

Legal Aspects of the Precautionary Principle

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Brexit Briefing

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Executive Summary

The *European Union (Withdrawal) Act 2018* requires the Secretary of State for the Environment, Food and Rural Affairs to publish a draft Bill by 26 December 2018 containing a set of environmental principles, including the precautionary principle. The Secretary of State is also required to publish a statement of policy relating to the application and interpretation of these. This British Academy Brexit Briefing is intended to facilitate debate on the content and wording of the Secretary of State's draft Bill and statement of policy in relation to the precautionary principle. The precautionary principle is controversial, in part because it is often mis-represented and misunderstood. A careful analysis of the content and legal status of this principle in EU and international law can help to inform decision-making within the post-Brexit UK.

The precautionary principle is enshrined in the Treaty on the Functioning of the European Union. While there are many different versions of the precautionary principle, each supports the basic proposition that it is better to be safe than sorry. It sanctions policy intervention in circumstances where the scientific evidence demonstrating the existence of a threat to human health or the environment is not unequivocal.

This Brexit Briefing adopts a legal perspective on the precautionary principle and demonstrates that the EU has endorsed a moderate version of this principle. Application of the precautionary principle within the EU is underpinned by a range of scientific and other constraints. For example, protective measures 'cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture that has not been scientifically verified'.

In a report published in 2001, the European Environment Agency coined the evocative phrase 'late lessons from early warnings'.¹ This report gathered evidence about situations in which policy-makers have acted too late to prevent harm to human health and the environment. The authors of the report formulate twelve 'late lessons' that can be drawn from their case studies. While many of these lessons stress the importance of improving the quality and range of information relied upon by regulators, the final lesson stresses the importance of 'avoid[ing] "*paralysis by analysis*" by acting to reduce potential harm when there are reasonable grounds for concern'. This, in a nutshell, is what the precautionary principle permits decision-makers to do. We can see an example of this in relation to the controversial and high-profile issue of whether neonicotinoid insecticides pose a threat to the survival of bees.

¹ *Late Lessons from Early Warnings: The precautionary principle 1896-2000* (Environmental Issue Report, No 22/2001).

Save the bees!

Following the loss of bee colonies in Europe, the EU took steps in 2013 to restrict the use of certain 'neonicotinoid' insecticides. The legality of these restrictions was challenged by manufacturers before the EU's General Court. The EU had relied upon a risk assessment conducted by the European Food Safety Authority which while establishing that the substances in question posed a risk to bees and honeybees also acknowledged areas of uncertainty due to a lack of scientific data. Calling the precautionary principle in aid, the General Court upheld the legality of the restrictions observing that 'the Commission need do no more than provide, in accordance with the general rules of evidence, solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the fact that the active substance in question satisfies the approval criteria' (Cases T429/13 and T451/13 Byer CropScience AG & Syngenta Crop Protection AG). Additional restrictions were introduced by the EU in 2018 following the collection of substantially more data that confirmed the existence of a risk to bees.

This Brexit Briefing provides an overview of the precautionary principle as it is currently interpreted and applied within the EU. It will begin by looking at the European Environment Agency's working definition of the precautionary principle to identify a number of the key elements and choices that are embedded within it (Part 3). It will then explore the origins of the precautionary principle in international and EU law (Parts 4-5), provide an overview of its content within the EU (Part 6) and raise two key questions relating to its application (Part 7). Part 8 of this Brexit Briefing considers the question of whether the precautionary principle has attained the status as a general principle of EU law. The Briefing concludes by setting out a series of key messages to assist those who are responsible for determining the content and status of the precautionary principle in the post-Brexit UK (Part 9).

Part 1: The precautionary principle in the *European Union (Withdrawal) Act 2018*

The *European Union (Withdrawal) Act 2018* provides for the '[m]aintenance of environmental principles' in section 16.² The Act seeks to tie the hands of the Government by imposing a duty on the Secretary of State to publish a draft Bill by 26 December 2018.³ This draft Bill will apply to England and to reserved matters across the rest of the UK. This draft Bill is intended to perform at least two functions. The first is to elaborate a set of environmental principles and the second is to provide for the establishment of a public authority with responsibility for enforcing environmental law.⁴ This section on the maintenance of environmental principles was included as a compromise following amendments proposed by the House of Lords.⁵ *The Withdrawal Act 2018* also confers special status on general principles of EU law when issues of retained EU law arise. A question may thus arise whether the precautionary principle is a general principle of EU law.

The *Withdrawal Act 2018* lists a series of environmental principles, 'however worded', which are to be included in the draft Bill. The precautionary principle is included among these, as too are most of the other principles contained in Article 191 of the Treaty on the Functioning of the European Union (TFEU). The *Withdrawal Act 2018* does not identify as a principle the requirement that environmental policy shall aim at a high level of protection.⁶ It does, however, include environmental an integration obligation, requiring the integration of environmental protection requirements into the definition and implementation of policies and activities.⁷

The Secretary of State is obliged to include in the draft Bill a statement of policy relating to the application and interpretation of the environmental principles in connection with the making and development of policies by Ministers of the Crown.⁸ The draft Bill must further impose a duty on Ministers of the Crown to have regard to this statement of policy in the circumstances provided for in it.⁹ The Secretary of State therefore enjoys quite substantial discretion not only in honing the wording of the environmental principles but also in shaping the role they are to play in the policy-making process.

2 *European Union (Withdrawal) Act 2018*, chapter 16 which received royal assent on 26 June 2018.

3 Namely, six months after the Act obtained royal assent. The Act does not specify which Secretary of State is to be responsible for so doing. In practice, the Secretary of State for the Environment, Food and Rural Affairs is likely to be responsible for this task.

4 Section 16(1)(1) in relation to the former and Section 16(1)(4) in relation to the latter. The Secretary of State may also include other provisions in this Bill as he or she deems appropriate.

5 The amendments were inserted by Lord Krebs, Baroness Jones, Baroness Bakewell and Lord Deben (Lord Amendments to the *European Union (Withdrawal) Bill*, 17 May 2018). The tabled amendments were considerably stronger than the final Act.

6 Article 191 TFEU states that Union policy on the environment shall aim at a high level of protection but does not label this as a principle.

7 An integration obligation of this kind is currently found in Article 11 TFEU. *The Withdrawal Act 2018* also includes the principle of sustainable development; and labels as 'principles' the three pillars of the Aarhus Convention, namely public access to information, public participation in environmental decision-making and access to justice in relation to environmental matters, requiring that these too are included in the Bill.

8 Section 16(1)(b) *Withdrawal Act 2018*.

9 Section 16(1)(c) *Withdrawal Act 2018*.

Part 2: A working definition of the precautionary principle

While there is no single version of the precautionary principle, the European Environment Agency has provided a useful working definition in its second *Late Lessons from Early Warnings report*:¹⁰

The precautionary principle provides justification for public policy and other actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health and/or the environment, using an appropriate strength of scientific evidence, and taking into account the pros and cons of action and inaction and their distribution.¹¹

This working definition exemplifies the importance of the manner in which various thresholds are drawn. This will determine how weak or strong a particular version of the precautionary principle is.¹² Four key elements included in this working definition are identified in the table below, and we will return to these in Part 6. First though, it is useful to consider the origins of the principle internationally and within the EU.

The Gateway	The Problem	Scientific Constraints	Other Constraints
Applies in situations of scientific complexity, uncertainty and ignorance	When there is potentially serious or irreversible threat	Using appropriate strength of scientific evidence	Taking into account the pros and cons of action and inaction and their distribution

Table 1: Key thresholds in the EEA's working definition of the precautionary principle

¹⁰ The full title of the 2013 report is *Late lessons from early warnings II: science, precaution and innovation* (EEA Report, 1/2013).

¹¹ *Ibid.*, p. 649 (emphasis removed).

¹² K. Garnett & D.J. Parsons, 'Multi-Case Review of the Application of the Precautionary Principle in European Union and Case Law' (2017) 37 *Risk Analysis* 502. These authors use three different variables to measure the strength of the precautionary principle: severity of potential harm, standard of evidence (or degree of uncertainty), and nature of the regulatory action.

Part 3: The origins of the precautionary principle in international law

Beginning in the 1980s, references to precaution and to the precautionary principle or precautionary approach started to find their way into international instruments, including a significant number of treaties.¹³ The principle was codified in clear form for the first time at the international level in Principle 15 of the non-binding Rio Declaration on Environment and Development which states:¹⁴

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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 prevent environmental degradation.

Since this time, the precautionary 'principle' or 'approach' has been included in an increasing number of international treaties and instruments, only some of which use the formulation included in the Rio Declaration.

There is strong disagreement about the status of the precautionary principle or approach in international law. At the least, there is 'a trend towards making this approach part of customary international law'.¹⁵ This has been recognised by the International Tribunal for the Law of the Sea,¹⁶ and the International Court of Justice has recognised that 'a precautionary approach may be relevant in the interpretation and application of the provisions of the Statute'.¹⁷

The status of the precautionary principle within WTO law is of considerable practical importance because it can play a role in determining the lawfulness of restrictions on trade. The Appellate Body of the WTO has considered it '[un]necessary and probably imprudent' to pronounce on the status of the precautionary principle as a principle of general or customary international law.¹⁸ It has nonetheless accepted that the principle finds explicit expression in the Sanitary and Phytosanitary Measures Agreement (SPS Agreement).¹⁹ The Appellate Body has endorsed a precautionary approach, arguing that WTO panels 'may...and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible e.g. life-terminating damage to human health are concerned'.²⁰

It should be noted that these observations about international law have all related broadly to environmental (including health) issues. They do not imply that the precautionary principle is accepted as being relevant across other areas of policy.

13 For an overview see M. Bocchi, 'The Reshaping of the Precautionary Principle by International Court: Judicial Dialogues or Parallel Monologues?' Geneva Jean Monnet Working Paper 2/2016 at: http://www.ceje.ch/files/2314/5933/0264/Geneva_JMWP_02-Bocchi.pdf

14 The text of this is available at: <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>.

15 Advisory Opinion, ITLOS Seabed Dispute Chamber, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area (2011, Case No. 17), para. 135.

16 Ibid.

17 The relevant treaty was the 1975 Statute of the River Uruguay concluded between Argentina and Uruguay.

18 WT/DS26/AB/R, EC - Measures Concerning Meat and Meat Products, para. 123. See also the second Hormones report at WT/D320/AB/R, United States - Continued Suspension of Obligations in the EC - Hormones Dispute.

19 Ibid (DS26), para. 124. This includes but is not confined to Article 5.7 of the SPS Agreement.

20 Ibid.

Part 4: The introduction of the precautionary principle in EU law

There was early recognition that EU action on the environment was to be based on a number of environmental principles. These were spelt out both in the EU's first Environmental Action Programme,²¹ and in the Single European Act which conferred explicit environmental competence on the European Community (as it then was) for the first time.²² However, the precautionary principle did not see the light of day in EU law until the Maastricht Agreement establishing the European Union which was concluded in 1992. This provided that EU environmental policy shall be based, *inter alia*, on the precautionary principle,²³ and this obligation is now enshrined in Article 191 TFEU. Although the Maastricht Treaty was concluded in the same year as the Rio Declaration on Environment and Development, the introduction of the principle into the EU's founding treaty is said to have been at the behest of Belgium and to have been influenced by the 'vorsorgeprinzip' (foresight principle) in German law.²⁴

While in the first instance, it was only the EU's environmental policy that was to be based on the precautionary principle, this principle has since then flowed into other areas of EU law, including notably the protection of public health.²⁵ This has, to a significant degree, been a result of the influence of the 'environmental integration obligation' in Article 11 TFEU which provides that 'environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development. The European Commission adopted a Communication on the Precautionary Principle in 2000.²⁶

21 1st Declaration of the Council of the European Communities and of the representatives of the Governments of the Member States meeting in the Council of 22 November 1973 on the programme of action of the European Communities on the environment, (73/C112/01, OJ C 112, 20.12.73), Part II

22 Article 130r(2) of EC Treaty as amended by the SEA which entered into force in 1987.

23 Article 130r(2) TEU.

24 E. Scotford, *Environmental Principles and the Evolution of Environmental Law* (OUP, 2017) kindle edition, loc. 3409. See also J. Peel, 'Precaution – A Matter of Principle, Approach or Process?' (2004) 5 *Melbourne J Int L*, fn. 1. noting that some ascribe Swedish origins to the principle.

25 Case T-74/00 *Artegodan v. Commission*, para. 183. For a full discussion see Scotford *ibid*, chapter 4.

26 COM(2000) 0001 final, Communication from the Commission on the Precautionary Principle.

Part 5: An overview of the precautionary principle in EU law

It is challenging to summarise the precautionary principle in EU law because its interpretation depends in part upon the specific wording of EU legislation. Using the elements that make up the EEA's working definition of the precautionary principle and drawing on the Commission's communication as well as the case law of the CJEU, this brief will identify some of the key aspects of the precautionary principle in EU law.

i) The gateway

Where there is scientific uncertainty as to the existence or extent of risks to human health or the environment, the precautionary principle allows for the adoption of protective measures without having to wait until the reality and seriousness of those risks become fully apparent.²⁷ The European Commission has emphasised that scientific uncertainty can arise from controversy regarding existing data or due to an absence of relevant data, and that it may be qualitative or quantitative in nature.²⁸ The European Court of Justice has recognised that scientific uncertainty can flow from the insufficiency, inconclusiveness or imprecision of the results of studies that have been conducted.²⁹

ii) The nature of the problem

By contrast with the working definition of the precautionary principle laid out by the European Environment Agency, the European Court of Justice has not limited the application of this principle to circumstances in which the threat being addressed is potentially serious or irreversible. Rather, it is for the decision-maker to assess whether potential risks exceed the threshold of what is acceptable to society, bearing in mind that the EU is committed to achieving a high level of protection for the environment and public health.³⁰ The setting of an appropriate or acceptable level of protection is viewed as a political responsibility,³¹ to be undertaken by the EU institutions, including the Member States within the Council of the European Union.³² This will depend upon the circumstances of a particular case, and the decision-maker may take account of the severity of the impact were the risk to occur, including the extent of possible adverse effects, their persistency or reversibility, and the possibility of delayed effects.³³ The level of protection deemed to be appropriate may shift over time as controversies over risk and precaution unfold.

The threshold above which risk will no longer be regarded as acceptable depends upon the wording of particular legislation and is frequently a question of interpretation for the European courts. The precautionary principle may require that a 'likelihood of real harm...persists',³⁴ the mere 'possibility of harmful effects',³⁵ or the existence of reasonable (scientific) doubt about the harmfulness of a product or activity.³⁶

27 Case C-236/01 *Monsanto Agricoltura Italia SpA and Others*, para. 111. The CJEU sometimes talks of protective measures and sometimes of preventive measures. They may be viewed as inter-changeable for the purpose of the discussion here.

28 Commission communication, supra n. 26, para. 5.1.3.

29 See e.g. Case C-157/14, *Neptune Distribution v. Minister for Economic Affairs and Finance*, para. 82; Case C-477/14, *Pillbox (38) UK Ltd v. Secretary of State for Health*, para. 55; Case C-269/13 P, *Acino v. Commission*, para. 58; Case C-192/01, *Commission v. Denmark*, para. 52. See e.g. Case T-13/99 *Pfizer*, para. 151.

30 Commission Communication, supra 26, para. 5 and Case T-257/07, *France v. Commission*, paras. 78-80.

32 See e.g. *Pfizer*, supra 30, para. 150 observing that WTO law permits Members to adopt their own 'appropriate level of protection'.

33 Commission Communication, supra 26, para. 5.1.2.

34 See the cases cited supra 29.

35 Case C-111/16, *Fidenato*, para. 44 & 50.

36 Case C-127/02, *Waddenzee*, para. 51; Case T-229/04, *Sweden v. Commission*, para. 170.

However, even in its strictest application of the precautionary principle, the CJEU has insisted that protective measures ‘cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified’.³⁷ EU institutions are not permitted to predicate their actions upon pursuit of a ‘zero-risk’ level of protection, where this includes the adoption of measures to guard against non-scientifically verified, hypothetical, risks.³⁸

iii) The scientific constraints

As this reference to hypothetical risks suggests, the CJEU places science at the heart of its interpretation of the precautionary principle. From the very start, the Commission has insisted that recourse to the precautionary principle requires not only the identification of potentially negative effects resulting from a phenomenon, product or procedure, but also a scientific evaluation of risk which is as ‘objective’ and ‘complete’ as possible.³⁹ This scientific evaluation should include an assessment of scientific uncertainties together with the possible consequences of inaction, and demonstrate the existence of a threat to the politically determined acceptable level of protection.⁴⁰

The Commission’s emphasis upon the importance of scientific evaluation has been taken up by the General Court (and the Court of First Instance as it was previously called) in a body of case law which is rich in detail about the scientific constraints which underpin the precautionary principle. While this case law cannot be fully described in this brief, a number of key elements are identified. It is, however, important to be aware that there is a rich body of literature in the environmental social sciences and science and technology studies that cautions that precautionary decision-making is inherently political and that it is misleading to suggest that it can be exclusively ‘science-based’. It is crucial to recognise uncertainties and disagreements in science and the importance of value judgment and public engagement in decision-making under conditions of uncertainty.⁴¹ Uncertainty can arise for different reasons, be it scientific complexity, scientific disagreement, the existence of gaps in knowledge or the enduring possibility of ‘unknown unknowns’.⁴²

Under EU law, measures adopted pursuant to the precautionary principle must be based on as thorough a risk assessment as possible.⁴³ This must meet the standards of excellence, independence and transparency.⁴⁴ It must provide the decision-maker with sufficiently reliable and cogent information to understand the ramifications of the scientific question raised, and to decide upon policy in full knowledge of the facts;⁴⁵ and enable the decision-maker to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk deemed acceptable for society.⁴⁶

37 *Ibid*, para. 147 & 161.

38 *Ibid* & Pfizer, supra 30, para. 152.

39 Commission Communication, supra 26, generally paras. 5 and 6.1. Case C-343/09, *Afton Chemicals v. Secretary of State for Transport*, para. 60.

40 *Ibid* (communication), para. 6.2.

41 Andy Stirling’s work is a good place to start in this respect. See for example, A. Stirling, ‘Opening Up the Politics of Knowledge and Power in Bioscience’ (2012) 10(1) *PLoS Biol.* 1.

42 The term ignorance is used to capture the ‘virtual certainty that there [are] factors that remained outside the scope of the risk assessment’, leading to ‘inevitable surprises’ or ‘unpredictable effects’ (see EEA, supra n 10, p 169).

43 Pfizer, supra 30, paras. 155 & 162. See also *France v. Commission*, supra 31, paras. 67-83, where the Court of First Instance (now the General Court) spells out the elements that make up a risk assessment in considerably more detail.

44 Pfizer, supra 30, para. 172.

45 Pfizer, supra 30, para. 162.

46 Pfizer, supra 30, para. 162.

Banning the use of antibiotic substances in animal farming

One of leading cases concerning the precautionary principle involved an EU prohibition on the use of certain antibiotic substances as an additive in food for poultry and pigs (Case T-13/99 Pfizer). The legality of this prohibition was challenged by the manufacturer of one of the substances before the EU's General Court. The EU's decision was based upon the existence of a risk that use of such substances in animal farming could pose a risk to human health by increasing antibiotic resistance in humans. The legality of the EU's prohibition was upheld by the General Court despite the fact that there was scientific disagreement about the existence and extent of this risk.

iv) Other constraints

In its Communication on the Precautionary Principle, the European Commission identified a number of 'general principles of risk management' and argued that reliance on the precautionary principle does not exempt decision-makers from applying them. It included as general principles of risk management: proportionality, non-discrimination, consistency, examination of the benefits and costs of action or lack of action as well as examination of scientific developments.⁴⁷ In keeping with these principles, the Commission argued that the precautionary principle cannot be relied upon to justify the adoption of arbitrary decisions.⁴⁸

The proportionality principle has emerged as of particular importance in the CJEU's case law regarding the precautionary principle. Proportionality encompasses three elements: a measure must be necessary and appropriate to attain its aim, must not be more restrictive or onerous than is necessary to do so, and the disadvantages caused by the measure must not be out of proportion with the aim pursued. In general, the scientific uncertainty that underpins measures based on the precautionary principle has been used by the CJEU as an element which weighs in favour of a finding that the measure is proportionate.⁴⁹

This last element of the proportionality principle is regarded as raising the question of whether a decision strikes an appropriate balance between the protection of public health, environment and consumer safety on the one hand, and economic interests, including the interests of traders, on the other. It therefore overlaps with the risk management principle identified by the Commission which requires an examination of the costs as well as the benefits of action and inaction. In keeping with the CJEU's observation that 'public health must take precedence over economic considerations',⁵⁰ it has been willing to grant the EU institutions wide room for manoeuvre in this regard.

⁴⁷ Commission Communication, supra 26, para. 6.3.

⁴⁸ Commission Communication, supra 26, paras. 5.1, 5.2.2. & 7.

⁴⁹ For a good discussion of the manner in which the precautionary principle informs the application of proportionality see Scotford, supra 24, chapter 4. See e.g. Afton Chemicals supra 39, para. 66.

⁵⁰ Pfizer, supra 30, para. 456.

Part 6: Two key questions regarding the precautionary principle in EU law

i) Does the precautionary principle ever require, rather than merely permit, the adoption of protective measures?

While the language used by the General Court has sometimes suggested that the precautionary principle can ‘require’ the adoption of measures to guard against risks to public health, safety or the environment, the European Court’s case law on the precautionary principle has served largely to expand rather than contract the regulatory freedom of EU institutions and Member States.⁵¹ However, two exceptions will be highlighted here.

The first looks like a typical precautionary principle case as it is concerned with the question of whether use of a product should be permitted within the EU. While most cases of this kind are brought by manufacturers who are unhappy that their product has been excluded from the EU market, this case was brought by Sweden which was unhappy that the Commission had sanctioned the herbicide paraquat for continued use.⁵²

According to the relevant EU legislation on plant protection products in force at that time, active substances could only be authorised if it was established that their residues and use, consequent on application consistent with good protection practice, does not have any harmful effects on human or animal health or groundwater, or an unacceptable influence on the environment.⁵³ However, substances that do not meet these requirements could still be authorised for use where they are made subject to restrictions on use which exclude the problematic uses of the substances.

Reading this latter provision in accordance with the precautionary principle, the General Court concluded that for such products to be authorised, it must be established ‘beyond a reasonable doubt’ that these restrictions on use make it possible to ensure that substance in question does not generate any of the prohibited effects on health or the environment.⁵⁴ In light of this, the Court annulled the Commission’s decision approving paraquat as an active substance for use within the EU. This was due to the existence of two studies which reached unfavourable conclusions regarding this substance and which consequently served to raise reasonable doubts as to its safety.

The second exception is more unusual and is significant because it emerges from the case law of the European Court of Justice as opposed to the General Court. This concerns Article 6(3) of the Habitats Directive which the European Court has construed in accordance with the precautionary principle.⁵⁵ In light of this, Member States are *required* to undertake an assessment of a plan or project unless it can be excluded on the basis of objective information that this plan or project will have significant effects on the protected site.⁵⁶ Where *doubt* remains as to the absence of significant effects, the

51 See e.g. *Artogodan*, supra 25, paras. 184 & 192; *Pfizer*, supra 30, para. 444; Case T-392/02, *Solvay Pharmaceuticals BV v. Council*, para. 12; *France v. Commission*, supra 31, para. 66

52 *Sweden v. Commission*, supra 36.

53 Article 5(1), Directive 94/414/EEC concerning the placing of plant protection products on the market. The current framework is established by Regulation 1107/2009 concerning the placing of plant protection products on the market.

54 *Sweden v. Commission*, supra 36, para. 170.

55 Directive 92/43 on the conservation of natural habitats and wild fauna and flora.

56 *Waddenzee*, supra 36, paras. 44-45.

assessment must be carried out.⁵⁷ Further, Member States may only authorise a plan or project where they can be certain, in light of the best scientific knowledge in the field, that the plan or project will not have lasting adverse effects on the integrity of the site.⁵⁸ ‘That is so where no reasonable scientific doubt remains as to the absence of such effects’.⁵⁹ Thus, authorisation must be refused where uncertainty as to its effects on the protected site remain.⁶⁰

Even here though, the strength of the precautionary principle is tempered by the fact that protective measures are required only in the case of significant effects (procedural obligation to conduct an impact assessment) and lasting adverse effects (substantive obligation not to approve the project). The Habitats Directive also contains an exception which permits the approval of plans or projects that may negatively affect the integrity of a site where this is justified by imperative reasons of overriding public interest.⁶¹ Thus, even though these habitats cases give rise to a stronger version of the precautionary principle, which requires rather than permits the adoption of protective measures when faced with scientific uncertainty about risk, there is still room to weigh up the advantages and disadvantages of adopting protective measures.

Nature conservation in the Waddenzee

In the *Waddenzee* case, the Court of Justice of the European Union invoked the precautionary principle in the context of nature conservation (C127/02 *Waddenzee*). The Waddenzee ecosystem is rich in flora and fauna, especially birds. Two nature protection organisations challenged the legality of the Dutch Secretary of State’s decision to grant mechanical cockle fishing licenses in the Waddenzee and argued that this should have been preceded by an environmental impact assessment in accordance with the EU’s Habitats Directive. The European Court agreed. Although it was accepted that most of the scientific studies consulted did not unequivocally indicate that cockle fishing would cause significant adverse effects to the Waddenzee ecosystem, neither could this be excluded on the basis of objective information. Mechanical cockle fishing in Dutch Waddenzee has since been banned.

ii) Does the precautionary principle ‘reverse the burden of proof’ in EU law?

The Commission’s communication on the precautionary principle states that ‘[t]he precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.’⁶² This is consistent with the European Court’s insistence that neither the EU institutions nor the Member States can adopt measures in order to guard against a risk which is merely ‘hypothetical’. It is then generally clear that it falls to the regulating authority to produce evidence of the existence of a potential risk. This will be easy when the threshold for demonstrating the existence of risk is low; e.g. requiring evidence of the possible existence of risk. It will, however, become harder as the threshold becomes more demanding, for example by requiring reasonable certainty, or likelihood, as to the existence of risk.⁶³ As was seen previously, the nature of this threshold varies under EU law.

57 Ibid, para. Para. 44.

58 Case C-258/11, *Sweetman & Others v. An Bord Pleanála*, para. 40.

59 Ibid (emphasis added).

60 Ibid, para. 41.

61 Directive 92/43, supra, Article 6(4).

62 Commission Communication, supra 26, para.. 51.

63 Late Lessons from Early Warnings II, supra 10, p. 659.

However, the Commission also observes in its communication that when the EU requires the prior approval of products before they are placed on the market ‘the legislator... has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise’. It is for the ‘business community’ to carry out the research necessary to demonstrate the absence of an unacceptable level of risk. Where the evidential threshold is set at a level which is strict, for example by requiring evidence that there is no reasonable scientific doubt about a product’s safety, this burden of proof may be difficult to fulfil.

The prior authorisation of products is widespread in EU law relating to the protection of the environment and public health. We saw a classic example in the Swedish paraquat case and the REACH Regulation on chemicals yields another important example in that Substances of Very High Concern require prior authorisation.

As these and many other examples suggest, reality is more complex than is suggested by the notion of reversing the burden. The Plant Protection Directive requires the prior authorisation of active substances because it has already been concluded that they ‘may involve risks and hazards for humans, animals and the environment’, and the directive includes a derogation for ‘low-risk’ active substances which are expected to pose only a low risk to human or animal health and the environment.⁶⁴ In the REACH Regulation, chemicals only require prior authorisation where they have been demonstrated to be hazardous, either due to their intrinsic properties or due to their persistence or potential for bioaccumulation.⁶⁵ Other chemicals can be included on the list of substances of very high concern only where there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those already listed.⁶⁶

This turns a spotlight on the question of what it means for a product or an activity to have sufficient hazardous potential for it to require prior authorisation. Table 27.4 below, extracted from the EEA’s second *Late Lessons, Early Warnings* report offer an insight into the different kinds of criteria that can be used.⁶⁷ This includes reasoning by analogy from known hazards (point 8), and ‘novelty’ (point 2) which is characterised by the existence of a low ‘knowledge/ignorance ratio’. The hazardous potential of novel products does not arise because of gaps or uncertainties in our stock of accumulated knowledge relating to that product, but because of our ignorance and consequent susceptibility to being unpleasantly surprised.⁶⁸ Viewed in this way, even prior authorisation requirements relating to novel products can be viewed as ‘hazard-based’ rather than involving a wholesale reversal of the burden of proof.⁶⁹

64 Regulation 1907/2009 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Recital 7 & Article 22.

65 Ibid, Article 57(a-e).

66 Ibid, Article 57(f).

67 Late Lessons from Early Warnings II, supra 10, p. 653.

68 Late Lessons from Early Warnings II, supra 10, pp. 653-655.

69 See e.g. the ‘notification procedure’ in Directive 2001/18 on the deliberate release of genetically modified organisms.

Box 27.4 Criteria for precautionary action: some features of evidence about the hazardous potential of agents that may justify precautionary action

1. Intrinsic toxicity/ecotoxicity data
2. Novelty (i.e. where there is a low 'knowledge/ignorance ratio')
3. Ecological or biological persistence
4. Potential for bioaccumulation
5. Large spatial range in the environment e.g. potential for global dispersion
6. Seriousness of potential hazards
7. Irreversibility of potential hazards
8. Analogous evidence from known hazards
9. Inequitable distribution of hazardous impacts on particular regions, people and generations
10. Availability of feasible alternatives
11. Potential for stimulating innovation
12. Potential and time scales for future learning

Box 27.4 reproduced from the EEA, *Late lessons from early warnings II: science, precaution and innovation* (EEA Report, 1/2013), p. 653

Part 7: The status of the precautionary principle as a principle of EU law in post-Brexit UK

The precautionary principle is labelled as a 'principle' in Article 191 TFEU but the question has arisen as to whether it may be considered to be a 'general principle of EU law'. General principles have a special, higher, status in EU law. Whilst the distinction between a 'principle of EU law' and a 'general principle of EU law' may sound esoteric, it has important implications, not least in relation to the *Withdrawal Act 2018*. This is because the *Withdrawal Act 2018* confers special status on general principles of EU law. It provides that any question as to the validity, meaning or effect of retained EU law is to be decided in accordance with retained case law and any retained general principles of law.⁷⁰ A general principle of law, for the purpose of the *Withdrawal Act 2018*, must have been recognised as such by the European Court in a case decided before exit day.⁷¹

The idea that the precautionary principle has attained the status of a general principle of EU law first arose as a result of the judgment of the EU's Court of First Instance (now the General Court) in the *Artegodan* case.⁷² In this judgment, the Court asserted that the precautionary principle 'can be defined as a general principle of Community law',⁷³ and an 'autonomous principle' which stems from the EU treaties.⁷⁴ There are nonetheless two reasons to doubt whether the precautionary principle should be regarded as a general principle. First, the European Court as opposed to the General Court, has never affirmed the status of the precautionary principle as a general principle. In one recent

⁷⁰ *Withdrawal Act 2018*, supra 2, s. 6.3. This is subject to certain limitations such as that in s. 5 concerning the Supreme Court. See also Schedule I(2) further limiting the role of retained general principles before UK courts. This states for example, that UK courts may not disapply or quash a UK law on the basis of a general principle.

⁷¹ *Withdrawal Act 2018*, supra 2, schedule I(2).

⁷² *Artegodan*, supra 25.

⁷³ *Artegodan* supra 25, para. 184.

⁷⁴ *Artegodan* supra 25.

case, the European Court described the principle as a ‘general principle of food law’ as opposed to a general principle of EU law.⁷⁵ Second, even the Court of First Instance (now the General Court) appears to have used the term ‘general’ to refer to the fact that the principle is applicable across different areas of EU law – notably public health/safety and the environment - and that it applies in these areas by virtue of the Treaties rather than because of any explicit reference in a legislative text. Thus, the principle is *generally* applicable as an autonomous principle throughout these different areas of EU law, rather than constituting a general principle in the formal sense as understood by the European Court.⁷⁶

Part 8: Key messages

This overview of the precautionary principle provides insights that could inform the Secretary of State’s formulation of the precautionary principle in the draft Bill to be published in December 2018.

First, there is no agreed definition of the precautionary principle and a number of key thresholds have to be set in order to render the principle operational. Drawing on the European Environment Agency’s working definition of the precautionary principle, this brief has identified four key thresholds. The manner in which the EU has drawn these thresholds is summarised in the table below. This demonstrates that the EU has adopted a moderate version of the precautionary principle.

The gateway	The problem	Scientific constraints	Other constraints
Scientific uncertainty as to the existence or extent of risks	Potential risks exceed the level that is deemed acceptable for society; with proviso that cannot seek to guard against ‘hypothetical’ risks	Based on as thorough a risk assessment as possible meeting standards of excellence, transparency and independence	Risk management principles including proportionality, non-discrimination, consistency and examination of the benefits and costs of action and inaction

Table II: Key thresholds underpinning the precautionary principle in EU law

Second, the inclusion of the precautionary principle in the EU has operated in the main to carve out additional room for manoeuvre for EU institutions and Member States when they adopt regulations. It is very rare, though not unknown, for the precautionary principle to serve as a basis for challenging decisions because they are insufficiently protective.

Third, within the EU, the precautionary principle applies not only in relation to environmental protection but also in other policy domains by virtue of the environmental integration obligation. Given that the *European Union (Withdrawal) Act 2018* stipulates that an environmental integration obligation is also to be included within the draft Bill retaining environmental principles, this diffusion is also likely to occur within the UK.

⁷⁵ Fidenato, supra 35, para. 46.

⁷⁶ See Scotford, supra 24, chapters 2 & 4 for an overview. Scotford supports the conclusion here that the precautionary principle is not a general principle of EU law.

Looking to EU experience, this is likely to be of particular importance in relation to consumer protection and the protection of public health.

Fourth, the precautionary principle has been interpreted by the CJEU in the context of the EU's commitment to achieving a high level of protection for the environment and human health. A commitment of this kind is absent from the text of the *Withdrawal Act 2018*. Moving forward, this absence could influence the interpretation of the precautionary principle in UK law, and lead to differences between the EU and the UK in the manner in which the key thresholds underpinning the precautionary principle are defined.

Fifth, following the UK's withdrawal from the EU, the precautionary principle will continue to be embedded in EU law and to be reflected in WTO law. Regardless of the UK's approach to this principle, it will continue to assist Member States of the EU and WTO in justifying reasonable trade restrictions that serve to protect the environment or human and animal health.

Sixth, contrary to the impression that is often given, it should not be assumed that the precautionary principle has attained the status of a general principle of EU law. As such, it is unlikely to be a retained general principle under the terms of the *Withdrawal Act 2018*.

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