lack of own infrastructures which the speeding up of its market building objectives required.

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[68] For an early version of this thesis, see Joerges, 'Paradoxes of Deregulatory Stategies at Community Level: The Example of Product Safety Policy', in G. Majone (ed.), *Deregulation or Reregulation? Regulatory Reform in Europe and in the United States* (London/New York 1990), 176.

Our paper did not simply deconstruct prevailing interpretations but also pointed to the resistance of the field. As has been documented, the standardisation community has defended its autonomy against the Community quite successfully. Equally important, the critics of the Community's interventionism could rely on a so-to-speak natural ally; the promotion of standards of regional validity seems out of step with the development and the needs of the globalising economy.

There are, however, analytical premises and normative messages underlying our story which we wish to make more explicit and develop further. As announced in our introduction, we will supplement our critique of the conventional (anti-)delegation debate by some more constructive suggestions. Our argument will proceed in three steps and try to respond to three observations:

i) The first step concerns the 'constitutional' dimensions of standardisation; although no public bureaucracy can and should take over, standardisation cannot be left to the expert standardisers.

ii) The interaction between standardisation bodies, national administrators, European officials and the wider public and the governance structures emerging from these interactions

do not fit into the institutional patterns foreseen within national legal systems or the European treaties; legal conceptualisations therefore have to redesign their references to the European polity.

iii) Our third set of observations concerns the normative importance of the links of standardisation with Europeanisation and internationalisation. Here we will distinguish between two aspects, namely: (a) the capacity of constitutional states to impose regulatory concerns on the standardisation praxis; (b) the capacity of national policy makers to pursue *industrial policy* objectives and to control *distributional effects* of standardisation. Our general normative suggestions as to the functions of standards and the institutional frameworks of standardisation will aim at ensuring a deliberative quality of decision-making processes rather than interest representation and administrative control. This perspective seeks to pay tribute to what has just been called the 'constitutional' dimension of standardisation. It does not try to re-establish industrial policy potentials and does hardly suffice to defend distributional concerns of nation states. And it goes without saying that our 'deliberative' ideals are easier to pursue within the EU than at the international level.

None of these three issues will be dealt with comprehensively. All we wish to document is that our so far quite deconstructive argument can be constructively linked with current debates on legitimate governance.

4.1. Standardisation and the Law: Some Constitutional Concerns

Standardisation has traditionally been organised by directly interested actors. Only gradually and in very diverse ways standardisation activities have been overshadowed by public law or selectively and indirectly linked to regulatory concerns. Suffice it here to point to issues such as the technological side of safety at work law,[69] and the efforts to include environmental policy objectives in product standardisation.[70] Standardisation, one may conclude, is too important to leave it to the standardisation community; it is too complex a mixture of cognitive, normative and political aspects, one must add, to be taken over by administrators.

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[69] See e.g. A. Bücker, *Von der Gefahrenabwehr zu Risikovorsorge und Risikomanagement im Arbeitsschutzrecht* (Berlin 1997), 58 ff.

[70] See e.g. J. Falke and Ch. 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) (Bremen 1995), and V. Brennecke, *Normsetzung durch private Verbände- Zur Verschränkung von staatlicher Steuerung und gesellschaftlicher Selbstregulierung im Umweltschutz (*Düsseldorf 1996).

This conclusion is in principle uncontested.[71] What remains controversial is how to design adequate institutional responses to these insights. We have hinted at our preferences: 'reflexive' mechanisms within standardisation procedures ensuring that consumer concerns and environmental implications be taken into account; no public control of standardisation as a matter of routine but powers to intervene in emergency cases; independent public information gathering; independence of the judiciary in its assessment of safety requirements; certification as an incentive to innovate. In somewhat abstract terms: 'regulatory competition' rather than uniformity; continuous critical discourses on the social responsibility of standards rather than centralised administrative prescriptions and controls. We refrain from elaborating on these ideas for two reasons; first, their 'implementation' will have to vary according to national institutional traditions and experiences; second, the design of an ideal system would be pointless because the real world processes of standardisation are characterised by simultaneous activities at various levels and at all these levels the relationship between standardisers and public officials and the broader public is distinct. We therefore do not even try to suggest how standardisation should be ideally embedded in the institutional

[71] Cf H. Voelzkow, *Private Regierungen in der Techniksteuerung. Eine sozialwissenschaftliche Analyse der technischen Normung* (Frankfurt a.M. 1996).

framework of a constitutional (nation) state but move immediately on to the European level.

4.2. Standardisation in the EU's Multi-level System

The delegation versus non-delegation debate may be one of those doctrinal exercises which seem to confirm widely shared prejudices among social scientists (and even legal practitioners) as to the (un-)seriousness of academic legal controversies. The debate has had the merit, however, to make us aware of the discrepancy between the institutional structures foreseen by the framers of the European treaties (and national constitutions) on the one hand and the actual functioning on the Union system on the other. The vain efforts to bridge or camouflage these tensions should not be taken lightly or belittled. The obstinacy of lawyers in their search for an answer to the delegation problem and their readiness to content themselves with overly formalistic responses needs to be understood in the light of the difficulties of developing alternatives. Our readiness to break so many frames at once comes at a price, as will become immediately apparent.

4.2.1. Analytical Advantages and Legal Difficulties

At the analytical side of our argument, the stakes are not too high. All well-established legal conceptualisations of the European Union presuppose the co-existence of constitutional nation states with specific *demoi* populating their territories. It is possible and elucidating to parallel the controversial legal perceptions of the European construct with competing schools of thought in political sciences; namely, intergovernmentalism on the one hand and neo-functionalism on the other.[72] It is equally possible for lawyers to subscribe to the many arguments suggesting that this once well-established dichotomy has to be overcome and be substituted by the portrayal of the EU as a 'multi-level system of governance'. Pertinent analyses highlight the erosion of nation-states while denying their transformation into a new European super state. The concept of governance used is flexible enough both firmly to capture certain *sui generis* characteristics of the emerging European polity such as its lack of internal hierarchy and its reliance upon 'Law', and to leave open the question of exactly where the European system lies on a scale between the traditional nation-state and looser forms of international co-operation.

[72] Cf. Joerges, 'Taking the Law Seriously: On Political Science and the Role of Law in the process of European Integration', (1996) 2 *ELJ* 107.

Rather than elaborate on this extremely brief sketch,[73] however, our use of aspects of the multi-level analysis might be better explained in the light of the compatibility of 'multi-levelism' with three general features of the Europeanisation of standardisation activities. First, the multi-level approach appears to be perfectly compatible with the conservation and jealous defence of 'competencies' at national level both of administrative bodies and non-governmental organisations *and* the superimposition of national by European systems of standardisation and frameworks of economic and social regulation. Secondly, this approach has the advantage of being able to conceptualise 'governance' independent from or beyond our formalised public/private and nation-state/Community dichotomies, and likewise seems compatible with what we 'know' about the erosion of national sovereignty on the one hand and the growth of regulatory powers at the European level on the other. Thirdly, and most important for our argument, this analytical framework allows the 'imperfection' of integration processes to be articulated. We insist on using quotation marks because we wish to underline that any effort to arrive at strictly uniform regulatory practices within the EU would be

[73] The literature is abundant; important contributions include Scharpf, above n. 39, Jachtenfuchs, 'Theoretical Perspectives on European Governance,' (1995) 1 *ELJ* 115; Jachtenfuchs and Kohler-Koch, 'Regieren im dynamischen Mehrebenensystem' in M. Jachtenfuchs & B. Kohler-Koch (eds), *Europäische Integration* (Opladen 1996), 15; Marks, Hooghe & Blank, 'European Integration Since the 1980s: State-centric Versus Multi-

inconceivable in view of both the economic disparities within the EU and the political diversity of European societies; it would hence even jeopardise the problem-solving capacities of Europe's sophisticated market management machinery.

The analytical adequacy of multi-level and network analyses becomes even more apparent once one considers in more detail the complex web of vertical, horizontal and diagonal interaction patterns among European and national governmental and non-governmental actors. Standardisation in general is structured in line with the agreement of 1984 between the Commission and CEN/CENELEC[74] and seems thus to confirm the dominating role of the European standardisation bodies with Commission acting as an agenda setter whereas the representatives of the Member States have, according to Directive 83/189,[75] merely an advisory role. This picture needs to be thoroughly refined, however. Not only did the Commission manage to scrutinise standardisation projects more or less intensively[76] and make standardisers accept participation of consumer organisations; important directives provide for a continuous supervision of implementation processes by regulatory committees, the members of which communicate quite intensively with national administrative

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level Governance,' (1996) 34 *JCMS* 343.

[74] Above, n. 13.

[75] Articles 5 and 6 of this Directive, above, n. 11.

bodies and non-governmental organisations, especially trade unions.[77] It would therefore be too simplistic to focus exclusively on the regular institutional patterns established by the New Approach. These patterns have been supplemented and modified with the intensified involvement of the Community at the borderlines of standardisation and social regulation. And it is important to note that the Community has a variety of options at its disposal to pursue what it regards as an important 'public' concern. In the broad field of the Machinery Directive (i.e. at the borderlines of standardisation, product regulation and safety at work legislation) it has chosen to rely on well-established models of co-operation of standardisers with specialised administrators and experts from the trade unions. The level of safety consumers are entitled to expect is not exclusively determined by standardisers but also by administrative bodies and courts. Environmental concerns are protected by a separate body of law. Even if the integration of environmental concerns into standardisation processes increases, this separate body of law can always be revitalised. European standardisation thus does not operate in a legal vacuum but is in varying intensity embedded

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[76] Cf Falke, above, n. 6.

[77] For a recent overview cf. the project which has been carried out at the Centre for European Law and politics, Bremen with the support of the Volkswagen-Stiftung. Cf Ch. Joerges (ed.), *Die Beurteilung der Sicherheit technischer Konsumgüter und der Gesundheitsrisiken von Lebensmittel der Praxis des Europäischen Ausschußwesens (Komitologie)* (Typescipt Centre for European Law and Politics, Bremen 1999).

into legal frameworks and constantly fed and controlled through networks of non-governmental and governmental actors.

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› Ñ › G ÿeed that antitrust law has failed to provide us with criteria which would allow us to determine whether a

standard is indispensable for establishing a market or meant to impede potential competitors; neither is it necessarily to indicate that antitrust law cannot provide us with valid distinctions between true and false, legitimate and illegitimate 'regulatory' concerns of standardisation. Be all that as it may: In the European and international arena, anti-competitive strategies of powerful economic actors usually go hand in hand with protectionist objectives of governments or pave the way for industrial policies and some more or less intense 'regulatory competition' among nation state based politico-industrial compounds.[78] We expect these dimensions to play an important role in the adoption of standards. But we also assume an in-built tendency of European standardisation bodies to reject within their regional competence protectionist and one-sided industrial policy objectives. We also expect international conflict settlements to resort to criteria which relate to 'legitimate' regulatory concerns in order to avoid an involvement into conflicts over economic interests.

4.3. Bringing the Law in

How do these observations and considerations relate to the legal system in general and to the anti-delegation doctrine in

[78] Cf. the study of A. Héritier *et al*., *Die Veränderung von Staatlichkeit*

particular? The following discussion will not deal with these issues comprehensively but present a general normative perspective, then suggest a legal classification of the type of governance within which European standardisation operates and finally indicate how the legal system should impose constraints upon standardisation activities and seek to influence decision-making.

4.3.1. Deliberative Supranationalism

Even though our sketch of recent efforts in political sciences to understand the 'nature of the European beast'[79] has been extremely brief, one may conclude that a shift of paradigmatic dimensions in the legal conceptualisation of European governance is overdue. The 'reality' of standardisation activities seems to confirm perfectly well the superiority of concepts such as multi-level governance and network over conventional legal conceptualisations of the European Community. This analytical superiority, however, remains legally meaningless without a concomitant normative reconstruction. Can the multi-level approach be made compatible with any meaningful assignment of competencies to national and European authorities? How

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in Europa (Opladen 1994), on environmental policy.

[79] Risse-Kappen, 'Exploring the nature of the beast: International relations theory and comparative policy analysis meet the European Union,

could the Law ensure the functioning of a non-hierarchical system of governance? What type of authority can be attributed to 'networks'? What kind of legitimacy would endorse their governance? Is that legitimacy at all reconcilable with any constitutional vision of democratic governance?

Even though we do not claim to dispose of ready-made answers to all of these questions we feel entitled to advocate a normative perspective which we have labelled 'deliberative supranationalism' and developed somewhat more fully elsewhere.[80] The term denotes a constitutional perspective for the European Union different on the one hand from orthodox interpretations of the Community as a system integrated through supranational law, but on the other hand also different from the renewed downgrading of the Union to a mere alliance of states ('*Staatenverbund*') and corresponding allusions to international law principles. In terms of legal or constitutional theory, this is a borrowing from theories of 'deliberative' democracy,[81] according to which the institutions of the democratic constitutional state

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(1996) 34 *JCMS* 53.

[80] Cf. Joerges and Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology', (1997) 3 *ELJ* 273; Joerges and Vos, 'Structures of Transnational Governance and Their Legitimacy', in J.A.E. Vervaele (ed.), *Compliance and Enforcement of European Community Law* (Den Haag/London/Boston 1999), 71 ff.

[81] We would refer here merely to the systematic portrayal in O. Gerstenberg, *Bürgerrechte und deliberative Demokratie. Elemente einer*

have downright constitutive importance for the legitimacy of modern law. Specifically from this theoretical perspective, Europe's much taunted 'democratic deficit' is in fact an objection against the claims of European law to immediate validity and primacy – and this objection only seems the stronger if it is assumed that one cannot expect the European Union's transformation into a stale entity in the foreseeable future.

'Deliberative Supranationalism' hence designates a mode of legal structuring of political processes that can be separated from the model of the national constitutional state with comprehensive tasks and powers and then offers a viable normative perspective for the supranational legal links among the EU's constitutional states in general and the legal constitution of Community political projects in particular. The specific feature of this view is that it conceives of the 'supranational' law not as rules preceding and overlying the national legal systems, but as deriving its validity from the 'deliberative' quality of its production. To simplify a longer argument: just because the Union cannot be conceived of as a legal hierarchy (or expected to develop into a state-like entity), the integrity of the integration process and of the transnational governance structures it produces will depend upon the taming of continuous bargaining and strategic interest

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pluralistischen Verfassungstheorie (Frankfurt a/M 1997).

formation, on the 'deliberative quality' of political processes which must be ensured by Law.

4.3.2. 'Good Governance' in the European Union

Standardisation, so we have noted more than once, relates to the normative world of Law and to the distinct world of knowledge – and it is due to this specific property that standardisation cannot be left to the expert standardisers nor taken over by administrative bodies or the political system. At a transnational level, we have added, standardisation activities relate to industrial policy objectives and affect the economic well-being of economic sectors and whole regions. A label capturing this mixture of private and public governance, of normative and cognitive dimensions of decision-making, of transnational problem-solving and intergovernmental plus inter-societal bargaining over economic interests is yet to be found.[82] We have chosen the term 'good governance' to denote our analytical premises and normative perspectives; standardisation is – public and private – 'governance'; it can neither be reduced to the application of legal rules and principles nor to a purely

[82] Cf on the following Joerges, 'Technocratic Regime and the Dream of Good Transnational Governance' and 'Multi-level Governance, Deliberative Politics and the Role of Law', both in Ch. Joerges & E. Vos (eds.), above n. 50, at 1 and 311, respectively.

technocratic exercise but requires political decisions over normative issues and economic interests; and it is for exactly this reason that standardisation needs legitimacy. The type of legitimacy we envisage has already been indicated: ‘good standardisation’ should result from the deliberative quality of decision-making processes. This quality, we have argued, has to be ensured by Law. But how?

4.3.3. Constitutionalisation in Bits and Pieces

The juridification of standardisation in the EU will not be brought about systematically. What we can observe already and expect to occur more frequently in the future is the adoption of legislative acts and the handing down of judgments which address pertinent aspects of the standardisation compound. This contribution can be expected to identify rules and principles with the potential of furthering 'deliberative' decision-making. At the end of an already overly lengthy argument, the presentation of a list of legal considerations may suffice to comply with such expectations:

A Standardisation Directive? Although the Community managed to strengthen European standardisation, it did not overcome its traditional infrastructures. In order to reduce the impact of the principle of national representation and to strengthen the implementation of European commitments, one could have expected an effort to adopt a standardisation directive aiming at some equivalence of standardisation procedures. Such an initiative was never taken. There may be no practical need for it because standardisers follow a surprisingly 'harmonised' set of internal procedures as it is: decision-making by consensus, public inquiry, obligations to deal somehow with comments received, and arbitration mechanisms for dispute resolution form a kind of

rudimentary common ‘internal administrative law’. To be sure, these mechanisms do not curb fears of bias towards certain interests. However, perhaps

> ‘the greater danger is that government bureaucrats, intent on ensuring that no consumer interest goes unsatisfied, will encumber a private standards-writing 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’.[83]

It would have been useless because such a directive would not cover the whole web of nationally divergent provisions relating to standardisation.

Primary Law and Directive 83/189. Even without direct interference by secondary law with national standardisation, the factual impact of the European policies has been enormous and the backing of this impact by Directive 83/189 and general provisions of primary law considerable. Article 28 EC (ex Article 30 EC) together with the said Directive impose specific ‘rationalised’ regulatory structures on the whole field of product regulation and by the same token discipline decision-making

[83] E. Bardach and R.A. Kagan, *Going by the Book - The Problem of Regulatory Unreasonableness* (Philadelphia 1982), 223.

processes by discriminating between (illegitimate) protectionist interests and (legitimate) regulatory concerns.

Surrounding Legal Structures. The New Approach's opening up of markets for products manufactured in accordance with standards is accompanied by general Community product safety law. The Directive on General Product Safety[84] gives national administrations considerable discretion to impose restrictions on the placing on the market of products or even to withdraw them if 'there is evidence' of danger notwithstanding conformity with laws, regulations or standards. The Product Liability Directive gives national courts even more leeway to consider for themselves whether those products meet 'legitimate consumer expectations',[85] or whether the standards concerned correspond to the 'state of scientific and technical knowledge' so that producers can be granted 'development risk' exemption.[86]

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[84] Directive 92/59/EEC, 1992 OJ L 228/24.

[85] Directive 85/374/EEC, OJ 1985 L 210/29. The Directive defines a 'defective' product in terms of consumer expectations and deliberately leaves out non-conformity with standards from the definition lest manufacturers be made into the 'Masters of their own Liability'. Cf H.C. Taschner, *Produkthaftung. Richtlinie des Rates vom 25. Juli 1985* (München 1986), at 79. Judicial consideration of 'legitimate expectations', however, may well – and often will – include the use of technical standards.

[86] The 'development risk' exemption was no doubt intended to be limited to the objective state of knowledge, not to the state of knowledge of the manufacturer or to the possibility to know about the state of knowledge. The Court of Justice has, however, lowered the threshold in that 'it is implicit (…) that the relevant scientific and technical knowledge must have been accessible at the time.' Cf Case C-300/95 *Commission v United*

The Legally Required Level of Expertise. Standardisation requires expertise but the type of expertise needed varies with the complexity of products and their inherent risks. In view of the fact, however, that European standardisation is to comply with binding safety requirements, standardisation organisations must be expected to live up to legally prescribed levels. To cite a seemingly far fetched example:

> 'The drafting and adaptation of Community rules governing cosmetic products are founded on scientific and technical assessments which must themselves be based on the results of the latest international research (...)'.[87]

This standard is presented as an indispensable implication of the kind of risks cosmetic products may present. Moreover, in adopting this standard the ECJ implicitly disempowered two Community institutions; neither the Commission nor the 'Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector', which consists exclusively of representatives of the Member States, is in a position to carry out the type of assessment which, '*in the nature of things and apart from any provision laid down to that effect*' requires the

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Kingdom [1997] ECR I-2649.

[87] Case C-212/91 *Angelopharm v Freie und Hansestadt Hamburg* [ECR] 1994 I-171, at 210.

assistance of 'experts on scientific and technical issues delegated by the Member States'.[88] Is that too far-fetched an interpretation, as Bradley argues?[89] Even if this were so, decision-making processes both at Community and national level will in controversial cases *de facto* be forced to resort to the rationalising power of high levels of expertise.[90]

From Interest Representation to Participation in Deliberation. One widespread reaction to the difficulties of representative democracies to govern technical developments on the one hand and the risk that interest groups capture self-regulatory bodies on the other, is a quest for a broader societal representation of 'interests' within such bodies. We have discussed how the Community has tried this way out. But how would one determine the entitlement to represent 'interests' in Europe's non-unitary polity?[91] And how could the transformation of such 'interests' into sound technical assessments be ensured? The key to 'good governance' in the field of standardisation is not balanced

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[88] *Ibid*. at 211 (para. 33).

[89] Bradley, 'Institutional Aspects of Comitology: scenes from the cutting room floor', in Ch. Joerges an & E.Vos (eds.), above n. 50.

[90] Revealing in that context the Report of the WTO Appellate Body 'EC Measures Concerning Meat and Meat Products (Hormones)', adopted on 13.02.1998, WT/DS26/AB/R, WT/DS48/AB/R (www.wto.org).

[91] Cf Curtin, 'Civil Society' and the European Union: Opening Spaces for Deliberative Democracy?, in Academy of European Law (ed.), *Collected Courses of the Academy of European Law VII/1* (Den Haag/Boston/London 1999), 185 ff.

interest representation but thorough deliberation. Under this orientation, the internal and external principles and rules relating to decision-making in European standardisation do indeed convey legitimacy: legislative ‘essential safety requirements’ provide some guidance as to the priorities and normative commitments of standardisation; the Commission is capable of substantiating these prerogatives further in the mandates which serve as a basis for specific standardisation projects; its ‘safety consultants’ should in principle be able to ensure a continuous information flow between the ‘private’ and ‘public’ European spheres while the involvement of various DGs should ensure that a broad range of regulatory concerns is taken into account; the quality of standards can be supervised by many administrative bodies and non-governmental actors throughout the EU; the safeguard clauses of directives and the independence of the administrative and judicial web of product safety laws bridge standardisation and the public sphere not in a hierarchical sense but through the potential to take action independently.

4.3.4. Intra EU Implications and Globalisation

Our focus on the deliberative quality of standardisation processes and the ‘social responsibility’ (the level of user and environmental safety) of standards seems to turn the European project upside down. After all, it was not some pan-European

concern for safety and the environment but the Community's market building initiative which motivated the Europeanisation of standardisation, and it was an interest and belief in the economic advantages of the bigger market which made European governments accept the rules and institutions of the new internal market. Our analysis does not deny the unifying force of economic interests. What we assert is that standardisation does not and should not operate in splendid social isolation, neither at European level nor within the European nation states. A shift in legal debates from concerns for uniformity of standards in the European market to European-wide deliberation about their quality should be understood as a tribute to the context within which standardisation is to operate.

We have announced not to deal in any systematic way with globalisation and we keep that promise. We would nevertheless like to note that in our analytical and normative perspectives the differences are a matter of degree, not of principle. Just like the governance structures of European standardisation, the 'regimes' of international standardisation are guided by internal rules and surrounded by legal systems. We would at least try to develop strategies which use the dependence and embeddedness of international standardisation as a chance to promote deliberative decision-making processes.