European Commission

Science for Environment Policy

# FUTURE BRIEF: The precautionary principle: decision-making under uncertainty

September 2017
Issue 18

Environment

## Science for Environment Policy

**The precautionary principle: decision-making under uncertainty**

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# Contents



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**To cite this publication:**

Science for Environment Policy (2017) *The Precautionary Priniple: decision making under uncertainty*. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at:
http://ec.europa.eu/science-environment-policy

**Acknowledgements**

We wish to thank the scientific adviser Professor Elen Stokes (Birmingham Law School) for her input to this report. Final responsibility for the content and accuracy of the report, however, lies solely with the author.

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ISBN 978-92-79-67015-2
ISSN 2363-278X
DOI 10.2779/709033

## Introduction

# The precautionary principle: its role in law and policy

***One of the greatest challenges facing today's environmental policymakers is how to deal with complex risks, such as those associated with climate change. These risks are difficult to deal with because they are not precisely calculable in advance. Where there is scientific uncertainty about the full extent of possible harms but 'doing nothing' is also risky, decision-makers may use the precautionary principle. This Future Brief explores the role of the precautionary principle in EU law and policy, and examines key points of discussion drawn from the evidence.***

*Inattendu situation* © iStock/Bplanet 2015

Incomplete information, inconclusive evidence and public controversy can make it difficult to achieve consensus over the appropriate response to hazardous substances or activities, but these are precisely the sorts of conditions that often demand hard and fast decisions.

The precautionary principle is designed to assist with decision-making under uncertainty and is a core principle of EU environmental law, enshrined in Article 191(2) of the Treaty on the Functioning of the EU. The classic definition of 'a precautionary approach' comes from the 1992 Rio Declaration on Environment and Development, which states 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 prevent environmental degradation"* (UNEP 1992).

In other words, a precautionary approach captures the idea that regulatory intervention may still be legitimate, even if the supporting evidence is incomplete or speculative and the economic costs of regulation are high. Better safe than sorry. In the *Communication on the Precautionary Principle from 2000*[1], the European Commission clarified that:

> *"Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.*
>
> *The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty" (European Commission, 2000, COM (2000) 1 final).*

The European Commission also refers to the need for 'reasonable grounds for concern' about potential risks. Crucially, this means that the principle ought only to be used if a risk is deemed to be plausible. Any regulatory measures introduced as a result of the precautionary principle should also be subject to review in light of new scientific data, and may have to be modified or abolished as new scientific data become available.

In this sense, the Communication provides a step-by-step guide to applying the principle; however, it is not prescriptive and is designed to be flexible, allowing for the variety of circumstances in which the principle might operate. The Commission notes that it is ultimately for decision-makers and the courts to flesh out the details.

The Communication is just one account of the precautionary principle; others can be found in different legal contexts. Even within EU law, the precautionary principle is highly malleable and performs many different functions (Scotford, 2017). As a result, the precautionary principle is seen as more complex and dynamic than the principle of *prevention*, which addresses better-understood risks to the environment. In reality, it is difficult to draw a sharp line between 'precaution' and 'prevention', given that science always entails elements of doubt and uncertainty. One notable difference, however, is that the principle of prevention has not generated the same level of controversy as the precautionary principle — possibly because the idea of acting on *known* risks is less objectionable, given the EU's emphasis on 'evidence-based policy'.

The precautionary principle has been applied to a diverse range of fields, including health protection, environmental regulation, biodiversity management and emerging technologies. It may be difficult to reach agreement on exactly how to implement the precautionary principle, because understandings of risk can vary among decision-makers, stakeholders and citizens. No doubt the precautionary principle will continue to spark debate about the best ways of dealing with environmental change.


Risk management concept © iStock/Cacaroot 2016

1. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l32042

# 1. Scientific uncertainty

Scientific uncertainty is key to understanding how and why the precautionary principle applies (von Schomberg, 2012).

The development of 'evidence-based policy' has highlighted the challenges of dealing with environmental uncertainty (Stirling, 2016). It is unrealistic to expect regulatory science to provide totally conclusive information to governments on public health or environmental issues — as some element of uncertainty is an unavoidable part of scientific inquiry. It can be difficult to determine exactly when and how to act on potential risks (Uggla *et al.*, 2012). Definitive answers to such questions are not available: principles like the precautionary principle are not rules that prescribe specific actions or outcomes.

The meaning of 'uncertainty' is also more complex than might be apparent. Science and technology studies have shown that uncertainty can stem from more than a simple lack of data or inadequate models of risk assessment. Uncertainty might also exist in the form of indeterminacy (where we don't know all the factors influencing the causal chains), ambiguity (where there are contradictory certainties), and ignorance (where we don't know what we don't know). The precautionary principle can play an important role in addressing these multiple layers of uncertainty.

To illustrate whether and how the precautionary principle might apply to different types of uncertainty, Von Schomberg (2012) considers four scenarios:

- The precautionary principle is not intended to apply to 'hypothetical effects and imaginary risk'; rather, it should be based on a scientific examination of the issue. Indeed, this has been confirmed on numerous occasions by the Court of Justice of the EU (see e.g. Case T-13/99 Pfizer Animal Health SA v Council of the European Union [2002] ECR II-03305).

- The precautionary principle will not apply where the desired level of protection is defined and the risk of harm can be quantified. This situation can be dealt with using 'normal' risk-management tools.

- Where an activity or substance poses a plausible threat of harm but there is insufficient scientific evidence, or a lack of agreement as to the nature or scale of the likely adverse effects, a precautionary approach can be justified.

- A precautionary approach might be warranted where the potential harms are known but the particular cause-effect relationships cannot be scientifically established.

As is clear, there is no single approach to the precautionary principle. Persson (2016) suggests that 'extra precaution' may be justified when dealing with important values (such as health and environmental protection), although these are systematically downplayed by more traditional decision methods; or when we suspect that the decision might lead to irreversible and severe consequences, and where the values at stake are also irreplaceable; or when it is more important to avoid false negatives than false positives. Understandings of the precautionary principle will continue to develop as conceptions of uncertainty evolve.

## 2. Criticisms and responses

A common criticism of the precautionary principle is that it is ill-defined. Concerns relate to ambiguous terms such as 'irreversible harm' or 'lack of full scientific certainty'. For example, Sandin (2006) criticises the Rio Declaration's formulation for only telling us what not to do, and for not defining a 'serious threat'.

Critics have suggested that these definitional problems undermine legal certainty (Morris, 2000) and produce inconsistent and unprincipled decisions (Marchant & Mossman, 2004). Some argue that particular versions of the principle are paralysing because they offer no guidance and forbid all courses of action (Sunstein, 2003).

Responses to criticisms of ambiguity include the argument that inconsistency is not caused by the principle itself, but rather by its application. Garnett & Parsons (2016) review a selection of EU cases which invoke the principle and suggest that the decision on whether to apply the precautionary principle in EU law can be unclear, 'with ambiguities inherent in determining what level of uncertainty and significance of hazard justifies invoking the precautionary principle' (Garnett & Parsons, 2017).

It has also been pointed out that conventional risk assessment is no more 'intrinsically immune' to manipulation than other decision principles (Stirling, 2016). The precautionary principle should not be understood as a precise formula but rather a 'flexible principle that ensures that decision-makers are not ignoring problems of scientific uncertainty' (Fisher, 2007).

Stirling (2016) emphasises that the precautionary principle can be used in multiple ways, in conjunction with various risk-assessment and foresight tools (Science for Environment Policy, 2016). The principle can be read as a simple requirement to take risks into account, even if they are unproven, which is an approach common to all mainstream fields of decision-making in conditions of uncertainty (Grant & Quiggin, 2013).

A further criticism of the precautionary principle is that it is anti-scientific and stifles innovation. This argument is most commonly directed at 'strong' interpretations of the principle — which may be understood as ruling out all developments that could have adverse health or environmental consequences.

This interpretation of the principle is attacked on the basis that it is never possible to eliminate risk altogether; there is no such thing as a zero-risk activity. An associated fear is that overly precautionary decision-making will discourage investment in technological development, leading 'in no direction at all' (Sunstein, 2003). The principle is also sometimes misunderstood by critics to mean 'excessive' regulation rather than precaution. Some of these concerns are voiced by industry representatives fearing burdensome rules because of the precautionary principle. However, others argue that applying the principle does not necessarily mean more stringent or costly regulation, and that it could simply be used to

Funny cartoon scientist with a question mark ©iStock/artenot 2013.

Wind power, development of. Pixabay/winniero 2016. Creative commons CC0

ensure better processes of decision-making rather than any particular outcome.

The Wingspread Conference Statement on the Precautionary Principle (issued following a meeting between scientists, philosophers, lawyers and environmental activists in Wisconsin, United States, in 1998) states that the application of the principle should involve 'open, informed and democratic' processes, and 'must include potentially affected parties'.

It does not follow that precaution is un- or anti-scientific. What is unscientific, says Stirling (2016), is to ignore multiple perspectives on uncertainty. The fact that the precautionary principle can encourage more open discussion of the value judgements underpinning methods of risk assessment and cost-benefit analysis can be said to make the principle more, rather than less, reasonable and accountable. The precautionary principle may also help to avoid situations in which standard risk analysis otherwise creates a bias in favour of taking chances on poorly understood risks (Grant & Quiggin, 2013).

One response to arguments that the precautionary principle is too strong (and thus paralysing) or too weak (and thus meaningless) is that the principle may be used for a range of different purposes (such as strengthened standards, monitoring measures or licensing arrangements).

Braunisch *et al.* (2015) develop a 'gradated' approach to precaution, which goes beyond binary arguments ('anti-scientific'/'pro-scientific', 'anti-innovation/'pro-innovation'). Their case study on wind-power developments (see page 19) highlights the potential for a more nuanced application of the precautionary principle.

## *Case Study: Scientific uncertainty and climate change litigation*

A recent legal analysis suggests that using the precautionary principle in climate-change-related legal cases could increase the chances of success by overcoming problems of scientific uncertainty that are otherwise exploited by defendants (Omuko, 2016).

Frustrations over failure to tackle climate change has driven some public-interest groups, individuals and local governments to take corporations and national governments to court, particularly in Australia and the United States. In a recent example in Europe, a case was brought against the Dutch government by a Dutch NGO (Hague District court, 2015). In this landmark case, the court ruled that the government was neglecting its duties to address climate change adequately and ordered it to curb the Netherlands' emissions. However, this example is an exception to the general pattern. Elsewhere, most climate-change-related cases do not lead to successful rulings. Omuko (2016) argues that the main barrier to success is the 'proof problem'. This refers to two related issues:

- The first issue is the 'drop in the ocean' problem. This is an argument often used by defendants to claim that their emissions are too small compared with global emissions to cause any real impact.
- The second issue is scientific uncertainty. Although there is strong scientific evidence of climate change and its impacts, it is not possible to link a specific impact to a specific source of emissions — as is usually required by courts.

The precautionary principle may be used in these situations to take protective measures notwithstanding a lack of evidence of harm or straightforward causal relationships. In practice, it may allow courts to accept general evidence of climate change and its impacts. For instance, evidence of global sea-level rise could mean that erosion at a specific coastal site is likely. This approach was taken in an Australian case, where the court accepted the general consensus that climate change will lead to a risk of extreme weather events, and, therefore, did not grant a building permit to construct seaside apartments.[2]

The precautionary principle could also shift the burden of proof to the defendant. This occurred in the United States where the Environmental Protection Agency (EPA) was required to prove that greenhouse gas emissions from the transport industry do not contribute to climate change. The EPA failed to prove this and was ordered to regulate transport emissions. The court took a precautionary approach in this case, arguing that the EPA could not avoid its obligations because of some 'residual uncertainty' (Supreme Court of the United States, 2007).

Omuko (2016) argues that increased use of the precautionary principle in litigation could lead to more successful judgements and, consequently, place greater pressure on governments and businesses to be more proactive in their response to climate change.

2. Gippsland Coastal Board vs South Gippslands & Others: https://www.vcat.vic.gov.au/sites/default/files/resources/gippsland_coastal_board_v_south_gippsland_sc_and_others.pdf

# 3. Precautionary principle in practice: application in the EU

The precautionary principle was formally adopted in the Maastricht Treaty in 1992, and is one of the main principles on which EU environmental policy is based. Article 191(2) Treaty on the Functioning of the EU[3] imposes an obligation on EU institutions to ensure that EU environmental policy is based on the precautionary principle.

The principle has also been incorporated into a number of measures of secondary legislation (i.e. Regulations and Directives), which apply to Member States. For example, the principle underpins the 2007 Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[4], which gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances circulating in the EU market.

The European Commission's *Communication on the Precautionary Principle* provides additional information about the procedural steps that decision-makers are expected to take in implementing the precautionary principle.

The Communication states that an approach based on the precautionary principle should:

- start with the fullest possible scientific evaluation, identifying at each stage and as far as possible the degree of scientific uncertainty;
- entail an evaluation of various risk-management options, including the option of taking no precautionary action; and
- involve as early as possible and, to the extent reasonably possible, all interested parties.

The Communication goes on to explain that any measures adopted on the basis of the precautionary principle should also be:

- proportionate (i.e. should not go beyond what is appropriate);
- non-discriminatory and consistent (meaning that comparable situations should not be treated differently);
- based on cost-benefit analysis; and
- subject to review when new scientific information becomes available.

## 3.1 Scope for a more precautionary approach?

Some case studies, e.g. Harremoës *et al.* 2002, have suggested that, had the precautionary principle been applied in certain situations, for example to limit the use of specific habitat-damaging antifouling agents in paints for ships and boats, environmental harm could have been avoided (Santillo *et al.* 2001).

Patterson & Gray (2012) identify the UK Government's initial failure to adopt a precautionary approach to bovine spongiform encephalopathy (BSE) in British cattle, arguing that it was a major policy mistake to interpret 'no evidence of harm' as 'evidence of no harm'.

Historical case studies have led some to conclude that a more precautionary response was needed to manage human exposure to substances such as asbestos and dichlorodiphenyltrichloroethane (DDT) (Harremoës *et al.* 2002).

3. http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-the-functioning-of-the-european-union-and-comments/part-3-union-policies-and-internal-actions/title-xx-environment-climate-change/479-article-191.html
4. http://ec.europa.eu/environment/chemicals/reach/reach_en.htm


Business accident ©iStock/Bplanet 2014.

In a more recent example, the Organisation for Economic Co-operation and Development (OECD) has called for a precautionary approach to particular applications of nanotechnology, stating that "there is enough evidence to suggest that exposure to nanoparticles, particularly to those insoluble in water, should be minimised as a precaution."(OECD, 2005).

The precautionary principle is said to apply to the EU regulation of nanotechnologies because existing EU legislation, such as REACH, is already underpinned by the principle. REACH and chemical classification, labelling and packaging (CLP) are currently used as frameworks for the risk management of nanomaterials when they occur as substances or in mixtures.

However, as the framework in these areas has been established without specifying whether substances are nano- or non-nano-scale, there is an uncertainty as to whether relevant risk assessment, also leading to identification of adequate risk management, can be generally anticipated as the result of this framework. 'In order to close those gaps, it is necessary to turn to the precautionary principle and argue for an interpretation of the relevant provisions in the light thereof.' (Heselhaus, 2010).

While the European Commission states that current regulatory regimes reflect the precautionary principle, it notes that "additional precautionary action such as substance or use restrictions for individual substances (including on particular forms or modifications of nanomaterials) may become necessary if new information becomes available indicating serious potential risks" (European Commission, 2012).

## Case Study: How the UK Government has used the precautionary principle

In line with the EU principles, the UK Government implemented a precautionary approach to its decision-making and, as early as 1990, acknowledged it as a key principle of environmental policy. However, the UK has come under criticism from certain researchers and commentators for only implementing the precautionary principle as a last resort or when strongly influenced by public opinion or the EU (Boehmer-Christiansen, 1994).

Patterson & Gray (2016) have assessed whether the UK government uses the precautionary principle in an opportunistic or pragmatic manner in environmental decision-making. Case studies were used to examine the government's position, including their approach to the use of organophosphorous pesticides (OPs) in sheep dips and genetically-modified (GM) crops.

Official and non-official documents were consulted to assess the cases, including Parliamentary Select Committee reports, government departmental reports, scientific research reports and journal articles, and newspaper reports. In addition, 14 interviews were conducted with Members of Parliament, members of advisory committees, research scientists, and members of advocacy groups such as the Organophosphorus Information Network (OPIN).

OPs were commonly used in sheep dips to control skin parasites, such as lice and sheep scab, during the 1980s, when about 40 million sheep were treated once or twice a year. Farmers who were exposed to OPs during handling or spraying of the chemicals complained they suffered health problems, including headaches, flu-like symptoms, blurred vision, short-term memory loss and confusion.

Despite pressure from farmers, the government did not invoke the precautionary principle and, therefore, did not ban OPs. Three government committees (the Veterinary Products Committee,the Committee on the Safety of Medicines, and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment) had advised the government that there were no proven health risks from low exposure to OPs. Patterson & Gray (2016) suggest that the government took the view that banning OPs could lead to the use of other substances that could harm water quality within rivers. The government was criticised for its approach and it has been suggested that its decision may have been influenced by industry pressure.

When legislating on GM crops, the UK government started from a similar position. The government initially saw GM crops as a potential new market, as no hazards had been shown by early research. The government's position changed due to public opposition and EU policy (the EU having adopted a stronger precautionary approach).

GM crops generated negative public opinion and in 1998 the EU operated an unofficial moratorium on new approvals of GM products. Concerns included whether GM crops, such as plants resistant to insect pests, might escape into wild populations and impact negatively on biodiversity.

Organisations such as the Royal Society for the Protection of Birds and Friends of the Earth called for a halt to GM crop development. There were also concerns regarding potential impacts on human health.

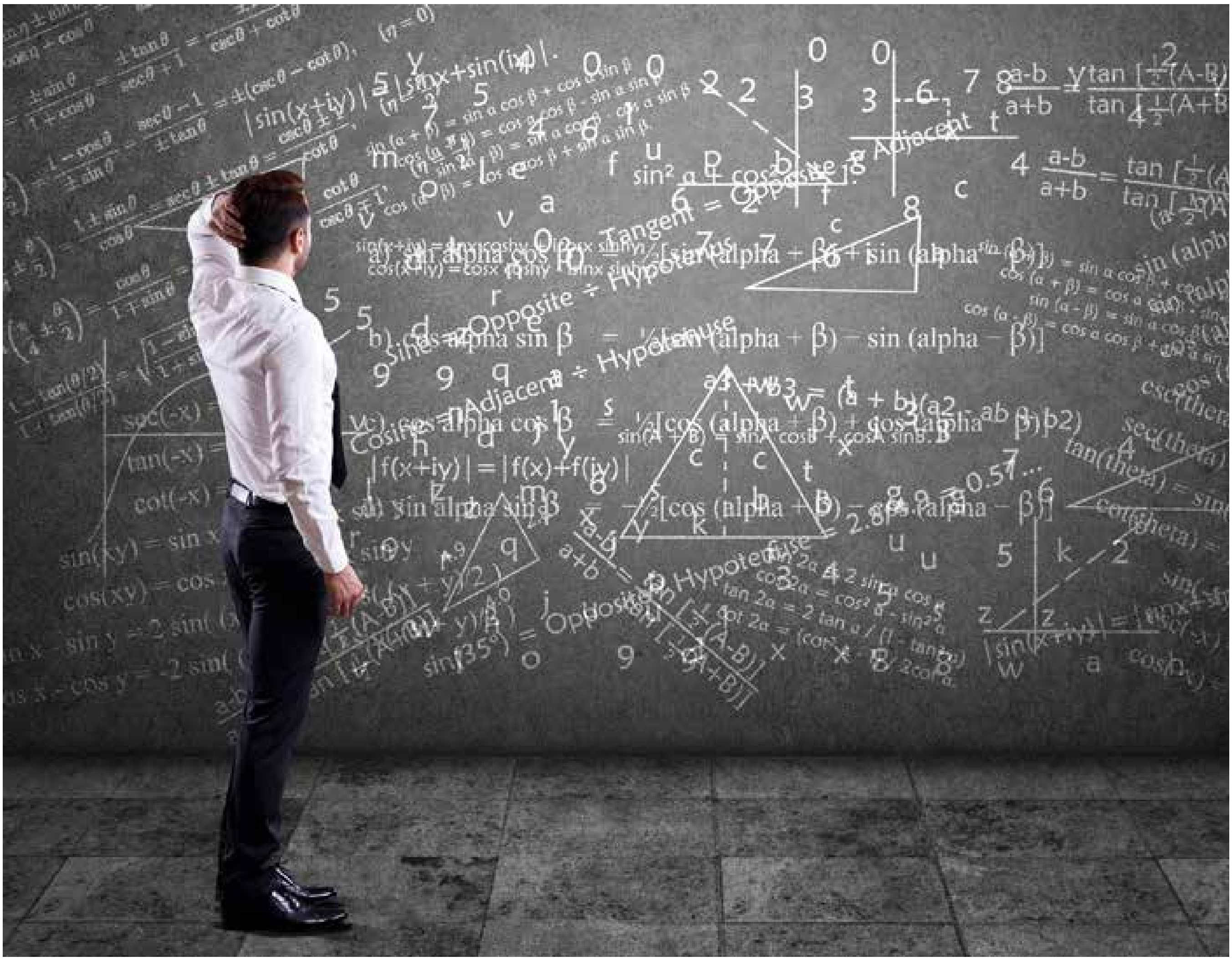
As a result, the UK Government delayed development of GM food crops until field trials had been completed. The government also formed a Cabinet Committee on Biotechnology and initiated public debate on genetic modification. The scientific review of GM crops found no evidence for banning them, but found gaps in the knowledge base and it was, therefore, decided that approval of products should be considered on a case-by-case basis.

Patterson & Gray (2016) describe this as a strong precautionary position, influenced by public opinion, NGOs, EU policy and the paucity of scientific knowledge. These factors and the need for an immediate decision on GM crops explain the different approach taken compared to that to OPs.

Some commentators have said that the UK Government reluctantly implemented the precautionary principle in these examples (Van Zwanenberg & Millstone, 2002). However, Patterson & Gray (2016) argue that the UK's approach is based on pragmatism and reflects the circumstances of each case.

A report by the UK Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA, 2002) suggests that the precautionary position adopted "should reflect the commitment to sustainable development that gives full weight to economic, social and environmental factors." It adds that the principle should not obstruct innovation and, applied properly, it is a positive policy tool "to encourage technological innovation and sustainable development by helping to engender stakeholder confidence that appropriate risk control measures are in place".

**Table 1** (opposite) presents a range of different views of precaution — ranging from 'weak' to 'strong', from a study by Garnett & Parsons (2017).



Business man solving mathematical equation ©iStock/triloks 2016.

| Attributes used to assess the strength of application of the precautionary principle | Weak precaution: 'uncertainty does not justify inaction' | Moderate precaution: 'uncertainty justifies action' | Strong precaution: 'uncertainty justifies shifting the burden and standard of proof' |
|---|---|---|---|
| **Severity of potential harm prompting precautionary action as referenced in international legislation and regulation** | Rio Declaration suggests that regulation is permitted to avoid 'serious and irreversible damage' | The European Commission Communication on the precautionary principle suggests the use of regulation proportional to the risk level, following preliminary objective scientific evaluation to avoid 'potentially dangerous effects' | The Wingspread Statement conveys that clear responsibility lies with the proponent in proving an activity is safe even if the cause-and-effect relationship cannot be determined scientifically to avoid 'threats of harm' |
| **Degree of epistemic uncertainty/ quality of evidence prompting precautionary action** | Regulation is permitted in the absence of full scientific certainty; significant precautionary action may be invoked under uncertainty | Research is needed to establish cause and effect (reduce uncertainty) upon which regulatory decisions are based; until then, precautionary action includes setting regulatory standards with large margins of safety built in through application of uncertainty factors | Uncertainty necessitates forbidding the potentially risky activity until the proponent of the activity demonstrates that it poses no (or acceptable) risk. And is sufficiently safe |
| **Nature of precautionary action/ measures taken and provision for review** | Presumption of risk management; banning very rare | Underlying presumption of risk management; banning possible, but is a last resort; measures are provisional or subject to review when new information or scientific evidence emerges | Presumption of risk avoidance; banning is likely |

**Table 1: Interpreting the strength of application of the precautionary principle.**
Source: Garnett & Parsons D. J. (2017) Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. *Risk Analysis,* 37: 502–516. .

## 3.2 Contexts of application

The precautionary principle may be used in different ways: for instance, it can aid the development of new rules and regulations, or it can be invoked when applying existing legislation. It can also result in different types of legal requirement depending on the context in which it is applied.

For example, under the Directive on the Deliberate Release of Genetically Modified Organisms (GMOs), suppliers of GMOs have to demonstrate the safety of the organism before it is placed on the EU market. There has been strong pressure to regulate GMOs in line with the precautionary principle, which has provoked criticism that the principle is being applied selectively. The criticism is that organisms which pose similar risks, but which have not been produced using genetic engineering, are not subject to the same precautionary approach (Morris, 2007).

BOX 1.

### Burden of proof and the release of GMOs

In 2001 the EU introduced legislation to reduce the risks related to **the deliberate release of GMOs into the environment (Directive 2001/18/EC)**. The objective of the Directive — to protect human health and the environment — is explicitly in accordance with the precautionary principle. Under the Directive, GMOs for cultivation must undergo an individual risk assessment to ensure safety, before being authorised for use in the EU. The burden of proof lies with suppliers of GMOs — i.e. the applicant for a GMO release is required to demonstrate safety, rather than regulatory agencies or third parties having to demonstrate a risk. This might be seen as a moderate interpretation of the precautionary principle.

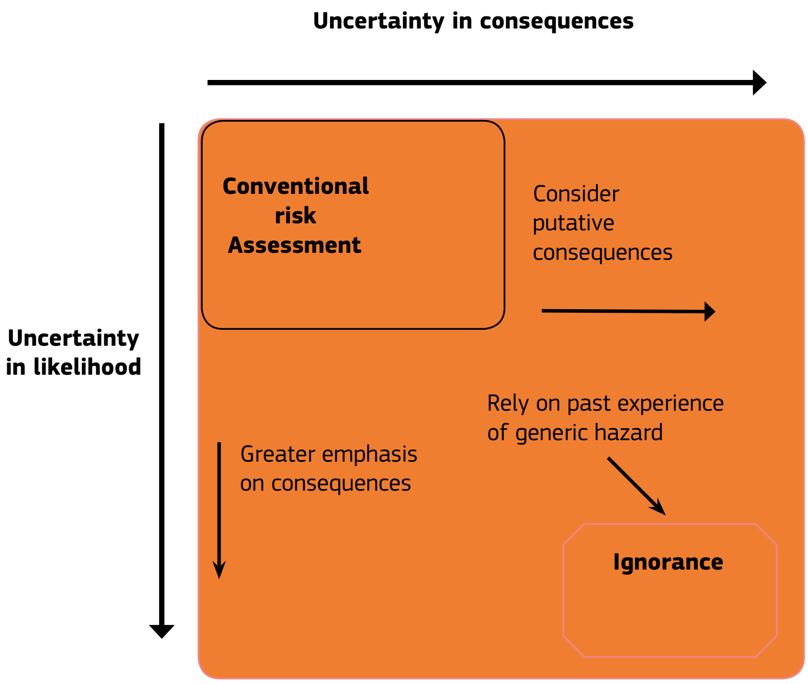
The **Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000)** allows countries to limit the use and release of GMOs in situations of scientific uncertainty with regard to potentially adverse ecological and health effects. In this case the principle was used to a lesser extent, given the fact that the Protocol allows decision-makers to take protective measures in regard to the import of GMOs even if supporting evidence is lacking, provided those measures are cost-effective.

In the **Norwegian Gene Technology Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms**, etc. (**amended 2005**), the deliberate release of organisms may only be approved when there is no risk of adverse effects on health or the environment, placing the burden of proof firmly on the prospective producer. Significant weight is also given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development, when deciding whether to grant an application. This legislation, therefore, makes strong use of the precautionary principle.

The burden of proof has been variously positioned in different contexts. The Wingspread definition of the precautionary principle states that "When an activity raises threats of harm to human health or the environment… the proponent of an activity, rather than the public, should bear the burden of proof" (Wingspread, 1998).

The EU REACH Regulation (EC) No. 1907/2006[5] on chemicals also places the burden of proof onto the supplier or manufacturer, requiring companies to identify and manage the risks associated with the substances they manufacture and market in the EU. They must demonstrate to the European Chemicals Agency how the substances can be safely used, and have to communicate health and safety information to the other users in the supply chain. The Regulation clearly states that its provisions "are underpinned by the precautionary principle" (Article 1(3)).

Tosun (2013) has found that Member States' interpretations of the precautionary principle can differ. For example, Swedish policymakers may regard the application of the precautionary principle as compulsory, in contrast to their counterparts in the UK, who may regard it as more of an enabling principle (see case study on the UK Government's approach, pages 11-12). The UK's former Interdepartmental Liaison Group on Risk Assessment emphasised that the precautionary principle can only be applied by making assumptions about consequences and likelihoods to generate 'credible scenarios' (i.e. in the practice of assessing the status quo, ideal and worst-case scenarios) (see **Figure 1**).




*"In the upper left-hand corner — in the box labelled conventional risk assessment — consequences and likelihoods can be established and their robustness checked. Here conventional risk assessment gives an estimate of the risk generally accepted as valid by the stakeholders — the precautionary principle is not relevant. However, moving along the axes in Figure 1 the uncertainties increase, and the precautionary principle has to be invoked and applied to move to a decision. In these circumstances, reasonable assumptions have to be made about consequences and likelihoods… Each set of assumptions establishes a credible scenario."*

**Figure 1: An enabling principle: UK ILGRA's approach to establishing credible scenarios**
Source: Adapted from *The Precautionary Principle: Policy and Application. The need for a consistent approach.* United Kingdom Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA). 2002.

5. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410

## 3.3 Using the precautionary principle to manage environmental risks from technologies in the EU

Several emerging areas of technology, such as synthetic biology (Zhang, 2011), gene editing (Clark, 2006), nanotechnology (Hannah & Thompson, 2008) and climate geoengineering (Liu & Chen, 2015), are said to have the potential to generate uncertain risks for the environment. Von Schomberg (2012) outlines how the principle has been used for nanotechnology. In the 2000s, new legislation was not immediately proposed for nanotechnology, which provided policymakers with flexibility to respond to risks as the technology developed. For example, scientific uncertainty and a lack of consensus on definitions meant it was not feasible to develop technology-specific legislation.

The EC's Recommendation on a code of conduct for responsible nanosciences and nanotechnology research[6] (European Commission, 2009) was designed to help foster collaboration and communication between relevant parties, including policymakers, researchers, industry and civil society. On the basis of a precautionary approach, France, for example, has introduced a mandatory nanotechnology reporting scheme, which requires companies to file a declaration for each nanomaterial they produce, import or distribute.

Stirling (2016) provides a general framework for using the precautionary principle with practical implications for emerging technologies. The framework sets out 17 key considerations, each representing a quality that should be demonstrated in a precautionary technology appraisal. The criteria for appraisal include independence from vested institutional, disciplinary, economic and political interests, and examination of a greater range of uncertainties, sensitivities and possible scenarios.

The framework includes an initial screening process so that only the most appropriate issues are subject to a precautionary appraisal. Questions such as 'is the threat scientifically uncertain?', and, 'is the threat socio-politically ambiguous?' will help to determine when a precautionary appraisal, stakeholder deliberation and risk assessment are needed.

Stirling (2016) envisages a process in which these stages are interlinked rather than completely separate, and in which they all feed into the communication, evaluation and management of identified threats (see **Figure 2**).

Doubt ©iStock/ Topp_Yimgrimm 2015

6. http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf

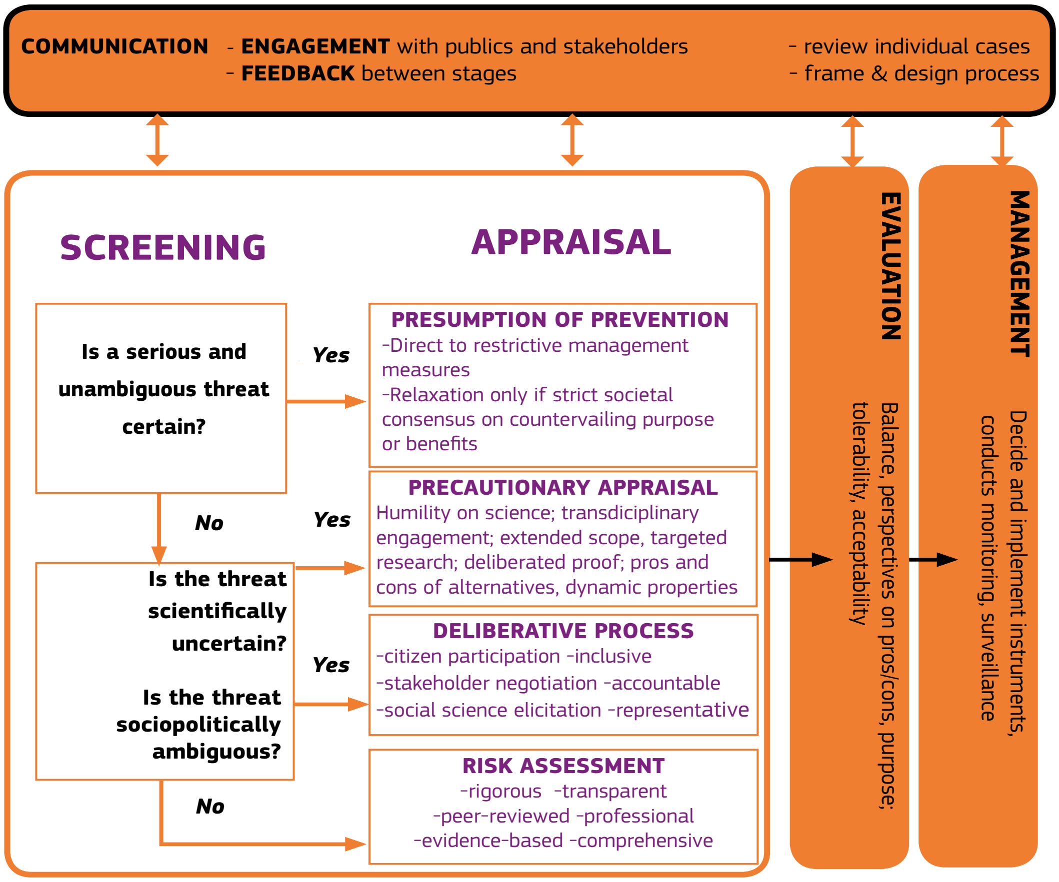



**Figure 2: An illustrative general framework for using the precautionary principle**

Source: Adapted from: Stirling, *Precaution in the Governance of Technology*. SWPS 2016-14 (July): Working Paper Series. Science Policy Research Unit. University of Sussex.

Solution ©iStock/ oatawa 2016.

BOX 2.

## The precautionary principle and the innovation principle

Scientific and technological advance continues to be a vital part of the EU's innovation agenda. The precautionary principle — enshrined in Article 191(2) of the Treaty on the Functioning of the EU — is sometimes viewed as a potential barrier to the innovation principle. According to the Council — in its conclusions from 27/05/2016 — this innovation principle should be applied when considering, developing or updating EU policy or regulatory measures. It entails taking into account the impact on research and innovation[7] and should ensure that the choice, design and regulatory tools encourage, rather than impede, innovation.

According to the European Political Strategy Centre (EPSC), the European Commission's in-house think tank, the precautionary principle is, however, vital for innovation, because, especially at the developmental stage of a new technology, the possibility of a risk often cannot be eliminated. The precautionary principle provides essential procedures and standards to assess, appraise and control risks. A crucial element of the risk management, as encapsulated by the precautionary principle, is the consideration of the potential benefits and costs of action, or inaction (European Political Strategy Centre, 2016).

7. The Council also called upon the Commission, together with Member States, to further determine the use of the innovation principle and to evaluate its potential impact.

## *Case Study: The precautionary principle in biodiversity management — capercaillies in the Black Forest*

There are often calls to use the precautionary principle in the context of planning new wind farms (Braunisch *et al*, 2015), when available evidence indicates that such development could cause ecological harm. Harm might be in the form of collisions with flying species, the loss and fragmentation of habitat due to construction, and avoidance of the area by wildlife.

As a precautionary measure, therefore, wind farms are generally not placed in important habitats. However, the exact size of a turbine-free zone around a habitat are fiercely debated due to the scientific uncertainties relating to specific species and locations.

Braunisch *et al.* propose a new wildlife-friendly method, based on the precautionary principle, for determining prohibition zones for wind farms in ecologically important areas. This approach was applied to the case of wind-farm planning in the Black Forest, Germany, a hotspot for new wind farms.

The forest is also home to a relatively large but highly vulnerable population of capercaillies (*Tetrao urogallus*) (also known as wood grouse), a species protected by the EU Birds Directive[8]. It is unclear how the low-flying capercaillies are affected by turbines, but it is known from wider research that they are highly sensitive to human activity. Therefore, it is assumed that there is a high likelihood that they will be affected by the wind farms.

Braunisch *et al.* categorise areas of land on a scale of 1–4, based on the area's importance for the survival of the local capercaillie population. According to their method, turbines should not be placed within a 1-km radius of the most important areas (category 1) as here they are very likely to bring harm to capercaillies. Developers are free to place turbines in areas which appear to be of no importance, and which are graded as category 4. For areas under categories 2 and 3, turbines could pose a risk. Braunisch *et al.* recommend a detailed assessment of the bird population at these sites before deciding whether turbines are acceptable here, or whether their impacts could be minimised.

To develop the four categories, Braunisch *et al.* considered a range of factors, including land where capercaillies are currently found; suitable additional habitat that would be needed to ensure a thriving population in the long term; and land that forms corridors or stepping stones between patches of habitat. They also assessed the quality of each habitat patch, its size, its accessibility and whether it is an existing reproduction site.

A habitat suitability model was used to assess each site with regard to its long-term potential to provide and naturally support suitable habitat (such as forest) structures for capercaillies. It used data from historic capercaillie patches and took into account forest availability and fragmentation, climatic conditions and soil conditions as well as aspects of human disturbance.

Braunisch *et al.* concluded that the precautionary principle is a crucial part of conservation policymaking, but suggested that public acceptance of this method is strongly contingent on the coherence of arguments regarding the probability of the threat and the credibility of the proposed measures.

Braunisch *et al.* say that their particular approach makes the best possible use of available evidence and helps to increase public acceptance of the precautionary principle, by avoiding criticisms that it is unscientific and that it leads to regulations that are either too restrictive or not prohibitive enough.

8. http://ec.europa.eu/environment/nature/legislation/birdsdirective/index_en.htm

BOX 3.

**Future research directions**

Some authors argue that, in recent years, international and EU agreements, court rulings and communications from the EU have helped to develop a greater understanding of the precautionary principle (von Schomberg, 2012). However Tosun (2013) states that there is still only a limited appreciation of how precautionary policies are made, and highlights the following future research directions:

- How does the political situation influence the development of precautionary policies in the EU?
- Are precautionary policies made in a distinctive way compared to other policies?
- What are the political reasons for policymakers to use the precautionary principle?
- Does policy change on the basis of new scientific evidence?

# 4. Conclusion

Since its incorporation in the Rio Declaration (1992), the precautionary approach has developed into a core principle of sustainable development. Proponents of the precautionary principle say it is a valuable legal principle with substantial precedent, which deals with threats of serious or irreversible damage or adverse consequences, where lack of full scientific certainty may otherwise prevent important measures or protections for the environment or human health.

The principle has been subject to multiple strands of criticism, such as arguments that it is not well defined, which undermines legal certainty; that it stifles innovation; and that it is inconsistently applied, leading to unprincipled decision-making. There has also been resistance from various business stakeholders, and some scientists, who would rather have full scientific proof of causal links between products or processes and harmful side effects, or who argue that standard risk-assessment procedures are complete and sufficient as they stand.

The principle can be invoked in cases when regulators have to take decisions in advance of scientific 'certainty' on an issue or risk, or to create the impetus to take a decision by removing excuses for inaction on the grounds of scientific knowns. It is said that one of the clearest benefits of the principle is its overt recognition of uncertainties and the negotiated nature of decision-making.

In essence, the principle is about considering carefully whether a technology or activity is safe or not. Many researchers (e.g. von Schomberg, 2012) conclude that the application of the principle is necessarily negotiated in response to the topic to which it is applied — and, indeed, that this is one of its advantages, in that it encourages, rather than closes down, dialogue.

The principle has potential to be used to enable and encourage democratic, transparent and inclusive decision-making processes where different voices are heard and considered. Although this can also be seen as a weakness, its proponents say that the principle provides room for debate about the values at stake in each particular case.

Indeed, it is hoped that the regulation of technology in future will be based not only on encouraging research, innovation and knowledge in practice but also on the balancing of views between different stakeholders.

Several studies show that the idea of 'full scientific proof' can be misleading, and that risks, value and knowledge are contingent and evolving. Hence, the precautionary principle may prove useful in identifying the complexities of decision-making in the face of uncertainty.

Some researchers and policymakers (e.g. United Kingdom Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA), 2002) have proposed general frameworks or guidelines for using the precautionary principle — for example, by compiling lists of common circumstances when precaution might be warranted, scenario-based guidance or advice with regard to emerging risks.

The EC's Communication on the precautionary principle (EC, 2000) establishes general principles of decisions based on the precautionary principle, and in so doing asserts the importance of the fullest possible scientific evaluation, risk evaluation and evaluation of consequences, as well as participation of all interested parties.

Although the precautionary principle has become embedded in the culture and practice of EU environmental protection, its character means that it will necessarily continue to evolve and take shape under changing and context-specific conditions.

As the research presented in this Future Brief shows, the precautionary principle is not a fixed or universally applicable rule, but is rather a tool to better understand uncertainties and controversies in high-stakes decision-making.

Directions on a chalk board with world globe crystal ball ©iStock/ jxfzsy 2016

# References

Baudenbacher C., Tresselt P. & Orlygsson T. (2005) *The EFTA Court: Ten years On*. Bloomsbury Publishing.Boehmer-Christiansen, S., (1994) The precautionary principle in Germany — enabling government. In: T. O'Riordan and J. Cameron, eds. *Interpreting the precautionary principle*. London: Earthscan: 31–60.

Bohannon, J. (2002) Zambia Rejects GM Corn on Scientists' Advice. *Science* 298: 1153.

Boutillon, S. (2002) The Precautionary Principle: Development of an International Standard, 23 *Michigan Journal of International Law*. 429: 430–468. Available: *http://repository.law.umich.edu/mjil/vol23/iss2/7 http://repository.law.umich.edu/cgi/viewcontent.cgi?article=1363&context=mjil [Accessed 31 August 2017].*

Braunisch, V., Coppes, J., Bächle, S. & Suchant, R. (2015) Underpinning the precautionary principle with evidence: A spatial concept for guiding wind power development in endangered species' habitats. *Journal for Nature Conservation*. 24: 31–40. DOI: 10.1016/j.jnc.2015.01.003.

Byrne, D. (2004) The Regulation of Food Safety and the Use of Traceability/Tracing in the EU and USA: Convergence or Divergence?' Speech to *Food Safety Conference*, Washington, D.C., 19 March, 2004.

Clark E.A. (2006) Environmental risks of genetic engineering. *Euphytica*. 148: 1–2: 47–60.

EFTA *Surveillance Authority v. Norway* (2001) Case E-3/00, 2 C.M.L.R. 47, European Free Trade Association Court, Luxembourg.

European Political Strategy Centre (EPSC) Strategic Notes (30 June 2016). Issue 14: *Towards an Innovation Principle Endorsed by Better Regulation*. Available from *https://ec.europa.eu/epsc/publications/strategic-notes/towards-innovation-principle-endorsed-better-regulation_en [Accessed 21 August 2017]*.

European Commission (2000) *Communication (COM (2000) 1 final on the precautionary principle*. Available from: *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al32042 [Accessed 21 August 2017]*.

European Commission v Denmark (2003) Case C-192/01. Court judgement. Available from: *http://curia.europa.eu/juris/liste.jsf?language=en&num=C-192/01 [Accessed 31 August 2017]*.

European Commission v France (2004) Case C-24/00 Court judgement. Available from: *http://curia.europa.eu/juris/showPdf.jsf?text=&docid=48892&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=154133*

European Commission (2009) *Commission recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research*, C (2008) 424. Available from: *http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-recommendation-pe0894c08424_en.pdf [Accessed 21 August 2017]*

European Commission (2012) Staff Working Paper: Types and uses of nanomaterials, including safety aspects Accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials SWD (2012) 288 final. Available from: *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012DC0572 [Accessed 31 August 2017]*.

European Political Strategy Centre (2016) *Towards an Innovation Principle. Endorsed by Better Regulation*. Issue 14. Available: *https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf [Accessed 31 August 2017]*.

European Union, *Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community*, 13 December 2007, 2007/C 306/01, available at: *http://www.refworld.org/docid/476258d32.html [Accessed 5 July 2017]*.

Fisher, E., Jones, J., Schomberg, R. (2007) Implementing the Precautionary Principle: Perspectives and Prospects. *Review of European, Comparative & International Environmental Law*. 16: Issue 3: 376–379. DOI: 10.1111/j.1467-9388.2007.00576_4.x.

Garnett, K . & Parsons D. J. (2017) Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. *Risk Analysis*, 37: 502–516. Doi:10.1111/risa.12633.

Gollier, C., Jullien, B., Treich, N., (2000) Scientific progress and irreversibility: an economic interpretation of the 'Precautionary Principle'. *Journal of Public Economics*, 75: pp. 229–253

Grant, S. & Quiggin, J. (2013) Bounded awareness, heuristics and the Precautionary Principle. *Journal of Economic Behavior & Organization*. 93: 17–31.

Hague District Court, Chamber for commercial Affairs (2015). Case number / cause list number: C/09/456689 / HA ZA 131396. Available from: *https://elaw.org/system/files/urgenda_0.pdf*

Hannah W. & Thompson P. B. (2011) Nanotechnology, risk and the environment: a review. *Journal of Environmental. Monitoring*. 10: pp 29–300.

Harremoës P., *et al.*, eds. (2002) *The precautionary principle in the twentieth century: late lessons from early warnings*. London: Earthscan: 170–184.

Kheifets L. (2001) The Precautionary Principle and EMF: Implementation and Evaluation. *Journal of Risk Research*. 4(2): 113–125.

Marchant, G. E. & K. L. Mossman, K. L. (2004) *Arbitrary & Capricious: The Precautionary Principle in the European Union Courts*. AEI Press, Washington, D.C

Liu Z. & Chen Y. (2015) Impacts, risks, and governance of climate engineering. *Advances in Climate Change Research*. 6: 3-4:197–201.

Morris, S. H. (2007) EU biotech crop regulations and environmental risk: A case of the emperor's new clothes? *Trends in Biotechnology*. 25 (1): 2–6.

OECD, 2005, *Opportunities and Risks of Nanomaterials*. Report in cooperation with the OECD International Futures Programme. OECD and Allianz. Available from: *http://www.oecd.org/science/nanosafety/44108334.pdf*

Omuko, L. A. (2016) Applying the Precautionary Principle to Address the "Proof Problem" in Climate Change Litigation. *Tilburg Law Review*. 21(1): 52–71. DOI: 10.1163/22112596-02101003.

Patterson, A. & Gray, T. (2012) Unprincipled? The British government's pragmatic approach to the precautionary principle. *Environmental Politics*. 21(3): 432-450. DOI:10.1080/09644016.2012.671573

Persson, E. (2016) What are the core ideas behind the Precautionary Principle? *Science of The Total Environment,* 557–558: 134–141. DOI: 10.1016/j.scitotenv.2016.03.034.

Pfizer Animal Health v Council of the European Union (2002) T-13/99. Available from: *http://curia.europa.eu/juris/liste.jsf?language=en&num=T-13/99* [Accessed 31 August, 2017].

Rumsfeld, D. (2002) Statement to Press. Washington.

Sandin, P. (2006). A paradox out of context: Harris and Holm on the precautionary principle. *Cambridge Quarterly of Health Care Ethics*. 15: 175–180.

Santillo, D., Johnston P., & Langston W. J., Tributyltin (TBT) antifoulants: a tale of ships, snails and imposex. In: Harremoës, P., Gee, D., MacGarvin, M. (2002) *Late lessons from early warnings: the precautionary principle 1896–2000*. Luxembourg. European Environment Agency.

Scotford, E. (2017) *Environmental Principles and the Evolution of Environmental Law*. Oxford, Hart.

Science and Environmental Health Network (1998) Wingspread Conference on the Precautionary Principle.

Science for Environment Policy (2016). *Identifying emerging risks for environmental policies*. Future Brief, Issue 13.

Stirling, A. (2016) *Precaution in the governance of technology*. SWPS 2016–14 (July): Working Paper Series. Science Policy Research Unit. University of Sussex.

Sunstein, C. R., (2003) Beyond the precautionary principle. *University of Pennsylvania Law Review*, 151: 1003–1058

Supreme Court of the United States (2007). Massachusetts *et al.* v. Environmental Protection Agency *et al.* Available from: *https://www.law.cornell.edu/supct/html/05-1120.ZS.html*

Tosun, J. (2013) How the EU handles uncertain risks: Understanding the role of the precautionary principle. *Journal of European Public Policy*. 20(10): 105–119. DOI:10.1080/13501763.2013.834549.

Uggla, Y., Forsberg, M. & Larsson, S. (2012) Dissimilar framings of forest biodiversity preservation: Uncertainty and legal ambiguity as contributing factors. *Forest Policy and Economics*. 62: 36–42. DOI:10.1016/j.forpol.2015.07.007.

United Kingdom Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA) (2002) *The Precautionary Principle: Policy and Application. The need for a consistent approach*. Available from: *http://www.hse.gov.uk/aboutus/meetings/committees/ilgra/pppa.pdf*

KH-BB-17-002-EN-N

United Nations Environment Programme (UNEP) (1992) Rio Declaration on Environment and Development. Available: *http://www.jus.uio.no/lm/environmental.development.rio.declaration.1992/portrait.a4.pdf* [*Accessed 31 August 2017*].

United Nations Educational, Scientific and Cultural Organization (UNESCO) (2005) *The Precautionary Principle*. Available: *http://unesdoc.unesco.org/images/0013/001395/139578e.pdf* [*Accessed 31 August 2017*].

Van Zwanenberg, P. & Millstone, E., (2002) Mad cow disease 1980–2000: how reassurances undermined precaution. In: Harremoes P. *et al.*, eds. *The precautionary principle in the twentieth century: late lessons from early warnings*. London: Earthscan: 170–184.

Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. *European Journal of Risk Regulation*. 2: 147–156.

Zhang, J. Y., Marris, C. and Rose, N. (2011) *The Transnational Governance of Synthetic Biology: Scientific uncertainty, cross-borderness and the 'art' of governance*. BIOS Working Paper, BIOS, London School of Economics and Political Science, London.

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