

The Precautionary Principle In European Community Food Law *By Craig Simpson, Steptoe & Johnson LLP (EU Regulatory Practice)*

Introduction

This article considers the precautionary principle (hereafter, “the principle”) in the context of European Community food law,¹ an area in which the principle has become a central tenet over the last 10 years. Building on my presentation to the Food Law Group on November 15 2004, it analyses:

- the basic elements of the principle;
- development of the principle over the last decade in the public health and food law area;
- why the principle has become fundamental in EU food law;
- where the principle, and the precautionary approach more generally, is visible in current EU food law; and
- aspects of the principle still being debated, including recent food caselaw in the European courts² and relevant WTO disputes.

It specifically examines the principle in food safety law at Community and international, rather than at individual Member State, level.³

The Basics—what is the precautionary principle?

Although referred to in Community food law since the mid-1990s, the principle was not formally established in food legislation until adoption of key EC Regulation 178/2002 on general principles of food law.⁴ Article 7 of that Regulation, entitled “Precautionary principle”, states that: “In specified circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment” (Article 7(1)).

¹ I use the term food law widely to refer to law concerning both food and animal feed and related public health issues.

² The Court of Justice of the European Communities and the Court of First Instance of the European Communities.

³ Given that Community legislation and European court jurisprudence can be binding on Member States, the comments will nevertheless be of direct relevance to decision-makers at national level.

⁴ *Regulation (EC) No 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*, OJEC L 031, 1 February 2002, pp. 1-24.

To summarise, then, the elements necessary for a proper application of the principle are:

- existence of scientific uncertainty – without scientific uncertainty, a measure cannot properly be described as precautionary, rather it would be a response to a definite food safety or public health threat;
- potential public health risk and consequent possibility of harmful effects;
- an assessment of the risk based on available science must have been carried out – this element continues to be a bone of contention between the EU and other countries;
- the measure must be temporary (i.e. pending more conclusive scientific evidence); and
- proportionate in terms of both what it requires and the length of its duration.

It can be said that the principle is now an accepted basis of political decision-making in public health measures (including food safety measures) taken by Community institutions and national governments. In the United Kingdom, Tony Blair has described it as the “better-safe-than-sorry” principle and has publicly maintained that “responsible science and responsible policy-making operate on the precautionary principle”.⁵ The outcomes of the official enquiries into BSE and mobile phones at the end of the 1990s demonstrated the principle being applied by the UK government.

Origins of the Precautionary Principle

The principle arose initially in 1970s German environmental legislation as the ‘*Vorsorgeprinzip*’—an obligation to act in the face of a threat of irreversible damage to the environment. Various high-level international environmental treaties in the late 1980s and early 1990s, such as the 1987 Ministerial Declaration on the North Sea and the 1992 UNCED Rio Declaration on the environment and development, then adopted the principle, albeit without referring to it specifically as the precautionary principle.

The first reference to the principle in primary Community law appears in the 1992 Treaty on European Union (“Maastricht Treaty”), which inserted a new Article 130r(2) (now Article 174(2)) into the EC Treaty. This established that “Community policy on the environment...should be based on the precautionary principle” but did not define the principle.

The European Court of Justice (“ECJ”) judgment in the 1996 BSE case (*C-180/96 United Kingdom v. the Commission*)⁶ was the catalyst for the extension of the application of the

⁵ [Science matters](#), Prime Minister’s speech to the Royal Society, ePolitix, 23 May 2002.

⁶ [1998] ECR I-2265.

principle from environmental law and policy into the public health and food area. This case concerned a UK challenge to the Commission Decision⁷ temporarily prohibiting export of beef and related products from the UK to other Member States following a UK independent scientific report linking human Creutzfeld-Jakob disease and BSE. Without actually using the term precautionary principle, the ECJ upheld the Commission export ban by finding that “when there is uncertainty as to the existence or extent of risks to human health, Community institutions may take protective measures without having to wait until the reality and seriousness of those risks becomes fully apparent”.⁸ Despite the fact that the EC Treaty appeared to confine the principle to Community environmental policy, the ECJ evidently felt that the particular circumstances of the BSE crisis permitted some judicial creativity in relying on the principle to justify adopting a Community-level measure in the public health field.⁹

Then followed the European Commission’s 1997 Green Paper on Food Law¹⁰ which recognised both that “a precautionary approach is the rule [for an effective food safety policy] in case scientific evidence is incomplete or unconvincing one way or the other which makes a full risk assessment impossible”¹¹ and that precautionary measures must be based on a risk assessment.

This emphasis on risk assessment acknowledged the WTO dispute¹² between the United States and the European Union concerning the application of the WTO Agreement on Sanitary and Phytosanitary Measures (“the SPS Agreement”) to the EU ban on US beef imports administered with certain bovine growth hormones. In particular, whilst recognising Member States' right under the SPS Agreement to decide the chosen level of public health protection, the Green Paper emphasised that precautionary measures must not be used to

⁷ *Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy*, OJEC L 78, 27 March 1996, p. 47.

⁸ Paragraph 99.

⁹ The rationale used in the case to apply the principle outside of environmental policy has been followed in subsequent caselaw - for example, Case T-199/96 *Bergaderm and Goupil v. Commission* [1998] ECR II-2805, paragraph 66. In 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 *Artogodan GmbH and Others v. Commission of the European Communities*, ECR II - 4945, paragraphs 182-184, the ECJ held that “although the precautionary principle is mentioned in the Treaty only in connection with environmental policy, it is broader in scope...an autonomous principle stemming from the [environment and public health] Treaty provisions”.

¹⁰ Commission Green Paper, *The general principles of food law in the European Union* COM (97) 176, Brussels, 30 April 1997.

¹¹ Part I, Section 5 of the Green Paper, p. 10.

¹² Report of the WTO Appeal Body in the decision *Community Measures concerning Meat and Meat Products (hormones)*, WT/DS26/AB/R (16 January 1999).

justify what are really trade protectionist measures, and that the risk assessment requirement was a way of preventing this.¹³

In its final Report in the beef hormones dispute, the WTO Appellate Body found that the relevant EU Directive¹⁴ (an SPS measure) violated Article 5.7 of the SPS Agreement, which reflected the principle.¹⁵ As the ban was not provisional (a requirement of Article 5.7), the EC was forced to argue that the measure was based on a more general principle of international law outside the strict confines of Article 5.7. The Appellate Body found that any wider concept of the principle¹⁶ could not be relied on to override the specific obligations of Article 5.7 and, on that basis, concluded that the ban was not a legitimate measure for two reasons.

Firstly, it was not “sufficiently supported or warranted by [a] risk assessment”¹⁷ as Article 5.7 required. Secondly, the Appellate Body found that the measure had not been provisionally adopted within the meaning of Article 5.7 since it had already been in force for 10 years without any evidence of a subsequent Community scientific review of the risks justifying the measure. The requirement for a precautionary measure to be provisional was reconfirmed in the WTO variety testing dispute,¹⁸ which concerned Japan’s requirement to test varieties of certain agricultural produce for the efficacy of treatment against codling moths. In contrast to the EC argument in the beef hormones case, Japan claimed that the measure was provisional and therefore complied with Article 5.7. However, the Appellate Body found that Japan had not complied with its obligation to actively seek additional information in order to review its measure within a reasonable period of time and was therefore in violation of Article 5.7.

The WTO requirement for a risk assessment was adhered to by the European Court of First Instance in the subsequent *Alpharma* case.¹⁹ Alpharma brought an action for loss of profit

¹³ Part VI, Section 2.1, pp. 59-60.

¹⁴ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, Official Journal L 125, 23 May 1996, pp. 3-9.

¹⁵ Article 5.7: “In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time”.

¹⁶ Whilst the Appellate Body explicitly acknowledged that “there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle”, it nevertheless commented that it would be “unnecessary, and probably unwise” for it to find on the status of the principle in international law (paragraph 124).

¹⁷ Paragraph 186 of the Report.

¹⁸ Report of the WTO Appeal Body in the decision *Japan - Measures affecting agricultural products*, WT/DS76/AB/R (22 February 1999).

¹⁹ Case T-70/99, *Alpharma Inc. v Council of the European Union* [1999] ECR II-3495.

flowing from a Community Regulation²⁰ withdrawing a certain antibiotic from a Community positive list of feed additives which Alpharma used in its production of human medicines and livestock growth promoters. Alpharma argued that the Commission had acted illegally in withdrawing the substance on the basis of a ‘zero risk’ approach without first having carried out a proper scientific assessment of the risks. The Court found in favour of Alpharma, stating that “a preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been verified”.²¹

The White Paper on Food Safety of January 2000 noted simply that “the precautionary principle will be applied in risk management decisions”²² and anticipated the most extensive Community pronouncement on the principle to date, namely the Commission Communication on the Precautionary Principle.²³ Central to the Communication was the conceptual separation between, on the one hand, scientific risk assessment, and, on the other, the entirely separate political risk management decision of whether, and if so, how to respond to a human health risk. This logic was subsequently adopted in food safety Regulation 178/2002 which, apart from containing the first Community legislative definition of the principle, established the European Food Safety Authority (“EFSA”) to carry out risk assessments independently of the Commission’s risk management role of deciding on necessary precautionary food safety measures.

Why has the precautionary principle become so central to European food safety law?

Following a perceived lacklustre and much-criticised Community response to the various food safety crises of the 1980s and 1990s, the European Commission recognised that there was an overriding need to regain credibility with the European consumer. The main lesson from the BSE crisis was that lack of conclusive evidence should never *in itself* prevent adoption of food safety measures. The precautionary principle was a solution to this risk management vacuum in giving an acceptable label to measures taken in the face of scientific uncertainty, where a risk was suspected, but not proven. Adoption of a risk management approach based on the precautionary principle, which took into account factors other than science, such as public opinion (as reflected in, or driven by, the media) and ethical concerns,

²⁰ Council Regulation (EC) No 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs, Official Journal L 351, 29 December 1998, pp. 4-8.

²¹ Paragraph 156.

²² Brussels, 12 January 2000 COM (1999) 719 final, p. 9.

²³ Communication from the Commission on the precautionary principle, Brussels 2 February 2000 COM(2000) 1 final.

was key to credibility. The precautionary approach reflected the Commission's realisation that it could not afford to ride roughshod over public opinion, even where science did not conclusively demonstrate a risk.

Evidence of the principle in current EU food safety law

The application of the principle, or more specifically a risk management approach based on the precautionary principle, is evident in today's EU food safety law in a number of different ways:

Pre-market authorisation requirements

An obligation on industry to prove safety of food or food substances through submitting of a scientific dossier before sale reflects the precautionary—'assumed dangerous until proven otherwise'—approach. This requirement, imposed by many Community food safety (and other) legislative measures, has proven contentious with industry, especially when applied to substances that have previously benefited from free circulation in the European Union. An obvious example is the application of this requirement in the Food Supplements Directive²⁴ to vitamins and minerals already marketed in the Community. This is currently under the spotlight in two UK actions for judicial review of the UK implementing legislation with an associated request by the UK High Courts for a preliminary ruling by the ECJ.²⁵

Pre-market authorisation also underlies the two principal current Community food legislative proposals: the Fortified Foods and Nutrition and Health Claims Regulations.²⁶ The former establishes a list of so-called 'substances under Community scrutiny' such as caffeine or certain amino acids, where a risk is identified but scientific uncertainty persists. The latter proposal includes requirements for establishing nutrient profiles according to prescribed criteria and prior authorisation for health claims appearing on food labelling.²⁷

²⁴ Article 4(6), *Directive 2002/46/EC of the European Parliament and of the Council of June 10, 2002 on the approximation of the laws of the Member States relating to Food Supplements*, OJEC L 183, 12 July 2002, p. 51.

²⁵ *R v. Secretary of State for Health, ex parte (1) The National Association of Health Food Stores and (2) The Health Food Manufacturers Association* (Case No. CO/5332/2003) and *R v. Secretary of State for Health, ex parte (1) Alliance for Natural Health and (2) Nutri-Link Limited* (Case No. CO/5364/2003) with references for a preliminary rulings Cases C-154/04 and C-155/04 respectively.

²⁶ *Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to food, 2003/0262 (COD)* and *Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on food, 2003/0165 (COD)*.

²⁷ Articles 4(1) and Article 10(1).

Safeguard Measures

The principle is also evident in the standard safeguard measures provision found in most EU food legislation. The Treaty provides that Community harmonising measures aimed at establishing the internal market (including in the health area) “shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30 [for example, the protection of health and life of humans], provisional measures subject to a Community control procedure”.²⁸ Most food safety measures therefore provide that a Member State may, “where it has serious grounds”, suspend or restrict circulation of a food on its territory until the Commission decides, on an opinion from EFSA, whether that measure is justifiable. In the *Monsanto* case, which involved an Italian safeguard measure under the Novel Foods Regulation,²⁹ the ECJ found, following the *Alpharma* jurisprudence, that “protective measures adopted under the safeguard clause [of the Novel Foods Regulation] may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified”.³⁰

European Court Judgments

Finally, we frequently see the principle quoted by national authorities defending food measures challenged as national trade protectionism. Some recent examples are mentioned below.

Aspects of the principle still being debated

The limits of the application of the principle in food law are still being defined in the European Courts.

What constitutes a valid risk assessment?

One question that still has not received a consistent answer from the Courts is what will or will not be interpreted as constituting a valid risk assessment in the food area. Judgments in

²⁸ Article 95(10) EC Treaty.

²⁹ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJEC L 043, 14 February 1997, pp. 1-7

³⁰ Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others*, [2003] ECR I-8105, paragraph 106.

three recent cases (all of which involve the Commission challenging national bans on fortified foods) provide some guidance, but also raise uncertainties.

In *Commission v. Denmark*, banning fortified foods unless there was a need among the Danish population for the relevant nutrients was held to be a breach of free movement of goods. The Court stressed that the risk assessment must be based on “the most reliable scientific data available and the most recent results of *international* research”.³¹ Yet, inconsistently, in the subsequent *Commission v. France* case, the Court allowed the French public health authority to rely on a purely national-level opinion, without reference to international research. The Court went as far as to say that, in principle, France could decide at what level it wished to ensure the protection of public health *even if* “no argument based on mainstream toxicology” suggested a risk.³² This is, at least, consistent with the statement in the Communication that “even if scientific advice is supported only by a minority fraction of the scientific Community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised”.³³

Effectively, then, it seemed that despite the emphasis on international science in the earlier Danish judgment, a national risk assessment would be accepted, even if contrary to mainstream international scientific opinion. What the Courts require is that the decision-maker can prove convincingly that a risk assessment was undertaken that evidenced some plausible risk (even if this risk is not widely accepted) and was genuinely relied upon in adopting the measure. It seems that it will be left to future European court judgments to clarify what level of science is or is not accepted.

What the Court in *Commission v. France* did make clear was that a risk assessment needs to be sufficiently specific to the alleged risk to be valid. It ultimately dismissed the risk assessment on the basis that the opinion “merely refer[red] vaguely to the possibility of a general risk of excessive intake, without specifying the vitamins concerned, the extent to which limits would be exceeded or the risk raised thereby”.³⁴

Neither may an outdated risk assessment be relied on. In *Commission v. Italian Republic*, the Commission pointed out that the assessment relied upon by the Italian public health

³¹ Case C-192/01, *Commission of the European Communities v. Kingdom of Denmark*, ECR I-9693, paragraph 51.

³² Case C-24/00, *Commission of the European Communities v. French Republic*, ECR I-0000, paragraph 67.

³³ See section 6.2, p. 16 of the Communication.

³⁴ Paragraph 61.

authority had been replaced by a subsequent assessment by the same body that had dismissed the public health risk suggested in the initial report. The Court therefore had no choice but to dismiss the Italian measure.³⁵

What other factors properly justify a precautionary food safety measure?

A further question is what factors, in addition to scientific risk assessment, may properly be considered as justifying adoption of a precautionary food safety measure. At risk of oversimplifying, generally speaking the US or international view is that precautionary measures cannot be based on factors other than a risk assessment. Historically, third countries have treated Community measures based on ‘other factors’ with suspicion as barriers imposed to protect Community markets from international trade.

In contrast, the European view is that such factors are of equal or, in some cases, more importance than science in deciding whether a precautionary measure should be taken. The Commission recognises that precautionary measures are political decisions taken, to quote the Commission Communication, “under varying degrees of pressure from public opinion”.³⁶ This difference is reflected in the contrasting food safety regulatory set up on either side of the Atlantic: the Community’s split between EFSA as risk assessor and Commission as political risk manager is not mirrored in the US FDA, which combines both roles.

The difference is also apparent in legislative definitions of the precautionary principle. Article 7.2 of Regulation 178/2002 permits that “regard be had to...other factors as legitimate in the matter under consideration” in adopting precautionary measures. More specifically, Recital 19 of the Regulation recognises “that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls”. This echoes the suggestion in the *Communication* that “acceptability to the public” is a relevant factor.

However, David Byrne, until recently Commissioner responsible for food safety, has been careful to allay US fears of protectionism in stressing that the principle “is not a wild card

³⁵ Case C-420/01, *Commission of the European Communities v. Italian Republic*, ECR I-6445, paragraph 32.

³⁶ See Section 5.2.1., p 15 of the Communication.

that can be played at any moment as a pretext for unjustified measures”.³⁷ Significantly, except to the extent of permitting consideration of “relevant economic factors”,³⁸ there is no equivalent provision in the SPS Agreement.

This difference is central to major international trade disputes—namely, the previous beef hormones case³⁹ and the current WTO dispute regarding an alleged *de facto* EC moratorium on the authorisation and marketing of GM products.⁴⁰ The role of public opinion, as much as, if not more than, science, is clearly behind the EC’s GM position. EFSA’s Executive Director Geoffrey Podger has publicly described the EC position as a response to “ethical concerns”. In the GM dispute, the US argues that the EC *de facto* moratorium on approval of GM foods and safeguard measures taken by six Member States are not based on scientific principles established by a risk assessment and therefore violate the SPS Agreement. The EC responds that these are provisional measures under the precautionary principle. The outcome of the Dispute Settlement Panel Decision, and the inevitable Appellate Body Decision, remains to be seen but is expected to be issued in the latter half of 2005.

Regarding ‘other factors’ considered in adoption of Community food safety measures, the ECJ in *Commission v. Denmark* said that “the nutritional need of the population of a Member State” may be considered in deciding on precautionary measures, provided that the measure is not based solely on this.⁴¹ As an example in EC legislation, the Food Supplements Directive specifically permits “the sensitivity of different consumer groups to be considered” in setting maximum levels of vitamins and minerals.⁴²

Can the principle impose an obligation to adopt a measure?

For example, could a Member State successfully argue that that the Commission, as Community legislator, failed to comply with an obligation to take the precautionary measure of excluding a certain substance from a positive list, on the basis that science suggested a risk?

³⁷ ‘The Regulation of Food Safety and the Use of Traceability /Tracing in the EU and USA: Convergence or Divergence?’, Speech 04/142 of David Byrne European Commissioner for Health and Consumer Protection, Washington DC, 19 March 2004.

³⁸ SPS Agreement, Article 5(3).

³⁹ See footnote 12.

⁴⁰ *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*, WTO Dispute Settlement cases DS291, DS292 and DS293 initiated by the U.S., Canada and Argentina in May 2003.

⁴¹ See footnote 31, paragraph 54.

⁴² See footnote 24, Article 5(1)(a).

The answer from the EU perspective appears to be no. The principle provides an accepted justification to adopt measures where science is inconclusive. This is distinct from imposing an obligation to do so. The Commission Communication specifically recognises that “the appropriate response in a given situation is thus the result of an eminently political decision, a function of the risk level that is “acceptable” to a society on which the risk is imposed” and that therefore “the decision to do nothing may be a response in its own right”.⁴³ To find otherwise would threaten the margin of discretion of the Commission as political decision maker, which is excepted from judicial review by the European courts except in narrow circumstances.⁴⁴

The position in the United States is less clear. It is notable that the wording of the US 1988 ‘Wingspread Statement’, probably the best-known US statement of the principle, provides that “when an activity raises threats of harm to the environment or human health, precautionary measure *should* [not “may”] be taken even if some cause and effect relationships are not fully established”.

With the current predominance for pre-market authorisation and positive lists, it appears likely that such an argument will be made in the European courts in relation to nutrients or foods considered by prudent Member States or consumer groups as dangerous.

Conclusion

Beginning with the extension of its application into the public health area by the ECJ in 1996, the principle has become pervasive in Community food safety law. Areas where the principle, or a precautionary approach, is visible in food safety include pre-market authorisation requirements, safeguard measures and European court judgments concerning national- or Community-level measures challenged as disguised protectionism.

Where scientific uncertainty might previously have led to inaction, Community institutions today rely on the principle to pursue food safety initiatives in the face of scientific uncertainty and recognise such measures as a crucial element of regaining public confidence in Community-level food safety legislation and policy.

⁴³ See section 5.2.1, p. 15 of the Communication.

⁴⁴ See section 5.2.2, p. 15 of the Communication: “The Court has consistently held that when the Commission or any other Community institution has broad discretionary powers, notably as regards the nature and scope of the measures it adopts, review by the Court must be limited to examining whether the institution committed a manifest error or misuse of power or manifestly exceeded the limits of its power of appraisal”.

Since the WTO Appellate Body's Report in the beef hormones case, both Community institutions and courts recognise—in line with both the US view and international agreements—that a valid precautionary measure must be based on a scientific risk assessment. The question which remains unanswered, however, is exactly what constitutes a proper risk assessment.

A second unresolved question on application of the principle in the public health area is the extent to which 'other factors', in addition to scientific risk assessment, may properly be considered as justifying adoption of a precautionary food safety measure. In contrast to the international position, the EU favours an application of the principle based on factors other than pure science, in particular public opinion on ethical concerns—the prime example currently being the GM debate. The effect of this is that Community-level measures may be adopted in circumstances where the result of the risk assessment is not the determining factor in adoption of a precautionary measure. Such an approach is regarded with suspicion outside of the Community as being a cover for disguised Community trade protectionism.

In the same way that Community food law followed the WTO jurisprudence regarding the requirement for risk assessment as a crucial element of precautionary measures, it may be hoped that the forthcoming Dispute Settlement Panel Decision in the WTO GM case will provide some clarification on both outstanding questions later this year.

Brussels, 24 January 2005

Craig Simpson

© 2005, Craig Simpson, Steptoe & Johnson LLP. All Rights Reserved.