

Prof. N. de Sadeleer¹

The Precautionary Principle in EU Law

24

Introduction

Known at the start of the 1990s by only a few specialists of environmental law, the precautionary principle has within the space of a decade experienced a meteoric rise and, as a result, been able to establish itself as a new general principle of international law. In addition, it has not only come to occupy an uncontested position in International but also in EU law as well as in several European countries (particularly in France), to the point where it overshadows the principle of prevention. Furthermore, the precautionary principle has been applied increasingly often in a wide array of areas ranging from classical environmental issues (nature, water, air, ...) to wider areas such as food safety (mad cow disease, the spread of genetically modified organisms, ...) as well as health issues (the French HIV blood-contamination scandal, health claims linked to phthalates in PVC toys and endocrine disruptors, among other issues). The precautionary principle has quickly developed into one of the foundations of the high level of environmental protection in the EU and as an obligation laid down by the Treaty on the Functioning of the European Union (TFEU).²

The significance of the principle lies also in its challenge to traditional legal systems, many of which are permeated by the need of certainty. The operator's civil liability can be incurred provided that the victim is able to shed light on the link of causation between the operator's behaviour and the ensuing damage. A WTO member is able to enact a food safety measure provided that its regulatory choice is based upon clear scientific evidence resulting from a risk assessment.³ This presupposes continuous recourse to scientific expertise, with experts being able to provide flawless data to both courts and decision-makers. How-

ever, at first glance precaution provides for the possibility to act while uncertainties have not yet been cleared.

As regard the EU legal order, particular attention should be drawn to the fact that pursuant to Article 191(2) TFEU,

'Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay',

This provision is rather unique. Indeed, the environmental policy is the only EU policy to proclaim such a cluster of policy principles.⁴ Moreover, this is the sole Treaty provision to embody the precautionary principle.

It is the aim of this chapter to explain how precaution has been fleshed out into more precise legal obligations and interpreted by EU courts. The discussion in this chapter will be structured in the following manner:

- meaning and status of the principle;
- relationship with scientific as well as policy issues;
- the manner in which the EU case-law has been carving out the implementation of the principle.

1. Meaning and status of the precautionary principle

1.1. Meaning of the principle

This section will not reopen discussion on the meaning of this principle, other than to recall its function as the expression of a philosophy of anticipated action, not requiring that the entire corpus of scientific proof be collated in order for a public authority to be able to adopt a preventive measure. While there are multiple definitions of this principle in international law, every enunciation of the principle contains the elements of an anticipatory regulatory approach in face of uncertainty. In a nutshell, precaution epitomizes a paradigmatic shift. Whereas, under a preventive approach the decision-maker intervenes provided that the threats to the environment are tangible, pursuant to the precautionary principle authorities are prepared to tackle risks for which there is no definitive proof that there is a link of causation between the suspected activity and the harm or whether the suspected damage will materialize. In other words, precaution means that the absence of scientific certainty – or conversely the scientific uncertainty – as to the exi-

1. Prof. N. de Sadeleer is Professor UCLouvain, Saint-Louis and Guest Professor Lund University and Jean Monnet Chair Holder.

2. Case C-127/02 *Waddenzee*, [2005] ECR I-6515, at para. 44.

3. See Article SPS Agreement, *European Communities – DS 26 Measures concerning meat and meat products (hormones)*, Appellate Body, Doc WT/DS 26 & 48/AB/R (16th January 1998), para. 196; *Australia – DS 21 Measures concerning the importation of salmonids*, Appellate Body, Doc WT/DS18/AB/R (20 October 1998), para. 129. Attention should be drawn to the fact in interpreting Article 5(7) of the SPS Agreement, the WTO Appellate Body took the view in *Japan-Measures affecting the importation of apples* that the application of the safeguard clause enshrined in that provision, which previously was deemed to reflect the precautionary principle, 'is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence' (*Japan-Measures affecting the importation of apples*, para. 184). In contrast, in situations in which the data available has been sufficient to allow for diverging scientific assessments, Article 5(7) has not been considered to apply. As a result, under the SPS Agreement, a safeguard measure can't be triggered by uncertainty but exclusively by insufficient results.

4. As regard the scope of this provision, see N. de Sadeleer, *Commentaire J. Mégret. Environnement et Marché intérieur* (Brussels: ULB 2010).

stence or the extent of a risk should henceforward no longer delay the adoption of preventative measures to protect the environment. However, the undefined principle offers no guidance about actions to take in face of uncertainty.

1.2. *Absence of definition*

Even though there are various definitions of the precautionary principle in international environmental law, the precautionary principle has not been defined by the Treaty framers. Broadly speaking, the lack of definition could be justified on the grounds that the implementation of this principle across a wide range of policies is rather contextual. In some instances, the EU institutions have been clarifying the conditions under which the precautionary principle has to be applied.⁵ Moreover, EU courts have also introduced extremely useful clarifications on the application of this principle. Last but not least, regulations or directives provide for more comprehensive definition. By way of illustration, the EU General Food Law offers a comprehensive definition of the precautionary principle.⁶

1.3. *Binding principle*

The use of the indicative in paragraph 2 rather than the conditional confirms that such principles are binding: 'Union policy on the environment ... shall aim (and) ... shall be based on ...'. In contrast to other rules of indeterminate content, the precautionary principle set out in Article 191(2) TFEU is thus mandatory.⁷ As a result, EU institutions have to abide by this principle.⁸ In other words, EU measures not complying with the precautionary principle are likely to be subject to judicial review, though courts leave to the institutions a rather broad margin for discretion, provided a number of formal conditions are met. In

addition, as discussed below, Member States are obliged to apply the precautionary principle when carrying out action in the environment field that has been harmonized by secondary EU law.⁹

That said, given its generality, the precautionary principle always allows for the possibility of accommodation. As to be seen, there is indeed some discretion as to ways in which to flesh out these principles in more concrete measures. In other words, the EU institutions may depart it under particular circumstances. Nonetheless, that discretion can become inexistent where the principle is fleshed out in a comprehensive authorization scheme.¹⁰

1.4. *The status of the principle in the EU legal order*

Although EU lawmakers are reluctant to define the principle, as will be seen the EU courts have been endorsing such an anticipatory approach. The jurisprudential definition of the precautionary principle runs as follows:

'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'.¹¹

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 giving precedence to the requirements related to the protection of those interests over economic interests'.¹² Furthermore, the Court of First Instance (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'.¹³

Whereas the European Court of Justice (ECJ) has been more careful in speculating about the nature of that principle, the CFI took the view that that precaution was a general principle of EU law.¹⁴ Whether the Court of

5. To fill this gap, the European Commission produced in February 2000 a communication seeking to inform all interested parties of the manner in which the Commission applies or intends to apply the precautionary principle when taking decisions relating to the containment of risk (COM 2001/1).

6. See Article 7 of Regulation (EC) No 178/2002 Regulation (EC) No 178/2002 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. OJ. L 31, 1.

7. G. Winter, *The legal nature of environmental principles in international, EC and German law*, in: R. Macrory, (ed.) *Principles of European Environmental Law* (Groeningen, Europa Law Publishing, 2004), p. 19, and p. 22 et seq.; contra E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart 2007) 212.

8. In the *Artegoda* case, the CFI held that the precautionary principle constituted 'a general principle of EU law requiring the competent authorities to take appropriate measures' (Case T-74/00, *Artegoda* [2002] ECR II-4945, para. 184). Against this background, the principle 'requires', pursuant to the rules applying to the re-authorisation of a medicinal product, 'the suspension or the withdrawal of marketing authorisation when new scientific evidence give rise to serious doubt as to the efficacy and the safety of the product' (*Ibidem*, para. 192). 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 apparent (Case T-13/99, *Pfizer* [2002] ECR II-3305, para. 444).

9. Case C-127/02, *Waddenzee*, [2005] ECR I-6515, para. 44.

10. See T-229/04, *Sweden v Commission* [2007] ECR I-2437.

11. See Case C-157/96 *National Farmers' Union and Others*, [1998] ECR I-2211, at para. 63; Case C-180/96 *United Kingdom v Commission*, [1998] ECR I-2285, at para. 99; and Case C-236/01, *Monsanto Agricoltura Italia*, at para. 111. See also Case T-13/99, *Pfizer* [2002] ECR II-3305, at para. 139.

12. Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegoda* [2002] ECR II-4945, para. 184.

13. *Ibidem*, para. 184.

14. *Ibidem*, para. 184.

justice will endorse that interpretation remains to be seen.

1.5. *The status of the principle in the Member States legal orders*

Given that the EU environmental policy has been giving rise to a sheer number of directives, we shall assess first whether the precautionary principle encapsulated in Article 192(2) TFEU applies at national level.

A distinction must be drawn between areas covered by secondary law and those which are not. Furthermore, a distinction should also be drawn between principles that are explicit in EU secondary legislation and those that are implicit.

In areas that have not been harmonized, given that they are addressed to EU institutions, the precautionary principle enshrined in Article 192(2) TFEU cannot constrain national authorities and is accordingly devoid of direct effect. As a result, Member State actions may not, in principle, be reviewed on the basis of the Article 192(2) precautionary principle.

That said, particular attention has been hitherto drawn to the fact that Member States are bound by a swathe of directives and regulations aiming at protecting the environment. The question arises as to whether the Member States' authorities could eschew the Treaty principle on the grounds that it is not enshrined in the directives that they have to implement. In areas that have been harmonized by directives or regulations, the Treaty's environmental principles may apply both directly and indirectly to Member States through secondary legislation.

First, the precautionary principle may apply in an autonomous manner to national authorities if the latter are obliged to implement EU directives that recognize one or more of the principles contained in Article 192(2) TFEU as such. By way of illustration, in both Directive 2001/18/EC on the deliberate release of GMOs and Regulation 1107/2009 on the placing on the market of plant protection products, the precautionary principle is explicitly mentioned.¹⁵ In this case, the principle embodied in secondary legislations requires national authorities to conduct risk assessments of GMOs and plant protection products in the light of the precautionary principle. By the same token, when applying the waste hierarchy, the Member States 'shall take into account' a cluster of principles, among which 'the general environmental protection principles of precaution and sustainability, ...'.¹⁶

Second, the Article 192(2) TFEU precautionary principle can underpin implicitly the whole regulatory framework

contemplated by the EC lawmaker. Where an environmental principle is not explicitly set out either in the operative provisions or in the recitals of the preamble of a directive or a regulation it may nevertheless directly apply to Member States insofar as Article 4(3) TEU obliges the Member States to 'take all appropriate measures ... to ensure fulfillment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Union and 'facilitate the achievement of the Union's tasks' as well as 'abstain from any measure which could jeopardize the attainment of the objectives' of the Treaty. Read in the light of the precautionary principle enshrined in Article 191(2) TFEU, Article 4(3) TEU imposes on national authorities wide-ranging obligations of environmental protection, preservation, conservation, prevention and precaution.¹⁷ By way of illustration, the precautionary principle requires the national authorities to interpret strictly the environmental obligations stemming from secondary law, irrespective of whether the directives or regulations encapsulate or not the principle. For instance, with respect to the assessment procedure laid down in the Habitats Directive 92/43/EC, account must be taken of the principle of precaution referred to in Article 192(2) TFEU although the principle is not mentioned as such in that directive.¹⁸

1.6. *The precautionary principle: shield or sword?*

The precautionary principle enshrined in Article 191(2) TFEU is likely to be seen as a double-edged sword.

On one hand, the EU lawmaker justifies the validity of his regulatory measures in the light of the principle encapsulated in Article 192(2) TFEU. As a result, in actions for annulment brought pursuant to Article 263 TFEU by private parties against a EU measure aiming at limiting health or environmental risks, the institutions have been regularly invoking principles such as precaution to justify the soundness of their measures.

On the other hand, in infringement cases brought in virtue of Article 258 TFEU by the Commission against Member States' environmental measures, the national authorities may invoke the principles as a shield in order to justify the validity of their measures hindering for instance free trade in goods.¹⁹ For instance, there has been increasing use of the precautionary principle by Member States to derogate from the principle of movement of goods where the matter has not been harmonized or with a view to departing from internal market harmonization in virtue

15. Article 1 of Directive 2001/18/EC on the deliberate release of GMOs; Article 1(4) of Regulation 1107/2009 No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ, L 309, 24 November 2009, 1.

16. Article 4(2) of directive 2008/98/EC on waste. OJ L 312, p. 3.

17. A. Doyle and T. Carney, 'Precaution and Prevention: Giving Effect to Article 130y Without Direct Effect', 8 *EELR* (1999), 44.

18. In *Waddenzee*, the ECJ assessed the validity of a Dutch project in the light of the EC precautionary principle (Case C-127/02, *Waddenzee* (2004) ECR I-7405, para. 44). Remarkably enough, that judgment significantly departs from earlier judgments of the Dutch Council of State which refused to take into consideration the principle of precaution on the ground that it was not codified in the Dutch environmental legislation (12 May 2000, n° E03.96.0068 A8 2000/395).

19. J. Zander, *Different Kinds of Precaution* (Cambridge: CUP 2010) 113.

of Article 114(4) and (5) TFEU.²⁰ To some extent, EU secondary law may encourage the use of a principle as a shield. By way of illustration, pursuant to the Regulation (EC) No 1107/2009:

'Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorized in their territory.'²¹

It appears that EU courts are at their most deferential in cases in which the Commission invokes the precautionary principle. However, the courts requirements will be set much higher when Member States invoke the same principle with a view to justifying safeguard measures.

2. The precautionary principle caught between scientific controversies and anticipatory actions

2.1. The limitations of science

It ought to be remembered that the precautionary principle came to centre stage in the field of environment policy in response to the limitations of science in assessing complex and uncertain ecological risks.²² Indeed, environmental risks and in particular global risks confront assessors with serious difficulties: uncertainty is a persistent feature both of understanding the chain of causation²³ as well as predicting the outcomes. Furthermore, the distance in time and space between sources and damages, the cumulative and synergistic effects, the unpredictable reactions of some ecosystems (potential resilience), and the large scale of impacts compound the methodological difficulties in assessing these risks.²⁴ Indeed, there is a strong deficit in predictive capability. Scientific uncertainty exists whenever there is no adequate theoretical or empirical basis for assigning probabilities to the occurrence or the extent of a risk. The following examples are illustrative of the ways in which uncertainty pervades the risk assessment process:

- insufficiency: for instance, the various scientific disciplines involved in assessing the risk are not sufficiently developed to explain the cause-and-effect relationship;²⁵
- inconclusiveness: the realities of science dictate that the scientists, whatever the quality of their investigations, will never be able to eliminate some uncertainties;²⁶ for instance, there may be too many unpredictable variables to enable the identification of the relative influences of each factor;
- imprecision: could be caused by the fact that the data to analyze the risks are not available or are out-of-date, information gaps, measurement errors, contradictions, indeterminacy, ambiguity ...

Although unpredictable risks are rising, authorities tend to wait in the face of uncertainty and to react only to crisis events. They characteristically err towards belated and costly measures.²⁷ This can be explained by the fact that damage to the environment is likely to be more controversial than damage to health. Whereas one usually agrees that activities endangering human health should be restricted or banned, people usually disagree whether ecosystems, ecosystemic processes, species of plants and animals, or micro-organisms deserve any kind of protection.

In this respect, precaution aims to bridge the gap between scientists working on the frontiers of scientific knowledge and decision-makers willing to act to prevent environmental degradation.

2.2. Risk analysis

At the outset, it should be stressed that the principle is located within the broader context of the principle of risk analysis, which comprises a two-step process: risk assessment and risk management. The point here is not to delve into the highly complex world of risk analysis. It is merely to emphasize some of the key issues arising in the discussion of the implementation of a precautionary measure.

20. Case C-3/00 *Denmark v Commission* (2003) ECR II-2643 and Joined Cases T-366/03 and T-235/04 *Germany v Austria* (2005) ECR II-4005.

21. Article 1(4) of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ, L 309, 24 November 2009, L.

22. See, among others, N. de Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law', 12 *European Law Journal* (March 2006) 139; and N. de Sadeleer, 'The Precautionary Principle Applied to Food Safety', 4 *European Consumer Law Review*, 2009(1) 147-169.

23. For instance, the French food safety Agency (AFSSA) claimed that there exist more than forty possible cases that might explain the observed trends of honeybee decline. See AFSSA, *Weakening, Collapse and Mortality of Bee Colonies* (Paris: AFSSA 2008).

24. J. Kasperson, 'Introduction: Global environmental risk and society', in J. Kasperson and R. Kasperson (eds.), *Global Environmental Risk* (London: Earthscan 2001) 4.

25. Typical in this respect is Regulation [EC] 1829/2003 on GM food and feed recognizing that, in some cases, scientific risk assessments cannot provide all information on which a risk management decision should be based (recital 32 of the Preamble).

26. A quantitative risk assessment exercised performed by 11 different teams in the EC came up with 11 different results that differed by a million fold. See S. Contini, A. Amendola and I. Ziomas (1991) *Benchmark Exercise on Major Hazard Analysis* (Ispra, European Commission Joint Research Center. By the same token, different models for assessing carcinogenicity can result in cancer predictions that differ by a factor of 100 or more when extrapolated to low doses. E.g. M. Shapiro (1990) 'Toxic Substances Policy' In D. Portney (ed.) *Public Policies for Environmental Protection*, Washington, Resources for the Futures, p. 218. Given 'the uncertainty inherent in assessing the public health risks posed by the use of food additives', the ECJ acknowledges the possibility to conduct legitimately different risk assessments yielding to different scientific evidence (Case C-3/00, *Denmark v Commission*, (2003) ECR I-2643, para. 63).

27. EEA, *Late Lessons from Early Warnings: the Precautionary Principle 1896-2000* (Copenhagen, EEA, 2001) 168.

Account must nonetheless be taken of the fact that 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 recognize a margin of autonomy for the body authorized *in fine* to make a decision on the risk (risk management).²⁸ 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 assessments.²⁹

Therefore, a brief discussion of the concepts risk assessment and risk management is warranted to make clear the baseline against which the precautionary principle has to be applied.³⁰

2.3. Risk assessment

Though the precautionary principle acknowledges the limits of a traditional scientific approach, it does not however discard a genuine scientific approach. It is settled case-law that the precautionary principle is not designed to prevent purely hypothetical risks. These risks are deemed to be based on mere hypotheses that have not been scientifically confirmed.³¹

First, the probability of the occurrence of harm is determined using a *risk assessment* procedure, in which experts examine both hazard and exposure – generally by mathematical modelling – in order to calculate an acceptable or tolerable level of contamination or exposure.³² According to the EU courts, a scientific risk assessment requires:

'the identification of the biological, chemical and physical agents liable to give rise to adverse health effects which may be present in a given food or group of foods and which call for scientific assessment in order better to understand them'.³³

This systematic process involves a four-step approach:

- hazard identification (does a substance give rise to an adverse effect such as cancer, birth defects, etc.);
- dose-response assessment (how potent a carcinogen is it?);
- exposure assessment (which groups of people are exposed to the substance, what is the environmental vehicle of exposure –air, water, soil-, for how long, and at what levels?);
- and risk characterisation (what is the likelihood that any particular exposed person will get cancer?).

Nonetheless, as indicated above, it may be impossible to carry out a full risk assessment because such investigations operate at the frontiers of scientific knowledge. As a matter of fact, 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, their assessments will demonstrate that there is a high degree of scientific and practical uncertainty in that regard. 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. 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 occurrence of the risk. Indeed, the ECJ and the CFI alike expressed the view 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'.³⁴

28. In this respect, the EC Regulation (EC) 178/2002 establishing the general principles of a general presumption against food legislation distinguishes in particular 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)).

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

30. On the topic of risk assessment and risk management, e.g. C. Noiville and N. de Sadeleer, 'La gestion des risques écologiques et sanitaires à l'épreuve des chiffres. Le droit entre enjeux scientifiques et politiques' (2001) 2 *Revue du Droit de l'Union Européenne* 389-449. On risk analysis in EC Law, see T. Christoforou, 'Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts?', in: *Le commerce international des OGM* (Paris: Documentation Française 2002) 213-283.

31. Case T-13/98 *Pfizer*, above, para. 143; Case C-236/01, *Monsanto Agricoltura*, above, para. 106; Case C-3/00, *Commission v Denmark*, above, para. 49; Case T-229/04, *Sweden v Commission*, [2007] ECR I-2437. See also Case E-3/00, *EFSA Surveillance Authority v Norway*, paras. 38 to 38.

32. US National Research Council (1983) 3 *Risk Assessment in the Federal Government: Managing the Process* 13.

33. Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, para. 156; Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, para. 169; Case C-236/01, *Monsanto Agricoltura Italia* [2003] ECR I-8105, para. 179. See to that effect, *inter alia*, Article 3(9) to (14) of Regulation (EC) No 178/2002 of the General Food Law Regulation (OJ 2002 L 31, p. 1) and points 5.1.1 and 5.1.2 of and Annex III to the Communication from the Commission on the precautionary principle of 2 February 2000 (COM(2000)1).

34. Case C-192/01, *Commission v Denmark*, [2003] ECR I-9693, para. 55. Moreover, these criteria are listed in the Commission's communication on the precautionary principle, COM(2001)1, 10.

However, there is no further indication as regard the manner in which these three criteria should be interpreted.³⁵

2.4. Risk management

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. Indeed, 'societal, economic, traditional, ethical and environmental factors as well the feasibility of controls' might appear as factors legitimising the regulation of a specific risk.³⁶

However, it is not very easy to trace the boundary between the scientific domain and the political approach to risk management, as there is no natural break between the two spheres which are supposed to become involved at different stages in the decision-making process.³⁷ In reality, as will be seen, assessment and management overlap in a permanent reciprocal interplay. The assessment of a risk often results from a managerial decision; conversely, new assessments are made following management decisions. Additionally, this separation is by no means watertight.

Furthermore, it should be stressed at the outset that a number of public institutions consider the precautionary principle merely a risk management tool that has nothing to do with risk assessment.³⁸ By way of illustration, the

European Commission Communication of February 2000 describes precaution as a risk management tool which is part of a risk analysis framework.³⁹ Likewise, the precautionary principle is seen by the ECJ as constituting 'an integral part of the decision-making processes leading the adoption of any measure for the protection of human health'.⁴⁰

3. EU courts case-law

3.1. Introductory comments

In looking at the EU courts' case-law, one needs to draw a line between on the one hand the health and food safety cases,⁴¹ where scientific knowledge is far more advanced than it is in the environmental sector, and on the other hand genuine environmental cases (climate change, nature conservation) where the uncertainties are far more important given the difficulty of predicting the reactions of ecosystems to ecological risks. In addition, the stricter approach endorsed by the EU courts with respect to the health and food safety cases can be explained by the fact that those cases chiefly deal with the placing on the market of products (GMOs, food additives, medicinal products) where a fundamental principle of Treaty law, the free movement of goods, is at stake. In sharp contrast to this, the environmental cases so far decided by the ECJ deal mostly with the interpretation of provisions of several environmental directives, rather than with the functioning of the internal market and the fundamental principle of free movement of goods. We shall restrict ourselves to comment upon the environmental cases, though many of them overlap to some extent health issues. It should at this point be noted that in contrast to EU food safety and chemicals regulations where the principle is expressly defined,⁴² few environmental directives or regulations specifically mention the precautionary principle in their operative provisions. Nonetheless, given the broad definition endorsed by EU courts, the precautionary principle covers an array of environmental issues ranging from wildlife conservation measures to chemical management issues.

35. The criteria might differ. Whereas it is settled case-law that EU institutions might act whenever the 'scientific evidence is insufficient, inconclusive or uncertain', under Article 6(2) of the 1995 UN FAO Code of Conduct for Responsible Fisheries and the 1995 UN Agreement on Straddling Fish Stocks and Highly Migratory Fish Stocks, the obligation to endorse a precautionary approach reads as follows: 'States shall be more cautious when information is uncertain, unreliable or inadequate'.

36. E.g. recital 19 of the preamble of Regulation (EC) EC Regulation on food law. By the same token, Regulation (EC) 1829/2003 on GM food and feed provides that as risk assessments cannot provide all the information on which a risk management decision should be based, 'other legitimate factors relevant to the matter under consideration' may be taken into account (Article 6(6)). Likewise, the European Courts acknowledge the possibility to include 'consumers' concerns' in the process of balancing. E.g. Cases T-344 & 345/00, *LEVA & Pharmacia Enterprises v. Commission*, judgment of 26 Feb. 2003, para 66.

37. This distinction was rejected by the Appellate Body of the WTO, as not being inherent in the SPS Agreement (*EC Measures Concerning Meat and Meat Products (Hormones)* Jan. 16 1998 (WT/DS26/AB/R)). For a critique of the premises underpinning the distinction between risk assessment and risk management, see N. de Sadeleer, *Environmental Principles* (Oxford: OUP 2005) 184-186.

38. See for instance, the positions defended by the EC Commission in her Communication on the Precautionary Principle and by the Scientific Steering Committee's Working Group on Harmonisation of Risk Assessment Procedures in the Scientific Committees advising the European Commission in the area of human and environmental health (First Report on the Harmonisation of risk assessment procedures, 2000).

39. While the communication is typically a soft-law instrument, it is not devoid however of any legal consequences. Indeed, applying the principle of equal treatment, the EC judiciary can ascertain whether an EC measure is consistent with the guidelines that the institutions have laid down for themselves by adopting such a communication.

40. Case C-236/01, *Monsanto*, para. 133.

41. Indeed, these last years, the precautionary principle has been regularly invoked before the EU courts in major food safety and drugs cases. The 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. See N. de Sadeleer (ed.) *Implementing the Precautionary Principle, Approaches from the Nordic Countries, EU and USA* (London: Earthscan 2007) and 'The Precautionary Principle in EC Health and Environmental Law', *European Law Journal*, Volume 12, March 2006, 139-172.

42. Article 7 of Regulation 178/2002/EC; Article 1 REACH; Article 1(4) Regulation 1107/2009.

As will be seen, relying explicitly or implicitly upon the precautionary principle, the ECJ departs from a literal interpretation of obligations laid down in secondary law. Moreover, the cases commented on in this section are testament to the binding effect of the principle as regards Member States' actions.

It is important to note at the outset that the intensity of review exercised by EU Courts varies extensively. One needs to draw a line between, on one hand, the lawsuits brought by a private party against a directive, a regulation or a decision and, on the other hand, the actions for infringement of EU law brought by the Commission against Member States. Whereas in the former cases, the courts have to balance private freedoms (i.e., the right to property, the freedom to pursue a trade or business) vis-à-vis an EU public interest (i.e., the objective of a high level of health's protection), in the latter cases, the courts have to weigh an EU public interest (free movement of goods enshrined in articles 34-36 TFEU) against a national public interest (the willingness to depart from EC harmonized standards according to Article 114(4)(5) TFEU or to maintain a measure impinging upon trade according to Article 36 TFEU or the *Cassis de Dijon* case law⁴³). As far as the Member States' precautionary measures are concerned, the ECJ appears to apply more strictly the principle of precaution to the extent that those measures could jeopardize the functioning of the internal market.⁴⁴

3.2. Justification of restrictions brought to economic freedoms

The precautionary principle can lower the scientific hurdles national regulators face while trying to protect environmental values to the detriment of certain economic freedoms, such as the free movement of goods. This may be illustrated by the following cases.

The *Toolex* judgment provides striking evidence of the use of the precautionary principle in the resolution of a conflict between undertakings and a Member State, which departed from EU harmonized standards.⁴⁵ Interestingly, the case does not refer to the principle specifically, but does apply the anticipative approach in face of uncertainty behind the principle. The *Toolex* case arose from a challenge to the Swedish decision to ban the chemical substance trichloroethylene, which had been classified as a category 3 carcinogen under Directive 67/548/EEC⁴⁶

on the classification of dangerous substances.⁴⁷ Although the Swedish ban was tantamount to a measure having an effect equivalent to a quantitative restriction within the meaning of former Article 28 EC (Article 34 TFEU), the ECJ took the view that it was compatible with the Treaty insofar as it was necessary for the effective protection of the health and life of human beings despite the scientific uncertainties surrounding the effects of exposure to the chemical.⁴⁸ In other words, the lingering uncertainties regarding the impacts of this hazardous substance used in industry did not preclude the Swedish authorities from regulating it, and, as a result, to restrict the free movement of goods in that country; although that substance could be freely traded within the EU.

Another case in point is *Bluhme*, where the ECJ ruled that a Danish wildlife measure prohibiting the import of any species of bee other than the endemic population *Apis mellifera mellifera* into a Baltic island was justified under former Article 30 EC (Article 36 TFEU), notwithstanding the lack of conclusive evidence establishing both, the exact nature as a matter of taxonomy of the endemic population and its risk of extinction.⁴⁹

A final illustrative example is that of listing wild animals that can be traded. According to the ECJ case law, an application to include a species of mammal on a national list of protected species that cannot be subject to trading may be refused by the competent national administrative authorities only if the holding of specimens of that species poses a genuine risk to the protection of the environment or other imperative requirements such as animal welfare. This requirement appears necessary to comply with the free movement of goods. An application to have a species included on the list of species of mammals that may be held or traded may be refused by the competent authorities only on the basis of a full assessment of the risk posed to the environment. Nevertheless, the precautionary principle leaves the Member States some room for manoeuvre in order to cope with uncertain scientific issues (such as how to determine the negative impact of trading a mammal species on the conservation of their wild populations). Accordingly, the ECJ has taken the view that: 'Where it proves impossible to determine with certainty the existence or extent of the risk envisaged because of the insufficiency, inconclusiveness or imprecision of the results of the studies conducted, but the likelihood of real harm to human or animal health or to the

43. Case C-120/78, [1979] ECR 649.

44. See the reasoning of Advocate General Poiares Maduro in its opinion delivered on 14 September 2004 in ECJ 2 December 2004, Case C-41/02, *Commission v Netherlands*, ECR I-11375 at para. 30. According to the Advocate General, 'the discretion that Member States are allowed as regards recourse to the precautionary principle is increasingly restricted the further they depart from scientific analysis and the more they rely on policy judgment', in particular in cases of lack of data on account of the novelty of the product or a lack of resources in conducting scientific research (para. 33). The ECJ did not address that issue.

45. Case C-473/98, *Toolex* [2000] ECR I-5681.

46. OJ, 196, p. 1.

47. Several scientists contended with that classification owing to the hazards entailed by the use of the substance in question. Given that the EC committee was unable to reach agreement on an evaluation of that substance (Opinion of AG Mischo, delivered on 21 March 2000, para. 63 in Case C-473/98, *Toolex*, ECR I-5681), the Swedish Government decided to ban the substance on the grounds that its use was endangering workers' health, and consequently, endorsed a more stringent approach than the one contemplated at the EC level.

48. See Case C-473/98, *Toolex*, above, at para. 47.

49. Case C-67/97 *Bluhme* (1998) ECR I-8033.

environment persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.⁵⁰

3.3. *The action for annulment in virtue of Article 263 TFEU: The extent to which EU institutions are bound by the precautionary principle*

Given that the precautionary principle is binding on the EU institutions, it can be invoked in an action for annulment by the applicant (for instance, by an institution or a private party) before the ECJ or the GC to contend with the validity of secondary legislation (mostly, in the field of environmental protection, consisting of directives and regulations). The applicant may therefore argue before the EU courts that the lawmaker has wrongly failed to apply the principle. The fact that such a TFEU principle has been infringed will constitute a ground for annulment. So far, the principle has been mostly invoked in lawsuits dealing with health safety issues. Nonetheless, environmental cases are highlighting a new role for the principle as a means to control the discretion of the EU institutions.

As regard the actions for annulment, it needs merely to be pointed out that the EU courts are fully aware of the difficulties of regulating either in controversial cases or where action is urgently needed. Therefore, they rightly show themselves to be 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 facts.⁵¹ It must be circumscribed to sanctioning manifest errors of appraisal and misuse of powers. In this respect, when invoking the principle or the idea of precaution, the ECJ⁵² and the CFI⁵³ 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 EU judiciary has shown judicial restraint as it is not entitled to substitute its

assessment of the facts for that of the EU institutions on which the Treaty confers sole responsibility for that duty.⁵⁴

The judgement in *Armand Mondiet* provides a good illustration of the role that the precautionary principle can play in justifying secondary legislation enacted in the face of uncertainty. In this case, the regulation at issue aimed at protecting cetaceans taken against a background of scientific uncertainty.⁵⁵ A ship owner challenged EC Regulation 345/92⁵⁶ forbidding the use of tangle nets of over 2.5 kilometres in length, on the grounds that no scientific data justified this measure and that it did not conform to the only information available although the Regulation provided that conservation measures should be drawn up 'in view of the information that was available'.⁵⁷ The ECJ took the view that in the exercise of its powers, the Council could not be forced to follow particular scientific opinions.⁵⁸ It follows that the Council did not make any manifest error of appraisal by banning certain tangle nets despite the uncertainties.

Scientific issues are gathering momentum with respect to the complex relationship between internal market rules and environmental policy. For instance, paragraph 5 of Article 114 TFEU (former Article 95 EC) authorizes the Member States, insofar as certain conditions are fulfilled, to 'introduce' more stringent measures than those provided for by an EU measure related to the functioning of the internal market. These new measures must be based on 'new scientific evidence'. The question arose as to whether an Austrian province could ban genetically modified organisms (GMOs) on its territory with the aim of protecting nature as well as organic farming pursuant to that paragraph. The EC Commission contended that the scientific evidence gathered by the Austrian authorities in the light of the precautionary principle was not 'new scientific evidence' in the sense of paragraph 5 of Article 114 TFEU. Advocate General Sharpston took the following view in her conclusions: 'Having regard to the stress laid by the appellants on the precautionary principle, I would add that, relevant though the principle may undoubtedly be when assessing new evidence concerning a new situation, no amount of precaution can actually render that evidence or that situation new. The novelty of both situation and evidence is a dual criterion which must be satisfied before the precautionary principle

50. Case C-219/07, *Nationale Raad van Dierenkwekers en Liefhebbers VZW*, [2008], at para. 38.

51. Case T-13/99, *Pfizer* [2002] ECR II-3305, at para. 169.

52. See Case 174/82, *Sandoz*, [1983] ECR 2445, at para. 17; Case C-331/88, *Fedesa*, [1990] ECR I-4023, at para. 9; Case C-180/96, *UK v Commission* [1998] ECR I-2269, at paras. 99 and 100; and Case C-127/95, *Northbrook Laboratories Ltd* [1998] ECR I-1531.

53. See Case T-199/96, *Laboratoires pharmaceutiques Bergaderm S.A.*, [1998] ECR II-2805, at paras. 66 and 67. In Case T-13/99, *Pfizer Animal Health v Council* [2002], ECR II-3305; and T-70/99 *Alpharma v Council*, [2002] ECR II-3305 the CFI noted that 'the legislature has a discretionary power which corresponds to the political responsibilities given to it by [Article 40 TFEU] Article 34 of the EC Treaty and [Article 49 TFEU]. 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' (para. 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-257/07R, *France v Commission*, [2007] at para. 67.

54. See Case T-13/99, *Pfizer*, above, at para. 169.

55. Case C-405/92, *Armand Mondiet*, [1993] ECR I-6176.

56. EC Regulation 345/92 of 27 January 1992 amending for the eleventh time Regulation (EEC) No 3094/86 laying down certain technical measures for the conservation of fishery resources (no longer in force).

57. Advocate General Gulmann concurred with the Commission's argument that 'it is sometimes necessary to adopt measures as a precaution'. In order to conserve tuna stocks, for which insufficient scientific data existed, total allowable catch (TAC) had been based on that principle [Opinion of Advocate General M. Gulmann in ECJ 24 November 1993, Case C-405/92, *Armand Mondiet*, [1993] ECR I-6176, para. 28.

58. Case C-405/92, *Armand Mondiet*, above, at paras 31-36.

comes into play.⁵⁹ The ECJ dismissed the appeal lodged by the Austrian authorities, claiming that the CFI did not appear to have erred in law by stating that EFSA's findings concerning the absence of scientific evidence demonstrating the existence of a specific problem had been taken into consideration by the Commission.⁶⁰ In other words, the principle does not prevail over the obligation for the Member State to bear the burden of the proof as regard the novelty of the scientific evidence.

Unlike waste management policy, the regulatory approach as regards the safety of chemicals has been underpinned by rather cumbersome, time-consuming and expensive scientific assessments.⁶¹ Indeed, chemicals policies have been related to a general preference for a certainty-seeking regulatory style in which formal, science-based and standardised risk assessment has been singled out as the predominant tool for decision-making relating to chemicals. Though chemicals assessment procedures have been calling for absolute certainty, data are nonetheless incomplete and results may be unclear or contradictory. As it is difficult to establish causal links between exposure to chemicals and health or environmental effects, there is generally a significant degree of uncertainty in estimates of the probability and magnitude of effects associated with a chemical agent. As the result of limited knowledge, experts are not always able to provide conclusive evidence of a threat to human health and the environment. It follows that the precautionary principle has been at the core of the negotiations of REACH regulation and the Regulation (EC) No 1107/2009 concerning the placing of plant protection products, both of which proclaim the precautionary principle.⁶² Besides, both the CFI and the CJ have been endorsing lately a harder look at the Commission's attempts to relax somewhat the level of safety requirements in the area of active substances found in plant protection products and chemicals.

Against that background, the principle can indeed shed new light on the duty to place on the market only products not endangering human health. In this respect, the *Paraquat* judgment handed down by the CFI on 11 July 2007 is a case in point. Paraquat is an active substance used in plant-protection products. Such active substances can be listed under Annex I to former Directive 91/414⁶³ regulating the placing of plant protection products on the market and use of plant protection products containing the active substance 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. Adjudicating an action for annulment lodged by Sweden against an European Commission decision listing Paraquat under Annex I to Directive 91/414/EC in spite of the hazards entailed by the use of the active substance, the CFI stressed that it follows from Article 5(1) of Directive 91/414:

'interpreted in combination with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving 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

Another recent case raises some of the same issues, but in the context of an entirely different procedure. The European Parliament and Denmark sought review before the ECJ of a general exemption granted by the EU Commission for the use of a chemical hazardous substance known as a flame retardant, deca-BDE, in electrical and electronic equipment. The applicants argued that the conditions laid down by the Community legislature in Article 5(1) of Directive 2002/95 of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment had not been met. They claimed that the decision at stake ran counter to the objective pursued by that legislature of establishing the principle of the prohibition of the components referred to in that directive. In analysing the preamble, the CJ reached the conclusion that the intention of the legislature was to prohibit hazardous products referred to in the directive and to grant exemptions 'only in accordance with carefully defined conditions'.⁶⁵ The ECJ expressed the view in *obiter dictum* that:

'Such an objective, in compliance with [Article 168 TFEU], according to which a high level of human health protection is to be ensured in the definition

59. Conclusions of Advocate General Sharpston delivered on 15 May 2007 *Joined Cases C-439/05 P and C-454/05 P. Land Oberösterreich and Republic of Austria v Commission of the European Communities*, para. 134.

60. *Joined Cases C-439/05 P and C-454/05 P. Land Oberösterreich and Republic of Austria v Commission of the European Communities*, ECR I-7441, para. 64.

61. The current system of assessing chemicals has been 'overloaded because of the difficulty of applying a cumbersome and expensive testing and assessment regime to the very large number of chemicals already on the market'. E.g. UK Royal Commission on Environmental Pollution (2003), *XXIVth Report on Chemicals in Products* (Norwich, TSO) 9.

62. Article 1 REACH and Article 1(4) of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ, L 309, 24 November 2009, 1. In addition, the EU is party to the 2001 Stockholm Convention on Persistent Organic Pollutants (POPs) that lays down the precautionary approach as its main objective (Preamble, para. 8; Article 4, Article 8(7)) and to the 2001 London IMO Convention on the Control of Harmful Anti-fouling Systems on Ships, which establishes a precautionary mechanism to prevent the potential future use of other harmful substances in anti-fouling systems (Article 6(3) and (5); preamble, fifth recital).

63. Directive 91/414 of 15 July 1991 concerning the placing of plant protection products on the market, OJ, L 230, 1. This directive has been replaced by Regulation (EC) No 1107/2009.

64. ECJ 11 July 2007, Case T-229/04, *Sweden v Commission*, [2007] ECR I-2437, paras. 161 and 224.

65. Para. 170.

and implementation of all Community policies and activities, and in compliance with [Article 192(2) TFEU], according to which EU policy on the environment is to aim at a high level of protection and is based on the principles of precaution and preventive action justifies the strict interpretation of the conditions for exemption.⁶⁶

In this judgment, the precautionary principle was not applied by the ECJ as a ground for annulment, but as an interpretative principle supporting a strict interpretation of the basic safety requirements laid down by the EU lawmaker.

3.4. Preliminary ruling requests in virtue of Article 267 TFEU and action for infringement in virtue of Articles 258-260 TFEU: The extent to which national authorities are bound by the principle

Pursuant to Article 258 TFEU, the European Commission regularly brings Member States before the CJ for failure to implement EU directives and regulations aimed at protecting the environment. In addition, pursuant to Article 267 TFEU, national courts refer questions to the CJ for preliminary rulings as to the validity and the scope of ambit of EU environmental directives and regulations. Whether the action is for infringement of EU law or whether it is a request for preliminary ruling, the defendant Member States usually support a somewhat narrow interpretation of EU environmental obligations, whereas national non-governmental organizations (NGOs) and the European Commission lean toward a purposive interpretation of the obligations at stake.

In a case concerning marketing approval for genetically modified maize, the ECJ held that the principle of precaution implies that the former EC Directive 90/220/EEC relating to the placing on the market of GMOs should be interpreted in such a way that gives full weight to environmental protection requirements. Accordingly, the precautionary principle did not affect the interpretation of Article 13 of that directive, according to which national authorities are under an obligation to give their consent to GM products already authorized by the Commission.⁶⁷ One of the arguments made by the ECJ was that the precautionary principle was already reflected in the Directive, in both the notifier's obligation to inform the competent authorities immediately of new information regarding the risks of the product to human health or the environment and the subsequent duty of these authorities to inform the Commission and the other Member States about such information, and in the right of a Member State to provisionally restrict or prohibit the use and/or sale on its territory of a GMO under the conditions set

out in Article 16.⁶⁸ However, 'the system of protection put in place by Directive 90/220/EEC, in particular by Articles 4, 12(4) and 16, necessarily implies that the Member State concerned cannot be obliged to give its consent if in the meantime it has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment.'⁶⁹

In English, the mood, verb tense and construction of this phrase all constituted an *a priori* invitation to the court to recognise that the French State was bound (*compétence liée*) by the decision of the European Commission to allow commercialisation of genetically modified maize.⁷⁰ Nevertheless, the precautionary principle allowed the ECJ to reach a far more nuanced solution, by recognising the right of a Member State to oppose commercialisation of GMOs on grounds of the appearance of new risks. In this decision, the precautionary principle took the form of an interpretative principle of law, which served to correct the effect of a provision whose meaning could nevertheless be directly established. In other words, the principle of precaution appears capable of modifying the meaning even of a relatively clear text in favour of greater environmental protection in the face of uncertainty.

A further example is the differentiation between waste and product, which has been the subject of much heated academic debate as well as litigation in EC law.⁷¹ Pursuant to Article 192(2) TFEU, EU environmental policy aims at a high level of protection and must be based, in particular, on the precautionary principle and the principle that preventive action should be taken.⁷² It follows that the concept of waste cannot be interpreted restrictively.

As far as biodiversity is concerned, attempts to conserve habitats and their species must grapple with a wide range of uncertainties as well as ignorance.⁷³ The difficulties are compounded by the lack of sufficient data as well as the complexity to model the functioning of ecosystems and to understand the complex relationship between human activities and the state of conservation of ecosystems and species. Indeed there are still major gaps in understanding how ecosystems and species interact and

68. *Ibid.*, at para. 44.

69. *Ibid.*, at para. 45.

70. *Ibid.*, at paras. 28-30.

71. N. de Sadeleer, 'Waste, Products and By-products', 1:4 *Journal of European Environmental & Planning Law*, 2005, 46; N. de Sadeleer, 'EC Waste Law or How to Juggle with Legal Concepts. Drawing the Line between Waste, Residues, Secondary Materials, By-products, Disposal and Recovery Operations', 2:6 *Journal of European Environmental & Planning Law* (2005), 46.

72. Cases C-418/97 and C-419/97, *ARCO Chemie Nederland*, (2000), ECR I-4512, para. 39; Case C-9/00, *Falun Granit Oy* (2002) ECR I-3533, para. 23; Case C-1/03, *Paul Van de Walle*, (2004) ECR I-7613, para. 45; and see N. de Sadeleer, 'Note under Case C-1/03', *CMLRev.*, 2006, Vol. 43, n° 1, 207-223.

73. R. Cooney and B. Dickson (eds.), *Biodiversity & the Precautionary Principle* (London, Earthscan, 2005).

66. Cases C-14/06 and C-295/06, *European Parliament v Commission*, [2007] ECR I-7441, paras. 74 - 75.

67. Case C-6/99, *Greenpeace France et Ministère des Affaires Étrangères*, [2000] ECR I-1676.

react against new threats. In some cases, uncertainties cannot be reduced in gathering more accurate data; in other words, uncertainty is intractable. Accordingly, in adjudicating a number of nature protection cases, the ECJ has been endeavouring a precautionary approach. In so doing, the ECJ took implicitly into consideration the precautionary obligation flowing from the CBD, a mixed international agreement.⁷⁴

An illustrative example is a judgement concerning wild birds. In *Association pour la protection des animaux sauvages et préfet de Maine-et-Loire et préfet de La Loire-Atlantique*, the ECJ favoured a determination of the end of the hunting season in a manner that guaranteed the optimal level of protection for avifauna.⁷⁵ It judged that in the absence of 'scientific and technical data relevant to each individual case' – that is, in cases of uncertainty – Member States should adopt a single date for ending the season, equivalent to 'that fixed for the species which is the earliest to migrate,' and not 'the maximum period of migratory activity'. This means that so long as a degree of uncertainty remains concerning the timing of pre-mating migrations of migratory birds, the strictest method of determining the close of the hunting season should override methods attempting to accommodate hunting interests on the basis of scientific approximation.

By ruling against Spain in *Marismas de Santoña* for not having protected wetlands of importance for certain migratory species of birds, in conformity with Directive 79/409/EEC, the ECJ again adopted a precautionary approach. As no reduction in the number of protected birds had been observed, the Spanish authorities disputed that the destruction of a valuable ornithological site violated the requirements of the Directive. Their argument was rejected, however, on the grounds that the obligation to preserve the natural habitats in question applied whether or not the population of protected birds was disappearing from these areas.⁷⁶ In so ruling, the ECJ considered the context of uncertainty resulting from the fact that destruction of a natural habitat does not necessarily translate into an immediate decline in its animal populations:

The obligations on Member States, ... exist before any reduction is observed in the number of birds or any risk

of a protected species becoming extinct has materialised.⁷⁷

Also, the ECJ has handed down a landmark case assessing the validity of Dutch environmental impact assessment (EIA) regulation on fishing activities taking place within bird special protection areas in the sea of Wadden. In order for the project to be authorised, Article 6(3) of the Habitats Directive⁷⁸ provides for a specific environmental impact assessment procedure of plans or projects 'likely' to affect a conservation site.⁷⁹ According to the Court, since the impact study regime covers plans and projects 'likely' to affect a site, the wording of this provision implies that the conductor of the study must be able to identify, according to the precautionary principle, even those damages that are still uncertain.⁸⁰ In addition, the Habitats Directive's authorisation regime requires that the competent authority ensure that the project at stake will not adversely affect the integrity of the site concerned. Accordingly, the authorisation can only be passed where the assessment demonstrates the absence of risks for the integrity of the site. 'Where doubt remains as to the absence of adverse effect on the integrity of the site', the Directive requires, in line with the precautionary principle, the competent authority to refrain from issuing the authorisation.⁸¹ Although it is likely to restrict economic and property rights, this authorisation criterion 'integrates the precautionary principle'.⁸² Conversely, a less stringent criterion would not be as effective in ensuring the fulfilment of the conservation objectives set forth by the EC lawmaker.⁸³ In accordance with the logic of the precautionary principle, authorities can, if necessary, order additional investigations to remove the uncertainty.⁸⁴ Of course, one should be aware that the strict interpretation endorsed by the ECJ is a consequence of the manner in which the authorisation regime of projects endangering threatened habitats has been formulated by the EC lawmaker.

Conclusion

The precautionary principle first emerged in the environmental sphere, and was later transposed into the area of public health, being enshrined in the TFEU as well as in framework acts and applied widely by European courts. The principle aims to bridge the gap between scientists

74. The Preamble of the 1992 Convention on Biological Diversity (CBD) provides that 'where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat. Though this statement is not binding on the grounds that it is encapsulated in the preamble of the agreement and not its operative provisions, it is not however devoid of legal effects. See Case C-67/97 *Bluhme* [1998] ECR I-8033, paras 36 and 38.

75. Case C-435/93, *Association pour la protection des animaux sauvages et préfet de Maine-et-Loire et préfet de La Loire-Atlantique* [1994] ECR I-67, para. 21.

76. Case C-355/90, *Commission v Spain* [1993] ECR I-6159, para. 28.

77. *Ibid.*, para. 54.

78. Directive 92/43/EC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 7.

79. For a description of this procedure, see N. de Sadeleer, 'Habitats Conservation in EC Law: From Nature Sanctuaries to Ecological Networks', 5 *Yb EEL* (2005), 215.

80. ECJ 7 September 2004 Case C-127/02, *Waddenzee*, [2005] ECR I-6515, para. 44.

81. *Ibid.*, at para. 57.

82. *Ibid.*, at para. 58.

83. *Ibid.*

84. See also the Opinion of Advocate General Kokott in *Waddenzee*, *ibid.*, paras. 99-111.

working on the frontiers of scientific knowledge and decision-makers willing to act to determine how safe is safe enough. To sum up, the principle urges the institutions as well as the national authorities within the UE legal realm to act or to abstain from action, in cases of uncertainty. In all cases, it should encourage the delay, and in some cases even the abandonment, of activities suspected of having serious impacts for the environment. Inversely, it should accelerate the adoption of decisions intended to ensure better environmental protection, even if their merits are not unanimously endorsed by all experts. In other words, 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.

As seen above, precaution is determined by the features of the various sectoral policies dealing with environmental risks: fisheries, chemical substances, nature protection, GMOs, pesticides, food safety, marine pollution, waste management, etc. Precaution is therefore likely to vary as a function of the level of uncertainty permeating each of these areas but also of the political imperatives of the field in question. As a result, a multitude of differing measures may follow from this one principle.

In any case, the principle must be seen as part of a dynamic and not a static process. Decisions taken under the aegis of precaution should be understood as open to review in light of new scientific evidence.