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Integrating Scientific Expertise into Regulatory Decision-Making.

Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures

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ROBERT SCHUMAN CENTRE

Integrating Scientific Expertise into Regulatory Decision-Making

Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures

CHRISTIAN JOERGES

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CHRISTIAN JOERGES* / **

1. AN ANALYTICAL FRAMEWORK

The European Court of Justice 'cannot shy away from technical questions'. This observation of Advocate General Walter van Gerven in his opinion in the *TU München* case[1] is certainly valid. The European Court of Justice (ECJ) has indeed in many contexts been forced to take a stand on issues involving the legal assessment of non-legal evidence in general[2], and scientific expertise in particular.[3] It is one thing, however, to acknowledge that the ECJ's involvement in such issues has proved to be unavoidable and quite another to assess its performance in dealing with that challenge. The involvement of courts and administrative bodies poses multi-faceted problems. To these the European legal system adds further genuine difficulties stemming from its specific institutional features and the constraints they imply. It is, of course, possible and instructive to contrast the performance of the European legal system with

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1 Case C-269/90 *Hauptzollamt München-Mitte v Technische Universität München* [1991] ECR I-5469 at 5483.

2 Ellen Vos's celex research for a few keywords ('scientific committees'; 'scientific'; 'technical'; 'risk and health'; 'risk and safety') has brought to light more than 60 cases which were directly in point.

3 It is common to differentiate between these two categories of knowledge (see e.g. Claudio M Radaelli, 'The Role of Knowledge in the Policy Process' *Journal of European Public Policy* 2 (1995), 159-183), although resort to non-scientific expertise such as economic analyses as used in so many fields of economic regulation, poses similar problems; furthermore, an insulation of scientifically based decision-making criteria from other policy concerns such as the economic consequences of standard-setting in the field of social regulation here under consideration, is to be understood as a deliberate choice which presupposes a specific institutional setting and needs to be based on an adequate design of such an institutional framework.

international debates on the legal regulation of scientifically controversial issues, or to compare the attitudes of national courts or administrative bodies and their experiences with traditional and modern regulatory approaches.[4] But any such comparison will have to carefully reflect upon its own yardsticks.[5]

References to expertise occur in many fields and angles of modern legal systems; the categories of knowledge required vary, as does the intensity of its impact on decision-making. The Community system, however, is not comprehensive in two important respects. Its own need for expertise typically arises in the context of European regulatory activities, i.e. in the field of economic regulation and competition policy on the one hand and in the various areas of social regulation on the other. It is in this latter field of social regulation that resort to 'scientific expertise' plays a highly prominent role. Outside the field of agricultural policy, where the protection of health and consumers has always been treated as an integral element of 'market'-building[6], the intense involvement of the Community in social regulation has taken place in conjunction with its efforts to complete and to manage the Internal Market. As a result of these linkages with primarily economic objectives, the European system must implement its social regulation at a complex crossroads of often merely functional Community and residual Member State competencies. Equally important, the Community remains dependent upon the cooperation of national courts, administrative bodies and non-governmental actors in the implementation of its policies. Last but not least, judicial review at the European level is usually prompted by preliminary proceedings under Article 177, which do not however foresee a comprehensive or definite resolution of the regulatory issues concerned.

This background to the jurisprudence of the ECJ will not be addressed comprehensively in this paper nor will it be traced through a detailed

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[4] Cf. Rolf Rausch, *Die Kontrolle von Tatsachenfeststellungen und -würdigungen durch den Gerichtshof der europäischen Gemeinschaften. Zu gerichtlichen Nachprüfung von Kommissionsentscheidungen im Vergleich zum deutschen und französischen Recht* (Duncker & Humblot, 1994); Schlacke, S., Die europäische Regulierung der Sicherheit von Zusatzstoffen, Typescript (Centre for European legal Policy, Bremen 1995); on machinery safety cf. Bücker, A., *Die rechtliche Regulierung der Sicherheit von Maschinen unter dem Einfluß der europäischen Rechtsangleichung - Von der Gefahrenabwehr zur Risikovorsorge*, PhD. Thesis (Bremen, 1996).

[5] Cf. generally Dehousse, R., 'Comparing National and EC Law: The Problem of the Level of Analysis', (1994) 42 *American Journal of Comparative Law* 761.

[6] Cf. *infra* 2.2.1.

description of legislative developments. It will rather be presented, first, by a general observation on the attractiveness of scientifically endorsed decision-making criteria for the European legal system; second, by an outline of regulatory patterns that have emerged in the Europeanized fields of social regulation; and third, by a hypothesis concerning the constitutional importance of these developments and the challenges they present to the ECJ. These observations and assumptions will then serve as guide through the ECJ's jurisprudence. Because of its dependence on partly trans-legal and non-positivist premises, it goes without saying that this kind of interpretation cannot claim any definite or exclusive validity. But it is submitted that any meaningful interpretation of the ECJ's case-law needs to resort to the kind of framework employed here. It is only through its refinement and improvement that one can (and should!) search for an interpretation of greater explanatory strength and more thorough normative plausibility.

1.1. The Territorial Boundaries of Legal Systems and the Trans-legal Status of Scientific Knowledge

The resort of legal systems to scientific expertise is inextricably linked with modern technological developments and the social responses they provoke. Along with improvements in scientific knowledge which enable us to detect the sources of 'dangers', to identify the likely implications of activities, and thus to transform 'dangers' into 'risks'[7] legal systems have come under pressure to integrate this knowledge and to devise regulatory schemes which allow for its use. This story need not be retold here.[8] But there is one aspect of particular importance in the Community context which should be stressed.

Recourse to scientific expertise in regulatory decision-making gains authoritative validity only through its attribution to some specific legal system which endorses the bindingness of scientific findings, ensures the enforcement of expert assessments, and takes responsibility for prohibiting activities and/or accepting risks. The reach of legal systems, be they nationally or supranationally organized, remains limited to their territorial boundaries. From the viewpoint of the scientific community, this segmentation seems contrary to

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[7] Cf. N. Luhmann, *Soziologie des Risikos*, Berlin-NewYork: de Gruyter, 1991, 9 ff.

[8] See more generally W. Köck, 'Die rechtliche Bewältigung technischer Risiken', *Kritische Justiz* 1993, 125 ff.

the standards of science – there is no such thing as German physics or European mathematics. To be sure, cultural and political traditions have shaped the practices of engineering, for instance, or the schools of thought in medicine and other disciplines. It is equally true that one has to differentiate between the scientific level of risk analysis and the practices of risk management which involve political and policy questions such as the acceptability of risks and regulatory responses to them.[9] And yet, the standards of science as well as the techniques of risk assessment claim universal validity. Where scientists cannot agree, they nonetheless continue to interpret their controversies as a scientific exercise and entrust the scientific community with the competence to assess their claims. The integration of scientific expertise into legal systems may therefore be seen as a paradox. By resorting to scientific expertise, legal systems subject themselves to 'external' validity criteria. By the same token, through a reliance on scientific assessments, they overcome their built-in parochialism; the legal system becomes entitled to a recognition of its position beyond its own borders.

These interfaces between science-based evaluations and legal decision-making lend themselves to prudent and strategic exploitation in the Community context. On the one hand, Community law may, wherever it manages to promote science-based standards of validity, ensure its own authority without the usual entanglements in complex controversies over competencies, conflicting economic interests and highly sensitive issues of political accountability. Member States, on the other hand, when pointing to scientific expertise as providing support for their regulatory concerns, can hardly be accused of promoting one-sidedly some parochial or projectionist interest.

1.2. 'Negative Integration', the Europeanization of Social Regulation and the Emergence of Regulatory Networks

The resort to science cannot occur in a legal vacuum. It presupposes legal provisions and regulatory frameworks to facilitate the recourse to expertise and expert assessments. The Community has thus had to devise and build up an adequate environment in order to exploit the integrating functions of scientific expertise.

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[9] Cf. Gouldner, A.W., 'Cosmopolitans and Locals: Towards an Analysis of Latent Social Roles' (1957) *Administrative Science Quarterly* 281-306 and (1958) 444-480.

Article 30 EC, as interpreted by the ECJ, has been the main source of inspiration in primary law. This provision is to be read in conjunction with Article 36 EC and the explicit recognition of enumerated regulatory concerns therein. The Court's jurisprudence on Article 30 EC has been praised and criticized for its 'deregulatory' implications. A closer look, however, reveals that these observations are inadequate in that they fail to substantiate the criteria on which the ECJ based its controls. What the Court did was to impose standards of regulatory reasonableness on Member States, albeit in a way which severely restricts regulatory discretion and forces Member States to provide scientific bases for protective policies they wish to pursue.[10]

Because of these in-built limitations of control over regulatory policies that can be exercised under Article 30, this provision has proven to be a far from perfect tool for overcoming barriers to trade. In order to realize its objective of completing the Internal Market, the Community was bound to pursue a strategy which delegitimized national regulatory policies, while at the same time ensuring that 'reasonable' regulatory concerns were taken care of within sophisticated European regulatory frameworks. Product regulation provides the most telling example.[11] The Community never tried to simply guarantee the free circulation of goods. It also sought to ensure their acceptability – and was therefore forced to replace not only mandatory national legislation but even non-mandatory product standards. It did so by promoting innovative regulatory schemes at European level, which have now reached the point of almost comprehensively covering the whole range of technical goods and other products.

The market rationale for reregulation at European level does not apply to 'process regulation'. The interest configurations in pertinent fields seem to render it unlikely that economically less advanced Member States might accept costly regulatory standards which would deprive them of their competitive advantages towards jurisdictions with stricter standards.[12] The analytical distinction between product- and process-oriented regulation is, however, proves to be less clear-cut if one considers the outcome of European policies.

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[10] Cf. *infra* 2.1.

[11] Cf. Ch. Joerges, 'Paradoxes of deregulatory strategies 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: Pinter - New York: St. Martin's Press, 1990, 176-197.

[12] Cf. for an elaboration of this argument F.W. Scharpf, Negative and Positive Integration in the Political Economy of European Welfare States, *EUI Jean Monnet Chair Papers* 28 (1995), 15-20.

As the Community's safety at work legislation in particular demonstrates, the 'technical' and 'political' interdependence of product and process regulation can be such that they are dealt with as one sole package. Even in areas of environmental legislation which clearly have no impact on the quality of products, the European policy process has not resulted in a 'race to the bottom'. In the case of air quality regulation, Héritier and her collaborators[13] have detected a theoretically unpredicted form of 'regulatory competition'; namely, efforts on the part of the most important Member States to impose their own regulatory approaches on the whole of the Community. Their political moves have been motivated by economic advantages stemming from such regulatory victories, but have not been directed towards environmental deregulation.

The processes of reregulating Europe have taken place despite the well-known constraints under which the Community's system is to operate. The Community does not dispose of the coercive power that the modern State once monopolized. Adoption of legislative acts still depends upon the consent of at least a qualified majority of the Member States. Compliance with regulations and even the rulings of the ECJ depends upon the obedience of national institutions. Most noteworthy in our present context are the scarcity of administrative resources and the lack of genuine administrative powers. These constraints have influenced both the design of European regulatory techniques and the strategies of implementation[14]:

- At all stages of the process of planning new initiatives and in the implementation of Community policies, the Commission ensures the cooperation of national actors.

- Increasingly, the Community encourages and requests not only mutual recognition of decisions taken by national bodies but a continuous cooperation among national administrations. This includes the assignment of

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[13] A. Héritier, S. Mingers, Ch. Knill, M. Becka, *Die Veränderung von Staatlichkeit in Europa. Ein regulativer Wettbewerb: Deutschland, Großbritannien, Frankreich,* Opladen: Leske & Budrich 1994.

[14] Cf. more extensively Ch. Joerges, 'Rationalisierungsprozesse im Recht der Produktsicherheit: Öffentliches Recht und Haftungsrecht unter dem Einfluß der Europäischen Integration', [1994] 27 *Jahrbuch des Umwelt- und Technikrechts* 141; idem, *Die Beurteilung der Sicherheit technischer Konsumgüter und der Gesundheit von Lebensmitteln in der Praxis des europäischen Ausschußwesens ('Komitologie')*, ZERP-Diskussionspapier 1/95.

specific tasks, and thus amounts to a division of labour among Member States.

- When preparing decisions on the acceptable level of risk and during the whole process of implementation, the Community establishes scientific committees or otherwise guarantees scientific advice; when concretizing the essential safety requirements of directives adopted under the New Approach to Technical Harmonization and Standards, the Commission relies on the expertise of European standardization organizations.

1.3. Denationalized Governance Structures and the European Legitimacy Problem

Interest formation and decision-making in the kinds of networks described above fit neither into the institutional structures foreseen within national constitutional States nor into those of the European Community. It seems equally impossible to explain the emergence and the functioning of these networks within the neo-functionalist or intergovernmentalist paradigms of integration research. They may be most adequately conceptualized as multi-level games with a strong interdependence of national and supranational institutions, as well as national and transnational non-governmental actors.[15] Positive characterizations in legal terms are extremely difficult because they cannot build upon any elaborated model of political governance and legal institutions. Lawyers do, of course, observe all the elements of Europeanized regulatory networks, the continuous presence of Commission officials and representatives of national governments, the involvement of national and supranational non-governmental organisations in the processes of policy formation and implementation, the dependence of Community law on its support by national administrative bodies, and the compliance of courts. It is equally apparent that decision-making within European networks is not

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[15] Cf. F.W. Scharpf, 'Community and autonomy: multi-level policy-making in the European Union', *Journal of European Public Policy* 1 (1994), 219-242; E. Grande, 'Forschungspolitik und die Einflußlogik europäischer Politikverflechtung'. Beitrag für den Arbeitskreis 'Europäische Integration' des 19. DVPW-Kongresses, Potsdam, 25-28 August 1995. For recent general accounts cf. S. Hix, Approaches to the Study of the European Community: The Challenge to Comparative Politics, (1994) 17 *West European Politics*, 1-24; M. Jachtenfuchs, 'Theoretical Perspectives on European Governance', (1995) 1 *European Law Journal*, 115-133.

restricted to purely technical issues, but regularly affects economic interests and often normatively and politically sensitive concerns. Because of these implications, the 'functioning' of regulatory networks will in the last resort be dependent upon their legitimacy.

This delicate category cannot be neglected. But for the reasons just outlined, it seems futile to address it directly on the basis of some abstract preconceived normative model of social regulation in Europe. It seems equally unlikely that legislators and courts will come up with perfect and comprehensive solutions. What one is entitled to expect, however, is a sensitivity in principle, especially on the part of the ECJ, for the legitimacy of its rulings, which can be interpreted as a background agenda of the specific issues and contexts the Court is to address.

2. The Jurisprudence of the European Court of Justice

If international governance structures for social regulation are to emerge, scientific expertise can be expected to fulfil a prominent role in processing information and delivering commonly acceptable criteria for the assessment of risks. If one must attribute practical importance to these new governance structures, the acceptance of their decisional output by both the Community and the Member States must be ascertainable. The problem with this contention is, however, that it can only be validated indirectly. The search for denationalized legal structures must therefore take some detours. The following review of the jurisprudence of the ECJ will first turn to European primary law, which at first sight is only concerned with the imposition of restraints on unilateral national legislation. It will then examine controversies over regulatory competencies and inter-institutional conflicts. The primary focus of these analyses will be the resort to scientific expertise as a means to overcome the territorial boundaries of legal systems. Special attention will be paid, however, to the limits of such a strategy, which can be attributed either to the normative sensitivity of the ECJ or to its awareness of the practical need to supplement the validation of science-based decision-making with transnational frameworks for risk management (*infra* 2.1. and 2.2.). This more indirect confirmation of the ECJ's readiness to accept and to promote denationalized governance structures will be followed by an examination of those judgments which have more directly addressed the legal issues of European social regulation. These cases are few in number and their review will demonstrate that the law of denationalized governance is still at an infant stage. But it will become apparent that the ECJ has, despite its limited capacity to structure Europe's regulatory practice, at least started to

pronounce principles and rules which provide some guidance for future developments.

2.1. Regulatory Competencies and Scientific Expertise

Among the constitutional issues to be confronted in the Europeanization of social regulation, controversies over the Community's competencies can be expected to play, and indeed have played, a prominent role. 'Social regulation' is a type of policy that the original Treaty on the European Economic Community had not foreseen. Its prominence at Community level is a consequence of the market-building efforts which have ranked high on the European agenda since 1985 and the adoption of the Single European Act. It was this policy that prompted reregulatory activities especially in the field of product, safety-at-work and environmental legislation and that led to the emergence of European regulatory networks.[16] Precisely because the adoption and implementation of the new regulatory policies have occurred very much as an unpredicted discovery process, constitutional issues only gradually became apparent and have been left unresolved or even unexplored in many respects. This somewhat complacent attitude seems to a certain degree understandable. Insistence on the elaboration and clarification of constitutional issues prior to the adoption of new policies can have quite destructive implications when it leads to the conclusion that a socially desirable activity cannot be pursued for want of pertinent constitutional mandates.

The many-faceted delineation of Community and Member State competencies serves well to illustrate these general observations. Prior to the shift to majority voting in 1987, the Community objective of achieving a Common Market was restricted substantively by the explicit recognition of residuary national competencies in Article 36 and institutionally by the unanimity requirement for Community directives replacing national legislation. The consent of Member States to Community measures reduced the likelihood of controversies over the scope of 'functional' competencies derived from Article 100. That situation changed with majority voting and the Community's mandate to pursue a 'high level' of health, safety, environmental and consumer protection.

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[16] Cf. *supra* 1.2. and more extensively Ch. Joerges, 'Markt ohne Staat?, Die Wirtschaftsverfassung der Gemeinschaft und die Regulative Politik', in R. Wildenmann (ed.), *Staatswerdung Europas. Optionen für eine Europäische Union*, Baden-Baden: Nomos 1991, 225 ff. with further references.

2.1.1. Article 30 and the Disciplining of the Member States

The most obvious example demonstrating how scientific universalism can be used to overcome the particularism of legal systems is offered by the extremely rich jurisprudence on Articles 30 and 36. This potential emerged from the well-known structuring of the meaning of these provisions by the ECJ. According to the famous holding in *Dassonville*, the prohibition by Article 30 of measures having an effect equivalent to quantitative restrictions covers 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade'.[17] This broad interpretation of the notion of equivalent effect leaves Article 36 unaffected. However, the regulatory objective which this Article exempts from the principle enshrined in Article 30, made the *Dassonville* formula a potential threat, especially to areas such as consumer and environmental protection. In its famous *Cassis de Dijon* decision, the ECJ found a way to uphold the potential for supervision of Member States opened up by *Dassonville* while at the same time tempering the anxieties of Member States about the Community's incursion into their regulatory concerns. The Court explained that essential public interests related, for example, to the protection of public health, consumer protection and environmental policy[18] were not to be qualified as measures of equivalent effect.[19]

The many subtleties of the Court's jurisprudence – the changing scope of its supervision of Member States[20], its deregulatory effects and their impact on the protection of consumers, the instrumentalization of Article 30 as a means to promote Community legislation – need concern us here only in two respects. First, to what degree did the Court substitute legal criteria with scientific assessments, thereby overcoming the territorial boundaries of legal competencies? And second, in so far as the Member States were required to respect scientific expertise, how did the ECJ determine and delineate the validity of scientific assessments?

2.1.2. The Imposition of Science-based Criteria on National Legislatures

Cassis de Dijon has become famous for promoting a principle that the ECJ did not endorse; namely, the duty of Member States to open up their borders to

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17 Case 8/78 *Procureur du Roi v Dassonville* [1974] ECR 837.

18 Case 303/86 *Commission v Denmark* [1988] ECR 4607 (Danish Bottle case).

19 Case 120/78 *Cassis de Dijon* [1979] ECR 649.

20 Cf. Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6126; and now Case C-391/92 *Commission v Greece* [1995] ECR I-1621.

products lawfully marketed elsewhere in the Community.[21] The message of the *Dassonville / Cassis de Dijon* jurisprudence was more modest, but nonetheless daring. The ECJ's distinction between legitimate and illegitimate regulatory concerns imposed a conceptual framework on the Member States within which they had substantiate their regulatory interests. Furthermore, and even more importantly, the ECJ requested Member States to take only such action which is 'proportionate to the aim in view'.[22] In order to become an effective supervisory tool, the principle of proportionality needed to be concretised further. At that point, science came into view. This occurred with three variations, with foodstuffs law providing the most elaborated example.

Member States must not only state their views as to the risks for public health, but 'the risk must be measured, not according to the yardstick of general conjecture but on the bases of relevant scientific research'.[23] This is by no means a trivial requirement. It restricts legislative discretion and imposes standards on decision-making processes within the Member States. Once it had been established that legislation must be backed by relevant scientific evidence, it became unavoidable to decide upon the properties of such evidence. This delicate issue came up again and again when importers of foodstuffs, in response to being summoned by national authorities because of a violation of domestic law, invoked the *Cassis de Dijon* principle. When assessing the validity of national legislation, the Court asked Member States to respect 'the findings of international scientific research, and in particular of the work of the Community's Scientific Committee for Food[24], the Codex Alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)'.[25]

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[21] Cf. notably the Communication from the *Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in case 120/78* ('Cassis de Dijon'), OJ 1980 C 256, 2.

[22] The principle of proportionality is an import into Community law from German constitutional law (cf. Zuleeg, M., 'Deutsches und europäisches Verwaltungsrecht - Wechselseitige Einwirkungen' (1994) 53 *Veröffentlichungen der Vereinigung Deutscher Staatrechtslehrer* 153-201 at 171-172 with further references). The principle has been cited as 'underlying the last sentence of Article 36 since Case 174/82 *Sandoz* [1983] ECR 2463; Case 247/84 *Motte* [1985] ECR 3887, and Case 174/82 *Muller* [1986] ECR 1511.

[23] Cf. as a recent example Case 17/93 *Van der Veldt* [1994] ECR I-3537 at 3560 .

[24] Cf. as to its tasks and composition, the pertinent Commission decisions in OJ 1974 L 136, 1 and OJ 1986 L 163, 40.

[25] Cf. e.g., Case 178/84 *Reinheitsgebot* [1987] ECR 1227 at 1274.

The authority attributed to the international and European expert community need not be unconditional. In a judgment concerning residues in foodstuffs[26], the ECJ introduced the concept of '*per se*' dangerous substances. The prohibition of such substances does not require the establishment of a 'danger', but may form a more general policy designed to prevent their presence.[27] 'The authorities of the importing Member State are, however, obliged to review the prescribed maximum level if it appears to them (!) that the reasons which led to its establishment have changed, for example, as a result of the discovery of a new use for such and such a pesticide.'[28]

A second retraction concerns objective differences among the Member States such as 'climatic conditions, the normal diet of the population and their state of health'.[29] The most prominent example is provided by the beer case, where Germany, in defence of its *Reinheitsgebot,* argued that it was particularly desirable to prohibit the use of any additive in the manufacture of this product because 'more beer is consumed by Germans than any other foodstuff'.[30] This argument was not taken seriously by the ECJ.[31] It has, however, been accepted in a series of other decisions, such as *Melkunie.*[32] There the Court approved the Dutch *Melkbesluit*, prohibiting micro-organisms beyond a threshold number in pasteurized milk in view of the Dutch habit of keeping 'such products for a period of time in less suitable conditions than those in the distributor's plant'.[33] Giving in to the national conditions argument implies a partitioning of the Internal Market. It should be noted that the Court supported this concession by pointing to a broad acceptance of the Dutch standards on daily intake both in

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[26] Case 94/83 *Albert Heijn BV* [1984] 3263.

[27] Case 94/83 at 3279-80.

[28] Case 94/83 at 3280.

[29] Case 94/83 at 3280.

[30] Case 178/84 *Reinheitsgebot* [1987] ECR 1227, report for the hearing at 1236.

[31] Cf. *infra* 2.1.4. for one of the Court's reasons, namely the lack of consistency in Germany's legislation. The Court also referred to the requirement also repeated the argument of Case 304/84 *Muller* [1986] ECR 1511 that Member States are to provide a procedure for traders to apply for the authorization of additives contained in foreign products but prohibited in the importing state, cf. *infra* 2.1.4. In my reading, the Court's reasoning reflects its own uncertainty about Germany's insistence on the degree of uncertainty in the assessment of the risks involved; cf. p. 1274 and the opinion of Advocate General Sir Gordon Slynn at 1257-1260.

[32] Case 97/83 *Melkunie* [1984] ECR 2367.

[33] At 2386 para. 19.

other Member States and outside the Community.[34] The *Melkunie* judgment can therefore be read as giving priority to a high level of protection not adopted by the Community, but reflecting a broadly accepted tendency.

2.1.3. Scientific Uncertainties

Both the distinction between ordinary and *per se* dangerous substances in the *Albert Heijn* case and the consideration of local conditions in the *Melkunie* judgment overlap with a second differentiation of fundamental importance.[35] As the Court has consistently held since *Eyssen Nisin*[36], Member States cannot be reproached for discriminating arbitrarily or disguisedly restricting trade between Member States within the meaning of Article 36 when protective measures seem reasonable in view of 'difficulties and uncertainties' of risk assessments equally encountered by other countries or international organizations. As this reasoning indicates, the existence of uncertainties by no means entitles Member States to adopt whatever policy they may feel to be appropriate. Although the Court has repeatedly stated that, in the absence of harmonization, it is up to the Member States to decide how to react to 'uncertainties at the present stage of research'[37], its reasoning in all pertinent cases[38] is concerned with restrictions of the competencies of Member States to autonomously decide upon their regulatory policies. Where they are in principle entitled to require the explicit approval of plant production products, they must not 'unnecessarily require technical or chemical or laboratory tests when the same analyses have already been carried out in another Member State and their results are available to those authorities or may at their request be placed at their disposal'.[39] They are entitled to request the authorization of additives to foodstuffs, the more so since limiting the use of additives is 'in accordance with a joint approach adopted by the Member States'.[40] They are not required when

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[34] Cf. the opinion of Advocate General VerLoren van Themaat at 2395.

[35] On the following cf. the comprehensive analysis of S. Schlacke, 'Das Vorsorgeprinzip in der Rechtsprechung des EuGH - Eine Analyse am Beispiel der Rechtsprechung zur Warenverkehrsfreiheit von Lebensmitteln', *Europäische Grundrechte-Zeitschrift* 1996 (forthcoming).

[36] Case 53/80 *Eyssen Nisin* [1981] 409 at 422f.

[37] See, for instance, case 174/82 *Sandoz BV* [1983] 2445 para. 16 citing as a precedent Case 277/80 *Biologische Producten* [1981] ECR 3277, although the formula is not to be found there.

[38] Including Case 304/84 *Claude Muller* [1986] ECR 1511 although the references to the international scientific community in that case are quite unspecific (cf. especially at 1529).

[39] Case 272/80 *Biologische Producten* [1981] ECR 3277 at 3292.

[40] Case 2047/84 *Léon Motte* [1985] 3887 at 3904.

deciding upon authorisation to attribute binding force to the opinions of the Community's Scientific Committee. But they must refer an importer's application 'to a committee of experts in order to obtain an opinion on the harmfulness of the additive, the degree of the human organism's tolerance of it and the necessity, value and suitability of its use'.[41] If it is then established by the authorities of the importing Member State that there is a 'real need' for that additive, 'they may not (...) refuse authorisation solely on the ground that it is contained in the imported foodstuff'.[42]

2.1.4. Legislative Coherence

One facet of the Court's interpretation of the proportionality principle deserves particular mention. As the Court has consistently held, national regulations must be 'appropriate' to meet the legislature's ends. This ends-means rationality is a well-defined concept in political sociology. Its plausibility as a yardstick for the functioning of legal systems seems, however, highly questionable. Two cases may serve to illustrate this point.

In its decision on the compatibility with Article 30 of a French requirement for the construction of woodworking machines[43], the Court explained that France must only prescribe a specific level of protection but must not impede the importation of products solely on the ground that they are manufactured using an alternative technique.[44] The Court added that the safety design of machines is to be seen as an element of a regulatory 'concept', which may give priority either to the construction or to the training of workers using machines. It then left France with the freedom to pursue its own safety philosophy. The famous judgment on the German *Reinheitsgebot*[45] is a second case in point. The Court there attached particular importance to the fact that Germany permitted the use of the additive in question in virtually all beverages with the exception of beer. To interpret the proportionality principle as prohibiting a general ban for beer is to require Germany to adopt a regulatory approach which is in line with that of the Community.[46] The Community now

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[41] At 3906.

[42] At 3905; cf. Case 174/82 *Sandoz* [1983] 2445.

[43] Case 188/84 *Woodworking Machines* [1986] ECR 419.

[44] Para. 16.

[45] Case 178/84 *Commission v Germany* [1987] ECR 1227.

[46] Namely, the shift away from regulating the composition of specific foodstuffs in favour of horizontal legislation following the Commission's adoption of the 'New Approach' in the

favours 'horizontal' regulations, which deal with additives as such and no longer prescribe the composition of particular foodstuffs. Within this approach it is perfectly reasonable to provide for procedures which enable traders to apply for an authorization.[47] At the same time, this regulatory technique does not preclude Member States from pursuing policies aiming at a high level of protection. But such policies are to adhere to a regulatory scheme which ensures some consistency in risk policies.

It does not seem easy to reconcile the holdings on French woodworking machines and German beer. As both cases show, it is one thing to require Member States to take account of the findings of scientific institutions and quite another to ensure the equivalence of regulatory philosophies. We will have to return later to these limits of the Court's interference with the regulatory autonomy of Member States.[48] One interim conclusion can, however, be drawn at this point. The ECJ's references to the normative importance of scientific evidence can neither be attributed exclusively to the Community nor to national legal systems. Both the Community and the Member States play important roles in authorizing risk policies. But the interaction between them is infiltrated by trends and actors outside their boundaries. Policy trends promoted by states inside and outside the Community, standards of scientific expertise formulated by international organizations, or even the prevailing view within the international scientific community may enjoy normative validity. Member States are requested to design their legislation in a way that enables integration of scientific findings and they are bound to give credit to scientific analyses undertaken beyond their territories.

2.1.5. *Instrumentalizing the Commission's Powers under Article 100a (4)*

The legal relevance of transnational science and infranational policy communities has been confirmed by the Court's handling of the only controversy to date that has been fought out under Article 100a (4).[49] The history of this controversy is complicated but sufficiently well-known. At issue was the compatibility of the German prohibition of pentachlorophenol (PCP),

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foodstuffs sector; cf. the Commission's Communication COM (85) 603 final of 8 November 1985.

[47] Cf. case 178/84 *Reinheitsgebot* at 1274 and case 304/84 *Muller* [1986] ECR 1511 (again the Court cites a precedent which does not really contain the position the Court is attributing to it.)

[48] *Infra* 2.2.2. and 3.2.

[49] Case C-41/93 *France v Commission* [1994] ECR I-1829.

which was stricter than the pertinent Community Directive 91/173/EEC adopted by qualified majority on 21 March 1991 against Germany's vote.[50] The Commission had explicitly endorsed Germany's position – and France complained. This is how the controversy over Germany's legislation muted into a legal controversy between the Commission and France. The ECJ used the opportunity to teach the Commission a lesson and to upgrade its position at the same time.

The Court achieved this result by first attributing a constitutive importance[51] to the supervision of unilateral action taken by Member States under Article 100a (4) to which it could therefore apply the requirements of Article 190. By doing so, the Court shifted the burden of providing good reasons for Germany's legislation to the Commission.[52] This then led the Commission to consult a scientist of international standing, Professor Rappe from the University of Umea, Sweden. In its decision of 14 September 1994[53], the Commission was able to explain in detail why it considered Germany's position to be justified and announced that it would re-examine the adequacy of the Community Directive on the basis of further research it had commissioned. It is important to note that Sweden, at the time of the proceedings, had not yet joined the Community. This aspect of the controversy only underlines what is already obvious: the validity of scientific findings cannot depend on the boundary of the legal system which integrates these findings into its laws.

2.2. The Defence of Community Competencies

The ECJ is famous (in the sense of *fameux*) for rarely questioning the Community's own competencies *vis-à-vis* the Member States. Significantly enough, conflicts over the Community's regulatory competencies have come up in a field where the Community is acting on the basis of majority decisions, namely in the field of agricultural policy. Majority voting at Community level tends to favour 'positive' integration, i.e. the adoption of measures which aim at the imposition of a regulatory framework on the functioning of the Internal Market. The questioning of the Community's competence then typically serves as a means to restore the veto power which the unanimity rule once implied.

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[50] Cf. OJ 1991 L 85, 34.

[51] Cf. on this point Advocate General *Tesauro* at 1836.

[52] Cf. 1849-1850.

[53] OJ 1994 L 316, 43.

The ECJ's tendency to defend the Community's regulatory powers thus supports 'market building through positive regulation'. This is typically achieved by adherence to the stricter standards at Community level. Where uniform standards cannot be realized, a favouring of high standards may at least pave the way for future legislation.

2.2.1. Article 43, EC Protectionism and the Politicization of Social Regulation

Real world conflicts, however, are usually more complex. They do not simply involve the dichotomy between the free market and social regulation, but simultaneously concern more trivial policy objectives. A case of exemplary importance may suffice to illustrate this point.[54]

Through Directive 85/649/EEC of 31 December 1985[55], adopted by a qualified majority on the basis of Article 43, the EC prohibited the use of hormones in livestock farming. The effect of this policy was to prevent the import of American products into the Community. The legal controversy within the Community over the policy did not address this trade issue directly. It was rather concerned with the regulatory contents of Community law. Even the questioning of Community competencies played but a minor role. The argument brought forward by the United Kingdom was that, in view of its health objectives, Directive 85/649/EEC should have been based upon Article 100. That provision requires unanimity. It would thus have enabled the United Kingdom to veto the Community prohibition. The Court response to this challenge was unambiguous: 'Efforts to achieve the objectives of the common agricultural policy (...) cannot disregard requirements relating to the public interest such as the protection of consumers or the protection of health and life of humans and animals (...)'.[56] The all-encompassing 'nature' of the Treaty provisions on agricultural policy thus served as a means to justify a 'positive' measure and to refute the questioning of its legal basis.[57]

A further complaint by the United Kingdom related to the failure of the statement of reasons in the Directive to take into consideration a scientific report which had been prepared in accordance with Article 8 of Directive 81/602/EEC on the prohibition of 'certain substances having a hormonal action

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[54] Case 68/86 *United Kingdom v Council* [1988] ECR 855.

[55] OJ 1985 L 382, 228.

[56] At 896 (para. 12).

[57] This reasoning was repeated in Case C-331/88 *Fedesa and Others* [1990] ECR I-4023 at 4065.

and of any substances having a thyrostatic action'.[58] Again, the Court rejected that complaint somewhat bluntly: the said Article 'imposed an obligation on the Commission only. (...) Consequently, the Council was not under an obligation to refer to those antecedents'.[59] This answer is unsatisfactory because the complainants had based their argument on the principle of proportionality which the Court imported into Community law and explicitly interpreted as requiring national legislation to take scientific findings into account.[60]

This inconsistency appears less surprising, and at the same time more interesting, if one considers the sensitivity of the issues involved. The scientific report on the risks of hormone use, commissioned in accordance with Directive 81/602/EEC, had led the Commission to reconsider the strict prohibition of Community law.[61] Its announcement of a policy change then met with strong opposition from both the Economic and Social Committee (ECOSOC)[62] and the European Parliament.[63] Following the European Parliament's resolution, the Commission cancelled further meetings of the scientific group entrusted with the examination of reports the Commission had received. Political opposition to the Commission's readiness to reconsider the Community's hormones policy was thus translated into giving reference to the 'interests of consumers in general (since it could be seen that meat from animals treated with hormones is widely rejected)'.[64] This type of consumer protection cannot, and need not be, supported by scientific evidence. Once its legitimacy as an objective of agricultural policy in general and the hormones directive in particular is accepted, there is 'really no reason to examine the health problem (...) and so the fact that in the preamble to the contested directive the Council did not go

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[58] OJ 1981 L 222, 32.

[59] At 900 (para. 35).

[60] Cf. *Supra* 2.1.2.; in the follow-up case *Fedesa and Others (supra* note 57), the competence issue was similarly overlaid by arguments on the justification and reasonableness of Community law. In its response to the complaint that the Community had infringed 'legitimate expectations of traders' that hormones 'would not be prohibited in the absence of any objectively based doubt', the Court repeated the arguments it uses when dealing with national legislation (cf. 2.1.2.); 'it need merely be stated that, faced with divergent appraisals by the national authorities of the Member States (...) the Council remained within the limits of its discretionary power (...), and respond in that way to the concerns expressed by the European Parliament, the Economic and Social Committee and by several consumer organisations' (at 4061-62).

[61] Cf. the Report of the Hearing at 856.

[62] OJ 1985 C 44, 14.

[63] OJ 1985 C 288, 158.

[64] Thus Advocate General Lenz at 882.

into the partial findings of the scientific group (...) certainly cannot be regarded as a failure to state reasons'.[65]

This is a serious observation with ironic legal consequences. European opposition to the use of hormones in livestock farming creates a broad collision of interest groups and public anxieties. Only the latter, however, is classified as a problem of social acceptability by experts of risk assessment. The ironic consequence of the Court's reasoning was that it excluded those political actors who could claim to represent the European public from articulating that concern. It is even more ironic that, had the Court given in to the arguments brought forward against the use of Article 43, it would actually have rendered those political actors helpless. Assuming the ECJ has given thought to all this, its judgment can be understood as supporting the political alliance between the majority of Member States and Europe's political institutions against the veto powers of the United Kingdom implied in the unanimity rule of Article 100. Nevertheless, the disregard of scientific evidence that the Commission had been prepared to bring to bear can hardly be heralded as a triumph of legitimate political authority over the neglect of public anxieties by insulated technocrats. The institutional mechanism actually endorsed by the Court was the bargaining process within the Council. Intergovernmental bargaining should not be equated with deliberative political processes on the social acceptability of technological developments.

2.2.2. The Scope of Secondary Law and Incomplete Harmonization

Once the Community has, through harmonization, 'occupied' a field of secondary legislation, the supremacy of European law in tandem with the principle of pre-emption are said in principle to exclude Member States from taking unilateral measures. Doctrinal statements of the said principles tend to convey simplistic messages.[66] One problem that the ECJ needs to address when determining the impact of Community legislation is the delimitation of harmonized and non-harmonized fields; i.e. the delimitation of Community from national competencies. The definition of medicinal products provides a particularly interesting example.

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[65] Advocate General Lenz at 882.

[66] Cf. A. Furrer, *Die Sperrwirkung des sekundären Gemeinschaftsrechts auf die nationalen Rechtsordnungen* (Nomos 1994).

In three cases dealing with Directive 65/65/EEC concerning proprietary medicinal products[67] the Court was faced with complaints alleging that Member States had unjustly classified products as medicines, thereby preventing their unauthorized marketing. *Van Bennekom*[68] concerned vitamins which the importer into the Netherlands regarded as foodstuffs[69]; in *Upjohn v Farzoo*[70] the parties litigated over the classification of a hair-restoring product as a cosmetic or medicinal product; Case C-290/90[71] involved a French eye lotion which Germany treated as a medicine. In all of these cases, the Court voted in favour of the stricter law. These holdings are remarkable because the Court's directions in terms of defining the concepts of medicinal products were not sufficient to achieve the Community's free-trade objective. In *Van Bennekom*, the Court construed Directive 65/65/EEC as covering products presented to and used by consumers as medicines; but it then referred to the uncertainties in assessing vitamin consumption and underlined the authority of Member States to determine for themselves to what risks they were prepared to expose consumers[72]. In *Upjohn*, the Court's broad interpretation of Directive 65/65/EEC was supported by all the intervening Member States; but at least in theory market integration could equally have been achieved under the Community legislation on cosmetics.[73] In the case on eye lotions, the Court again underlined the competence of national authorities to determine whether a particular product constitutes a medicinal product and then pointed to the conformity of Germany's practice with the views of the Council of Europe's European Pharmacopoeia Commission.[74]

What all of these cases demonstrate is the inherent weakness of harmonization policies which remain restricted to the adoption of common rules but fail to provide for the unification of their application.[75] Even the Court's insistence on its prerogatives in interpreting Community concepts proves to be an insufficient means to achieve the objectives of market integration. All the Court is able to do under such circumstances is to invoke the authority of

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67 OJ (English Special Edition) 1965-1966, 20.

68 Case 227/82 *Leendert van Bennekom* [1983] ECR 3883.

69 Cf. Case 174/82 *Officier van Justitie v. Sandoz* [1983] ECR 2445.

70 Case C-112/89 *Upjohn v Farzoo and Kortmann* [1991] ECR I-1703.

71 Case C-290/90 *Commission v Germany* [1992] ECR I-3317.

72 Case 227/82 *Leendert van Bennekom* [1983] ECR at 3901, 3902, 3905.

73 Cf. para. 26 of the opinion delivered by Advocate General Lenz.

74 Case C-290/90 *Commission v Germany* [1992] ECR I-at 3347.

75 Cf. *infra* 3.2.

scientific expertise as a yardstick for the assessment of both the reasonableness of national practices and the justification for Community intervention.[76]

2.2.3 Inter-institutional Conflicts

More recently, controversies concerning the proper bases for Community legislation have often been initiated by the European Parliament[77]; understandably so, if and because the legal bases for Community legislation determine the rights of the European Parliament in the legislative process. This type of institutional conflict between the European Parliament and the Council is not directly concerned with the mediating role of scientific expertise. This holds equally true for the Parliament's crusade against the delegation of regulatory tasks to the Commission under Article 145 and the comitology procedure[78] or its ongoing efforts to reduce the scope of Council regulations based on Article 43.[79] These conflicts are truly constitutional in that they concern rights of participation in legislative procedures and the potential role of the European Parliament in the implementation of Community legislation.

The relation of these institutional controversies to the role of science in Community law is only indirect, but still illuminating enough. Involvement of the European Parliament in the Community's legislative or administrative activities weakens the autonomy of the compound of Community and national administrations. At the same time, it challenges the functioning of the networks of experts managing risk regulation in Europe. One has, of course, to ask further whether the involvement of Parliament actually leads to a 'constructive' politicization of risk assessments. One must wonder whether the Parliament's protest against its exclusion from the implementation of legislation adopted under the procedures of Articles 189b or 189c is already backed by a convincing concept of parliamentary control of the Community's executive law-making.

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[76] Cf. Advocate General van Gerven's opinion in Case C-290/90 *Commission v Germany* [1992] ECR I-at 3335: 'If the Commission wishes to contest the data furnished by the Member State, it must do so on the basis of equally reliable data'.

[77] Cf. for a recent summary of the Court's jurisprudence, 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 Bundestages, Bremen 1995.

[78] Cf. Crams, H.A., 'Komitologie im Gesetzgebungsprozess der Europäischen Union und die Einbeziehung des Europäischen Parlaments' (1995) *Kritische Justiz* 112-131

[79] Cf. Case C-156/93 *European Parliament v Commission* [1995] ECR I-2019.

Before exploring these issues further, a second interim conclusion may be drawn. The controversies over the Community's competencies offer only very limited opportunities for questioning or defending the reasonableness of the Community's regulatory policies. Legal guarantees promoting such objectives have to be detected elsewhere. In the end, it will turn out that scientific expertise and its transnational status is to fulfil important functions in the juridification process.

2.3. The Community's Commitments in the Exercise of its Law-making Functions

The Community's commitments in the exercise of its powers stem from many sources. It makes some, albeit limited, sense to organize these sources in analogy to conventional hierarchy models of legal systems. Constitutional elements of the European legal system which rank high in their validity claims, such as human rights and the principle of proportionality, have only been introduced by the ECJ. Community primary law itself has undergone changes which are of fundamental importance in the present context. The jurisprudence of the ECJ spells out principles in practically marginal cases, which may turn out to be significant for the whole of Community law. And most importantly, the dynamics of the integration process further the emergence of unforeseen practices which then require normative ingenuity. All of these preliminary remarks serve to underline the infant state of European law and the need to exercise great caution in its interpretation.

2.3.1. Recent Developments in Primary Law

It still makes sense to start with provisions of the Treaty in pertinent policy fields. Thus Article 130r (3) explicitly requires that available scientific and technical data be taken into account in the Community's environmental policy. Article 130 (2) introduced the principle of 'precaution', which by its very nature presupposes that public authorities be open to scientific evaluations of risks to the environment; one may conclude that this principle should *a fortiori* be applicable to the protection of human health. The legal obligations that follow from these provisions still seem to be insufficiently explored.

Just because the ECJ has so far had very limited opportunities to consider the legal implications of these new provisions for the Community itself, a case

should be mentioned[80] which primarily concerned the pre-emptive effects of Directives 74/442/EEC and 84/631/EEC concerning waste[81] and the compatibility with Articles 30 and 36 of a Wallonian regulation prohibiting the import of waste. This issue concerned the tensions between two Community objectives; namely, the prohibition of discriminatory restrictions of trade on the one hand and the principle contained in Article 130r (2) that impairments to the environment should be remedied at their origin. The Court's readiness to give priority to environmental policy relates first of all to the Community itself. But it indirectly affects Member States because they are bound to adopt the Community's environmental policy in order to ensure the effectiveness of their legislation.[82] The Court's holding does not concern the integration of scientific expertise into the legal system. But it is a further illustration of the merging of two levels of governance; the Community system determines the design of national environmental policies and in that sense deploys a rationalizing effect.[83]

Because of their tendency to alienate legal systems from their cultural background and historical ties, rationalization processes not only improve the conditions for a 'denationalized' discussion of regulatory issues but also pave the way for resorting to scientific expertise as a regulatory tool. This interdependence can be illustrated by the recent *Angelopharm* judgment.[84] The proceeding started with the German producer of Sedaterm, a substance designed to prevent genetically-conditioned hair loss, opposing the prohibition of the marketing of his product which had been based on a German *Verordnung* implementing a Commission directive.[85] The complainant argued that Sedaterm was not injurious to human health and the *Verwaltungsgericht* Hamburg, having commissioned an expert's opinion from Professor Braun, was prepared to invalidate the German prohibition. However it felt unable to do so because the *Verordnung* was implementing Community law.

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[80] Case C-2/90 *Commission v Belgium* [1992] ECR I-4431.

[81] Directive 75/442/EEC on waste, OJ 1975 L 194, 47 and Directive 84/631/EEC on the supervision and control within the European Community of the transfrontier shipment of hazardous waste, OJ 1984 L 326, 31, as amended by Directive 87/112 EEC, OJ 1987 L 48, 31.

[82] Cf. para. 34.

[83] Cf. *supra* 2.1.3.

[84] Case C-212/91 *Angelopharm GmbH v Freie und Hansestadt Hamburg* [1993] ECR I-171.

[85] Twelfth Commission Directive 90/121/EEC of 20 February 1990 (OJ 1990 L 71, 40).

The ECJ, to which the case was referred, did not answer that question directly but addressed a logical precondition for the validity of the Sedaterm prohibition – namely the validity of the Commission directive that Germany had so faithfully implemented. The yardstick against which the ECJ then measured Community law is difficult to decipher. Having considered the not so ambiguous wording of the Cosmetics Directive which vests the Commission with the power to issue implementing directives[86], the Court stated: '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] To adopt this standard amounts to unauthorizing 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 assistance of 'experts on scientific and technical issues delegated by the Member States'.[88]

'The nature of things' is by its very nature a meta-positive principle. It is designed to promote the adequacy of regulatory policies by ensuring that they take the 'latest international research' into account. This type of guarantee is neither dependent upon an interference with individual rights; nor is it to be inferred from the requirements of Article 190 or shifting the burden of proof to this or that actor. All of these well-established legal techniques had been considered in the opinion of Advocate General Jacobs.[89] The Court was equally free to refer to its jurisprudence on the concept of medicinal products and, following the precedent of *Upjohn v Farzoo*[90], to classify Sedaterm as a medical product and then leave its assessment to the German authorities. The very fact that these alternatives were not chosen constitutes the importance of the Court's step towards a further rationalization of regulatory policies in *Angelopharm*. To be sure, the conditions which are to trigger off the obligation to consult science

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[86] Article 8(2) reads: 'The amendments necessary for adopting Annexes II to VII to technical progress shall be adopted in accordance with the same procedure [laid down in Article 10] after consultation of the Scientific Committee for Cosmetology at the initiative of the Commission or a Member State.'

[87] Case C-212/91 at 210.

[88] At 211 (para. 33).

[89] At, 190-192.

[90] Case C-112/89, [1991] ECR I-1703 cf. 2.2.2. *supra*.

need to be specified further and rules governing the selection of experts and the structuring of their deliberations will have to be developed. Follow-up problems of this kind are, however, inevitable wherever a re-conceptualization of legal approaches is initiated.[91]

2.3.2. Towards Differentiated Standards of Judicial Review under Article 190

One obvious candidate for the further juridification of the Community's regulatory practices, which has already been addressed in the context of controversies on Community competencies[92], is the statement-of-reasons requirement of Article 190. This provision seems to have the potential to structure legal reactions according to the complexities of European legislation and decision-making. Significantly enough, the initiators of pertinent proceedings tend to invoke Article 190 as an additional basis for their dissatisfaction with the Community's regulatory practices. This holds true for both the efforts of the European Parliament to defend or broaden its rights of participation[93] and for complaints concerning the proper basis of Community measures.[94]

The Court has adopted a differentiating approach. The Council tends to be treated as a regular legislator, enjoying wide margins of discretion.[95] The Commission, however, has been controlled more strictly. As has already been observed[96], the readiness of the Court to rigidly interpret the statement-of-reasons requirement where controversial assessments of risks are at stake indirectly imposes equivalent obligations on national legislators, who are thereby placed on the same footing as the Community executive.

A further step has been taken in relation to decisions concerning individual rights of direct action. The statement of reasons required by Article 190 'must disclose in a clear and unequivocal fashion the reasoning followed by the Community authority (...) in such a way as to make the persons concerned aware of the reasons for the measure and thus enable them to defend their rights and to enable the court to exercise its supervisory jurisdiction'. This is the

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[91] It should be pointed out that the Community can build upon its well-established practices of nominating members of its scientific committees and their procedures.

[92] Cf. 2.2.1. *supra.*

[93] Cf. 2.2.3. *supra.*

[94] Cf. 2.2.2. *supra.*

[95] Cf., for instance, Case C-331/88 *Fedesa and Others, supra* note 57, at 4063.

[96] Cf. 2.1.4. *supra.*

Court's own restatement of its prior jurisprudence in *Hauptzollamt München-Mitte v Technische Universität München*.[97] It sounds somewhat brightening.[98] And yet in the *TU München* case, the rejected formula led the Court to annul the decision in question.

The importance of this decision results from its concurrent recognition of basic procedural rights: where Community institutions have the power to carry out complex technical appraisals, respect for the rights of individuals is to be ensured by the 'duty of the competent Community institutions to examine carefully and impartially all the relevant aspects of the individual case, the rights of the persons concerned to make their views known and to have an adequately reasoned decision'.[99]

2.3.3. Testing Regulatory Reasonableness and the Principle of Proportionality

It seems fair to assume that the obligations imposed by the Community on Member States in the exercise of their legislative competencies must equally be respected by itself. Such equations will of course have to cautiously consider whether the Court's jurisprudence contains normative elements of general application or must be understood as a means to overcome legal barriers to market integration. Any conclusion based on the ECJ's resort to scientific expertise in the supervision of national legislation under Articles 30 and 36 will have to be prepared to differentiate between the need to establish a Community-wide reference framework for the assessment of regulatory policies and the use of the principle of proportionality as a normative yardstick of general validity for the balancing of regulatory concerns and private rights. Such caution is prompted by the interpretation of the Community's powers as originating from transfers of competencies originally vested with nation-states. The 'transferor' is supposed to respect the position obtained by the 'transferee'. Accordingly, one must not readily infer from the obligation of Member States to take Community objectives into account when pursuing their own regulatory concerns that an equivalent restriction holds in relation to the Community's own legislative discretion.

The Court has been very reluctant indeed to question the wisdom of any measures approved by the Council. Thus, in *Fedesa and Others*, the Court

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[97] Case C-269/90, [1991] ECR I-5469 at 5499.

[98] Cf. the opinion of Advocate General Jacobs at 5492-93.

[99] At 5499 (para. 14); on the further procedural and organizational implications cf. *infra* 2.3.4.

limited its review of the discretionary power conferred on the Council in the implementation of the common agricultural policy to 'examine whether the measure in question is vitiated by a manifest error or misuse of powers, or whether the authority in question has manifestly exceeded the limits of its discretion.'[100] This broad discretion is to shrink where measures are taken by the Commission acting alone or with one of its committees. In the above-mentioned *TU München* case the Court's quest for a substantiated statement of reasons implies that Community institutions are to base their decisions on a careful and impartial examination of all the aspects of the case.[101] Similarly, the Court's questioning of the capacity of the Commission and its Regulatory Committee to assess the risk of Sedaterm[102] restricts its discretionary power quite drastically. Last but not least, the Commission's (newly acquired) powers under the procedure of Article 100a (4) are severely limited by the Court's request for a qualified examination of national measures.[103]

All of these requirements do not merely concern the Commission and its Advisory, Administrative and Regulatory Committees. They relate to the legal system as such, and even challenge the authority of the ECJ. The Court's twofold objective of promoting the technical and scientific sophistication of regulatory decision-making while at the same time preserving its own supervisory powers and ensuring the protection of individual rights necessitates the development of a new body of rules and principles capable of bridging the gap between law and science. This is, however, by no means an unprecedented challenge.

2.3.4. Proceduralization of Legal Controls

The search for legal guarantees for the substantive adequacy of regulatory decisions and their fairness to individuals concerned has only been taken on occasionally and in quite different settings. One group of cases which has not yet been referred to is the judicial review of refusals of the Commission to recruit applicants on grounds of physical unfitness. Such decisions are taken on the basis of Staff Regulations which foresee an appraisal of the candidate's health by a medical committee. Review of such appraisals is limited to questions of the committee's constitution and its proper proceedings. But the

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[100] Case C-331/88 *Fedesa and Others*, *supra* note 57, at 4061; cf. 2.2.1. *supra*.

[101] Case C- C-269/90 *Hauptzollamt München-Mitte v Technische Universität München* [1991] ECR I-5469 at 5499 (para. 14).

[102] Cf. *supra* 2.3.1.

[103] Cf. *supra* 2.1.4.

Court has made it clear that judicial restraint is dependent upon the appropriateness of the complaints procedure as well as the objectivity of the committee's investigations.[104]

Much more directly in point is once again the Court's case-law on the decisional practices concerning the importation of Community Customs Tariff duties on scientific and other materials under Council Regulation 1789/75.[105] According to the procedure laid down in Regulation 2784/79[106], the Commission is to consult Member States and, if necessary, a group of experts comprising representatives of Member States. As to the practices of this group, Advocate General Jacobs observed that its composition of officials from the Ministries of Finance or Trade may render it 'unduly sensitive to the interests of manufacturers in their respective countries'.[107] Indeed, the group's refusal to accept the request of the *TU München* for the free importation of a microscope from Japan on the ground that an instrument of equivalent scientific value was available in the Community coincided all too obviously with the views of Philips submitted at each stage of the proceedings. This striking coincidence then led the Court to point out that the expert committee on which the Commission is to rely must be 'composed of persons possessing the necessary knowledge in the various fields concerned'[108]; furthermore, 'the person concerned should be able, during the actual proceedings before the Commission, to put his own case and properly make his views known on the relevant circumstances, and, where necessary, on the documents taken into account by the Community institutions'.[109]

Even easy cases can make good law. Integration of experts into the Community's regulatory decisions amounts to a delegation of legal responsibilities which needs to be compensated by adequate procedural safeguards. This message of the *TU München* case was even more clearly articulated in a different field of Community law, namely the Court's jurisprudence on the compatibility of self-regulatory practices with the competition rules of the Treaty and the duties of Member States under Article

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[104] Case 156/80 *Mobelli* [1981] ECR 1357 at para. 19; Case 265/83 *Suss v Commission* [1984] ECR 4029 at para. 11; cf. more recently Case T-10/93 *A v Commission* [1994] ECR II-179 (refusal to accept a HIV-positive candidate).

[105] OJ 1975 L 184, 1; amended by Regulation 1027/79, OJ 1979 L 134, 1.

[106] OJ 1979 L 318, 32.

[107] At 5490.

[108] At 5550 (para. 22).

[109] At 5501 (para. 25).

5.[110] The most interesting case in the present context concerns a German self-regulatory commission of experts from the transport sector entrusted by the Ministry of Transport with the task of fixing freight rates.[111] The Court accepted this type of supervised self-regulation assuming, however, that

- the commission was bound to respect the public interest in providing encompassing services;
- its composition corresponded to all the interests involved;
- the expert members did not pursue the interests of their undertakings;
- and the Ministry was represented at commission meetings and in a position to eventually reject commission proposals.

Apart from second-guessing as to whether the ECJ actually applied the principles it pronounced to the case at hand, one must ask whether the restraints imposed on economic self-regulation are exclusively designed to structure vertical relations between the Community and Member States. The better reasons militate in favour of a broader interpretation. Not only do Member States need to respect the regulatory objectives of free competition, but the Community itself needs to balance its twofold commitment to a system of undistorted competition *and* regulatory objectives explicitly laid down in the Treaty. The criteria developed by the Court for its supervision of economic self-regulation at national level provide guidance for exactly that task. They are particularly suited to structuring the participation of non-governmental bodies, such as the European standardization organizations, in concretizing legislatively defined essential safety requirements.

Administrative law in bits and pieces, one may conclude. But it seems possible to fit the puzzling and scattered evidence into a quite coherent picture. The Commission is bound to resort to scientific advice where the 'nature of things' so requires. The expertise it is supposed to take into account must be objective, impartial and of high calibre. All of these requirements have an impact on the composition of expert committees and on the procedures of risk assessments and management. Interested persons and institutions must have

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[110] On the following cf. for a more detailed analysis, in 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 Bundestages, Bremen 1995 at 147 ff.

[111] Case C-185/91 *Bundesanstalt für den Güterverkehr v Reiff* [1993] ECR I-5801.

access to files and be in a position to state their views. Compliance with all of these criteria is subject to judicial review. The picture, however, is still incomplete. One of its most irritating facets should now be further examined.

3. Governance Beyond the State: Some Tentative Deliberations

The normative problematic of the legal developments we have described so far can only be fully understood when they are analysed within the broader framework of Europe's institutional structures and the regulatory challenges posed by the integration process. This concluding section will therefore return to the theses and queries submitted at the beginning of the paper.[112] It will first summarize the findings on the ECJ's resort to the authority of science as a means of both overcoming the territorial boundaries of legal systems and improving the quality of regulatory decision-making. It will then point to the practical limits of these judicial strategies and finally address the core normative problem of the emerging European governance structures.

3.1. The Autonomy of Science and the Authority of Expert Communities

As has become apparent when considering the jurisprudence of the ECJ on the compatibility of national regulations with Community law, the Court's quest for 'objectivity' and 'proportionality' amounts to an assignment of regulatory authority to scientific communities.[113] We have then observed how the Court tends to subject Community institutions to equivalent obligations. Even when reviewing decisions taken by the Council, the ECJ has examined their compatibility with the majority view among national authorities.[114] Both the *PCP* and the *Angelopharm* judgments strengthened this tendency considerably. When interpreted as laying down a principle of general validity, the holding in *PCP* requires the Community to base its control of national policies on scientific evidence of international standing.[115] Similarly, the judgment in

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[112] *Supra* 1.3.

[113] Cf. *supra* 2.1.1. and 2.1.4.

[114] Cf. Case C-331/88 *Fedesa and Others*, *supra* note 57, at 4061.

[115] Cf. 2.1.4. *supra*.

Angelopharm forces the Commission, and implicitly the Community legislator, to seek scientific advice wherever the 'nature of things' so requires.[116]

The meta-legal authority of science can equally be identified as a basis for the ECJ's jurisprudence on the inter-state recognition of scientific appraisals and the opening up of national authorization procedures to foreign applications. These obligations are supported by Article 5 of the Treaty and are designed to implement the Community concept of mutual recognition, which in turn is to overcome the traditional conceptual limits of international administrative law. But the kind of obligation the ECJ has brought to bear refers once again to non-legal authorities. This becomes particularly clear when the Court accepts national regulatory autonomy in situations of scientific uncertainties and, at the same time, restricts that autonomy by invoking the state of international research.[117] It becomes equally apparent when national authorities are requested to make use of scientific analyses carried out in other Member States in their authorization procedures.[118]

One must certainly not assume that the ECJ is so naive as to believe in an unquestionable validity of expertise or in a clear demarcation line between 'certainty' and 'uncertainty' in science-based assessments. The scientific authority to which the Court refers is none other than a social construct. But the Court has not only indicated which scientific institutions and communities can claim authority, it has also addressed the needs and constraints of transforming scientific findings into risk-management policies. Pertinent case-law is abundant. The Court has been forced to consider linguistic problems and communication difficulties of German administrators[119]; the appropriateness of a Belgian nomination of the director of a water-purifying company as the competent authority to issue permits[120]; the Greek certificates for pasteurised butter[121]; and countless similar issues.[122]

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116 *Supra* 2.3.1.

117 Cf. *supra* 2.1.1. and as an additional example Case 54/85 *Mirépoix* [1986] ECR 1067 at 1079: 'National authorities are obliged to review the prohibition of a pesticide (...) it appears to them that the reasons which led to the adoption of such measures have changed, for example, as a result of the discovery of a new use for a particular pesticide, or as a result of further information becoming available through scientific research'.

118 Case 272/80 *Biologische Producten* [1981] 3277 at 3292; cf. 2.1.2. *supra.*

119 Case C-243/81 *Commission v Germany* [1984] ECR 1111.

120 Case C-372-374/85 *Ministère publique v. Traen* [1987] ECR 2141.

121 Case C-205/89 *Commission v Greece* [1991] ECR I-1361.

3.2. Practical Difficulties

The Court's entanglement in such a morass follows a compelling logic. Once the authority of science in risk assessments is established, the guidelines of risk-management practices must equally adhere to non-national standards. This logic, however, comes at a price. Cases on the compatibility of national risk-management practices are responses of the legal system to highly specific constellations. Judicial review is, of course, meant to resolve such matters. It may even detect and pronounce principles of general validity. But it is not capable of coherently building up the kind of infrastructures transnational risk-management practices require. Similar difficulties have been identified in the case-law on Directive 65/65/EEC.[123] Any European prerogative in determining the meaning of legal concepts, such as 'medicinal products', remains an insufficient means of achieving the free-trade objective, unless the Community ensures that the indispensable determination of normative requirements is supported by a Europeanization of implementation practices. The infrastructures which such backing presupposes cannot be imposed through Community legislation. It is even less conceivable that they be created through judicial review.

Where the judicial branch pronounces principles which tend to overburden the infrastructures of the legal system, financial support and legislative action become indispensable. And indeed, as has already been pointed out[124], Community legislation and many accompanying measures are responding to these needs. Suffice it here to point again to the omnipresence of expert committees in the preparation and implementation of Community legislation; the strengthening of the position of scientific committees within the Community's comitology, even prior to the *Angelopharm* judgment; and the furthering of cooperation among national administrative bodies and with non-governmental organizations. It is by no means clear to what degree the normative logic of the ECJ's jurisprudence, the Community's legislative initiatives as well as the many efforts to ensure the cooperation of national administrative bodies and non-governmental organizations have already

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[122] Cf., for instance, Case C-123/89 *United Foods et al v Belgium* [1981] ECR 995 (health inspection of fish); Case C-124/81 *Commission v United Kingdom* [1983] ECR 203 (license systems of milk inspection); Case 42/82R *Commission v France* [1982] 841 (customs clearance of Italian wine); Case C-426/92 *Germany v. Deutsches Milch-Kontor GmbH* [1994] ECR 2757 (detection of fraudulent practices).

[123] Cf. *supra* 2.2.2.

[124] Cf. supra 1.2.

established, or are likely to achieve, the building up of efficient infrastructures for denationalized European practices of risk assessment and management. One should at any rate be prepared to reckon with one latent difficulty: the need to ensure the legitimacy of regulatory decisions affecting the interests of enterprises and citizens all over Europe. The practical importance of this problem may be difficult to specify. There is nevertheless every reason to consider the potential of European law to ensure the normative quality of decision-making that European citizens have learned to appreciate within the boundaries of their constitutional States.

3.3. The Accountability of Denationalized Governance Structures

Assuming that 'we the peoples' of Europe do not want to build up a Federal State which would be entrusted with the tasks of social regulation; assuming further that Europeans are nevertheless interested in benefiting from an opening up of their formerly national economies; assuming, last but not least, that the Europeanization of markets requires institutional structures which ensures both the effectiveness and the legitimacy of risk assessments, then we are bound to strive for institutional solutions which transcend the boundaries of our constitutional States without replacing these States with a Europeanized equivalent. Social regulation thus provides a case of exemplary importance for the normative dilemmas of regulatory politics in transnational contexts: All the Member States and (the greater part of) their societies are interested in principle in the exchange of products and services; none, however, seems ready to waive the type of protection provided by the regulation of risks or to simply leave the level of protection to processes of regulatory competition. Even more important, each individual society asks for protection against risks originating beyond its own polity. And yet, the building up of European political institutions and administrative authorities entrusted with supranational competencies for all the sensitive issues of social regulation seems neither normatively desirable nor practically conceivable.

For the time being, institutional models which would resolve all of these difficulties are not readily available. What does seem possible at this stage is to summarize guidelines which should be taken into account in the development of institutional responses.

- Denationalized governance structures are to be conceived as complementing national and supranational institutions. Their social

acceptability and legitimacy will depend upon the concomitant institutionalization of economic freedoms and public responsibilities.

- Risk assessment and management policies within European networks should to reflect the concerns of European societies; they must mediate between the functional needs of efficient decision-making, its public transparency and accessibility for administrative and non-governmental actors.

- The legal system must continue its search for guarantees of regulatory reasonableness, procedural safeguards and the protection of rights. This search should be complemented by the institutionalization of political accountability. Such institutional innovations would have to correspond to the emerging structures of governance beyond intergovernmentalism and below supranationalism. One conceivable step might be the entrustment of parliamentary committees, composed of both European parliament members and national delegates, with the task of regularly reviewing the experiences of Community and national officials, of organizing hearings to which experts and non-governmental organizations would be invited, and of initiating legislative action at the European and national level.

These are but tentative suggestions. And yet the underlying normative vision should have become sufficiently clear. In the absence of a uniform European society and a European State, the structures of social regulation in Europe must resolve the tensions arising from the openness of markets on the one hand and the need to respond to 'legitimate' regulatory concerns on the other. The search to comply with, and mediate between, these two objectives needs to build upon their respective normative merits: societies granting freedoms or imposing regulatory burdens must consider the adverse extraterritorial effects of their policies. This obligation amounts to the granting of a voice to 'foreign' citizens and their representatives. European law can be interpreted as ensuring exactly such rights. In this vision, the quest for 'regulatory reasonableness' of national measures reflects the respect for concerns which are not represented in internal policy processes. Legal constraints imposed by European law to ensure the openness not only of markets but also of regulatory decision-making are by no means undemocratic; the building up of denationalized governance structures should therefore aim at the strengthening of deliberative processes dealing with the interests and concerns of those who are affected by, but not represented in, decision-making processes.

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