

The Precautionary Principle Applied to Food Safety – Lessons from EC Courts

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ABSTRACT

Known in the early 1990s by a few specialists in environmental law, the precautionary principle has within a decade established itself as a new general principle of Community law. In particular, Community case law has not only managed to extend the scope of application of the precautionary principle to all policies involving scientific uncertainty, but has also introduced extremely useful clarifications of the conditions under which the precautionary principle can be applied, in particular in the domains of public health and food safety.

RÉSUMÉ

Alors qu'il n'était connu au début des années 1990 que par quelques experts du droit de l'environnement, le principe de précaution s'est imposé en l'espace d'une décennie comme un nouveau principe général de droit communautaire. La jurisprudence des juridictions communautaires a contribué à l'émergence de ce principe en étendant notamment le champ d'application de la précaution à toute politique publique sujette à l'incertitude. En outre, la jurisprudence a énoncé un certain nombre de conditions pour appliquer ledit principe, notamment en matière de santé publique et de sécurité alimentaire.

I. INTRODUCTION

So far, the precautionary principle has only been proclaimed in EU primary law with other environmental law principles in paragraph 2 of Article 174 EC, a provision obliging institutions to base their environmental policies on various principles. As a result, the principle is not embedded within the health EC policy. None-

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theless, the development of the principle appears more advanced in the field of public health than in that of environment².

Praised by some, disparaged by others, the principle is no stranger to controversies. Whereas the academics have long clashed over the legal status of the principle, EC case law has not only managed to extend the scope of application of the precautionary principle to all policies involving scientific uncertainty, but has also introduced extremely useful clarifications on the application of the principle, in particular in the domain of public health. It is not the purpose of this paper to outline, even in broad terms, the irresistible rise of the precautionary principle and to summarise the controversies swirling around this process³. It will chiefly focus on recent Court of First Instance (CFI)⁴ and European Court of justice (ECJ)⁵ judgments dealing with health protection issues, which have clarified both the status of the principle and its manner of application.

II. LEGAL STATUS OF THE PRINCIPLE ACCORDING TO THE CASE LAW

The jurisprudential definition of the precautionary principle runs as follows :

² See in particular the Regulation (EC) n° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety, [2002] OJ L 31/1 [EC Regulation on food law], which enshrines the precautionary principle in relation to its application in food law.

³ For the genesis and impact of this principle on the Community legal order, see, among others, N. DE SADELEER, *Environmental Principles*, Oxford : Oxford University Press, 2002, 433 pp.; N. DE SADELEER, "The Precautionary Principle in EC Health and Environmental Law", [2006] *European Law Journal*, vol. 12 pp. 139-172.

⁴ Particular attention shall be paid to the judgments handed down on September 11th 2002 in the cases T-70/99, *Alpharma v. Council*, [2002] ECR II-3495; and T-13/99, *Pfizer Animal Health v. Council*, [2002] ECR II-3305, as well as the judgment of 26th November 2002 in the joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artego-dan GmbH and Others v. Commission*, [2002] ECR II-4945. These cases have one point in common : each of them involved a challenge to the decision of a Community institution to withdraw medicines and food additives in the name of protection of health.

⁵ As to judgments handed down by the ECJ, it is in this context important to mention *Monsanto Agricoltura Italia* ruled on 9th of September 2003 (Case C-236/01, [2003] ECR I-8105) and *Commission v. Denmark* (Case C-192/01, [2003] ECR I-9693). Those cases related to the qualification of a novel food and the prohibition of use of certain food additives.

“where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.”⁶

The field of health protection was immediately able to put the precautionary principle on a firm footing : on the one hand the objectives of environmental policy also embrace those of the protection of health [Article 174(1) EC] whilst, on the other hand, all policies and actions undertaken by the European Community should ensure an increased level of protection of human health (Article 152 EC). On the basis of these premises, the European Court of Justice extended, initially implicitly⁷ and then subsequently explicitly⁸, the precautionary principle to the domain of public health⁹.

As to the broad scope of the principle, further guidance has been provided by the CFI. In the case *Artgodan*, the CFI confirmed that the precautionary principle’s scope of application went wider than environmental policy insofar as it is intended to apply in all areas of Community action, with a view to ensuring an increased level of protection of health, the environment and consumer safety. According to the CFI, the extension of its field of application is justified by the requirement to pursue an increased level of consumer (Article 153 EC), environmental [Article 174(2) EC] and health (Article 3, b, EC) protection, as well as by the different integration clauses which the EC Treaty contains in the areas of environmental (Article 6 EC) and health [Article 152(1) EC] protection¹⁰.

Due to its highly abstract nature and particularly broad scope of application, the precautionary principle could then be defined “as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giv-

⁶ Case C-157/96, *National Farmers’ Union and Others*, [1998] ECR I-2211, §63; Case C-180/96, *United Kingdom v. Commission*, [1998] ECR I-2265, §99; and Case C-236/01, *Monsanto Agricoltura Italia*, §111. See also Case T-13/99, *Pfizer*, §139.

⁷ Case C-331/88, *Fedesa*, [1990] ECR I-4023, §9; Case C-180/96 R, *United Kingdom v. Commission* [1996] ECR I-3903, §93; Case T-76/96 R, *National Farmers’ Union (NFU)*, [1996] ECR II-815, §88. Though the principle is nowhere explicitly mentioned, these judgments are thoroughly infused with the language of precaution.

⁸ Case C-352/98 P, *Bergaderm*, [2000] ECR I-5291, §53.

⁹ This view is shared by the EC institutions [Commission on the Precautionary Principle, COM(2000) 1, §10; European Council Resolution on the Precautionary Principle, annex III to the presidency conclusions, Nice, 7-9 December 2000, 1].

¹⁰ Joined Cases T-74/00, *Artgodan*, *op. cit.*, §183.

ing precedence to the requirements related to the protection of those interests over economic interests”¹¹. Furthermore, the CFI laid particular emphasis upon the autonomous nature of the principle :

“Since the Community institutions are responsible, in all their spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an *autonomous principle* stemming from the above mentioned Treaty provisions.”¹²

Accordingly, the emphasis upon autonomy enhances the independent nature of that principle.

Whereas the ECJ has so far been more careful to speculate about the nature of that principle, the CFI has thus enshrined explicitly a new general principle of EC Law. Its establishment as such thus opened up the possibility of the application of the principle in areas where EC Law did not expressly provide for it.

III. PRECAUTIONARY PRINCIPLE AND RISK ANALYSIS

It should be stressed at the outset that the precautionary principle is located within the broader context of the principle of risk analysis, which comprises a two-step process : risk assessment and risk management.

First, the probability of the occurrence of harm is determined using a *risk assessment* procedure, in which experts examine both hazard and exposure in order to calculate an acceptable or tolerable level of contamination or exposure.

However, the risk is not just then a question for experts. It takes on a distinct individual meaning once situated within its political, social and economic context. Accordingly, when the risk assessment procedure is completed, a *risk management* decision must be taken by politicians, taking into account both legislative requirements and economic, political and normative dimensions of the problem. Risk management, in contrast to risk assessment, is the public process of deciding how safe is safe.

The first two stages are essential as they aim on the one hand to ensure as rigorous as possible a scientific basis for managing the risk (risk assessment) and, on the other hand to recognise a margin of autonomy for the body authorised *in fine* to

¹¹ Joined Cases T-74/00, *Artegodan, op. cit.*, § 184.

¹² *Ibid.*

make a decision on the risk (risk management)¹³. The distinction between the phases of assessment and management thus meets a dual requirement : on the one hand the need to base a political decision on scientific facts and on the other hand the need to maintain the autonomy of politics *vis-à-vis* the results of scientific assessments¹⁴.

Whilst the precautionary principle does require that decision makers adopt a risk-averse stance, must it accordingly oblige them to adopt preventive measures whenever a risk is suspected? The CFI's reply to this is that "a preventative measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified"¹⁵. There must exist a threshold of scientific plausibility. Put it simply, basic scientific knowledge is therefore necessary. In this way the CFI excluded from the scope of application of the principle such risks qualified as residual, that is speculative risks founded upon purely speculative factors and without a basis in science¹⁶. The result, according to the court, was that "the precautionary principle can therefore only apply in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated"¹⁷.

As to the assessment of suspected risks, the CFI highlighted two fold tasks whose components are complementary¹⁸ : (i) determining what level of risk is deemed to be unacceptable; (ii) conducting a scientific assessment of the risk.

As to the first obligation aforementioned, the determination of a level of risk which would be unacceptable from the perspective of the protection of human health

¹³ In this respect, the EC Regulation on food law distinguishes between assessment which "*shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner*" (Article 6.2) and management which must bear in mind the risk evaluation, "*other factors legitimate to the matter under consideration*" and the precautionary principle (Article 6.3).

¹⁴ Opinion of the Advocate General M. Jean Mischo, delivered 12 December 2002, in the case C-192/01, *Commission v. Denmark*, *op. cit.*, §92.

¹⁵ Case T-13/99, *Pfizer*, *op. cit.*, §143; see also Case C-236/01, *Monsanto Agricoltura*, *op. cit.*, §106; Case C-192/01, *Commission v. Denmark*, *op. cit.*, §49; Case E-3/00, *EFTA Surveillance Authority v. Norway*, §36-38.

¹⁶ Case T-392/02, *Solvay Pharmaceuticals v. Council*, [2003] ECR II-4555, §129; T-229/04, *Sweden v. Commission*, [2007] ECR II-2437, §161.

¹⁷ Case T-13/99, *Pfizer*, *op. cit.*, §146.

¹⁸ *Ibid.*, §149.

depends on the competent public authority's understanding of the specific circumstances of each particular case. In this respect, the CFI in fact considers that :

“it is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then [...] determine the level of the risk – *i.e.* the critical probability threshold for averse effects on human health and for the seriousness of those effects – which in their judgement is no longer acceptable for society [...]”¹⁹

Indeed, experts cannot assess risks without taking out the legal requirements as to the safety levels, which should serve as a yardstick against which the assessments should be carried out. The level of protection has to be determined on a case by case basis.

IV. RISK ASSESSMENT : A PREREQUISITE TO APPLY THE PRINCIPLE

A methodology is of course necessary in order to take risk seriously. In this case the verification of the serious nature of a hypothesis should be undertaken using a specific technique which is recognised as a means of risk assessment. As regards this obligation, the EC courts clearly stress the need to perform risk assessments while coping with uncertainties²⁰. Besides, the competent public authority should entrust this task to scientific experts²¹ who, on completion of the scientific process, provide it with scientific advice²², which, in the interest both of consumers and industry, should be based on “the principles of excellence, independence and transparency”²³.

¹⁹ Case T-13/99, *Pfizer*, *op. cit.*, §151. On this point see the judgement of 11 July 2000, *Kemikalieinspektionen*, C-473/98, [2000] ECR I-5681, §45.

²⁰ Case C-236/01, *Monsanto Agricoltura Italia*, *op. cit.*, §113-114; Case C-192/01, *Commission c. Denmark*, *op. cit.*, §47; Case T-13/99 *Pfizer*, *op. cit.*, §155-156.

²¹ Indeed, the institutions are not empowered to entrust a purely advisory body with the duty to perform the risk assessment. *E.g.* Case T-13/99, *Pfizer*, *op. cit.*, §289.

²² The European Court of Justice's decision in *Monsanto* requires that the identification of a health risk posed by a novel food should normally be carried out by “specialized scientific bodies” charged with assessing the risks inherent in novel food (Case C-236/01, *Monsanto*, *op. cit.*, §78-79 and 84). See also Case T-13/99, *Pfizer*, *op. cit.*, §157.

²³ Case T-13/99, *Pfizer*, §159. Those principles were applied to SCAN (Scientific Committee for Animal Nutrition) (§209) and to the Standing Committee which was not considered by the CFI as an independent scientific body in the light of the principle of transparency (§287).

A. Incomplete, insufficient or inconclusive risk assessment studies trigger the adoption of precautionary measures

The European Courts' reasoning stands on a two-step approach. First, a risk assessment has to be carried out with the aim of reducing the uncertainty. Nonetheless, as hinted as above, it may be impossible to carry out a full risk assessment because of the insufficiency of scientific data. Indeed, scientists do not necessarily have an answer to everything. Their investigations do not always allow for an identification of the risks in a convincing manner. Indeed, in many cases, the assessment of those factors will demonstrate that there is a high degree of scientific and practical uncertainty in that regard²⁴. In particular, in fields marked by uncertainty they must even point to the limits of their knowledge or, where appropriate, to their ignorance. It is precisely at this stage that the precautionary principle comes into play.

Rather than rendering the principle nugatory, courts consider the need to take preventive measures with a view to protecting the environment and human health despite the uncertainties.

In the landmark case *National Farmers' Union*, the ECJ stressed that :

“Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait the reality and seriousness of those risks become fully apparent”²⁵.

In subsequent cases, the ECJ as well as the CFI alike stressed that “where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the *insufficiency, inconclusiveness* or *imprecision* of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures”²⁶. It follows that a risk management measure could be decided despite the fact that the risk assessors were unable to determine the probability of the

²⁴ Case C-192/01, *Commission v. Denmark*, *op. cit.*, §51.

²⁵ Case C-180/96 R, *United Kingdom v. Commission*, *op. cit.*, §93.

²⁶ Case C-192/01, *Commission v. Denmark*, *op. cit.*, §52; see also Case E-3/00 *EFTA v. Norway*, *op. cit.*, §31. Endorsing the same line of reasoning, the CFI considered in *Alpharma and Pfizer* that “*the impossibility of carry[ing] out a full scientific risk assessment does not prevent the competent public authority from taking preventative measures, at very short notice if necessary, where such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society*” (Case T-13/99, *Pfizer*, *op. cit.*, §393).

occurrence of the risk²⁷. However, it is not entirely clear what the Courts meant while referring to insufficiency, inconclusiveness and imprecision. The factors triggering precautionary action are still open to debate²⁸.

Nevertheless, precaution is in no sense anti-scientific, as *Pfizer* and *Alpharma* must be interpreted as obliging the drafters of a precautionary measure to investigate as thoroughly as possible and with an appropriate methodology those risks with which they are confronted. According to the CFI the public authority, although the risk assessment is incomplete, should be in possession of “*sufficiently reliable and cogent information* to allow it to understand the ramifications of the scientific question raised”²⁹. In such a case, and “(n)otwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society.”³⁰

As a matter of course, the courts offer no guidance on what should be the “most reliable scientific evidence available” or the “cogent information”. However, some lessons can be drawn from the case law. The following requirements have to be met :

- the risk management decision in the face of uncertainty precluding the realisation of a full risk assessment study has to be based “on the *most reliable scientific data available* and the *most recent results of international research*”³¹;
- the decision must be based on “*solid and convincing evidence* which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety and/or efficacy of the [...] product”³²;

²⁷ It should be kept in mind that in the *Hormones* case, the WTO Appellate Body rejected the inclusion of the word ‘probability’ in the panel’s interpretation of the definition of risk assessment, considering that it introduced a quantitative dimension of the notion of risk and therefore implied a “higher degree or a threshold of potentiality or possibility”, whereas the word ‘potential’ in paragraph 4 of Annex A of the Agreement only relates to the possibility of an event occurring (§ 183-184).

²⁸ The following factors are deemed to be relevant to trigger a precautionary measure : the absence of proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure. *E.g.* EC Commission, Communication from the Commission on the Precautionary Principle, COM(2000) 1, § 6.2.

²⁹ Case T-13/99, *Pfizer*, *op. cit.*, § 162.

³⁰ Case T-13/99, *Pfizer*, *op. cit.*, § 196-197.

³¹ Case C-236/01, *Monsanto*, *op. cit.*, § 113; Case C-192/01, *Commission v. Denmark*, *op. cit.*, § 51.

³² See also Case T-74/00, *Artegodan*, *op. cit.*, § 192.

- the “reliable scientific evidence” should rely upon *recommendations made by international*³³, *EC*³⁴ or *national scientific bodies*³⁵;
- the risk must be backed up by the scientific *data available at the time* “when the precautionary measure was taken”³⁶;
- references to the *latest researches*³⁷ or to *new evidence*³⁸ on the subject enhance the quality of the decision;
- the specificity of the risk must be ascertained in the light of *geographical, ecological or societal particularities*³⁹.

Another issue arises for comment here. The linchpin of the precautionary measure is “uncertainty”, which is related both to the link of causation as well as the adverse effects. However, there is a whole range of different types of uncertainty ranging from lack of full evidence, measurement errors, lack of causal mechanisms, extrapolation uncertainty, inconclusiveness, contradictions, indeterminacy, ambiguity to ignorance. A complete discussion on the taxonomy of uncertainties prompting precautionary measures is beyond the scope of this paper.

³³ Case T-13/99 *Pfizer*, *op. cit.*, §300-310. In the case law on food additives, the ECJ has been stressing that Member States should rely upon the results of international scientific research and in particular the work of the Community’s Scientific Committee on Food. Another case in point is *Kemikalieinspektionen*, where the ECJ highlighted that evidence has been gathered by the International Cancer Research Agency, set up by the WHO as to the risk of cancer entailed by the use of the substance trichlorethylene. Likewise, national epidemiological studies are also relevant to substantiate the risk (Case C-473/98, *Kemikalieinspektionen*, *op. cit.*, §43).

³⁴ However, in *Pfizer* and *Alpharma* cases, the CFI did not refer to the opinion provided by the EC scientific body.

³⁵ Case C-3/00, *Commission v. Denmark*, [2002] ECR I-1305, §51.

³⁶ In *Pfizer*, the CFI concluded “that a preventative measure may be taken only if the risk, although the reality and extent thereof have not been ‘fully’ demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken”; Case T-13/99, *Pfizer*, *op. cit.*, § 145.

³⁷ Case C-473/98, *Kemikalieinspektionen*, *op. cit.*, §45.

³⁸ Of particular importance to the EC Commission is the new evidence gathered by Member States authorities while assessing request to depart from EC internal market rules in accordance with Article 95(4) or (5) EC Treaty. Failure to deliver new scientific evidence which was not already considered at the time of the adoption of the relevant EC threshold is bound to lead to a rejection of the derogation request. E.g. J. SCOTT and E. VOS, “The Juridification of Uncertainty : Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO” in Chr. JOERGES and R. DEHOUSSE (eds.), *Good Governance in Europe’s Integrated Market*, Oxford University Press, 2002, p. 256.

³⁹ In *Reinheitsgebot*, the ECJ has emphasized the importance of eating habits prevailing in a country for the presence of a specific risk to human health; Case 174/84, *Commission v. Germany (Reinheitsgebot)*, [1987] ECR 1227.

B. The safeguard clauses trigger the adoption of precautionary measures

So far, the Courts have pointed out that the safeguards clause contained in different directives and regulations – enabling Member States to deal with exceptional situations by enacting provisional measures – gives specific expression to the precautionary principle, and that the conditions governing recourse to these clauses [Article 95(5) EC Treaty] must therefore be interpreted in the light of that principle⁴⁰.

The interpretation of a safeguards clause in the light of the precautionary principle permits for certain relaxation of the requirement to carry out a risk assessment as complete as possible. Scientific evidence accessible to national authorities could support, in the light of the precautionary principle, preventive measures at variance with EU harmonized standards⁴¹.

That said, it needs to be pointed out that the safeguard clause does not represent the most salient expression of that principle. Indeed, such clauses can be invoked by Member States only provided specific circumstances are met. In addition, they are provisional.

V. RISK MANAGEMENT

Thus far, the discussion has concentrated upon the extent to which risk assessors have to highlight uncertain risks with a view to providing decision makers with the proper information. Indeed, risk is not just a matter for the experts. Various factors – *inter alia* the institutional, social and economic contexts – play a decisive role in the determination of the threshold above which the risk is judged unacceptable, thus requiring isolation by means of appropriate regulatory measures⁴². Is the “public” ready to accept the risk? Indeed, the regulation of risk is a matter

⁴⁰ Case C-6/99, *Greenpeace France*, [2000] ECR I-1651, §44; Case C-236/01, *Monsanto*, *op. cit.*, §110.

⁴¹ However, the ECJ rejected the appeal of the Austrian authorities contending that the Commission did not take into account the principle while adjudicating their request to ban GMOs production; Cases C-439/05P and C-454/05P, [2007] ECR I-7441. The ECJ endorsed a literal interpretation of paragraph 5 of Art. 95 EC.

⁴² By way of illustration, Regulation (EC) n° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([2003] OJ L 268/1) acknowledges the need to take into account at the level of risk management other legitimate factors.

involving highly political choices. Additional obligations arise consequently in respect to risk management.

However, those choices are likely to be reviewed by courts. This section will be dedicated to the questions arising at the risk management level. The discussion within this section will be structured in the following manner. We will begin by considering the issue of the non-binding nature of scientific opinions (A). We will continue by addressing the issue of what risks are deemed to be unacceptable (B). Last, we will address the question as to whether the precautionary principle is purely permissive or whether it might generate positive obligations for the competent authorities (C).

A. Scientific opinions : necessary but not a sufficient condition for risk regulation

It is settled case law that the EC institutions cannot be criticised, in cases concerning public health, for having taken the time necessary to address the relevant scientific issues and, in particular, for having referred them for a second examination by the competent scientific committee⁴³. However, whereas experts have scientific legitimacy, they have neither democratic legitimacy nor political responsibilities⁴⁴. Consequently, it is settled case law that the opinions of the scientific committees or the relevant agencies (such as the European Food Safety Authority) are not binding⁴⁵.

Accordingly, the CFI held in *Pfizer* that the institutions “may disregard the conclusions” drawn in the official scientific body opinion, “even though, in some places, it relies on certain aspects of the scientific analysis in the opinion”⁴⁶. In other words, the institutions may also avail themselves of those parts of the scientific reasoning which they do not dispute.

In so doing, the EC institutions are subject to specific obligations : they “must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the lat-

⁴³ Case C-151/98 P, *Pharos v. Commission*, [1999] ECR I-8157; Case C-352/98 P, *Bergaderm and Goupil v. Commission*, *op. cit.*, § 66.

⁴⁴ Case T-13/99, *Pfizer*, *op. cit.*, § 201.

⁴⁵ Case C-120/97, *Upjohn*, [1999] ECR I-223, § 47; Case C-405/92, *Mondiet*, [1993] ECR I-6133, § 31-32.

⁴⁶ Case T-13/99, *Pfizer*, *op. cit.*, § 200.

ter”. In addition, as a matter of procedure, “the statement of reasons must be of a scientific level at least commensurate with that of the opinion in question”⁴⁷.

The CFI judgment on France’s application for suspending a Commission Regulation softening BSE prevention regime is a good case in this respect. The fact that the Commission “not only expurgated without justification part of EFSA’s conclusions but also reproduced incorrectly that part of the conclusions which it retained” in a regulation does not allow it to state “that there is a ‘consensus’ in the scientific community that TSEs of animal origin, other than BSE, are not transmissible to humans”⁴⁸. As a result, the Commission’s claim “that the precautionary principle does not apply in this case, in view of the “purely hypothetical” nature of the risk of transmission to humans of TSE responsible agents of animal origin, other than BSE, and of the reliability of the discriminatory tests, likewise does not seem *prima facie* justified”⁴⁹.

B. Acceptable Risk

The Courts have already stressed that the competent public authority had, when confronted to uncertainty, to undertake a balancing of its obligations and then decide either to wait until the results of more detailed scientific research become available, or to act on the strength of existing scientific knowledge. Involving measures intended to protect human health, this balancing process depends on the level of risk determined by the authority “as being unacceptable for society” within the context of the particular circumstances of each individual case⁵⁰. Given that science is seen as a necessary but not as a sufficient condition for risk regulation, the political actors are endowed with a large degree of discretion as to the means of achieving safety objectives in the face of uncertainty. Nonetheless, their discretionary powers as regards the type of preventive measure must be exercised in a manner which is consistent with an array of constraints stemming from EU law, some of which were outline above (*e.g.* risk assessment, consultation of the scientific bodies), others being discussed below (proportionality).

That said, the question of the appropriate measure to avert the occurrence of uncertain risks is an open-ended one. Indeed, the various judgments commented

⁴⁷ Case T-13/99, *Pfizer, op. cit.*, § 199.

⁴⁸ Case T-257/07 R, *France v. Commission*, [2007] ECR II-4153), § 76-77.

⁴⁹ *Ibidem*, § 78.

⁵⁰ Case T-13/99 *Pfizer, op. cit.*, § 161.

in this article do not address the issue of what measures to take in the light of the precautionary principle.

It goes without saying that it is for the institution concerned to determine the level of protection which it considers appropriate for society, depending upon the circumstances of the particular case (see above II)⁵¹. As a result, the precautionary principle translates into a number of disparate measures whose intensity and scope may vary from one extreme to another. At one end of the spectrum, the focus could be placed on soft measures like that of information of the operators and the public about how risky products should be placed on the market and used. At the other end of the spectrum, precautionary measure may be absolute in character, if damage is prevented from occurring by the adoption of prohibition measures (embargo, ban, etc).

The question we face here is whether, in the light of the precautionary principle, the most stringent measures are acceptable. In this respect, one might equally question the scope of paragraph 145 of the *Pfizer* judgement where the court judged that “a ‘zero risk’ does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with the addition of antibiotics to feeding stuffs”⁵². Does this reasoning necessarily imply that any policy designed to eliminate risk is undesirable? Alternatively, is it possible to limit the scope of this interpretation to the single case of a product withdrawn from the market? The author is inclined to accept the latter reading. Within this context one can appreciate the significance both of the recognition by the appeal body of the WTO dispute resolution organ that the level of protection adopted within a risk management framework could itself aim at a zero risk⁵³, and of the European free trade association (EFTA) Court’s admission that a precautionary measure could in exceptional circumstances be directed at a risk level of zero⁵⁴. Additionally, according to the ECJ’s established case law on the proportionality of national measures limiting the use of food additives, the determination of the extent to which Member States intend to guarantee the protection of the health and life of persons is – in the

⁵¹ Case T-13/99, *Pfizer*, *op. cit.*, §151 and 153.

⁵² Case T-13/99, *Pfizer*, *op. cit.*, §142 and 146. See also Case T-257/07 R, *France v. Commission*, *op. cit.*, §79. Along the same lines, the EC Commission emphasizes in its Communication on the precautionary principle that “the measures envisaged [...] must not aim at zero risk, something which rarely exists” (COM(2000) 1, §6.3.1).

⁵³ WTO, European Communities – DS 26 Measures concerning meat and meat products, Appellate Body, Doc WT/DS 26 & 48/AB/R (16th January, 1998), *supra*, §187.

⁵⁴ Case E-3/00 *EFTA v. Norway*, *op. cit.*, §23.

absence of an exhaustive harmonisation at Community level – their own decision, although they must of course have regard to the requirements of the free circulation of goods throughout the Community. The margin for manoeuvre reserved to the Member States specifically allows them to set a very high level of protection where technical knowledge is not certain. *Melkunie* judgement is the embodiment of that approach⁵⁵. More recently, in *Walter Hahn* the Court accepted that a Member State could choose a tolerance equal to zero regarding the presence of listeriosis in fish⁵⁶. Last but not least, the *Fedesa* case (recognised as one of the earliest instances of the application of the precautionary principle) upheld the validity of measures based on a desire to eradicate consumer risk⁵⁷.

Bearing in mind the cases commented above, the debate on the acceptable level of protection has to be better anchored in its constitutional background. Although prevented from adopting a purely hypothetical approach to risk and orienting their decisions towards a level of “zero risk”⁵⁸, EC institutions must still however respect their Articles 95(3), 152(1), Article 152(3), and Article 174(2) EC obligations to ensure an increased level of protection of human health, consumer protection and the environment which, in order to ensure compatibility with this provision, need not technically be the highest possible⁵⁹. Finally, it could be argued that the decision to eliminate every risk is an issue involving purely political responsibility, and is as such one in which the judicial review should be highly deferential.

C. Permissive or compulsory?

Is the recourse to the precautionary principle obligatory or facultative?

In a first stage the ECJ held that “the institutions *may take* protective measures without having to await” full certainty⁶⁰.

Yet the CFI appeared to adopt a more categorical stance in the *Artegodan* case, holding that the precautionary principle constituted “a general principle of Community law requiring the competent authorities to take appropriate measures”⁶¹.

⁵⁵ Case 97/83, *Melkunie*, [1984] ECR 2367, § 15.

⁵⁶ Case C-121/00, *Hahn*, [2002] ECR I-9193, § 31.

⁵⁷ Case C-331/88, *Fedesa*, *op. cit.*

⁵⁸ Case T-13/99, *Pfizer*, *op. cit.*, § 145.

⁵⁹ On the reasonableness of the obligation to ensure a higher level of environmental protection, see the Court’s case C-284/95, *Safety Hi-Tech*, [1998] ECR I-4301, § 49.

⁶⁰ Case T-76/96 R, *op. cit.*, § 99.

⁶¹ Case T-74/00, *Artegodan*, *op. cit.*, § 184.

In *Pfizer*, the CFI observed that a public authority can, by reason of the precautionary principle, be *required* to act even before any adverse effects have become apparent⁶².

Besides, the principle can indeed shed a new light on the duty to place on the market only products not endangering human health. By way of illustration, the active substance used in plant-protection products can be listed under Annex I of Directive 91/414 regulating the placing of plant protection products on the market⁶³. Pursuant to Article 5 (1), the use of plant protection products containing the active substance are authorised inasmuch as the use of the products, “in the light of current scientific and technical knowledge”, will not have any harmful effects on animal health. Lately, the ECJ held that Article 5(1) of that directive, interpreted in combination with the precautionary principle, implies that “the existence of solid evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414”⁶⁴.

VI. JUDICIAL REVIEW OF THE RISK MANAGEMENT PROCESS

A. Extent of the review

In the majority of disputes, the contradicting interests of human protection and free movement of goods have to be weighed.

Being fully aware of the difficulties of regulating either in controversial cases or where action is urgently needed, the EC courts rightly show themselves little inclined to penalise institutions for any errors which they may have committed in their desire to safeguard the general interest. Hence, review must be limited, in cases in which the institutions are required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts⁶⁵. It must be circumscribed to sanctioning manifest error of appraisal and misuse of powers. In

⁶² Case T-13/99, *Pfizer*, *op. cit.*, §444.

⁶³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, [1991] OJ L 230/1.

⁶⁴ Case T-229/04, *Sweden v. Commission*, *op. cit.*, § 161 and 224.

⁶⁵ Case T-13/99, *Pfizer*, *op. cit.*, § 169.

this respect, invoking the principle or the idea of precaution, the ECJ⁶⁶ and the CFI⁶⁷ have on various occasions in the past rejected lawsuits founded on manifest errors of appraisal committed by the institutions when taking decisions which were not fully justified in the light of prevailing scientific knowledge. Indeed, the EC judicature shows judicial restraint as is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty⁶⁸.

This case law must be approved. Such freedom of action nevertheless seems indeed to be indispensable when the scientific proof collated by the Community institutions does not dictate a ready-made solution. By acting in this way, the courts reinforce administrative discretion in the implementation of policy.

B. Testing the Proportionality of the Precautionary Measure

The precautionary principle is intertwined with the principle of proportionality. As a matter of fact, most of the important cases decided by the European Courts with respect to precaution were brought by claimants averring that the contested regulation had been adopted in violation of the principle of proportionality insofar as the act in question was manifestly inappropriate for realising the pursued objective and that the institutions, which had a choice between various measures, had nonetheless not chosen the least restrictive one. While the function of the proportionality principle is well understood, its modes of application are still giving rise to conflicting opinions.

Needless to say that the intensity of review exercised by EC Courts varies extensively. Indeed, one should draw a distinction between lawsuits brought by a private party against an EC measure and lawsuits brought by the Commission against

⁶⁶ Case C-331/88, *Fedesa*, *op. cit.*, §9; Case C-180/96, *UK v. Commission*, *op. cit.*, §99 and 100; Case C-127/95, *Norbrook Laboratories Ltd*, [1998] ECR I-1531. See also Case 174/82, *Sandoz*, [1983] ECR 2445, §17.

⁶⁷ Case T-199/96, 16 July 1998, *Laboratoires pharmaceutiques Bergaderm s.a.*, [1990] ECR II-2805, §66-67. In *Pfizer and Alpharma*, the CFI noted that “the legislature has a discretionary power which corresponds to the political responsibilities given to it by Article 34 of the EC Treaty and Article 43 of the Treaty. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate, regard being had to the objective which the competent institution is seeking to pursue” (§412). The Court concluded that the adoption of the regulation in question did not constitute a manifestly inappropriate measure for the achievement of the pursued objective. See also Case T-257/07 R, *France v. Commission*, §67.

⁶⁸ Case T-13/99, *Pfizer*, *op. cit.*, §169.

a Member State. In the first hypothesis, the EC judicature has to balance a private *vis-à-vis* an EC public interest, in particular the protection of public health at the Community level. In the second hypothesis, the EC Courts have to balance an EC public interest (free movement of goods) against a national public interest (national health policy objectives).

1. *Necessity test*

This test requires a comparison between the various measures which are capable of achieving the desired result, and that the one which causes the least inconvenience be retained. *Pfizer* and *Alpharma* cases are illustrative of the central role the necessity test occupies in determining the proportionality of a precautionary measure. The claimants had argued that the Community authorities should have waited, in line with the practice of Canadian and Australian authorities, for the scientific studies to show a sufficient likelihood of risk. As far as the violation of the necessity test was concerned, the Court replied that :

“[t]he institutions cannot be criticised for having chosen to withdraw provisionally the authorisation of virginiamycin as an additive in feeding stuffs, in order to prevent the risk from becoming a reality, and, at the same time, to continue with the research that was already under way. Such an approach, moreover, was consonant with the precautionary principle, by reason of which a public authority can be required to act even before any adverse acts have become apparent.”⁶⁹

Furthermore, the court was persuaded that the use of such antibiotics was not “strictly necessary in animal husbandry and that there [were] alternative methods of animal husbandry even if they [could] lead to higher costs for farmers, and ultimately, consumers”⁷⁰. Recalling that the proportionality principle, which forms part of the general principles of Community Law, requires that the acts of the Community institutions do not go beyond the limits of that which is necessary for the realisation of the legitimate objectives pursued by the regulation at issue, the CFI confirmed that the regulation satisfied the necessity test.

2. *Weighing up the different interests*

After having confirmed the necessary character of the contested regulation, the Courts have still to balance the “pros and cons” of the decision to withdraw by

⁶⁹ Case T-13/99, *Pfizer*, *op. cit.*, §444.

⁷⁰ Case T-13/99, *Pfizer*, *op. cit.*, §459.

weighing up the different interests in play. The culmination of the testing procedure, the proportionality test *stricto sensu*, is supposed to allow the Community courts to compare the controversial decision with its objective effects, that is with its effective consequences on the well-founded subjective frame of reference consisting of the private interest of continuing to market a food additive. At this stage the proportionality principle no longer requires the balancing of the advantages and disadvantages of the proposed measure compared with the other alternatives; it rather requires a weighing up of the respective importance of the objective pursued by the contested measure with the interests which are threatened by that measure.

With a few exceptions, the requirement to balance interests in a strict sense is, as is known, the least well-established test in the Court's jurisprudence⁷¹.

Averring a violation of the third test, *Pfizer* claimed that a withdrawal of a product's authorisation could not be considered proportionate in the absence of a serious and identifiable risk and of proof that the source against which the action was to be undertaken constituted the most probable explanation for the risk which that action was intended to confront. Where these conditions are not fulfilled, the balance should tilt in favour of the holders of the marketing authorisations. Due to the great importance accorded to the protection of human health (below 3) as contrasted with economic considerations⁷², the CFI nonetheless found that the balance of interests was disadvantageous for the traders. The CFI also added that restrictions could be placed on the free exercise of professional activities – itself one of the general principles of EC Law – as long as these restrictions effectively responded to objectives of general interest pursued by the Community⁷³.

Last, as regard the proportionality of the measure with regard to the prevention, control and eradication of certain transmissible spongiform encephalopathies, the ECJ stated that this regime was supported by various scientific opinions. In particular, the ECJ stressed that in a new opinion “the Scientific Steering Committee emphasised that measures such as the ban on animal meal in animal feed and the removal of specified material reduced the risk for human health only in so far as they were actually put into place in an effective manner and that breaches, even of a minor nature, could significantly reduce the level of safety”⁷⁴. It follows from

⁷¹ See Case C-331/88, *Fedesa*, *op. cit.*

⁷² Case T-13/99, *Pfizer*, *op. cit.*, §456.

⁷³ Case T-13/99, *Pfizer*, *op. cit.*, §457.

⁷⁴ Case C-504/04, *Agrarproduktion Staebelow*, [2006] ECR I-679, §46.

several considerations that the rule requiring the slaughter and the destruction of the cohort of an infected bovine animal does not infringe the principle of proportionality in that it does not go beyond what was appropriate and necessary for the protection of animal and human health⁷⁵.

3. *Weighing of interests test and the Pre-eminence of the Protection of Public Health over Economic Interests*

The European Courts have been expressing the view on many occasions, in a wide variety of different settings, that the requirements related to the protection of health should take precedence over economic interests⁷⁶.

In line with the judgements of the Court of Justice and the Court of First Instance in *Alpharma* and *Pfizer*, the latter court enshrined a new general principle of Community Law in *Artegodan v. Commission*, by virtue of which the protection of public health should be accorded an importance indisputably privileged above that of economic considerations. The CFI considered that such a principle requires, in the first instance, dedicating exclusive attention to considerations relating to the protection of public health when considering whether to withdraw a medicine already placed on the market, and secondly, a re-evaluation of the balance of benefits and risks presented by the medicine when new facts raise doubts over its efficacy or safety. Thirdly, this new principle has an impact on the burden of proof placed on the architect of the decision to withdraw the authorisation to market a medicine, where such a decision is made with reference to the precautionary principle⁷⁷.

The effect of the general principle is that the holder of an authorisation to market a medicine, valid for five years, cannot invoke the principle of legal certainty and claim a specific protection of his interests for the duration of the validity of the authorisation if the competent authority establishes sufficiently *de jure* that the medicine no longer meets one of the criteria laid out in the Directive 65/65/CEE, having regard to the developments in scientific knowledge and new facts gathered through pharmacovigilance⁷⁸.

⁷⁵ *Ibidem*, §52.

⁷⁶ Case C-180/96, *op. cit.*, §93; Case C-183/95, *Affish*, [1997] ECR I-4315, §43; Case C-473/98, *Kemikalieinspektionen*, *op. cit.*, §45.

⁷⁷ Case T-74/00, *Artegodan*, *op. cit.*, §174.

⁷⁸ Case T-74/00, *Artegodan*, *op. cit.*, §177. Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, [1965] OJ 22/369.

The Courts are nevertheless silent on what is meant by its assertion “by giving precedence to the requirements related to the protection of those interests over economic interests”⁷⁹. So far, that assertion should not enable the authorities to eschew economic concerns while assessing the necessity of the measure at issue.

4. Proportionality in the light of the duty of re-examination

Of importance is the trend embedded within WTO and EC case law requiring institutions to re-examine their precautionary measures in the light of new scientific information⁸⁰. Indeed, it is still possible for the authority to loosen the straightjacket of precaution when new elements show that the suspected risk does not constitute as important a risk as had initially been feared. In the *BSE* case, the ECJ rules that the export ban was not disproportionate on the grounds, among other things, that the measures were temporary pending the results of further scientific studies⁸¹. *Pfizer* provides further insights into the assessment of the proportionality of a measure likely to be re-examined. Where such restrictions placed by way of the precautionary principle on the commercialisation of a product are not necessarily definitive, they thus appear all the more appropriate⁸². The withdrawal of the authorisation for virginiamycin as a growth promoter thus constituted a provisional measure which was subject to the Community institutions’ duty of re-examination⁸³.

5. Proportionality and countervailing risks

The elimination of one risk can mask the appearance of another. Thus curtailing a targeted risk can increase the occurrence of a countervailing risk. Often, though, the countervailing risks will be remote in time or place, or – significantly in our world of ultra specialisation – the new risks will be cognitively remote⁸⁴. In this sense, *Pfizer* and *Alpharma* are cases in point. The claimants had highlighted the fact that the prohibition of the use of antibiotics as growth promoters would have

⁷⁹ Case T-74/00, *Artogodan*, *op. cit.*

⁸⁰ As far as EC law is concerned, see EC Regulation on food law, Art. 7 (2); EC Commission Communication on the precautionary principle, §6.3.5. As to WTO law, see *SPS Agreement*, Art. 5 (7).

⁸¹ Case T-76/96R, *NFU*, *op. cit.*

⁸² Case T-13/99, *Pfizer*, *op. cit.*, §460.

⁸³ Case T-13/99, *Pfizer*, *op. cit.*, §460.

⁸⁴ J. SCOTT, “The precautionary principle before the European Courts”, in R. MACCRORY (ed.), *Principles of European Environmental Law*, Groeningen, Europa Law Pub., 2004, p. 65.

important negative effects on the environment, impacts which had not been taken into consideration by the Community authorities. The CFI replied that the contested regulation was founded “on a political choice, in respect of which the Community institutions were required to weigh up, on the one hand, maintaining, while awaiting further scientific studies, the authorisation of a product which primarily enables the agricultural sector to be more profitable and, on the other, banning the product for public health reasons”⁸⁵.

6. Proportionality and cost-benefit analysis

As far as the third test is concerned, the CFI considered in *Pfizer* that a cost/benefit analysis was a particular expression of the principle of proportionality in cases involving risk management⁸⁶. The assessment of the economic ramifications of the decision to withdraw carried out by various national bodies under the terms of the regulation’s procedure for adoption nonetheless satisfied this requirement of the principle of proportionality⁸⁷. Such analysis should be carried out prior to the adoption of the preventive measure. It follows that EC institutions are left with a large degree of discretion as to the means of assessing the economic costs entailed by the implementation of the measure at stake. In this respect, it should be pointed out that the different commitments of the EC institutions offer much leeway.

The Court’s requirement that the costs and benefits of a preventive measure be assessed gives rise to numerous questions. It should be apparent that, in contrast with US Law, this requirement is rarely stipulated in Community legislation. This obligation is moreover subject to lively criticism in American academic writing to the extent that it ignores so-called “incommensurables”, that is values which cannot be expressed in financial terms. In fact, while it is possible to calculate with precision the financial losses which result from the application of a precautionary measure, the financial benefits which could bring about the application of the pre-

⁸⁵ Case T-13/99, *Pfizer*, *op. cit.*, §468.

⁸⁶ Case T-13/99, *Pfizer*, *op. cit.*, §410.

⁸⁷ Case T-13/99, *Pfizer*, *op. cit.*, §469. The CFI points, for example, to the detailed analysis contained in the Swedish report of the economic effects of ceasing to use antibiotics for growth promotion in Sweden. That report was submitted to the Council during the procedure leading to the adoption of the contested regulation.

cautionary measure for the protection of human health are more difficult to evaluate⁸⁸. What price is to be put on human life?

Though, it would appear useful for the public authorities to formulate prior to regulation an idea of the economic impact of their measures, the requirement that they undertake a detailed economic evaluation of the costs and benefits of the measure would also appear to be open to criticism. Applied to the letter, such a requirement would risk leading to a complete paralysis of normative action on risk management, as has happened in the United States. The CFI's concession that the assessments carried out by the Danish and Swedish organs were satisfactory did not in fact appear to be applying the obligation derived from the proportionality principle in an excessively strict manner.

Nevertheless, the precautionary principle cannot legitimate a regulatory measure enacted on the grounds that the technology needs to be prohibited owing the lack of technological needs. In its judgment *Commission v. Denmark*, the Court condemned the Danish prohibition measure as disproportionate on the grounds that the criterion of the absence of the nutritional need of the population of a Member State "cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States"⁸⁹. Indeed, "the systematic prohibition under the Danish administrative practice on the marketing of enriched products which do not meet a nutritional need of the population does not enable Community law to be observed in regard to the identification and assessment of a real risk to public health, which requires a detailed assessment, case-by-case, of the effects which the addition of the minerals and vitamins in question could entail"⁹⁰.

VII. CONCLUSION

Precaution is testament to a new relationship with science where it is consulted less for the knowledge which it has to offer than for the doubts and concerns which it is in a position to raise. Confining scientific expertise to an ivory tower

⁸⁸ For an analysis of this subject, see F. ACKERMAN and L. HEINZERLING, *Priceless*, New York, The New Press, 2004; N. DE SADELEER, *Environmental Principles – From political Slogans to legal rules*, Oxford, Oxford University Press, 2002, 433 pp.; *Contra* C.R. SUNSTEIN, *Risk and Reasons*, Cambridge, CUP, 2002.

⁸⁹ Case C-192/01, *Commission c. Denmark*, *op. cit.*, § 54.

⁹⁰ Case C-192/01, *Commission c. Denmark*, *op. cit.*, § 56.

serves no purpose. On the contrary, the precautionary principle calls for bringing scientific expertise and the decision-making process closer to one another.

However, the precautionary principle did not take root in virgin soil, as it of necessity existed alongside other norms of the same type in the Treaty.

The principle first emerged in the environmental sphere. Interestingly enough, despite the fact that the principle is hitherto only encapsulated in the title on the protection of the environment, the EC lawmaker has been proclaiming it more widely in health protection acts (regulation on food law) rather than in environmental acts.

One further point may be worth making here. The principle has been construed by Courts in the field of health protection, and in particular food safety, with a view to avoiding unduly restrictive practices. Indeed, the cases commented above are mostly dealing with measures regulating or prohibiting products (food additives, sun creams, GMOs) with the aim of safeguarding public health. Reviewing those measures, the European courts are trying to avoid that EC or national authorities hinder the free movement of goods.