Risk versus Hazard before the EU Courts – A Comment*

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Introduction

Professor Lofstedt presents a convincing illustration of the inconsistencies inherent in a European system of regulation where Member States choose whether to regulate based on assessments of risks or hazards depending on the product concerned. Particularly striking is the candid comment of a Swedish official who seems to marvel at the conflicting positions of his own government. The quote reminds this author of an official in the Swedish Ministry of Environment who in an interview stated that the application of regulation would be widely different if the precautionary principle as included in the Swedish Environmental Code or the precautionary principle as included in the Swedish Planning Code were to be employed.[1] For a lawyer – or anyone else with an interest in the rule of law – such inconsistencies pose serious problems with regard to legal certainty. Unfortunately, those who could reasonably be expected to be most concerned with issues relating to the rule of law – national and European courts – have thus far proven reluctant to second-guess, or even criticise, decisions in the area of risk regulation. In this brief comment a few cases are discussed in order to illustrate the problem posed by the issue before the EU courts. Finally, a few modest suggestions for improvements are sketched.

The limited review doctrine

Most legal systems recognise that there are limits to what can be reviewed by the courts. Generally it is considered appropriate that policy decisions are not subjected to substantive judicial review, in order to safeguard appropriate room for manoeuvre for democratically elected governments.[2] With regard to acts issued by the EU institutions, the EU Courts' scope of review is confined to the Treaty on the Functioning of the European Union (TFEU) and legislation and decisions issued on its basis. However, the depth of review employed by the EU Courts is not defined in EU legislation. Instead, the EU Courts themselves have developed a doctrine of sorts to enable them to steer clear of issues where they otherwise would risk interfering with political decisions. In the area of risk regulation, this doctrine stems from the *Fedesa*-judgment, in which the Court of Justice stated that where discretionary powers have been delegated to the EU institutions, the judicial review of the Court of Justice is limited to examining if the decision in question was vitiated by a manifest error or misuse of powers, or whether the authority in question has manifestly exceeded the limits of its discretion.[3] Since *Fedesa*, the court has upheld its reasoning in the majority of its case law.[4] However, as is shown in the following section, some interesting exceptions from this general rule exist.

The reluctance of the EU Courts to delve into the detailed assessment of often complicated technical and scientific assessments is understandable as the Courts do not possess the expert knowledge or resources that it has to be assumed has been employed by the EU institutions when drafting a legislative act or decision.[5] The limited review doctrine thus effectively precludes any assessment by the Courts concerning the substance of decisions taken by the EU institutions, and favours a formal assessment. In principle, such a system could adequately protect the

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1 J. Zander, *The Application of the Precautionary Principle in Practice: Comparative Dimensions* (Cambridge: Cambridge University Press 2010), p. 26.

2 See, for example, C. Forsyth (ed.), *Judicial Review and the Constitution* (Oxford and Portland, Oregon: Hart Publishing 2007).

3 Case 331/88 *Fedesa* [1990] ECR I-4023, para. 8.

4 See, for example, Case 341/95 *Gianni Bettati v. Safety Hi-Tech* [1998] ECR I- 4335; Case 180/96 *United Kingdom v. Commission* [1998] ECR I-2265; Case T-13/99 *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-3305; Case C-77/09 *Gowan Comércio Internacional e Serviços v. Ministero della Salute*, judgment of 22 December 2010 (not yet reported).

5 N. de Sadeleer, "The Precautionary Principle in European Community Health and Environmental Law: Sword or Shield for the Nordic Countries?", in N. de Sadeleer (ed.), *Implementing the Precautionary Principle – Approaches from the Nordic Countries, EU and USA* (London: Earthscan 2007), pp. 10–58.

rights of affected parties, provided that a procedural framework against which decisions can be tested existed.[6] In the EU, the embryo of such a system is discernable in the Communication on the Precautionary Principle, where the European Commission fleshed out the considerations that should form the basis for regulatory decisions under scientific uncertainty.[7] However, the Communication is vague and non-binding, and the Courts have so far not been inclined to give it real teeth by expanding on it beyond fleeting references in cases before them. The result of the above can be seen in cases like *Pfizer*[8] and, more recently, in *Gowan*[9], where the EU institutions have been offered virtually boundless discretion not only to set the desired level of protection but also to decide on what is required for that level to be met. By granting the EU institutions such a wide margin of discretion, affected parties are effectively prevented from having access to any meaningful redress before the EU courts. Furthermore, and which is discussed in more detail next, it becomes near impossible to identify and predict what level of risk is considered acceptable by the EU institutions.

Three significant cases before the EU Courts

As was implied in Professor Lofstedt's article, major legislative acts in the EU, such as REACH and the General Food Law, generally focus on the assessment and management of risk. Hazard assessment is generally understood as a constituent part of risk assessment, but is not in itself sufficient to trigger regulation.[10] That a substance has hazardous properties should thus generally be considered together with issues concerning the exposure and character of the risk in order to determine the level of risk associated with a product. Furthermore, the Communication on the Precautionary Principle states that an assessment of costs and benefits should be performed before regulatory measures are issued.[11] Thus, from the outset, the EU institutions, at least on paper, seem to be of the opinion that risk rather than hazard should form the basis for regulation.

The EU Courts have echoed the sentiments outlined above in general terms and have consistently stated that measures taken under scientific uncertainty may not be based on "purely hypothetical considerations"[12] and must be "backed up with scientific data".[13] However, as the Courts restrict their depth of review, in practice they struggle to meet these objectives. For example, in *Pfizer*, which concerned a decision by the Council to ban the growth promoter Virginiamycin, the General Court did not go into detail in examining the relevant risk assessments against the criteria in the Communication on the Precautionary Principle.[14] Neither did it consider the costs or benefits involved in regulating the product. Instead it merely considered that the European Council had based its decision on "scientifically reliable and cogent information" and that it had "understood the ramification of the scientific question raised."[15] Considering that the ban was based on a request by Denmark, which had been described by the relevant EU scientific committee as "misleading", "made on the basis of a single unsubstantiated statement", "unsound and without foundation" and "contains no evidence that existing therapies are likely to be compromised", the threshold for regulation in the case is remarkably low. Consequently, considering the severe criticism levelled against the Danish study, the possibility for Pfizer to successfully challenge the ban was in essence non-existent.[16]

6 In part it could be argued that this could be achieved by employing a version of the "hard look" doctrine employed by US courts, see S. Jasanoff, *Science at the Bar* (Cambridge, Massachusetts: Harvard University Press 1990).

7 Communication on the Precautionary Principle, COM 2000/1.

8 Case T-13/99, *supra* note 4.

9 Case C-77/09, *supra* note 4.

10 Communication on the Precautionary Principle, *supra* note 7, pp. 13–14.

11 *Ibid.*, pp. 19–20

12 See, for example, Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, para. 106 and Case T-13/99, *supra* note 4, para. 143.

13 Case T-13/99, *supra* note 4, para. 144.

14 Although the Communication had not been adopted at the time of the Decision in question, the aim of the Communication was partly to summarise existing practice. Thus, it would have been possible for the General Court to more firmly endorse the criteria elaborated on there.

15 Case T-13/99, *supra* note 4, para. 162.

16 For a critical discussion of the *Pfizer* judgment, see K.-H. Ladeur, "The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental Law? Decision-making Under Conditions of Complexity in Multi-Level Political Systems", 40(6) *CMLR* (2003), p. 1455; see also G. E. Marchant and K. L. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Union Courts* (Washington: American Enterprise Institute Press 2004).

In *Sweden v. Commission*, Sweden challenged a decision of the European Commission to authorise the pesticide paraquat before the General Court.[17] Sweden argued that considering the hazardous nature of paraquat, the European Commission had not adhered to the precautionary principle when it allowed it to be placed on the market. In a surprising break with previous case law, the General Court did not refer to its limited review, but instead made a detailed assessment of the scientific evidence underlying the decision.[18] When performing this review, it made different assessments of a number of scientific studies that had previously been assessed by the relevant scientific committee. For example, it placed weight on a scientific study that had been dismissed by the scientific committee because the test subjects had not adhered to the relevant safety provisions.[19] Having performed this review, the Court declared that the scientific assessments by the relevant scientific committee, the rapporteur Member State and the European Commission were all flawed. In summary it seems that the well-documented toxic properties of paraquat were considered to be more important to the General Court than the risk the substance would pose under normal use. Thus, it would appear that the General Court was more concerned with the intrinsic hazard posed by the pesticide than its actual risk. By overturning the decision of the European Commission on such grounds, the General Court carried out precisely the type of substantive review that the European Courts have declared to lie outside its discretion in previous consistent case law.[20]

In the more recent *Gowan*-judgment, the Court of Justice once again employed a deferential review of a measure adopted by the European institutions to allow the use of the pesticide fenarimol only under strict conditions.[21] The case followed the adoption of a Directive by the European Commission which approved the marketing of fenarimol only under very limited conditions.[22] As a basis for its decision, the Commission argued that remaining uncertainty concerning the risk for endocrine disruption warranted a precautionary approach to fenarimol. The complainant, Gowan, argued before an Italian court that the Directive breached the principle of legal certainty, as well as constituted a misapplication of the precautionary principle. The Italian court referred the matter to the Court of Justice. In its judgment, the Court of Justice recognised that a risk assessment had been performed by the relevant scientific committee, and that the conclusion had been that fenarimol posed little risk under normal use and should be included in Annex I under Directive 91/414/EC. This would enable the product to be placed on the market. However, following the completion of the assessment of the scientific committee, a number of Member States raised concerns with regard to the potential for endocrine disruption in fenarimol, which prompted the European Commission to establish that the conditions for use should be restricted. Gowan argued before the courts that it had accounted for all studies relating to endocrine disruption and that the scientific committee had considered these when issuing its positive opinion. By ignoring this, and without proposing any new studies in support of a link between fenarimol and endocrine disruption, Gowan argued that the Commission had adopted a Directive which was unfounded scientifically, and which was based on a perception of hazard rather than the establishment of an unacceptable risk to the environment.[23]

In its judgment, the Court of Justice proved unmoved by the arguments of Gowan and stated that the Commission had previously raised the issue of endocrine disruption. Therefore it stated that the Directive could not be considered to be based on "purely hypothetical considerations".[24] However, the judgment makes no mention of any specific evidence or report that the Commission would have been relying on when preparing its proposal and nothing indicates that it would have been in possession of any indication of endocrine disruption that had not previously been considered by the scientific committee. Thus the Court of Justice in *Gowan* did not distinguish between issues of hazard and risk, and set a very low threshold for regulation in cases of scientific uncertainty.[25]

17 Case T-229/04 *Sweden v. Commission* [2007] ECR II-2437.

18 *Ibid.*, paras. 108–110 and 174–190.

19 *Ibid.*, paras. 180–185.

20 For a more detailed discussion of the case, see J. Zander, *The Application of the Precautionary Principle in Practice*, *supra* note 1, pp. 114–115.

21 Case C-77/09, *supra* note 4.

22 Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as an active substance (OJ 2003 L 349, p. 32).

23 Case C-77/09, *supra* note 4, para. 46.

24 *Ibid.*, paras. 77–78.

25 For a brief discussion of the judgment, echoing some of the same sentiments discussed here, see the blog entry of Dr. Alberto Alemanno, dated 28 December 2010, available on the Internet at <http://www.albertoalemanno.eu/articles/43875> (last accessed on 31 March 2011).

Conclusion and recommendations

Deciding on the desired level of protection from risks is an eminently political decision and should rightly be exempt from review by the courts. However, the reluctance of the EU Courts to substantively review detailed scientific assessments by the other EU institutions, although understandable, creates serious problems with foreseeability and effective redress for affected parties. The fact that the limited review doctrine is not always upheld in practice further confuses the issue. In order to remedy the existing situation, the Courts need to renew their focus toward ensuring a more consistent approach to risk regulation.

First, the Courts should make clear that the establishment of a scientifically ascertainable risk is a necessary starting point for regulation. Obviously, under scientific uncertainty, conclusive evidence of risk cannot be required, but a threshold finding of probability can. A challenging party should not have "to show conclusively" the non-existence of the risk, as the Courts held in *Pfizer* and, implicitly, in *Gowan*. Such an exceedingly high level of proof is near-impossible to meet, especially in instances of deep scientific uncertainty. Instead it should suffice that the challenging party shows that the risk is not probable. For example, if a relevant EU scientific committee has performed a rigorous risk assessment and come to the conclusion that a product does not pose a significant risk, the EU institutions should be required to produce at least some new evidence that has not been addressed during the comitology procedure in order to deviate from the assessment.

Second, the Courts should require that the regulator has considered other rational criteria when deciding on regulation. This should include an assessment of costs and benefits, as outlined in the Communication on the Precautionary Principle, and, importantly, an assessment of the risk tradeoffs involved.[26] Only if the total impact of a regulatory measure has been assessed can it be ascertained if the measure will have the effect that the desired level of protection is met. A move of the Courts in this direction would increase the judicial safeguards for parties affected by regulatory decisions, while at the same time improving the quality of risk regulation in the EU.

26 J.D. Graham and J. Wiener, *Risk versus Risk: Tradeoffs in Protecting Health and the Environment* (Cambridge, Massachusetts: Harvard University Press 1995); see also R. Lofstedt, "Risk versus Hazard – How to Regulate in the 21st Century", in this volume.