The precautionary principle

Definitions, applications and governance

IN-DEPTH ANALYSIS

EPRS | European Parliamentary Research Service
Author: Didier Bourguignon
Members' Research Service
December 2015 — PE 573.876

EN
(or. FR)

This publication takes stock of the debate and questions surrounding the precautionary principle in the European Union. It looks at different interpretations of the precautionary principle, references to it in international treaties on environmental protection, definitions developed by different institutions, as well as related European and international case law. It presents conflicting viewpoints on the precautionary principle and the arguments used to support them. The publication then studies how the precautionary principle is applied, setting out practical examples and the main challenges and opportunities it presents. Finally, the publication gives an overview of certain aspects of governance and the precautionary principle, namely risk governance, the science-policy interface and the links between precaution and innovation.

PE 573.876
ISBN 978-92-823-8480-0
doi:10.2861/821468
QA-01-15-945-EN-N

Original French manuscript completed in December 2015.
Translation completed in February 2016.

Disclaimer

eprs@ep.europa.eu
http://www.eprs.ep.parl.union.eu (intranet)
http://www.europarl.europa.eu/thinktank (internet)
http://epthinktank.eu (blog)

EXECUTIVE SUMMARY

The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high.

It first emerged during the 1970s in German law and has since been endorsed by the international community in a number of environmental treaties and by the EU in the Maastricht Treaty. It has also been recognised in the national legislation of certain Member States.

The precautionary principle divides opinions. Some see it as a pointless and potentially dangerous principle that hinders progress. Others believe that it helps protect human health and the environment from complex hazards.

There is no universally accepted definition of the precautionary principle. Interpretations mainly vary according to the degree of scientific uncertainty that could prompt action by the authorities. The European Commission, UNESCO and the European Environment Agency have each put forward their own definition. Furthermore, the European Court of Justice has contributed to its interpretation and the extension of its scope.

The application of the precautionary principle is also subject to different interpretations. Most experts agree that the precautionary principle does not call for specific measures such as bans or reversing the burden of proof. However, experts and institutions do not agree on the method for determining when to apply precautionary measures (cost-benefit analysis, risk trade-off analysis, cost-effectiveness analysis, pros and cons analysis of action and inaction, etc.). Examples of the application of the precautionary principle include declining bee populations, climate change, fish-stock management, genetically modified organisms or the use of antimicrobials as growth promoters.

The application of the precautionary principle presents many challenges, especially with regard to the treatment of complexity, hazard assessment, research and economic activities. However, it also presents opportunities, mainly regarding the possibility of reducing the overall costs of environmental and health research for society.

The precautionary principle is closely linked to governance. It raises a number of questions regarding risk governance (risk assessment, management and communication). Furthermore, since precautionary measures are usually applied following a political decision based on scientific knowledge, science-policy interfaces are particularly important. Since they are extremely diverse, these interfaces are confronted with several challenges. Finally, there is considerable debate about the link between precaution and innovation. The concept of 'responsible research and innovation', which is enshrined in the Horizon 2020 European research framework programme, seeks to reconcile these two aspects.

TABLE OF CONTENTS

Glossary

Ambiguity: a situation where the risks are recognised as inherently multifaceted and opinion is divided on the magnitude, characterisation and prioritisation of these facets.

Bayesian method: a statistical inference method based on assessing the probability of a hypothesis, prior to observing a random event.

Cost-benefit analysis: this compares the losses (monetary value) and costs of planned measures in order to ensure that the benefits outweigh the costs.

Cost-effectiveness analysis: this involves three steps, namely to a) establish an acceptable level of risk at policy level, based on scientific evidence; b) decide how to meet this constraint at minimum cost; and c) find out whether the objective is politically feasible.

EEA: European Environment Agency.

GMOs: Genetically Modified Organisms.

Governance: all actions, processes, traditions and institutions involved in the exercise of authority, decision-making and implementation.

Hazard: situation or risk that a substance or technology, by reason of its inherent characteristics or properties, could – under specific conditions of exposure – endanger people, property or the environment.

IARC: International Agency for Research on Cancer (agency of the World Health Organization).

Ignorance: a situation where the environmental and/or health impacts are unknown, with the result that the probabilities are also unknown; may lead to precautionary measures to minimise the impact of surprises.

IPCC: Intergovernmental Panel on Climate Change – set up by the United Nations Environment Programme and the World Meteorological Organization.

IRGC: International Risk Governance Council, an independent non-profit organisation.

Prevention: protection measures to reduce the risk of a situation with known environmental and/or health impacts and probabilities.

Risk: likelihood of an adverse event occurring because a hazard coincides with exposure to that hazard.

SPI: science-policy interface.

Uncertainty: a situation where environmental and/or human health impacts are likely but the probabilities are unknown; may lead to precautionary measures to reduce exposure to certain hazards.

UNFCCC: United Nations Framework Convention on Climate Change.

WTO: World Trade Organization.

1. Introduction

Living in the age of the 'risk society', as defined by the sociologist Ulrich Beck[1], creates situations that confront societies with new hazards for people, communities and their environment. Two reports published in 2001 and 2013[2] by the European Environment Agency (EEA) present several cases involving hazards where lessons were only learned belatedly, after several decades, despite early warnings. The cases studied include the practice of adding lead to petrol between the 1920s and 1990s, given that exposing children to lead has since been associated with brain damage (high exposure) and cognitive disorders (low exposure); anthropogenic emissions of mercury and its compounds into fresh and sea water, with human health impacts depending on concentrations, which led to the adoption of the Minamata Convention on Mercury in 2013 under the auspices of the United Nations Environment Agency (UNEP); the large-scale use of the pesticide DDT, a persistent organic pollutant with numerous adverse health effects; or the belated acknowledgement of the harmful effects of passive smoking.

In situations of scientific uncertainty where the stakes are high, the precautionary principle seeks to help decision-makers to act more promptly. Having originated in recent decades, the definition and use of the precautionary principle are still under development, and it continues to divide opinions. Some see it as an unscientific approach that hinders progress and leads to over-regulation. However, others believe that it helps to protect human health and the environment from complex hazards and to promote the type of progress that is better for people and their environment. The debate is often polarised between two diametrically opposed viewpoints. On the one hand, there is technological pessimism and the fear of 'sorcerers' apprentices', which urges stringent regulation of industrial activities. On the other hand, there is technological optimism and faith in progress, which would have us believe that all regulation is pointless. However, these caricatures obscure the extensive range of interpretations of the precautionary principle and the complexity of discussions on this subject.

2. Defining the precautionary principle

2.1. Origins

The precautionary principle originated in German law as the *Vorsorgeprinzip* (which can also be translated as the 'foresight principle') during the preparation of legislation on air pollution in the 1970s. Since then it has been adopted by other levels of governance and its application has been extended from environmental protection to other areas.

At the **international level**, references to the 'precautionary principle' or 'precautionary measures' appeared in the environmental agreements of the 1980s, starting with the 1985 Vienna Convention for the Protection of the Ozone Layer, which mentions

1 Pioneer in Cosmopolitan Sociology and Risk Society, U. Beck, 2014.

2 Late lessons from early warnings: the precautionary principle 1896-2000 and Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2001 and 2013.

'precautionary measures' in its preamble. The 1987 Ministerial Declaration of the Second International Conference on the Protection of the North Sea notes that:

> *'in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances* ***even before a causal link has been established by absolutely clear scientific evidence****' [emphasis added].*

The 1990, the Ministerial Declaration of the Third International Conference on the Protection of the North Sea expands the concept, stating that the contracting governments:

> *'will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate* ***even where there is no scientific evidence to prove a causal link between emissions and effects****' [emphasis added].*

The 1992 Rio Declaration on Environment and Development makes the precautionary approach a guiding principle for the management of forests:

> *'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 [emphasis added].*

Some treaties refer to the precautionary principle without defining its content[3] and others follow the Rio Declaration[4] in affirming that lack of full scientific certainty cannot be used to postpone measures. Since the early 1990s, the precautionary principle has been more or less explicitly incorporated in almost all international treaties on environmental protection[5].

At the **European level**, the precautionary principle was enshrined in the Maastricht Treaty in 1992. It is now included in Article 191 of the Treaty on the Functioning of the European Union among the principles underpinning EU environmental policy[6]. Like the other principles, it is not defined in the treaty.

At **national level**, several Member States, besides Germany, have incorporated the precautionary principle in their national legislation. France incorporated the precautionary principle in its Constitution in 2005. Sweden has made it a guiding principle of its environmental and public health policies, including it in the Swedish Environment Code in 1999. In some EU countries such as Belgium or the Netherlands, the courts recognise the precautionary principle provided that it has been included in a

---

[3] See, for example, Article 6 of the United Nations Fish Stocks Agreement (1995).

[4] See, for example, the preamble to the Convention on Biological Diversity (1992) or Article 3(3) of the United Nations Framework Convention on Climate Change (UNFCCC, 1992).

[5] These mainly concern marine pollution (e.g., the OSPAR Convention and the 1992 Helsinki Convention on the Baltic Sea); air pollution (e.g., the abovementioned 1985 Vienna Convention and the 1992 UNFCCC); nature conservation (e.g., the 1994 Fort Lauderdale Resolution relating to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); the abovementioned United Nations Convention on Biological Diversity and Fish Stocks Agreement, the Revised Management Procedure adopted by the International Whaling Commission in 1994); hazardous waste (e.g., the 1992 Bamako Convention); or water resources (e.g., the 1992 Helsinki Water Convention).

[6] The other principles are that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

specific law. In other EU countries such as Spain and the United Kingdom, the courts base their decisions on the precautionary principle only if the provisions under consideration derive from European legislation. Outside the EU, Australia incorporated the precautionary principle in its environmental policy in 1992.

The precautionary principle in EU and international law

A frequent question is whether the precautionary principle can be considered as a general principle of law. A general principle of law is an unwritten rule of law, recognised as superior to written rules (e.g., a law) and applied by the courts as a source of law[7]. Each legal system (e.g., national, international or European) has its general principles of law, which vary from one legal system to another.

The precautionary principle has been **recognised by the European Union** through a reference in the Maastricht Treaty. According to the EU Court of Justice 'the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.'[8] 'Competent authorities' refers to European institutions involved in preparing and applying secondary legislation, as well as Member States when acting within the scope of EU law.

However, the status of the precautionary principle as a general principle of **international law** is still in dispute. Some authors consider the precautionary principle to be a non-binding political guideline which is not recognised in customary international law, basing their reasoning mainly on the legal weakness of the precautionary principle in the area of international trade, particularly in the context of the WTO. Others consider that the precautionary principle has been widely adopted at international level, particularly since its inclusion in multilateral treaties such as the Convention on Biological Diversity and the United Nations Framework Convention on Climate Change, thus becoming a general principle of international law. The European Commission reasons that 'this principle has been progressively consolidated in international environmental law, and so it has since become a full-fledged and general principle of international law'.

2.2. Main interpretations of the precautionary principle

There is no universally accepted definition of the precautionary principle. The European Commission points out that its scope 'depends on trends in case law, which to some degree are influenced by prevailing social and political values' but goes on to say that the absence of a definition does not amount to legal uncertainty. Some legal scholars emphasise that the principle of self-determination, which is recognised as a principle of international law, does not have a standard definition either.

It could be said that the different interpretations of the principle share a common denominator, which is to avoid causing adverse impacts in situations of scientific uncertainty. Where risks are established with certainty, it is the prevention principle, as enshrined in the Treaty on the Functioning of the European Union, which can be brought into play to adopt hazard prevention measures.

---

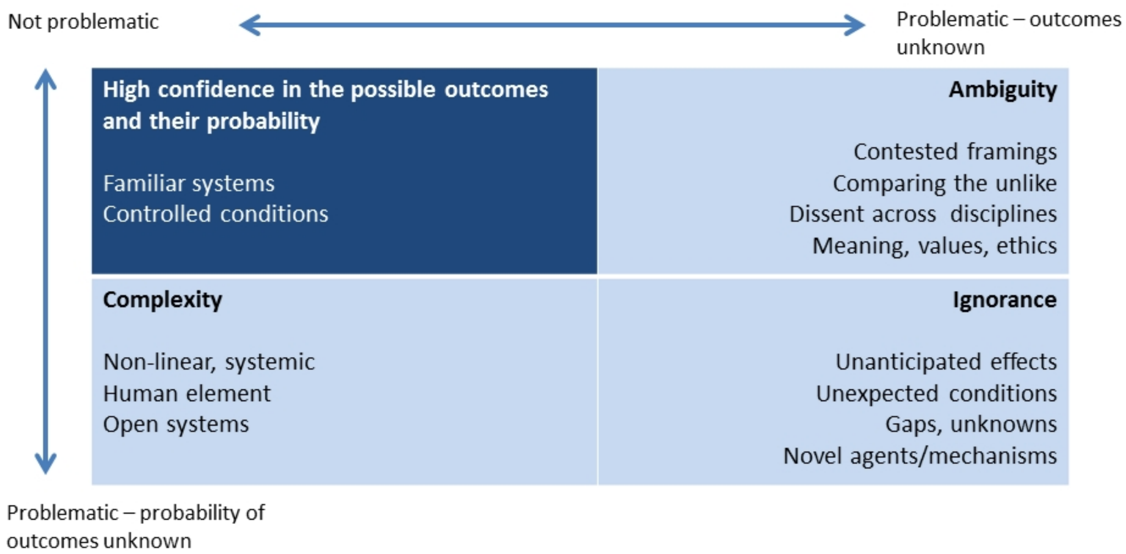
7 In environmental law, general legal principles of law can serve to establish a link between the ideal objective of environmental protection and the applicable laws.

8 Judgment in the case of *Artegodan* v. *Commission* of 26 November 2002 (T-74/00), paragraph 184.

A key variable of the different understandings of the precautionary principle is the **degree of scientific uncertainty** likely to lead to action from the authorities[9]. However, other variables also feature prominently in the different interpretations of the precautionary principle, including the severity of the risks involved, the magnitude of the stakes and the potential costs of action or inaction.

One way of looking at the precautionary principle might be to classify situations of uncertainty according to the **sources of uncertainty**, complexity, ambiguity and ignorance (see Figure 1). The top left-hand corner of the figure presents a situation where the outcomes and probabilities are known and the prevention principle would therefore apply. In practice, however, uncertainty could derive from several of these sources.

Figure 1 – Sources of uncertainty



Source: adapted from Risk, precaution and science: towards a more constructive policy debate, A. Stirling, EMBO reports, 2007.

Another way of looking at the precautionary principle might be based on **three schematic interpretations** depending on the degree of uncertainty, obligation and stringency. However, this approach disregards certain variables (i.e., the severity of the risks involved and the stakes) which may prove decisive when uncertainty is substantial.

- **First/minimal interpretation**: uncertainty does not justify inaction and warrants legislation despite the absence of complete scientific evidence concerning a particular hazard;
- **Second/median interpretation**: uncertainty justifies action and warrants legislation even if the link between cause and effect has not been fully established;
- **Third/maximal interpretation**: uncertainty necessitates legislation until the absence of hazard has been proven.

[9] The Intergovernmental Panel on Climate Change (IPCC) has therefore established a reference framework for the treatment of uncertainty based on a three-dimensional assessment (qualitative, quantitative and statistical) that can also be applied to other areas. For further details, see the IPCC synthesis report.

Table 1 – Three schematic interpretations of the precautionary principle

<table>
<tr><th>Bayesian probability</th><th>IPCC scale</th><th>Scientific usage</th><th>Example of definition</th><th colspan="3">Interpretation of the precautionary approach</th></tr>
<tr><td>99%</td><td>'virtually certain'</td><td>rigorously proven</td><td rowspan="3">Rio Declaration
UNFCCC</td><td rowspan="3">1/minimal</td><td rowspan="6">2/median</td><td rowspan="9">3/maximal</td></tr>
<tr><td>90–99%</td><td>'extremely likely'</td><td>substantially proven</td></tr>
<tr><td>80–90%</td><td rowspan="2">'likely'</td><td>very probable</td></tr>
<tr><td>67–80%</td><td>probable</td><td rowspan="3">Swedish environmental code
French environmental charter</td><td rowspan="6"></td></tr>
<tr><td>50–67%</td><td rowspan="2">'about as likely as not'</td><td>'more likely than not'</td></tr>
<tr><td>33–50%</td><td>Evidence points in this direction, but not fully proven</td></tr>
<tr><td>20–33%</td><td rowspan="2">'unlikely'</td><td>Evidence is beginning to accumulate in this direction</td><td rowspan="3">Ministerial Declaration of the Third International Conference on the Protection of the North Sea</td><td rowspan="3"></td></tr>
<tr><td>10–20%</td><td>Plausible, supported by some evidence</td></tr>
<tr><td>1-10%</td><td>'extremely unlikely'</td><td>Attractive</td></tr>
</table>

Sources: Precaution: the willingness to accept costs to avert uncertain dangers, C. Weiss in Coping with uncertainty: modelling and policy issues / K. Marti et al., Springer (2006); An inconvenient deliberation: the precautionary principle's contribution to the uncertainties surrounding climate change liability, M. Haritz, Wolters Kluwer (2011); IPCC synthesis report (2008).

One last way of looking at the precautionary principle might be based on a **procedural interpretation** characterised by four elements: (1) the potential hazards are characterised by serious, irreversible and uncertain consequences; (2) dynamic decision-making processes are both iterative and informative to allow learning over time; (3) the burden of proof is shared between the regulator and the proponent; and (4) no decision is prescribed a priori[10].

2.3. The positions of different institutions

2.3.1. European Commission

At the Council's[11] request, the European Commission adopted a Communication on the precautionary principle[12] early in 2000. In its Communication, the Commission sets out to establish its guidelines for applying the precautionary principle; build a common understanding of how to manage risks that science is not yet able to evaluate fully, and to avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism.

10 See, for instance, The case for a procedural version of the precautionary principle erring on the side of environmental preservation, A. Arcuri, Erasmus University Rotterdam, 2006.

11 In a resolution dated 28 June 1999, the Council called on the Commission 'to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle'.

12 Communication from the Commission on the precautionary principle, European Commission, COM(2000) 1.

The Commission put forward the following definition.

> *'Whether or not to invoke the precautionary principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.'*

It goes on to say that it is for the decision-makers and ultimately the courts to flesh out the principle. It explains that recourse to the precautionary principle is not discretionary and presupposes the identification of potentially negative effects and a scientific evaluation of an uncertain risk.

The Commission states that precautionary measures should respect other principles. Inter alia, they should be:

- proportional to the chosen level of protection;
- non-discriminatory;
- consistent with measures already taken;
- based on an examination of the benefits and costs of action or lack of action;
- subject to review in the light of new scientific data; and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The Commission also seeks 'to clarify a misunderstanding as regards the distinction between reliance on the precautionary principle and the search for zero risk, which in reality is rarely to be found'. It also emphasises that 'the precautionary principle is a general one which should in particular be taken into consideration in the fields of environmental protection and human, animal and plant health'.

Reactions to the Communication from the Commission

In its resolution of 14 December 2000, the **European Parliament** endorsed the Commission's approach to the precautionary principle. It considered that the EU should step up scientific research on the risks which are a major cause for concern as far as public opinion is concerned and that the conclusions of the risk assessment should include minority scientific opinions.

In its conclusions of 10 December 2000, the **European Council** also endorsed the Commission's approach. It considered that the risk assessment must be carried out in a multidisciplinary, independent and transparent manner and that the cost-benefit analysis must also take account of the public acceptability of the different options possible.

Industry representatives, mainly from the European Chemical Industry Council (CEFIC) and the American Chamber of Commerce to the European Union welcomed the principle's inclusion in a structured approach to risk analysis and were relatively satisfied with the Communication.

The **NGO, European Environmental Bureau**, regretted the lack of stakeholder involvement in the Communication's preparation and called for a wider approach to precautionary measures.

Some **commentators**[13] point out that the Communication deals exclusively with authorisation for new products on the internal market and has no general application. They emphasise that the most controversial aspects, in particular the acceptable level of risk, or the sequence of actions to be taken, remain unanswered.

---

[13] See, for instance, The case for a procedural version of the precautionary principle erring on the side of environmental preservation, A. Arcuri, Erasmus University Rotterdam, 2006; An inconvenient deliberation: the precautionary principle's contribution to the uncertainties surrounding climate change liability, M. Haritz, Wolters Kluwer, 2011.

2.3.2. UNESCO

In its 2005 report on the precautionary principle[14], UNESCO's[15] World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) put forward a 'working definition':

> *'When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.'*

The report defines morally unacceptable harm as harm that threatens human life or health, is effectively irreversible, inequitable to future generations, or is imposed without consideration of the human rights of those affected. The plausibility of harm should be based on scientific analysis subject to review. Measures taken as a result of a participatory process, must be proportional to the seriousness of the potential hazard and take into consideration their positive and negative consequences and moral implications.

2.3.3. European Environment Agency

The European Environment Agency's 2013 report on the precautionary principle[16] suggests a 'working definition' that avoids negatives (unlike other definitions such as the Rio Declaration's):

> *'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.'*

This definition underlines the complexity of biological and ecological systems characterised by multi-causality or scientific uncertainty or ignorance. It expands narrow conventional cost-benefit analysis into a broader analysis of the pros and cons, arguing that some costs (e.g., loss of public trust in science in case of serious harm) are unquantifiable.

2.4. Case law

The **Court of Justice of the European Union**'s interpretation of the precautionary principle broadens its scope. In a judgment concerning the transmissibility of bovine spongiform encephalopathy or 'Mad cow disease' to humans[17], the Court specified that the precautionary principle also applied to the protection of human health. In judgments concerning the transfer of resistance to antibiotics from animals to humans and the authorisation of medicines for human use[18], the Court found that the competent public authorities could be obliged to actively adopt precautionary measures. Furthermore, the Court applied a broad interpretation of the precautionary principle to nature conservation[19]. It considered that a project 'may be granted

[14] The Precautionary Principle, World Commission on the Ethics of Scientific Knowledge and Technology, UNESCO, 2005.

[15] United Nations Educational, Scientific and Cultural Organization.

[16] Late lessons from early warnings: science, precaution, innovation, p. 649, European Environment Agency, 2013.

[17] Judgments of 5 May 1998 in case C-157/96 (*The Queen* v. *Ministry of Agriculture*, paragraphs 63-64) and case C-180/96 (*United Kingdom* v. *Commission*, paragraphs 99-100).

[18] Judgments of 11 September 2002 in case T-13/99 (*Pfizer*, paragraph 444) and case T-70/99 (*Alpharma*, paragraph 355).

[19] Judgment of 7 September 2004 in case C-127/02 (*Waddenzee*, paragraph 45).

authorisation only on the condition that the competent national authorities are convinced that it will not adversely affect the integrity of the site concerned'. In a judgment[20] concerning waste water treatment, it considered that a degree of probable causality was sufficient to require Member States to adopt protection measures.

Although the precautionary principle is not explicitly mentioned in the agreements of the **World Trade Organization** (WTO), its Appellate Body, which handles disputes between the WTO's Member States has several times reached decisions that could be construed as admitting recourse to the precautionary principle[21]. In a case concerning European measures prohibiting the import of meat treated with growth hormones[22], the Appellate Body pointed out that the precautionary principle did indeed find reflection in a specific provision of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures[23] and that Members had the right 'to establish their own appropriate level of sanitary protection, which may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations'. Moreover, some authors argue that the GATT's general exceptions to protect health and natural resources[24] can have an effect equivalent to the application of the precautionary principle. In a case[25] concerning US measures prohibiting the import of shrimps caught in nets that do not allow sea turtles to escape, the Appellate Body defined sea turtles as an 'exhaustible natural resource' that warranted restrictive measures. In a dispute[26] concerning a French ban on asbestos and products containing asbestos, the Appellate Body confirmed that a country may take measures to protect human health from serious risks on the basis of a divergent opinion coming from qualified and respected sources.

Furthermore, in a 2009 judgment, the **European Court of Human Rights** held[27] that, even though the applicants had been unable to establish a causal link between exposure to cyanide and asthma, Romania was under an obligation to take adequate precautions to protect the public from potential harm.

---

20 Judgment of 23 September 2004 in case C-280/02 (*Commission* v. *France*, paragraph 34).

21 However, the panels that handle disputes at first instance were much more inclined to reject these types of measures, which are perceived as a threat to the security and stability of the multilateral trading system.

22 Appellate Body report of 16 January 1998 on Dispute DS26, paragraph 124.

23 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information [...]. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.' (Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures).

24 Article XX (b) and (g) on the General Agreement on Tariffs and Trade (GATT).

25 Appellate Body report of 12 October 1998 on Dispute DS58, paragraphs 129 to 134.

26 Appellate Body report of 12 March 2001 on Dispute DS135, paragraphs 167, 168 and 178.

27 Judgment in the case of Tătar v. Romania of 27 January 2009, (Application No 67021/01) paragraphs 106 and 107 (not available in English).

2.5. Conflicting viewpoints

2.5.1. A pointless and potentially dangerous principle

There are those who consider the precautionary principle to be arbitrary and unscientific[28]. Since it is based on ideological value judgments, it may lead to paralysis and threaten human progress. Since it is simply a question of common sense, it should not be raised to the status of a principle. Some sociologists see it as a response to fears that the human mind can nurture in situations of risk and uncertainty[29].

This view mainly refers to the maximalist interpretation of the precautionary principle. It is partly based on the following premise: scientists can accurately predict environmental and health threats; scientists can provide technical solutions to these hazards; and the most cost-effective approach is to take action when hazards arise.

Some of the arguments used to support these views are presented below.

- Since absolute scientific certainty can never be achieved, the precautionary principle could logically be applied to any activity since its consequences would always include an element of uncertainty.
- A stringent application of the precautionary principle would not only undermine progress by depriving society of useful products (such as antibiotics and vaccines), but would also deprive it of a source of knowledge.
- The precautionary principle could isolate the European Union internationally, damage world trade and complicate international regulatory cooperation to a considerable extent[30].

Alternatives to the precautionary principle have been suggested. These include an anti-catastrophe principle with a narrow scope and strong focus on costs and benefits[31].

2.5.2. A useful principle for averting complex hazards

Others see the precautionary principle as reducing serious and irreversible environmental and public health hazards, including by drawing lessons from past mistakes. They argue that this helps society address the evolving, complex and systemic challenges currently facing it by facilitating people-centric progress.

This view mainly refers to the minimalist interpretations of the precautionary principle. It is partly based on the following premise: scientists cannot accurately predict environmental and health threats; the environment is inherently vulnerable; there are alternative procedures and products that are less hazardous.

Some of the arguments used to support these views are presented below.

- The precautionary principle may make it possible to establish regulatory mechanisms aimed at aligning business and societal interests in a context where companies often do not have to pay the full cost of adverse environmental and health effects (despite the polluter-pays principle) and some of them (e.g., the

---

[28] See, for instance, Arbitrary and Capricious: The Precautionary Principle in the European Union Courts, G. Marchant and K. Mossman, American Enterprise Institute Press, 2004.

[29] *L'inquiétant principe de précaution*, G. Bronner and E. Géhin, PUF, 2010.

[30] Precautionary Tale, R. Bailey, 1999; Ecofundamentalism: a Critique of Extreme Environmentalism, R. Hannesson, Lexington Books, 2014; What price safety? The precautionary principle and its policy implications, G. Majone, European University Institute, 2002.

[31] Laws of Fear: Beyond the precautionary principle C. Sunstein, Cambridge University Press, 2005.

tobacco industry) exert various forms of pressure on decision-making processes.

- The precautionary principle provides a framework that helps to achieve a better balance in public health policies and to mitigate difficulties associated with scientific demonstration prior to justifying preventative measures[32].

3. Applying the precautionary principle

3.1. Possible precautionary measures

Many authors point out that even the strictest interpretation of the precautionary principle does not require or advocate any **specific measure** (such as a ban). It does however call for informed, transparent and accountable decision-making, reflecting the different conditions of scientific uncertainty.

Applying the precautionary principle can result in a **reversal of the burden of proof**. While some argue that this reversal is one of the main features of this principle, there are more who say that a reversal of the burden of proof is only a possible consequence of the interpretation made of the precautionary principle. This is also the opinion the European Commission expresses in its Communication on the precautionary principle. A decision to reverse the burden of proof may be based on considerations such as the cost of collecting information or incentives arising from the rules on the burden of proof.

Several **methods** can be used to determine whether it is appropriate to take precautionary measures. These include **cost-benefit analysis** incorporating Bayesian risk assessment. The European Commission states that prior examination should include an economic cost-benefit analysis where this is 'appropriate and possible' while also pointing out that other analysis methods (e.g., on the socio-economic impact) and non-economic considerations (e.g., health) may also be relevant. However, cost-benefit analysis is criticised by those who consider it inappropriate if there is uncertainty about the hazards (and therefore the costs). **Risk trade-off analysis** is another method that is sometimes used in administrative law in the United States. However, it has sometimes been criticised for overestimating the negative effects of regulation. **Cost-effectiveness analysis** is another method, which aims to enable policy-makers to pre-establish an acceptable level of risk at the lowest cost, without however specifying how this level is determined. The European Environment Agency recommends assessing the **pros and cons of action and inaction** more broadly by including also the unquantifiable aspects.

3.2. Examples of the precautionary principle's application

The precautionary principle is now recognised in many (non-) legislative acts of the European Union, including the REACH Regulation; the Directive on genetically modified organisms; the Regulation establishing the European Food Safety Authority; or the Regulation on plant protection products[33].

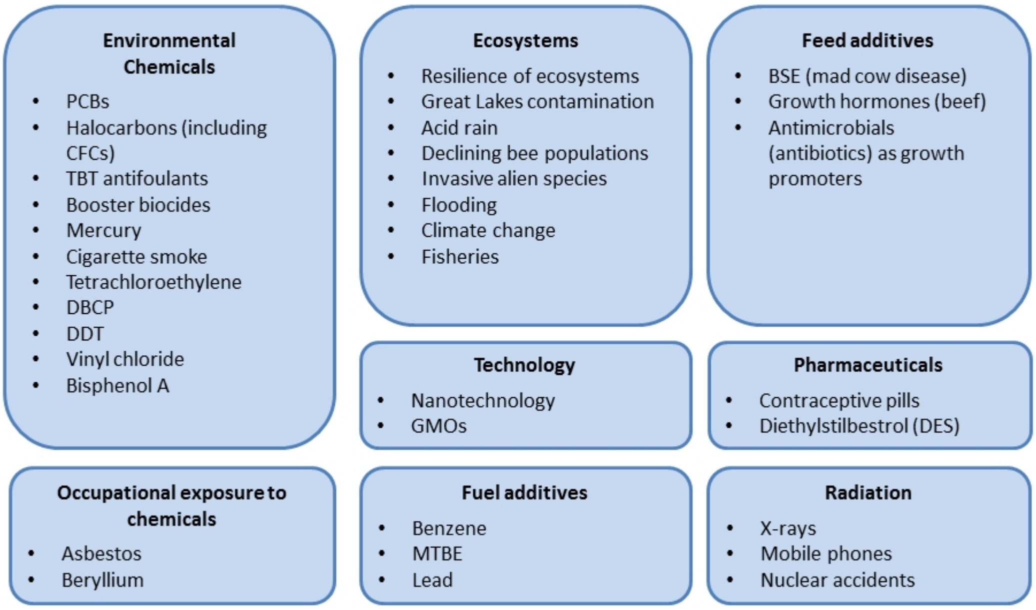
---

[32] Why did business not react with precaution to early warnings?, M. Le Menestrel and J. Rode in Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2013; Implications of the precautionary principle for primary prevention and research, P. Grandjean, Annual Review of Public Health, 2004.

[33] Regulation No 1907/2006, Directive 2001/18/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1107/2009.

In its reports on the application of the precautionary principle, the EEA identifies several cases where this principle has been applied and where it could be applied.

Figure 2 — Case Studies addressed in EEA reports on the precautionary principle



Sources: adapted from Late lessons from early warnings: the precautionary principle 1896-2000 and Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2002 and 2013.

The European Environment Agency gives examples where the precautionary principle has been applied to varying degrees. These include the following cases involving chemical substances, impact on ecosystems, technology or feed additives.

- **Halocarbons**: These substances include CFCs, HFCs and PFCs and their use as refrigerants became widespread in the 1930s and subsequently in aerosol sprays. In 1974, scientists suggested that they could destroy the ozone layer. Some countries began to restrict or ban their use in 1977. In 1987, the Montreal Protocol provided for the phase-out of ozone depleting substances.
- **Vinyl chloride**: Following the first indications of risks to human health (skin and bone conditions, liver cancer) in the 1950s and 1960s and after denying the risks for some time, the chemical industry financed carcinogenic tests and then significantly lowered the exposure limits. The International Agency for Research on Cancer (IARC) has recognised vinyl chloride as a 'human carcinogen' since 1979.
- **Asbestos**: Due to its soundproofing and resistant properties, its use in various materials became widespread in the 19th century. Scientists began to issue warnings about the health effects for workers exposed to asbestos in the early 20th century. Several decades later it was discovered that exposure to asbestos dust could cause asbestosis (a lung disease), lung cancer and mesothelioma (cancer affecting the mesothelium, a membrane that surrounds and protects the internal organs) after a long latency period (20-40 years). After a number of Member States adopted national measures, the EU banned all types of asbestos in 1999[34].
- **Declining bee populations**: In 1994, it emerged that many domestic bees in France were becoming disoriented. This had an impact on beehives and the pollination of crops. Suspicion fell on Gaucho, a pesticide of the neonicotinoid family applied as a coating on sunflower seeds. In 1999, the French ministry of agriculture temporarily

[34] Canada challenged the ban in France before the WTO Dispute Settlement Body. In 2001, the Appellate Body rejected the appeal (Dispute DS135).

banned the coating of sunflower seeds in pesticides, in application of the precautionary principle. The ban was extended to other products and varieties in 2004. In 2013, the European Commission restricted the use of three neonicotinoids[35].

- **Climate change**: Following initial warnings issued by scientists in the late 19th century, a World Climate Research Programme was established in 1980. The UNFCCC, signed in 1992, mentions the need for precautionary measures. Since its creation in 1988, the IPCC has developed a framework for quantifying scientific uncertainty. This framework has evolved as successive reports[36] have been prepared, as has scientific consensus on climate change, with the result that measures can now be treated as preventative rather than precautionary[37].
- **Fisheries**: When industrial fishing intensified in the second half of the 20th century, pressure on fishery resources increased significantly while resources tended to be overestimated. As a result, the North Sea herring was almost wiped out during the 1970s. Faced with declining cod stocks in the late 1980s, Norway introduced a moratorium in the 1990s, while Canada failed to act before cod stocks collapsed in 1992. Since the 2000s, an ecosystem-based approach to integrated fisheries management has been in place in the European Union.
- **GMOs**: The health and environmental benefits and hazards of genetically modified organisms (GMOs) continue to generate debate. Although they have been introduced on a large scale in the Americas, most EU Member States have preferred to adopt precautionary measures restricting or banning their cultivation[38].
- **Antimicrobials as growth promoters**: Since the late 1940s, antibiotics have been added to feed to accelerate the growth of livestock and productivity. Antibiotic resistance in bacteria was observed in the 1950s and the possibility of transferring resistance to other species of bacteria was documented in the 1960s. In 1985, Sweden banned this use of antibiotics because of its uncertain long-term effects. In 1998, the European Union took the precaution of prohibiting the use of four antibiotics for this purpose[39].

The EEA also notes other cases involving **divergent risk assessments** such as the pesticide DBCP and its impact on male fertility; certain applications of nanotechnology; or Bisphenol A, which is present in many forms of plastic and suspected of causing endocrine disruption. Many case studies mentioned in the EEA's reports have not been subject to precautionary measures at this time.

---

[35] For further details, see: Les abeilles dans l'UE: un bilan de santé inquiétant, European Parliament Research Service, 2014.

[36] For further details, see: The evolution of the IPCC's approach to assessing uncertainty, M. MacGarvin, in Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2013, p. 331-335.

[37] Compare the first report (1990) and the fifth report (2014).

[38] Directive (EU) 2015/412 confirms this approach by enabling Member States to restrict or prohibit GMO cultivation in their territory after its authorisation in the EU.

[39] This decision was challenged by Pfizer in 1999 in the EU Court of Justice. The application was rejected in 2002 (case T-13/99).

Application of precautionary measures in the United States and Europe

The United States applied a more broadly cautious approach than Europe until the 1970s, when the principle emerged in Europe. There followed a period when the US and EU approaches converged until the 1990s, when Europe adopted a stricter approach than the US and enshrined the precautionary principle in the Maastricht Treaty.

A 2002 study[40] on the application of precautionary measures suggests that the approaches applied on either side of the Atlantic are not that different. The difference lies mainly in the issues to which precautions are applied (the EU is more cautious than the US with regard to growth hormones in beef whereas the US has taken more precautions than the EU with respect to BSE). Some consider that certain US food safety laws, for instance, apply the precautionary principle without explicitly mentioning it[41]. Furthermore, the Silver Book of the National Research Council[42] advises the US Environmental Protection Agency to take into account and report on uncertainty and variability in all stages of the risk assessment, which suggests that these factors can be taken into account.

The United States has since applied a general approach whereby a hazard must be proved before public measures can be taken. In the United States, the term 'precautionary approach' is more readily used than 'precautionary principle'. Other approaches have been put forward, such as the concept of 'prudent vigilance', which combines self-regulation and careful monitoring, advocated by the US Commission for the Study of Bioethical Issues in 2010[43]. Although there is no fundamental difference between this concept and the precautionary principle, it clearly reflects a US preference for a pragmatic rather than a regulatory approach, and a willingness to allow companies more freedom[44].

These differences in approach, which can mostly be attributed to cultural differences, have been highlighted during the debate on the Transatlantic Trade and Investment Partnership (TTIP). In its resolution on TTIP[45] of 8 July 2015, the European Parliament urged the Commission to ensure that the agreement respects the precautionary principle.

Many authors fear that superfluous precautionary measures could be taken on the basis of unfounded public fears. However, in a study of 88 cases identified as potential **false positives** (where the authorities take precautions which later prove unnecessary), Hansen and Tickner[46] concluded that four of the 88 cases led to unnecessary measures[47] and that there was little risk of false positives. They also point out that

---

40 Comparing Precaution in the United States and Europe, J. Wiener and M. Rogers, Journal of Risk Research, 2002.

41 Food Quality Protection Act (1996); for further details, see Pesticides, Children's Health Policy and Common Law Tort Claims, A. Klass, Minnesota Journal of Law, Science & Technology, 2005.

42 Science and Decisions: Advancing Risk Assessment, Committee on Improving Risk Analysis Approaches used by the US EPA, National Research Council, 2009.

43 This concept is defined as 'an ongoing process of prudent vigilance that carefully monitors, identifies, and mitigates potential and realized harms over time' (The Ethics of Synthetic Biology and Emerging Technologies, Presidential Commission for the Study of Bioethical Issues, 2010, p. 8).

44 Precaution or prudent vigilance as guiding the path to global food security?, M. Kaiser, in The ethics of consumption, H. Röcklinsberg and P. Sandin (Ed.), Wageningen Academic Publishers, 2013.

45 European Parliament resolution of 8 July 2015 containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP) (2014/2228(INI)).

46 The precautionary principle and false alarms — lessons learned, S. Hansen and J. Tickner, in Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2013.

47 Swine flu (1976/United States), saccharin (1977), food irradiation (1970s) and Southern leaf corn blight (1971/United States).

there were few parallels between these cases that could allow general conclusions to be drawn for the future.

3.3. Challenges and opportunities

The application of the precautionary approach presents many **challenges**. Adverse human health and environmental impacts usually take the form of interactions within **complex systems** influenced by multiple risk factors and causes. For instance, declining bee colonies may be linked to viruses, climate change and neonicotinoid pesticides, while intelligence quotient (IQ) loss in children may be linked to exposure to lead, methylmercury and polychlorinated biphenyls (PCBs), as well as to socio-economic factors. Moreover, there may be a considerable delay between exposure and noticeable effects (as in the case of asbestos). Finally, the increased vulnerability of some groups (e.g. children and elderly people) adds to the complexity and creates differences in acceptable exposure levels.

Hazard assessment presents several challenges, in particular tensions between false positives and false negatives[48]. Many authors point out that scientific studies are designed to minimise false negatives rather than false positives for the simple reason that science requires a solid foundation on which to build knowledge. This has led many authors to conclude that in the environmental and health spheres, this means that the chances of coming down on the side of the environment or health have been kept deliberately low. Moreover, the method generally used to determine whether the data observed are statistically significant, which is criticised for its weaknesses[49], does not always make it possible to reach conclusions in good time[50]. Finally, the EEA's reports on the precautionary principle suggest that adverse effects often turn out to be more diversified and extensive than initially anticipated[51], and stress that absence of evidence of harm is not evidence of absence of harm.

The application of the precautionary principle to **research** also highlights several challenges. A study[52] on scientific articles published between 2000 and 2009 points out that academic research on environmental hazards focuses on a few well-studied chemical substances (e.g., heavy metals, PCBs and DDT) whereas research on other widely used substances[53] and, even more markedly, emerging chemical substances remains scant[54]. The author goes on to explain that, traditionally, research has a

48 False positives (also called 'type I errors') occur when a study concludes, for instance, that a non-hazardous substance is hazardous. Conversely, false negatives (also called 'type II errors') occur when a study concludes that a hazardous substance is non-hazardous.

49 See, for instance, Scientific method: Statistical errors, R. Nuzzo, Nature, 2014.

50 Thus, Taylor and Gerrodette note that '[i]n certain circumstances, a population [of wild animals] might go extinct before a significant decline could be detected'. The Uses of Statistical Power in Conservation Biology: The Vaquita and Northern Spotted Owl, B. Taylor and T. Gerrodette, Conservation Biology, 1993.

51 For instance, lead was initially associated with IQ loss in children and has since been linked to heart disease in adults; PCBs were found to cause infertility in eagles and subsequently neurological disorders in children, and cancer.

52 Science for precautionary decision-making, P. Grandjean in Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2013.

53 For example, perfluorinated compounds, which are often used in non-stick coatings for kitchen utensils or stain-resistant textile finishes.

54 The author attributes these results to the traditional scientific paradigm where replication and verification are essential, to the investment of research institutes in highly qualified personnel and

narrow focus, which has the advantage of addressing a single factor under specific circumstances but is ill-suited to gauging the complexity of environmental hazards which might have multiple and cumulative causes. A study on the funding allocated to research on environmental, health and safety hazards under the EU research framework programmes since 1996 suggests that research on these hazards represented just 0.6% of total funding under the framework programmes during that period[55].

The application of the precautionary principle can present two main challenges for **businesses**. Firstly, amendments to legislation based on the precautionary principle may create costs and legal uncertainty for businesses and may therefore hinder their development or threaten their survival. Furthermore, when companies see early warning signs that their products might present a hazard, they are faced with financial and ethical dilemmas.

Nevertheless, applying the precautionary principle can present **opportunities**. A report published by the Organisation for Economic Cooperation and Development (OECD)[56] shows that the **costs of inaction for society** are sometimes substantial and, in certain cases, can weigh heavily on economies[57]. Applying the precautionary principle can reduce these costs even though it is not easy to estimate potential future costs in order to allow comparison with the cost of regulatory measures. The precautionary principle can also serve to **correct market failures** that emerge when society has to pay for the external costs of adverse environmental and health effects caused by economic operators. It may also help to avoid **lengthy compensation proceedings** which can drag on for decades[58]. In a **transition** towards a more sustainable economy, as envisaged in EU policies[59], the precautionary principle can help to avoid hazards in highly complex and uncertain situations. Applying the precautionary principle to **environmental and health research** can provide an opportunity to review strategies (to take account of societal information needs concerning poorly understood hazards), methodologies (in order to extend knowledge) and ways to communicate on risks (to facilitate judgments on the potential scale of possible environmental hazards)[60].

---

costly infrastructure, as well as to funding agencies and science journals, which tend to concentrate on known hazards.

[55] Funding for information and communication technologies, nanotechnology and biotechnology was 0.09%, 2.3% and 4%, respectively. See Adequate and anticipatory research on the potential hazards of emerging technologies: a case of myopia and inertia?, S. Hansen and D. Gee, Journal of Epidemiology and Community Health, 2014.

[56] Costs of Inaction on Environmental Policy Challenges: Summary Report, OECD, 2008.

[57] In particular, the report mentions air pollution, water pollution, climate change, industrial accidents, and the management of natural resources.

[58] For example, it took almost 50 years (from 1956 to 2004) for victims to secure fair compensation and the court's acknowledgment of Chisso Corporation's liability for discharging methylmercury into Minamata Bay, Japan.

[59] See the 7th Environment Action Programme, adopted by the European Parliament and the Council in 2013 and SOER 2015: The European environment – state and outlook 2015, published by the European Environment Agency in 2015.

[60] For further details, see Implications of the precautionary principle for primary prevention and research, P. Grandjean, Annual Review of Public Health, 2004.

4. Governance

The 7th Environment Action Programme ('Living well, within the limits of our planet'), adopted by the European Parliament and the Council in 2013, recognises the importance of governance and sets the following objective for 2020:

> *'policy-makers and stakeholders [to] have a more informed basis for developing and implementing environment and climate policies, including understanding the environmental impacts of human activities and measuring the costs and benefits of action and the costs of inaction'.*

Furthermore, the 7th Environment Action Programme points out that:

> *'there is a need to better understand the potential risks to the environment and human health associated with new technologies, and to assess and manage such technologies better. This is a precondition for public acceptance of new technologies, as well as for the Union's capacity to identify and respond to potential risks associated with technological developments in an effective and timely manner. Major technological innovations should be accompanied by public dialogues and participatory processes'.*

4.1. Risk governance

Risk governance is the process whereby society takes and implements collective decisions on activities with uncertain consequences in terms of potential costs and benefits. Most risk governance models have three main aspects, which the European Commission also mentions in its Communication on the precautionary principle.

The **first** is **risk assessment**. According to the European Commission, it should ideally be based on four components:

- hazard identification;
- hazard characterisation, which consists in determining the nature and severity of the adverse effects[61];
- appraisal of exposure, which consists in evaluating the exposure of the population or environment to the hazard;
- risk characterisation, which consists in estimating the probability, frequency and severity of the known or potential adverse environmental or health effects liable to occur.

The EEA highlights several challenges posed by risk assessment: how to deal with systemic risks (such as resource depletion, climate change, demographic growth or loss of ecosystem resilience) facing society[62]; how to reflect complexity, ambiguity and ignorance when estimating probabilities and presenting this information to policy-makers; with regard to chemical substances, how to reflect exposure to multiple substances and differing tolerance thresholds within the same population[63].

---

[61] With regard to chemical substances, it is at this stage that a relationship between the amount of the hazardous substance and the effect has to be established.

[62] One example of a response could be the MUST-B project of the European Food Safety Authority (EFSA), which aims to develop a holistic approach to the integrated risk assessment of multiple stressors in honeybees.

[63] Several initiatives suggest responses, such as the State of the Art Report on Mixture Toxicity, A. Kortenkamp, 2009; the European Commission's single data access point, Information Platform for Chemical Monitoring; or the human exposome project.

Furthermore, it is important to handle expert contributions wisely. Several studies[64] indicate that expert advice can be more subjective than it seems. There are ways to improve the objectivity of expert advice (especially by using expert groups that are as diverse as possible and ensuring transparency) but they remain underused. The EEA also emphasises that in cases where knowledge of innovative technology resides with industry, there may be tension between the need to receive expert advice, on the one hand, and to ensure that this advice is independent, on the other. Greater transparency could be one way to overcome this problem[65].

The **second** is **risk management**. The International Risk Governance Council[66] defines this as the design and implementation of the actions and remedies required to avoid, reduce, transfer or retain the risks. This also includes the generation, assessment, evaluation and selection of risk reduction options as well as their implementation and monitoring.

A range of measures can be used to manage risk. In all cases, the degree of proof required to justify action will depend, in particular, on the relationship between the cost of the measure and the degree of risk. A trade-off between the risk under consideration and the risks posed by regulation may be necessary, as illustrated by the case of nitrates used as preservatives in meat[67]. The measures used to manage the risk include environmental bonds whereby a company launching a new technology sets aside a predetermined sum by depositing bonds with an insurance company to cover possible liability for damage.

The **third component** of risk governance is **risk communication** (and **stakeholder participation**). Effective communication exposes the risk. It enables the stakeholders to identify a risk and understand how it could affect them. However, it is not just a one-way information flow, but can be an opportunity to establish dialogue with stakeholders.

The EEA believes that risk communication should explain the reasons underlying risk management decisions, including the value judgments underpinning trade-offs between divergent objectives (e.g., energy supply and environmental protection). There is also the question of how to communicate risk in a transparent manner without generating disproportionate public concern.

Others have suggested **alternative risk governance models**. Stirling advocates a model comprising five phases (screening, appraisal, evaluation, management and communication)[68]. The IRGC suggests a four-step model embedded in a set of wider contexts (see Figure 3) as well as a 'concern assessment', defined as 'a systematic analysis of the associations and perceived consequences (benefits and risks) that stakeholders, individuals, groups or different cultures may associate with a hazard or cause of hazard'.

---

64 See Policy advice: Use experts wisely, W. Sutherland and M. Burgman, Nature, 2015.

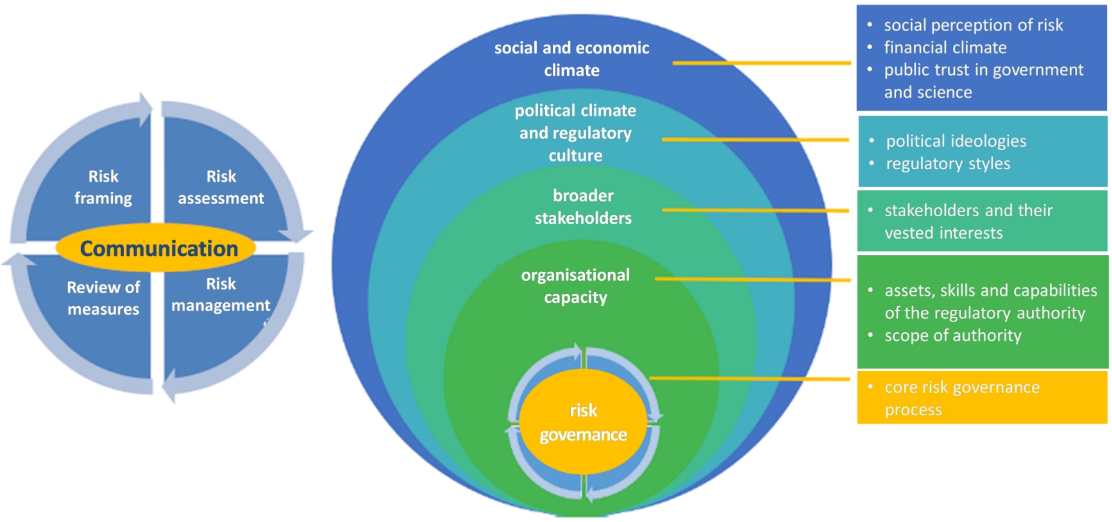
65 See, for instance, the Decision of the European Ombudsman of 28 January 2015 concerning the European Food Safety Authority (346/2013/SID).

66 An Introduction to the IRGC Risk Governance Framework, International Risk Governance Council, 2012.

67 Although nitrates can produce carcinogenic substances when they react with other food in the body, they prevent the growth of toxins that cause potentially fatal food poisoning.

68 Model presented in Risk, precaution and science: towards a more constructive policy debate, A. Stirling, EMBO reports, 2007.

Figure 3 — Governance model of the International Risk Governance Council



Source: adapted from An Introduction to the IRGC Risk Governance Framework, International Risk Governance Council, 2012.

Some authors consider a narrow focus on risks to be an inadequate response to incomplete knowledge and advocate approaches that are plural (i.e., setting out several reasonable interpretations) and conditional (i.e., for each alternative, explicitly exploring the questions, values or intentions) to enable a sophisticated and informed policy debate on broader questions[69].

4.2. Science-policy interface

As the European Commission points out in its Communication on the precautionary principle, the application of precautionary measures is 'the result of an eminently political decision, a function of the risk level that is "acceptable" to the society on which the risk is imposed'. Nevertheless, scientific knowledge often contributes to the development of these policies. In a context where values and knowledge are interdependent, the science-policy interface is central to governance. Examples of science-policy interface include the IPCC's on climate change, at global level, or the European Commission's European Political Strategy Centre (EPSC)[70].

There are **several intersections between science and policy**, including the impact of science on the environment and society – and therefore policy – mainly through technological development, and, conversely, the impact of the natural and social environment on science, as illustrated by anthropogenic climate change. **Challenges arising at the intersection between science and policy**[71] include:

- contributing scientific input to policy-making under conditions of complexity and uncertainty;
- striking the balance between curiosity-driven science (e.g., basic research) and issue-driven science (e.g., development and innovation) and converting their results into policy-relevant knowledge; and
- reaffirming the role that scientific explanations play in helping to understand an

---

[69] Stirling mentions the way the Bank of England's Monetary Policy Committee interacts with its experts when setting policy interest rates as an example of a plural and conditional approach. See Keep it Complex, A. Stirling, Nature, 2010.

[70] The EPSC succeeded the Bureau of European Policy Advisers (BEPA) on 1 January 2015.

[71] A rationale for science-policy interfaces, S. van den Hove, Futures, 2007.

issue and emphasising the inherent limitations of predictions.

A report published by the SPIRAL project[72], funded under the 7th Framework Programme, studies nine **examples of science-policy interfaces** for biodiversity at national, European and international level. **Lessons** drawn from this study include:

- the balance to be struck between a formal approach and the need for adaptability;
- an open and transparent format complemented by a review process to ensure credibility;
- the persistent dominance of the linear model (one-way transfer of knowledge from science to policy), which hinders the development of more dynamic interfaces; and
- the need to address environmental issues through interdisciplinary interfaces involving a broad diversity of experts and transdisciplinary approaches that integrate various scientific disciplines.

Several stakeholders have issued **recommendations** on science-policy interfaces. Anne Glover, chief scientific adviser to the European Commission from 2011 to 2014, calls for evidence gathering to be completely disconnected from political imperatives, and for more transparency in the evidence-gathering process[73]. The EEA points out that public authorities often use structures and methods of the past to assess the potential hazards of technologies of the future rather than adopt more sophisticated, flexible and relevant approaches. It goes on to say that governance systems need to recognise more systematically and explicitly the conflicting values underpinning all societal and environmental issues. Van den Hove points out that scientific knowledge passed on through the science-policy interface should systematically include information on boundaries, uncertainties, indeterminacy, and ambiguity, as well as acknowledgement of ignorance and of the irreducible plurality of valid standpoints.

4.3. Precaution and innovation

There are those who believe that the precautionary principle can **stifle innovation**. The NGO European Risk Forum argues that regulation which concentrates solely on avoiding risk and removing scientific uncertainty, stifles technological innovation. It mentions the examples of chemical substances and antimicrobials. It suggests complementing the precautionary principle with an innovation principle[74], advocating that '[w]henever EU institutions consider policy or regulatory proposals, impact on innovation should be fully assessed and addressed'.

In contrast, there are others who believe that the precautionary principle can **boost innovation**. The EEA points out that appropriate use of the precautionary principle can promote a wide range of technologies and activities. It goes on to say that whereas dominant corporations characterised by top-down innovation can create technological lock-ins and crowd out innovation and the development of alternatives, bottom-up innovation can generate a wider variety of innovations and react more promptly to adverse environmental or health effects. In particular, it cites the example of farming innovations relating to GMOs and the development of agroecology.

---

[72] For a summary, see Reality-check for science-policy interfaces.

[73] EU twisting facts to fit political agenda, chief scientist says, EurActiv, 2014.

[74] See Better Framework for Innovation: Fuelling EU policies with an Innovation Principle, European Risk Forum, BusinessEurope and the European Round Table of Industrialists, 2015.

Beyond the tension or complementarity between precaution and innovation, the concept of **responsible research and innovation**[75] is a cross-cutting issue in Horizon 2020, the EU research and innovation framework programme which aims to foster social and environmental responsibility and ethics in the governance of science and technology. The concept is generally defined as research and innovation activities that:

- respond to significant societal needs and challenges;
- involve a range of stakeholders for the purpose of mutual learning; and
- anticipate potential problems, identify alternatives and study the underlying values.

This concept does not only provide a response in cases of scientific uncertainty (where the precautionary principle may apply), but can also be used to drive innovation by taking ethical acceptability and societal needs into consideration[76].

Some authors emphasise that innovation is not an **end in itself** but a **means** of improving well-being and contributing to environmental, social and economic sustainability. They advocate widening a concept of innovation to include not only technological innovation, but also non-technological, social, institutional, organisational and behavioural innovation[77].

5. Outlook

Although the precautionary principle, which is enshrined in the Treaty on the Functioning of the European Union and many international environmental treaties, has provided some solutions for responding to complex environmental and health hazards, its definition is still under discussion and its status in international law is still in dispute. The main focus of debate has now shifted to its scope of application since there are those who wish to limit it and those who wish to extend it.

Technological (and non-technological) innovations can be expected to play a central role in the transition to a decarbonised, sustainable and circular economy, as envisaged in EU policies and the vision set out in the 7th Environment Action Programme:

> *'In 2050, we live well, within the planet's ecological limits. Our prosperity and healthy environment stem from an innovative, circular economy where nothing is wasted and where natural resources are managed sustainably, and biodiversity is protected, valued and restored in ways that enhance our society's resilience. Our low-carbon growth has long been decoupled from resource use, setting the pace for a safe and sustainable global society.'*

The precautionary principle may be invoked to address the complexities and uncertainties inherent in such a transition.

Furthermore, the question of adapting risk governance and science-policy interfaces in order to respond to these challenges could be raised if – as suggested by the European Environment Agency – the four main approaches to environmental protection (i.e.,

75 See Responsible research & innovation, European Commission.

76 Assessment of science and technologies: Advising for and with responsibility, E. M. Forsberg et al., Technology in Society, 2015.

77 The Innovation Union: A perfect means to confused ends?, S. van den Hove, J. McGlade, P. Mottet, M. H. Depledge, Environmental Science and Policy, 2012.

mitigate, adapt, avoid and restore the damage caused)[78] were more effectively taken on board in order to facilitate this transition.

[78] Responding to systemic challenges: from vision to transition in SOER 2015: The European environment – state and outlook 2015, European Environment Agency, 2015.

6. Main references

A rationale for science-policy interfaces, S. van den Hove, Futures, 2007.

An inconvenient deliberation: the precautionary principle's contribution to the uncertainties surrounding climate change liability, M. Haritz, Wolters Kluwer, 2011.

Assessment of science and technologies: Advising for and with responsibility, E. M. Forsberg et al., Technology in Society, 2015.

Comparing Precaution in the United States and Europe, J. Wiener and M. Rogers, Journal of Risk Research, 2002.

Costs of Inaction on Environmental Policy Challenges: Summary Report, OECD, 2008.

Late lessons from early warnings: science, precaution, innovation, European Environment Agency, 2013.

Late lessons from early warnings: the precautionary principle 1896-2000, European Environment Agency, 2001.

L'inquiétant principe de précaution, G. Bronner and E. Géhin, PUF, 2010.

The case for a procedural version of the precautionary principle erring on the side of environmental preservation, A. Arcuri, Erasmus University Rotterdam, 2006.

The Innovation Union: A perfect means to confused ends?, S. van den Hove, J. McGlade, P. Mottet, M. H. Depledge, Environmental Science and Policy, 2012.

The precautionary principle as a norm of customary international law, O. McIntyre and T. Mosedale, Journal of Environmental Law, 1997.

The precautionary principle in EC and WTO law: searching for a common understanding, I. Cheyne, Environmental Law Review, 2006.

Trading Precaution: The Precautionary Principle and the WTO, S. Shaw and R. Schwartz, UNU-IAS, 2005.

QA-01-15-945-EN-N

The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high. It first emerged during the 1970s and has since been enshrined in a number of international treaties on the environment, in the Treaty on the Functioning of the European Union and the national legislation of certain Member States.

The precautionary principle divides opinions. To some, it is unscientific and an obstacle to progress. To others, it is an approach that protects human health and the environment. Different stakeholders, experts and jurisdictions apply different definitions of the principle, mainly depending on the degree of scientific uncertainty required for the authorities to take action. Although most experts agree that the precautionary principle does not call for specific measures (such as a ban or reversal of the burden of proof), opinions are divided on the method for determining when to apply precautionary measures. The application of the precautionary principle presents many opportunities as well as challenges.

The precautionary principle is closely linked to governance. This has three aspects: risk governance (risk assessment, management and communication), science-policy interfaces and the link between precaution and innovation.

This is a publication of the
Members' Research Service

Directorate-General for Parliamentary Research Services, European Parliament

PE 573.876
ISBN 978-92-823-8480-0
doi:10.2861/821468