

Legitimising Regulatory Production Under Conditions of Scientific Uncertainty

The Role of the ECJ

ABSTRACT

The regulation of scientifically uncertain risks to health and the environment requires the regulator to balance unquantifiable incommensurables, which may have re-distributive consequences. Such decisions are controversial because they cannot be taken objectively. As such, they must be democratically legitimated, which means they have to fulfil two democratic ideals: They must emerge out of a discourse that is deliberative, rather than strategic; and they must be responsive to public concerns and arguments.

Responsiveness is of concern because membership of the Community both restricts the capacity of national regulators to respond to the public and transfers regulatory powers to more 'distant' European institutions. If, on the other hand, regulatory power is returned to national regulators there is the danger that it will not be used deliberatively.

When called upon to do so, the ECJ is responsible for reviewing the decisions of both national and Community regulatory institutions. National regulators are subject to a 'constitutional' style of review, European regulators to an 'administrative law' style of review. Both operate in ECJ's jurisprudential shadow, which has a fundamental impact on their regulatory decision-making. The ECJ can use it to promote the two democratic ideals. This paper examines a number of principles of review through which the ECJ might steer the Community's regulatory system towards greater legitimacy when dealing with scientifically uncertain risks.

THE REGULATION OF SCIENTIFICALLY UNCERTAIN RISKS IS CONTROVERSIAL

Decisions as to how, or indeed whether, to regulate a scientifically uncertain risk to health or the environment are controversial (i.e. they cannot be made objectively). They involve ‘practical questions’ which are ‘posed with a view to the acceptance or rejection of norms, especially norms for action, the claims to validity of which we can support or oppose with reasons.’¹ The grounds are threefold – these decisions involve the balancing of incommensurables, which are themselves unquantifiable, and in turn have re-distributive consequences.

One cannot *objectively* compare a regulation’s environmental or health benefits with its economic cost. These are **incommensurable** in the same way as apples are incommensurable with oranges. Any comparison requires a common denominator, which in this context, would require one to attribute an economic value to environmental and health protection. One cannot do this without reference to non-objective criteria, which means that the decision is controversial.

Scientific uncertainty operates potentially at many different levels: whether as to the probability of damage, the magnitude of the potential consequences, or indeed whether there is a causal link at all. Also, scientific opinion develops over time and there may be disagreements amongst scientists at any one time. Environmental and health regulation is doubly controversial in the context of this scientific uncertainty, because the benefits of a regulation are **unquantifiable**. Even if one could solve the incommensurability problem by attributing an economic value to health or environmental protection, it is impossible to compare an unknown health or environmental benefit with the economic cost of regulating it, without first deciding what weight to attach to that uncertainty. One could discounting the uncertainty completely, or assume that the worst-case-scenario is true, or indeed anything in between. But, that choice is itself controversial.

A state policy that results in the **re-distribution of wealth** is controversial because the state imposes a burden on some and not others. At first glance, the setting of health and environmental standards does not involve a re-distribution. However, whatever regulatory standard is chosen will have different impacts on different people because producers, consumers, environmental conditions and health problems vary. For instance, more technologically advanced producers can absorb higher environmental and health protection costs, whilst remaining competitive through better productivity rates. High regulatory standards enable them to penetrate other markets at the expense of their less technically advanced competitors. Likewise, more affluent consumers are in a better position to pay a premium for higher regulatory standards than are less affluent consumers.

¹ J. Habermas, *Theory and Practice*, p3

CONTROVERSIAL REGULATORY DECISION-MAKING MUST BE DELIBERATIVE AND RESPONSIVE

If the regulation of scientifically uncertain risks to health and the environment incorporates the values of the decision-maker (i.e. it is controversial) it is only appropriate, in a democratic society, that this power is subject to democratic control.² But what does democratic control entail?

The aggregate conception of democracy holds that democracy is merely a mechanism for aggregating conflicting individual interests in such a way that the legislature is persuaded to issue regulations that satisfy the greatest number of people, to the greatest possible extent. The deliberative conception of democracy does not treat individual interests as conflicting givens, to be aggregated through the political process, but holds that individual preferences are contingent and open to the persuasion of the better argument.³ Democracy is therefore about autonomous individuals deliberating with each other to decide upon the regulations they are to be governed by. To argue in favour of a regulation is to provide reasons, with the aim of convincing others, why, in good will, they should deem it to be equally in the interests of all. When reasons are contested, bringing about a rational acceptance requires a discourse in which the disputed claim is isolated and tested solely on the basis of rational arguments, not strategic interests. The argument that is objectively most persuasive wins out. Habermas calls this the **discourse principle**. It relies ‘upon a person’s capacity to be swayed by rational arguments and to lay aside particular interests and opinions in deference to overall fairness and the common interest of the collectivity’.⁴

The deliberative conception is intuitively more appealing than the aggregate conception of democracy, but, it is also more idealistic, especially given the pluralist nature of modern society and the fact that the regulatory terrain that we are dealing with here spreads over 15 Member States, each with its own peculiar regulatory concerns and traditions. However, this does not inexorably lead us to the conclusion that the deliberative conception is impracticable and that we must accept the less attractive aggregate solution. Deliberative democracy is relevant if individuals ‘who know that they disagree on moral, religious, and political issues, nevertheless share a commitment to the idea of conducting political argument on common ground.’⁵ The Community itself is a testimony to this possibility. Without it European integration hardly seems tenable. However, it is not the purpose of this paper to test the practicability of deliberative democracy, nor is this necessary to the paper’s conclusions. Instead, deliberative theory is used to derive **two democratic ideals**, which must be realised to some extent by all regulatory systems, which purport to be democratically legitimate.

As explained above, deliberative theory considers that legitimate regulation emerges out of a discourse in which the public employs rational argument to test the reasons for regulation. A regulatory system also requires institutions that transpose the outcomes of the public discourse into formal regulation. Both the public discourse and the discourse within these regulatory institutions should be **deliberative**, in the sense described above – this is the first democratic ideal. Furthermore, the formal institutionalised deliberation in the regulatory

² I. Pernice, *Auswirkungen des europäischen Binnenmarktes auf das Umweltrecht - Gemeinschafts(verfassungs-)rechtliche Grundlagen* NVwZ 201-211, at 210 *et seq.*

³ J. March & J. Olsen, *Rediscovering Institutions, The Organizational Basis of Politics*, p154

⁴ D. Curtin, *Postnational Democracy, The European Union in Search of a Political Philosophy*, p54

⁵ O. Gerstenberg, *Laws Polyarchy: A Comment on Cohen and Sabel*, *European Law Journal*, Vol. 3, No. 4, December 1997, p343, at 350

institutions must be **responsive** to the concerns and arguments, which emerge in the parallel public discourse. Craig explains that responsiveness is based on the idea that ‘input from the bottom can and should play a role in defining and refining the conception of the common good which operates within any particular area. This should not be the exclusive province of those in the governing institutions.’⁶ Regulatory institutions must not operate solely according to their own criterion of efficiency but, as Gerstenberg describes it, should ‘remain sensitive to, and irritable by, the interventions of society as a whole.... [T]he pathology of closure must be avoided.’⁷

APPLYING THE DEMOCRATIC IDEALS TO THE COMMUNITY’S REGULATORY SYSTEM

When regulatory standards differ from one country to the next they act as barriers to trade because producers must comply with the regulations of each country into which they wish to export their goods. To prevent these barriers becoming too significant and to secure certain policy objectives, such as health and environmental protection, the Community fulfils two distinct regulatory functions - it controls its Member States’ regulation and it produces its own harmonised regulation. The European control of national regulation reduces the capacity of national regulators to satisfy the regulatory demands of their national publics. The transfer of regulatory production from Member States to the Community means that regulatory decision-makers are situated at a greater ‘distance’ from the public. Either way, the public’s capacity to influence the Community’s regulatory system, and therefore the compliance of that system with the democratic ideal of responsiveness, is an issue.

The traditional means of subjecting regulatory decision-makers to democratic accountability is either directly, by requiring them to put themselves up for periodic public elections, or indirectly by placing them under the control of someone who does have to face periodic elections. However, this traditional method of accountability is hopelessly inadequate when confronted by the complexity and breadth of responsibility of the Community’s regulatory system. The state has taken on ever more regulatory tasks.⁸ Public concerns and arguments, not only change over time, but differ from one Member State to the next. However, to secure the benefits of the internal market, there must be a degree of harmonisation, or at the very least Member States must be subject to regulatory control to prevent trade barriers arising in the first place. The Community must mediate between the need to respond to the diversity of conditions and risk perceptions in the Community, the need to prevent market fragmentation and the need to protect human health and the environment. No definitive regulatory solution is ever possible, because regulation must continually stay abreast of changing scientific knowledge and new regulatory concerns. Adding all of this together - regulation is an on-going, never-ending and increasingly specialised process, which requires the continual involvement of dedicated experts. At the same time, our democratic tradition is deeply rooted in the idea of a chain of command that reaches from all those who exercise legislative power to those (‘where-the-buck-stops’), who’s tenure in office is subject to our continuing support, which we are entitled to withdraw when they come up for re-election. Nevertheless, this ‘chain of command’ structure of accountability cannot, on its own, ensure the responsiveness of the Community’s vast regulatory system. Whilst it is possibly still appropriate within a

⁶ P. Craig, *The Nature of the Community*, in *The Evolution of EU Law*, P Craig & G. deBurca (Eds.), at p41

⁷ O. Gerstenberg, *Laws Polyarchy: A Comment on Cohen and Sabel*, *European Law Journal*, Vol. 3, No. 4, December 1997, p343, at 354

⁸ See ideas on the ‘regulatory state’

national regulatory system, the Community must use other mechanisms to ensure responsiveness.

If responsiveness were our only concern we could leave regulatory decision-making to the Member States and subject them to little Community regulatory control. Their regulatory decision-makers are likely to be far more responsive than any regulator could be when producing regulations at the European level. However, as well as being responsive, regulatory decision-makers must also be deliberative. Joerges and Neyer argue that bringing national regulators together at the European level to produce harmonised regulatory standards causes them to reason with each other in a deliberative manner as to what regulatory solution is best for the Community as a whole. They are 'civilised' by their exposure to 'transnational arenas scrutinising the validity of their arguments.'⁹

THE ROLE OF THE ECJ IN PROMOTING DEMOCRATIC LEGITIMACY

The ECJ has a 'process-perfecting function'¹⁰ when it reviews the decisions of national and Community regulatory institutions. In developing its jurisprudence, it has the potential to ensure that regulatory institutions, at both national and European levels, are both responsive to the public and deliberative, in the sense described above.

When the ECJ examines national or European regulations for their compatibility with European law it must decide upon its intensity of review. It tends to subject European regulations to a less rigorous standard of review than national regulations.¹¹ European regulations are subject to an 'administrative law' style of review, whereas national regulations are subject to a far more stringent 'constitutional' style of review. It is appropriate that the ECJ operates this dual standard of review because national and European regulations have differing impacts. If a European regulation is inappropriate, whatever other detrimental effects it has, it will not lead to market fragmentation. Whenever a Member State unilaterally adopts a regulatory measure, even if compliant with European law (i.e. it is pursuant to one of its residual powers under the EC Treaty) it will hinder the free movement of goods. Therefore, beyond the 'administrative law' aim of promoting well reasoned, rational and proportionate decision-making, in the case of the ECJ's control of national regulations there is also an underlying 'constitutional' agenda to create and maintain an integrated European market.

Both national and European regulators operate in the knowledge that their work may well be subject to the ECJ's judicial scrutiny. National regulators know that this will take the form of a 'constitutional' type of review by the ECJ. Whereas, European regulators know that they are subject to a possible 'administrative law' type of review. Each operates in the shadow of this potential judicial review. To ensure that their regulations are review-proof, both procedurally and substantively, they must be continually aware of, and work within the confines of, this jurisprudential shadow. Consequently, the ECJ plays a pivotal role in proceduralising, guiding and structuring the process of regulatory production at both national and European levels. In developing their jurisprudence they should have an eye to promoting deliberative

⁹ Joerges & Neyer p293-298

¹⁰ O. Gerstenberg, *Laws Polyarchy: A Comment on Cohen and Sabel*, European Law Journal, Vol. 3, No. 4, December 1997, p343, at 357

¹¹ Compare for example *R. v. Minister for Agriculture, Fisheries and Food ex parte Fedesa* (case C-331/88, (1990) ECR 4023, para. 14), in which the ECJ applied a deferential 'manifestly inappropriate' test to examine whether a Council Directive was proportional, with *Wachauf v. Germany* (Case 5/88, (1989) ECR 2609).

and responsive regulatory decision-makers, with the aim of improving the Community's legitimacy. Below I fill out the jurisprudential shadow by sketching a number of principles, which might be used to achieve this end.

THE JURISPRUDENCIAL SHADOW

Appropriate Consultation

To some extent the ECJ has developed a doctrine of 'a legitimate expectation of consultation'. This means that whenever an individual or organisation is individually and directly affected by a regulation, they have certain rights to be heard in the decision-making process. A regulation is procedurally faulty if the regulatory institution responsible fails to accord them these rights.

NGOs or other interest groups, which are not directly affected by a regulation, but which nevertheless claim to represent particular groups or interests that are directly affected, might be accorded certain consultation rights by the ECJ. These groups have the potential to organise public deliberation as well as transmit the results into (and influence the deliberation within) regulatory institutions. However, the ECJ must also be aware that such groups may be unrepresentative of broader public interests. Forcing regulatory institutions to be responsive to unrepresentative groups is not the same thing as the responsiveness that this paper is about. Weiler draws an analogy with the neo-corporatism that operates within nation states, in which governments, industry and labour come together to strive for some kind of accommodation of each other's positions.¹² The common factor is the side-stepping of the normal political processes in favour of input from selected organised interests, to the exclusion of broader affected interests. Technocratic solutions are favoured and ideology and politics are distrusted. Representational monopolies are encouraged, and there is a lack of transparency or procedural guarantees. If the ECJ did seek to use NGOs and other interest groups as a means of promoting responsiveness all of these problems must be considered and avoided.

Whenever regulatory decisions raises controversial issues, Everson suggests the ECJ should review the Community's regulatory institutions according to two criteria: Firstly, the 'quality' and 'relevance' of the regulatory knowledge and considerations they assess. Secondly, the respect they show to wider social and ethical values. She argues that the ECJ should consider whether the regulatory institution is able to demonstrate that they adopted a universal rather than a particularist approach.

Transparency

The ECJ has used Article 253 (which requires that Community measures are accompanied by a statement of reasons) to impose a duty on the Community's regulatory institutions to disclose their reasoning, in a clear and unequivocal fashion, in such a way as to make the persons affected by those regulations aware of the reasons for them and to enable them to defend their rights.¹³ The ECJ points out that a statement of reasoning allows it to exercise its duty of review. Thereby, the ECJ demonstrates that it is concerned with the quality of the discussions taking place in the regulatory institution and with the relevance of the regulatory knowledge they use.

¹² J. Weiler, U. Haltern, & F. Mayer, *European Democracy and its Critique*, in J. Hayward (ed.), *The Crisis of Representation in the European Union*, p32

¹³ Case 205/85 *Nicolet Instrument v. Hauptzollamt Frankfurt am Main-Flughafen* [1986] ECR 2049

The ECJ might also require regulatory decision-makers to publish, as a matter of course: their reasoning; the scientific-technical criteria behind their decisions; and all the views they considered (including those rejected).

Rationality

Regulatory decision-making occurs across a Community of 15 Member States, each with its own regulatory concerns and traditions. This opens up more issues and assumptions to challenge and means that conflicts have to be settled by reaching explicit agreement on a wider range of contestable matters. The ECJ's jurisprudence helps to solve co-ordination problems that arise under these conditions and thereby promotes deliberative regulatory problem-solving. In effect, a requirement of rationality, as defined by the ECJ's jurisprudence, functions a filter to the regulatory discourse. Regulators are aware that should any of their decisions fall to be reviewed by the ECJ, the rational-objective reasons for them will be the ones they will have to use in defending their decision. Therefore, the procedural arrangements and the substantive rules that govern the permissibility of health and environmental regulations function to circumscribe the legitimate modes and objectives of regulatory policy. In effect, the ECJ's jurisprudence channels deliberation within a particular set of norms and objectives, which are not up for grabs, but which constitute the very rules of the game itself. Given that conflict resolution is easier the more deliberation is restricted to a limited number of problematic validity claims, the ECJ, in acting as gate-keepers to the regulatory discussion, creates an arena in which agreement is easier to achieve through the discourse principle, rather than strategic bargaining.

The ECJ checks that all relevant technical and scientific data has been evaluated. It also asks whether a regulation fit into a coherent whole. In other words, does it display an internal consistency with other regulations, which are used in the same or related areas. If not, this might be taken as *prima facie* evidence that it is arbitrary, irrational, or discriminatory.

The obligation to give reasons should counter-act the tendency of regulatory institutions to disguise political issues as purely technical-scientific ones.

Scientific rationality

When the Community uses its power under Article 95(1) to harmonise national health and environmental measures it must take into account 'any new development based on scientific facts.'¹⁴ Likewise, when it produces regulations under Article 175(1) it must take 'account of available scientific and technical data'.¹⁵ Taking its trend from the EC Treaty, the ECJ centres its review (both constitutional and administrative) on the need to give objective reasons and more particularly a requirement of scientific justification. A national regulation that prohibits a product, which is authorised in the Member State in which it is produced, is not permitted if, taking into account the habits or conditions prevailing in the importing Member State, it is not considered harmful by international scientific research and in particular the findings of any relevant Community or United Nations scientific committee.¹⁶ At the same time the ECJ has ruled that, whilst Member States must respect the findings of these scientific committees this

¹⁴ Article 95(3) EC Treaty; the reference to 'scientific facts' was introduced by the Amsterdam Treaty.

¹⁵ Article 174(3) EC Treaty

¹⁶ Case 178/1984 *Reinheitsgebot* [1987] ECR 1227, paragraph 44

does not mean that they must automatically follow their advice to the letter,¹⁷ particularly when there is some scientific uncertainty.¹⁸ But, in all cases, a Member State must take account of the scientific findings of these bodies and the onus is on them ‘to show in each case, in the light of national [conditions and] habits and with due regard to the results of international research, that the rules are necessary to give effective protection’.¹⁹

The Precautionary Principle

In the *BSE* case,²⁰ the ECJ developed a theory of the precautionary principle to be applied when it reviews regulatory decisions taken under conditions of scientific uncertainty. In effect, it created a weighted proportionality test, which involves two steps. Firstly, the precautionary principle must be triggered by the existence of a threshold level of scientific evidence, which the Advocate General described as ‘a real risk..., which ... no-one has been able to rule out’.²¹ The degree of scientific evidence required to pass the threshold test must vary according to the nature of the risk and the potential magnitude of damage – a mere suspicion of catastrophic consequences might be enough, whereas more concrete evidence of less significant consequences might not. Secondly, once the threshold test is made out; the ECJ asks whether or not the regulation was ‘manifestly inappropriate’.²² A scientifically uncertain risk functions to de-intensify the ECJ’s normal standard or review and in so going defends regulatory discretion from the encroachment of strong scientific justification requirements. It thereby enlarges the margin of discretion available to the regulatory institution, who can use this to respond more sensitively to public concerns in the way they handle scientific knowledge. The ECJ appears in this way to promote responsiveness, or at least the capacity of the regulatory institution to be responsive if they so desire.

Composition

In *Angelopharm*²³ the ECJ made it clear that, whilst experts need not have the final say, their testimony must be heard. In this case neither the committee in question, nor the Commission, was in a position to draft or adopt regulatory measures without first assessing the scientific and technical evidence. If experts are to be consulted on a complex technical matter, the regulatory institution using them must ensure that they are appropriately chosen.²⁴ The ECJ might also review the independence and objectivity of the experts that are appointed by a regulatory institution.

Competence

The ECJ might promote responsiveness by rigorously enforcing the *Meroni* doctrine. This doctrine limits the powers of non-majoritarian regulatory institutions to specific, well-defined, technical tasks such as the evaluation of technical and scientific information - preventing them

¹⁷ See also Case 272/80 *Biologische Produkten* [1981] ECR 3277 at 3292 and Case 2047/84 *Leon Motte* [1985] 3887 at 3904.

¹⁸ Case 174/1982 *Sandoz BV* [1983] ECR 2445, paragraphs 10, 16, and 17

¹⁹ Case 304/1984 *Claude Muller* [1986] ECR 1511, paragraph 26

²⁰ Case C-157/1996 *The Queen v Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union* 1998 ECR I-2211

²¹ Opinion of the Advocate General Tesauro in Case C-180/96 and C-157/96, paragraph 22

²² Case C-27/95 *Woodspring District Council*, (1997) ECR I-1847, paragraphs 37 and 38

²³ [1993] ECR I-171

²⁴ Case C-269/1990 *Technische Universität München v. Hauptzollamt München-Mitte* [1991] ECR I-5469, see also the Advocate General’s opinion

from usurping powers, which are more appropriately exercised by democratically accountable institutions.

Standing

Whether or not certain groups have sufficient standing to challenge a regulatory decision may well affect the responsiveness of a regulatory institution. If that institution is confident that no individual or group (with sufficient financial etc. means) will have standing to bring a case to challenge its decision, it need not worry about any of the other principles of review described above. A more liberal standing rule, especially one that sought to bring NGOs into the judicial review process, might prevent this from happening.

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