SCIENTIFIC UNCERTAINTY AND THE PRECAUTIONARY PRINCIPLE

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A INTRODUCTION

The relationship between law and science can be said to be an uneasy one, beset by conflicts of both method and objective.[1] Despite this, however, the science-law relationship is often of considerable importance. Nowhere is this more evident than in relation to environmental law. Through scientific disciplines such as ecology, chemistry, physics, geosciences and so on, scientific knowledge is developed which is then used to form the basis of environmental protection laws. Indeed, scientific research is often initiated with the primary aim of facilitating the making of law and policies.[2] Of course science also plays another role: that of innovation and the creation of new techniques, methods and technologies, which can impact the environment, often in a negative way. Thus a symbiotic relationship is established whereby science not only is needed to inform the law but also is necessarily regulated by it.

The overwhelming reliance on science in developing environmental law has given rise to difficult issues however. One such issue is how the law can or should regulate risk in the face of scientific uncertainty. In modernist thought, science was regarded as a higher universal domain of thought containing ultimate truths and capable of giving definitive, certain answers. Today, given the massive increase in technologies, methods and forms of knowledge it has long since been recognised that this is not always the case.[3] Despite the leaps and strides that scientific knowledge has taken in recent years, there is still much we are uncertain about, and even more but which we are entirely ignorant.[4]

In environmental law one devise that has developed to deal with situations where it is clear that we do not know enough, or are not certain enough, is the precautionary principle. This principle can be seen as part of a rejection of the modernist science-law paradigm, in

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1 MA Berger & LM Solan 'The Uneasy Relationship Between Science and the Law: An Essay and Introduction' (2008) 73(3) *Brooklyn Law Review* 847 <http://works.bepress.com/lawrence_solan/70> (2 March 2010). Such conflicts can commonly be seen, for example, where the level of certainty scientists can offer falls far below the level needed for proving causation in legal arenas. For a more detailed discussion of the relationship between scientific evidence and environmental law see Biondi and others (eds) *Scientific Evidence in European Environmental Rule-Making: The Case of the Landfill and End-of-Life Vehicles Directives* (Kluwer Law International New York 2003).

2 One example relates to the obligation on producers or manufacturers of certain products, who have to prove their substance is not hazardous before it can be authorised by the relevant competent authority. Thus the impetus for researching the characteristics and properties of that substance is the regulatory requirements rather than pure scientific interest.

3 For a critique of science in modernity and the postmodern incredulity towards metanarratives, see JF Lyotard *The Postmodern Condition: A Report on Knowledge* (Manchester University Press Minneapolis 1984).

4 CFCs and asbestos are good examples of ignorance and uncertainty in the past. Scientific uncertainty played a large part in the late reaction to claims of the dangers of asbestos (made as early as 1898) which we now know only too well are well-founded; asbestos is the main cause of mesothelioma, a very rare cancer of the chest or abdomen lining, and is also a cause of lung cancer. In relation to ignorance, the effect of chlorofluorocarbons and their damage to the ozone layer were not even contemplated prior to 1974, having been considered safe to use before then. The confirmation of the hole over the Antarctic in 1985 was essentially by accident. See discussion of these issues and other 'acting too late' scenarios in European Environmental Agency's Report *Late lessons from early warnings: the precautionary principle 1896 – 2000* (2002) Environmental Issue Report No. 22 < http://www.eea.europa.eu/publications/environmental_issue_report_2001_22> (4 May 2009).

favour of a post-modern approach, which embraces the reality that science is not omniscient.[5] Where circumstances arise in which the scientific knowledge available is not capable of ruling out adverse effects or fully identifying all possible risks, the precautionary principle allows public authorities to act without conclusive evidence, as waiting for full information it may ultimately be acting too late.[6]

The aim of this article is to analyse the nature of the precautionary principle as a means of dealing with scientific uncertainty in risk analysis. To set the scene, the origin and aim of the principle will be looked at briefly. The scope of the principle and the type of risks which attract precautionary measures will then be considered, along with some of the principle's limitations. Finally, the way in which the principle has been applied by courts and competent authorities will be reviewed with a view to determining what legal effects the principle has had and may potentially have.

B ORIGIN

As is characteristic of principles of law, the precautionary principle has developed in an incremental fashion.[7] The precautionary principle is said to have its origins in the German concept *'Vorsorgeprinzip,'* a concept which is literally translated as the 'precaution' or 'foresight' principle and which has been employed in German regulations since the 1970s.[8] It has been both an express and implicit part of numerous international treaties and conventions on environmental law since the 1980's.[9] In the European context, the principle is enshrined in article 174(2) of the EC Treaty, which states that:

> Community 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 Community. It shall be based on the precautionary principle and on the principles that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

Article 174(2) is addressed to Community institutions and requires that community policy on the environment be made in light of the principles set out therein. The exact legal force of that provision has been much debated however. In one view, it is contended that the strong wording of article 174(2) –"*shall be based on*"- indicates that the provision is legally binding, placing an obligation on Community institutions to apply the principles when developing environmental policy.[10] It is accepted that this obligation can, in certain circumstances, be departed from however.[11] It is this possibility for exemptions and derogations that leads Krämer to voice the opposing view that principles are not legally binding in nature, being merely "general guidelines for Community environmental policy."[12] However, as one commentator points out, while the principles in article 174(2) may be too indeterminate to be

5 For an analysis of the precautionary principle as a postmodern approach to law see N de Sadeleer *Environmental Principles; From Political Slogans to Legal Rules* (Oxford University Press Oxford 2005).
6 ibid n 4.
7 G Winter 'The Legal Nature of Environmental Principles in International, EC and German Law' in M Rory ed *Principles of European Environmental Law* (Europa Law Publishing 2004).
8 For example the '*Vorsorgeprinzip'* can be seen in Germanys Clean Air Act, 1974.
9 See, *inter alia*; Montreal Protocol on Substances that Deplete the Ozone Layer, 1987; The Rio Declaration on Environment, 1992; Cartegena Protocol on Biosafety, 2000.
10 de Sadeleer (n 5) 321.
11 ibid 322.
12 L Krämer *EC Environmental Law* 4th ed (London Sweet and Maxwell 2000) 10.

relied on as the basis for a claim relating to an omission to act, "the EC Courts have already demonstrated that there is a possibility to review secondary legislation according to article 174(2) principles."[13] A number of these cases will be considered. First, however, it is necessary to set out the rationale behind the precautionary principle.

C AIM

It may be said that the aim of the precautionary principle is to facilitate decision-making in the face of uncertainty. Put simply, it allows public authorities to choose the 'better safe than sorry' option. It should be noted that, although the introduction of precaution provides more freedom for decision-makers, under article 174(3) Community institutions are still obliged to have regard to, *inter alia*, available scientific and technical data and to take account of the potential costs and benefits of choosing to act or not.[14] Thus the precautionary principle doesn't give authorities a *carte blanche* under which scientific knowledge can be ignored or disproportionate measures taken.[15] However, the principle does essentially ensure that a lack of conclusive evidence regarding possible threats to health or the environment is not relied on as the reason for not taking action to prevent harm.[16] This objective was the exact foundation upon which the European Court of Justice (ECJ) formed its decision in Case C-180/96 *United Kingdom v Commission*, (the '*BSE case'*); a case which is lauded as being the first in which a precautionary approach adopted by a Community institution was upheld on the basis of article 174(2) (ex Art 130r).[17] The case concerned a decision of the Commission to take emergency measures banning the export of beef and beef products from the UK in response to the 'mad cow disease' crisis. The UK contested the decision on a number of grounds, including that the Community had misused its powers, that the ban was an unjustified restriction of the free movement of goods within the Community and that the measures taken by the Commission were in breach of the principle of proportionality.[18] However, the court did not agree, holding that "[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."[19] Although the ECJ never referred explicitly to the principle of precaution, it explained that the approach it took was borne out of article 130r EC Treaty (now article 174(2)), in which the principle of precaution is set down.

D SCOPE

There is no doubt that the precautionary principle is now well established as a relevant principle of Community environmental law. However aside from its brief mention in article 174(2), the precautionary principle is not further referred to or defined in the EC Treaty. Thus the true nature and scope of the precautionary principle from a European perspective is

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13 de Sadeleer (n 5) 322-3.

14 S Tromans 'High Talk and Low Cunning: Putting Environmental Principles into Legal Practice' (1995) *JPEL* 779, 782.

15 ibid.

16 E Fisher 'Is the Precautionary Principle Justiciable?' (2001) 13(3) *JEL* 315, 316.

17 Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* ECR I-2265. See also Case C-157/96 *National Farmers Union and Others* [1998] ECR I-2211

18 Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* [1998] ECR I-2265, para 31.

19 ibid para 99.

to be discerned by looking at the principle in context and analysing how it has been applied by both the judiciary and the legislature. This analysis is usefully supplemented by the Commissions Communication in 2000, which shed some light on what the principle means by offering definitions and guidelines for its application.[20] According to the Commission the application of the precautionary principle is envisaged:

> where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.[21]

As can be seen from the above quote, the scope of application of the principle extends beyond the strictly environmental sphere as set down in article 174(2), encompassing effects on human and animal health also. This extension is said to be validated by article 6 EC Treaty which calls for the integration of environmental protection requirements into the other policies and activities of the Community.[22] Consequently, the precautionary principle has been relied on in a number of cases concerning human health, including the aforementioned *BSE case* and cases concerning the use of antibiotics as additives in animal feed.[23] In an express recognition of this more expansive interpretation of the precautionary principle, the Court of First Instance (CFI) has declared that 'the precautionary principle can 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.'[24] - a pronouncement which shows how the principle's scope now extends far beyond its original settings.

E APPLICATION

The precautionary principle is applied in the general framework of risk analysis.[25] Whether the principle applies purely to the risk management element of risk analysis or to the whole process, including risk assessment, has been the subject of some debate.[26] However it seems clear that, at the very least, the precautionary principle operates as a risk management tool, relied on by decision-makers in deciding whether or not to act and what measures to take, once the factors triggering the principle have been established.[27] According to the

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20 European Commission, Communication from the Commission on the Precautionary Principle, COM (2000) 1. (Hereafter referred to as the 'Commission's Communication').

21 ibid 8.

22 Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II -3305, at 114. See also Douma Wybe 'Fleshing out the Precautionary Principle' (2003) 15(3) *JEL* 372, 398.

23 BSE cases: C-157/96 *National Farmers Union and Others* [1998] ECR I-2211; Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities*. Antibiotic Cases: Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II -3305; Case T-70/99 *Alpharma Inc v Council of the European Union* [2002] ECR II-3495.

24 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 *Artegodan GmbH v Commission* [200] ECR II-4945, para 184.

25 Commission's Communication (n 20) 13.

26 Compare the opinion of the Commission that the precautionary principle has nothing to do with risk assessment (Commission's Communication p 13), with the views expressed by Fisher (n 16) and de Sadeleer (n 5) 186. De Sadeleer in particular opposes the Commissions stance that the precautionary principle applies narrowly to risk management alone, arguing that the principle influences, or at least should influence the methodology of risk assessment also.

27 (n 20) 13 *ff*.

Commission, these factors include the initial identification of a potential hazard, followed by a scientific evaluation of that hazard including an assessment of risk, which aims to set out the probability of adverse effects and the severity of those effects. This risk assessment is to be as comprehensive as possible, consisting of hazard identification and characterisation, appraisal of exposure and risk characterisation.[28] Finally some scientific uncertainty must exist, for example a gap in data or disputes over existing data, which makes it impossible to determine with sufficient certainty the risk in question.

It is this uncertainty, establishing a *potential* risk, which is the 'triggering factor' for the precautionary principle. [29] Uncertainty, however, is of course inherent in the concept of risk; where the slightest doubt exists as to whether an event will occur, risk is present. Thus, in order to prevent the precautionary principle from becoming inoperable, efforts have been made to create classification systems to distinguish various types of risks and to better clarify the type of risk the precautionary principle applies to.

F RISK THRESHOLD – UNCERTAINTY

There are numerous theories in existence which attempt to elaborate the concept of risk. One such formulation categorises risk in terms of *dangers* or *certain risks*, *uncertain risks* and *residual risks*.[30] In this model, *certain risks* are risks which are certain to the extent that their impact and probability are known, however they are still classifiable as 'risks' as it is not sure exactly when the impact will happen.[31] Where a certain risk is at issue, preventative measures are justified under the principle that preventative action should be taken, leaving no need for recourse to the principle of precaution. At the other end of the scale are *residual risks*, which have been described as "risks resting on purely speculative considerations without any scientific foundation."[32] The rate of scientific development and research today has given rise to an abundance of new risks, so that it is hard to know which risks are real and which are hypothetical.[33] To allow every risk of mere hypothetical or speculative nature to be subject to precautionary measures would surely stifle innovation and scientific progress. Thus residual risks do not attract either the principle of precaution or prevention; they must simply be tolerated by society.[34] Finally, falling somewhere in between the above two extremes are *uncertain risks*, neither hypothetical nor fully known. It is this category to which the precautionary principle applies.[35]

The various categories of risk and their significance to the precautionary principle have also been considered by the European judiciary, although not necessarily using the same terms of classification.[36] Earlier decisions, such as the *BSE case*, stating only that Community institutions do not need to wait until the reality and seriousness of the risk are fully apparent before taking measures, made for a somewhat ambiguous guide to what is required by way of risk, allowing decision-makers an almost unlimited discretion as to the

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28For definitions of the various components of risk assessment see the Commission's Communication 29.
29 (n 20) 13.
30 de Sadeleer cites A. Reich, Gefahr-Risiko-Restrisiko (Werner Düsseldorf 1989) as one source for the distinction between 'Dangers' (Gefahren), 'Residual Risks' (Restrisiko) and 'Risks' (Risiko) upon which his own theory is based; (n 5) 156.
31 ibid 158.
32 ibid.
33 ibid 152.
34 ibid 157-8.
35 ibid 157.
36 The CFI have preferred to distinguish 'risks', 'hazards' and 'hypothetical risks.' See, for example, Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II -3305.

kind of risks against which they could take precautionary measures. However, the issue has since been more fully discussed, most notably in the important case of *Pfizer Animal Health SA v Council.*[37] That case arose out of the Council's decision to ban the use of the antibiotic virginiamycin in animal feed. [38] Concern had been growing that the use of such antibiotics was increasing resistance to those antibiotics in humans, based on the assumption that resistance in animals is transmissible to humans.[39] The decision was taken on a precautionary basis, as it was common ground that at the time the measure was adopted neither the reality nor the seriousness of the risk had been scientifically proven.[40] Pfizer contested the decision, arguing, *inter alia*, that it was a misapplication of the precautionary principle, as the Council did not correctly assess the risk and applied an illegitimate 'zero risk' test.[41] Further, it was argued that the measures were adopted without proper scientific basis, as, according to Pfizer, the current scientific knowledge on the matter was 'either totally absent or inadequate'.[42] Interestingly, when asked at the hearing what amount of proof would suffice before authorisation could be withdrawn, Pfizer stated: "It would be proven with the first dead man. It would be proven with the first infection, or with the first proof of colonisation, or the first proof of transfer in a human.'[43]

Unsurprisingly, any idea that Community institutions have to wait until people are dying or at least harmed before they can ban a substance was categorically rejected by the CFI.[44] In delivering its judgment, the court began by confirming the decision in the '*BSE case'* that, on the basis of the precautionary principle the Community institutions did not have to wait until the reality and the seriousness of the risks were fully apparent before taking preventative action.[45] However it went on to state that precautionary measures "cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified."[46] It follows that this judgment appears to have set down slightly higher threshold for judging whether the principle can apply than the cases preceding it. Relying on the Commission's Communication, the CFI made it clear that before any preventative action can be taken a risk assessment is necessary, which involves first determining the degree of risk acceptable - which cannot be at 'zero-risk' level - and then

37 Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II –3305.

38 Council Regulation (EC) No 2821/98 of 17 November 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs, [1998] OJ L351/4.

39 The fear was that the heightened resistance of humans to the antibiotics they were exposed to after consuming the animals would decrease the effectiveness of those antibiotics when used to fight bacteria in humans and thus give rise to complications in the treatment of disease which could ultimately be fatal to humans. There was also concern about 'cross-resistance'; a phenomenon whereby 'a bacterium resistant to one member class of antibiotics may also become resistant to other antibiotics of the same class'. See Case T-13/99 *Pfizer* para 32.

40 Case T-13/99 *Pfizer* para 113.

41 ibid para 32.

42 ibid para 50.

43 ibid para 379. However the first sentence of that quote has since been removed from the judgment, at the request of Pfizer, and so is not to be found on the website at present. See case analysis by Wybe Douma, ibid (n 22) 399.

44 Case T-13/99 *Pfizer* para 388.

45 ibid para 139.

46 ibid para 143. On this point, see also Case T-70/99 *Alpharma Inc v Council of the European Union* [2002] ECR II-3495, para 156. Although issued a year earlier, the Commission's Communication appears to be in line with these decisions as it states that the precautionary principle may be applied where 'reasonable grounds for concern' exist; a requirement which effectively rules out hypothetical or speculative risks. See Commission's Communication (n 10) 8.

conducting a scientific assessment of the risks.[47] Although conclusive evidence is not required, the court stated that the risk must be "adequately backed up by the scientific data available at the time when the measure was taken."[48] Accordingly, where there is 'basic scientific knowledge' on which to ground the risk, although the data has not yet been fully validated, the risk is 'uncertain' in terms of the classification mentioned earlier and the precautionary principle can apply. [49]

The requirement for precautionary measures to have some basis in available scientific data raises questions regarding the comparative weight of different scientific opinions and forms of data and the level of freedom competent authorities enjoy in choosing one opinion over another. Crucially, it would appear that the scientific knowledge forming the basis for concern about a potential risk need not be the majority view on the subject.[50] As noted in the Commission's Communication, due account is to be taken of scientific opinions that have the support of only a minority fraction of the scientific community, with the important proviso that "the credibility and reputation of this fraction are recognised."[51] On a similar note, the CFI has emphasised the broad level of discretion enjoyed by Community institutions in taking decisions on precautionary measures, and it was held in *Pfizer* that the Council was free to follow an opinion other than that of their scientific advisory body, SCAN, once specific reasons were given.[52] However, the expert scientific evidence that is relied on instead must be the result of a proper and impartial examination, meeting the requirements of "excellence, independence and transparency."[53] Ultimately, it appears that the most important factor will be that a given measure is taken in light of "the best scientific data available and the most recent results of international research."[54] These safeguards purportedly justify the wide discretion then left to Community institutions and the limited scope of review of decisions, which will only be overturned on grounds of manifest error, misuse of powers or where the bounds of discretion have been clearly exceeded.[55]

G RISK THRESHOLD – DEGREE OF DAMAGE REQUIRED

In addition to the uncertainty thresholds mentioned above, another threshold that may be applied to delineate the scope of the precautionary principle, relates to the degree of damage that is foreseen as a result of the potential risk. Thus a precondition to the application of the principle may be that the impact resulting from the risk be significant, severe or persistent or irreversible.[56] The precautionary principle in international law often comes with such words of qualification. For example the 1992 Rio Declaration on Environment and Development states at principle 15 that: "Where there are threats of *serious or irreversible damage*, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to

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47Case T-13/99 *Pfizer*, para 149. The CFI cites the Commissions Communication as the source for its description of what risk assessment involves.
48 ibid para 144.
49 Nicolas de Sadeleer 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12(2) *Env Law Journal* 139, 148.
50 (n 20) 17.
51 ibid.
52 Case T-13/99 *Pfizer*, para 199.
53 ibid paras 158, 159 and 268.
54Case T-70/99 *Alpharma*, para 171 and 175 ; Case C-192/01 *Commission of the European Communities v Kingdom of Denmark*, ECR I-9693 para 51.
55 Case T-13/99 *Pfizer* para 169; Case T-70/99 *Alpharma* para 180.
56 See discussion by de Sadeleer (n 5) 161-167.

prevent environmental degradation"[57] (emphasis added). Similarly, the 1992 UN Convention on Biological Diversity anticipates a precautionary approach where there is a threat of a *significant* reduction or loss of biodiversity.[58]

As article 174(2) doesn't define the precautionary principle, it comes as no surprise that it does not set down comparable words of qualification. In the absence of an express guideline, it appears from the case law that the question that must be asked is; 'what level of risk is acceptable for society?' In *Pfizer*, the court made it clear that "it is for the Community institutions to determine the level of protection which they deem appropriate for society" against which the acceptableness of risks is measured.[59] Determining the degree of risk that is unacceptable may involve looking at the severity of the impact were the risk to occur, the persistence of the impact. [60] Ultimately, the decision is political in nature, and the kind of risks deemed to require precautionary measures will be "influenced by prevailing social and political values."[61]

H PRINCIPLES OF APPLICATION

The Community institutions' broad discretion in setting standards of protection can be said to be due to the fact that such institutions are under an obligation to ensure a high level of protection for both the environment (article 174(2) EC Treaty) and human health (article 152(1) EC Treaty). However, a zero-risk approach is clearly untenable. Risks exist in everyday life; if we were to only proceed where we could be guaranteed no risks at all we would be very limited in our actions. Moreover, as noted above, the CFI in *Pfizer* expressed the view that a 'zero-risk' test is not an appropriate test for a public authority to apply. Similarly, the Commission has stated that aiming at 'zero-risk' would not be compatible with the principle of proportionality, a long-standing general principle of Community law that applies to all risk management measures.[62] The principle of proportionality is one of a number of general principles of risk management, which the Commission maintains should always apply when precautionary measures are taken.[63] Other principles include that of non-discrimination, consistency and a cost/benefit analysis of action or inaction. It should be noted, however, that this cost/benefit analysis is to be viewed in the light of the decisions of the European judiciary, which make it clear that the protection of public health takes precedence over economic considerations.[64]

The Commission's Communication goes on to state that measures based on the precautionary principle should be "capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment."[65] One way this is done is by shifting the burden of proof so that responsibility for producing evidence demonstrating the safety of a particular substance or product lies with the producer, manufacturer or importer.[66] This is the case where prior approval schemes exist, under which certain substances (eg pesticides, drugs or food additives) are deemed initially to be

57 Rio Declaration Environment and Development, adopted during the United Nations Conference on the Environment and Development (UNCED) 1992.
58 Preamble to the 1992 UN Convention on Biological Diversity.
59 Case T-13/99 *Pfizer*, para 151.
60 ibid para 153.
61 (n 20) 10.
62 (n 20) 18.
63 ibid.
64 Case T-13/99 *Pfizer* para 456.
65 (n 20) 4.
66 ibid 21.

hazardous substances until the contrary is proven.[67] So, for example, the new REACH regulation on chemicals requires that those proposing to manufacture or use certain chemicals must demonstrate that they can be used safely before they will be authorised by the authorities.[68] This wholly reverses the burden of proof as, previously, the onus was on regulatory authorities to demonstrate that a chemical was unsafe before its use could be restricted.

I PRECAUTIONARY ACTIONS OF MEMBER STATES

It is clear from the discussion above that the Community institutions play a large role in setting the standards for acceptable risks in society. However, where a matter is not subject to harmonisation at EU level it would appear that it is for Member State(s) themselves to determine the level of protection appropriate for their citizens and the level of risk they are willing to accept.[69] This can be quite controversial as, often, the measures taken by a Member State in response to perceived risks can be tantamount to an obstruction of the free movement of goods in the internal market. This was the case in Case C-473/98 *Kemikalieinspektion v Toolex*, where the ECJ upheld Sweden's decision to ban the industrial use of the toxic substance trichloroethylene on the basis of the precautionary principle.[70] It was accepted that the ban amounted to a restriction of free trade contrary to article 28 EC Treaty. However, the ECJ took account of the evidence submitted by Sweden concerning links between the use of trichloroethylene and the development of cancer in humans. In particular, it noted the fact that it was not possible at present to determine the threshold level above which exposure to the substance would pose a serious health risk to humans.[71] As there were no Community rules harmonising the use of trichloroethylene, the court held that article 30 of the EC Treaty was applicable, under which the ban was justified on the grounds of protection of health and life of humans, animals or plants.[72]

Toolex is to be contrasted with the situation in Case C-6/99 *Association Greenpeace France v Ministére de l'Agriculture et de la Péche* however. There, the ECJ had to consider whether interpreting certain provisions of Directive 90/220/EEC in such a way as to oblige Member States to give consent to a product that has received a favourable opinion from the Commission would be to disregard the precautionary principle.[73] The court noted that the approval of the product at issue (genetically modified organisms (GMOs)) was the subject of harmonised legislation, which already reflected the precautionary principle in a number of its provisions.[74] As such, once the provisions of the Directive have been complied with Member States were not allowed to refuse consent on the basis of the precautionary principle.[75]

Toolex and *Greenpeace* both concerned situations where national competent authorities elected to take precautionary measures. However, the imperative nature of the

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67 ibid.

68 REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

69 de Sadeleer (n 49) 163.

70 Case C-473/98 *Kemikalieinspektion v Toolex Alpha AB* [2000] ECR I-5681.

71 ibid para 45.

72 ibid para 49.

73 Case C-6/99 *Association Greenpeace France v Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651.

74 ibid para 41-47. Amongst others, the Court referred to art 12(4) which sets down an obligation to inform the Commission of new information regarding risks and the safeguard clause in art 16 which allows Member States to provisionally prohibit or restrict the use or sale of a product on its territory where it has justifiable reasons to suggest that it constitutes a risk to human health or the environment.

75 Case C-6/99 *Greenpeace*, para 42, 43 and 44.

precautionary principle at domestic level (ie how and when Member States can be *obliged* to take precautionary measures) is somewhat uncertain. It is clear that the principle may be relied on in national courts to challenge decisions taken on the basis of EC legislation incorporating the principle, either expressly (for example in the 2001/18/EC Directive on deliberate release of GMOs) or implicitly (for example Habitats Directive 92/43/EEC[76]). One recent example is the case of *Downs v Secretary of State for the Environment, Food and Rural Affairs.*[77] That case concerned a claim that the domestic regime for crop spraying in the UK was failing to comply with EC Directive 91/414/EEC concerning the placing of plant protection products (pesticides) on the market.[78] One of the requirements of the directive was that Member States ensure that a pesticide is not authorised unless it is established that it has no harmful effect on human or animal health, directly or indirectly. Collins J interpreted this to mean a prohibition of *any* harm that was more than merely transient or trifling, whether chronic or not.[79] Moreover, the judge stressed that "the fundamental requirement that human health be not harmed must … require that the precautionary principle is to be applied."[80] Thus, as the claimant had proffered solid evidence showing that residents had suffered harm to their health, or at the very least, raised doubts as to the safety of the pesticides, it was considered that the precautionary principle must clearly apply. It was held that the current controls on crop spraying did not meet the requirements of the Directive and that the Government had to "reconsider what needs to be done."[81]

However in the absence of EC legislation either expressly or implicitly setting out the precautionary principle, article 174(2) does not of itself impose any particular obligation on Member States. A leading case on this matter is *R v Secretary of State for the Environment, ex parte Duddridge*[82], where it was held that Article 130r (now Article 174(2)) did not impose an obligation on the Secretary of State to apply the precautionary principle when carrying out his duties under the Electricity Act 1989. According to Smith J, the principles in article 174(2) are merely intended to "underlie the Community's environmental policy" and article 174(2) was not intended to in itself create an obligation upon a Member State to take a specific action.[83] In coming to this decision, the decision of the ECJ in Case C-379/92 *Peralta* was referred to, in particular at paragraph 57 where it was stated that "Article 130r confines itself to defining the general objectives of the Community in environmental matters" - a judgement which has been described as being "fatal to an argument that [a]rticle 130r could have direct effect."[84]

Fisher remarks that in considering the precautionary principle not to have direct effect, the decision could be interpreted as regarding the precautionary principle in article 174(2) to be non-justiciable.[85] However Fisher goes on to note that although there has been some reluctance by national courts to accept arguments based on the precautionary principle alone, there has been less reluctance to uphold precautionary decisions taken by public

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76 The ECJ held has held that the precautionary principle underlies the Habitats Directive, although it is not explicitly mentioned therein. See Case 127/02 *Waddenzee* [2004] Env LR 14.

77 *Downs v Secretary of State for the Environment, Food and Rural Affairs* [2008] EWHC 2666.

78 The requirements of EC Directive 91/414/EEC were applied domestically by the Plant Protection Products Regulations 2005 (SI 2005 No. 1435).

79 [2008] EWHC 266 para 24.

80 ibid para 23.

81 ibid para 70.

82 *R v Secretary of State for Trade and Industry, ex parte Duddridge*, (1994) Queen's Bench Division, 7 *JEL* 224.

83 ibid 234.

84 David Hughes 'The Status of the 'Precautionary Principle in Law' (1995) 7 *JEL* 224, 243.

85 ibid (n 16) 323.

bodies.[86] In other words, the courts seem more willing to allow the principle to be used as a shield rather than as a sword. However, in the more recent UK case of *R v Tandridge District Council,*[87] it was accepted that "the existence of objectively unjustified fears in the locality could, in some circumstances, be a legitimate factor for a local authority to take into account when dealing with an application."[88] Although the court ultimately held that it had not been shown that the authority had not taken such local fears into account, an action may lie in situations where an authority had simply dismissed such fears without consideration.

Turning briefly to Ireland, it may be said that there has been very little discussion of the precautionary principle by our national courts. Nevertheless, the principle has been influential in certain cases, without being expressly mentioned. For example, the case of *Szabo (a minor) v ESAT Digifone Ltd* which concerned an application for an injunction against the erection of the defendant's mobile phone base station and mast beside the plaintiff's primary school on the grounds that it was dangerous to their health.[89] Being a *quia timet* action, the application was not based on harm actually suffered, but the threat of future harm to plaintiffs. Unusually for an interlocutory hearing, Geoghegan J considered the scientific evidence submitted by the parties in great detail. This was due to the highly contested nature of the scientific evidence offered by the parties and the fact that the granting of an injunction would be highly detrimental to the defendant's business. In the event, however, Geoghegan J was not persuaded by the plaintiff's expert witnesses, whose methods and sources were subject to sharp criticism by the other party's scientists. He stated that as there was no "proven substantial risk of danger" and it was "highly improbable at the very least" that any injury would be caused to the plaintiff pending the hearing, the application was dismissed.[90]

J CONCLUSION

The above analysis has looked at the precautionary principle in terms of the type of risk it applies to, competent authorities' obligations and discretions in taking precautionary measures and some of the effects these measures may have. Since the precautionary principle has been in operation, it has been relied on on numerous occasions, not only at EU level, but at domestic level also. It may be said that the principle has been put to greater use in the areas of human health and safety than the environment, despite the latter being the area from which it emerged.[91] This is most likely due to the fact that, as noted above, the decision to take precautionary measures is a political one and one that depends on the risks that society are willing to tolerate.

Although the Commission's Communication has been useful in better defining the precautionary principle and outlining guidelines for its application, it is submitted that the full capacity of the principle has not yet been seen. This is an inherent difficulty with abstract legal principles, which refer forward to the possibility of their application in a given case and when applied in a case, refer back to their abstract meaning, so that their meaning is always deferred.[92] While this allows for greater flexibility it also creates uncertainty as to the use to which the principle will next be put. In relation to the precautionary principle, while its exact

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86 ibid 324.
87 *R v Tandridge District Council and another, ex parte Al Fayed* [2000] 1 PLR 58.
88 ibid 61.
89 *Szabo (a Minor) v ESAT Digifone Ltd* [1998] 2 ILRM 102.
90 [1998] 2 ILRM 102, 110 and 112.
91 de Sadeleer (n 49).
92 Renowned philosopher Jacques Derrida coined the term 'deterrence' to describe this phenomenon.

contours and implications are still being worked out, concerns remain that it may be used to stifle innovation and dampen scientific progress. However, it is undeniable that in today's world of fast-paced technological and scientific advances such a principle is necessary. Socrates famously expressed wisdom to be in knowing that you do not know. The precautionary principle can be said to reflect this philosophical position by allowing us to accept the limitations of our knowledge and make wiser choices in light of them.