

## Chapter 29

### The Precautionary Principle in GMO regulations

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#### 1. Introduction

The Precautionary Principle has been accepted by many national governments as a basis for policy making, and it has become important both in international environmental law and international treaties (Freestone & Hey 1996; CBD 2000; EU 2000). Initially, the Precautionary Principle was developed to restrict marine pollution discharges in the absence of proof of environmental damage, and entered international policy with the Conferences on the Protection of the North Sea (in London 1987, The Hague, 1990, Bremen, 1994; Esbjerg, 1995) (Ducrotoy 1997).

With regard to GMO regulations, a precautionary approach plays an important role in the Cartagena Protocol on Biosafety (see Chapter 26), an international agreement mainly regulating the safe transfer, handling, use, and trans-boundary movement of GMOs. Article 1 specifies the objective of the Protocol:

*In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*

Accordingly, the Protocol allows countries to use the Precautionary Principle to limit the use and release of GMOs in situations of scientific uncertainty with regard to potentially adverse ecological and health effects.

We also find the Precautionary Principle in regulations such as the Norwegian Gene Technology Act of 1993 and the EU directive 2001/18/EC on deliberate release into the environment of GMOs (see Chapters 22 and 24). The Norwegian Gene Technology Act has included the Precautionary Principle in its preparatory work as well as in Appendix 4 of the newly revised regulations on Impact Assessments under the Gene Technology Act, where it is stated that the Precautionary Principle shall be used when evaluating possible hazards and damage for animal and human health and the environment. In the EU directive the Precautionary Principle is included in the objectives of the Act.

The Precautionary Principle is a normative principle for making practical decisions under conditions of scientific uncertainty. Its employment entails the identification of risk, scientific uncertainty and ignorance, and it involves transparent and inclusive decision making processes (Raffensperger & Tickner 1999). However, the application of the Precautionary Principle in risk assessment and management of GMO use and release is at present a subject of heated scientific and public controversies. In the view of the critics, the use of the Precautionary Principle places additional regulatory burden on GMO utilisation, and thereby reduces returns from innovation, limits utilisation of GMOs worldwide and provides disincentives for research. On the other hand,

advocates of the Precautionary Principle want to enhance safety procedures and to separate trade and environmental interests in decision making, and are often linking this to lack of knowledge and omitted biosafety research.

## 2. *The Precautionary Principle*

The Precautionary Principle is a normative principle for making practical decisions under conditions of scientific uncertainty. It has four central components: it is supposed to 1) initiate preventive action as a response to scientific uncertainty, 2) shift the burden of proof to the proponents of a potentially harmful activity, 3) explore alternative means to achieve the same goal, and 4) involve stakeholders in the decision making process (Kriebel et al. 2001). The actual content of the Precautionary Principle, however, and the practical implications of its implementation in policy issues are controversial (Raffensperger & Tickner 1999; Morris 2000). Several formulations of the Principle, ranging from ecocentric to anthropocentric, and from risk-adverse to risk-taking positions, have been put forward (see Boxes 29.1 and 29.2). A weak version of the Precautionary Principle is often grounded in narrow utilitarian ethics, and its application involves risk/cost-benefit analyses. In this context, the Principle may be used as an option to manage risks when they have been identified through risk analysis. For instance, the Rio Declaration employs the weighing of costs and benefits (Box 29.1), and similar wording has been reproduced in the preamble of the Convention on Biological Diversity and in Article 3 of the Framework Convention on Climate Change.

Strong versions of the Precautionary Principle embrace inherent values of the environment and often are founded in ecocentric views or duty-based concerns for non-human beings and ecosystems (see Chapter 7 for further elaboration). A strong version is active in nature and obliges regulators to take action, for instance by implementation of risk management procedures. The Wingspread Statement is considered to represent a strong version of the Precautionary Principle (Box 29.2).

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### **Box 29.1 Weak version of the Precautionary Principle**

#### *The Rio Declaration:*

In order to protect the environment, the precautionary approach should 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 (Agenda 21, 1992).

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Whatever version/formulation one uses, the implementation of the Precautionary Principle presupposes:

- I. Some threat of harm must have been identified
  - II. Scientific uncertainty exists with regard to the potential harm
  - III. There are criteria to guide proactive and precautionary measures.
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### **Box 29.2 Strong version of the Precautionary Principle**

#### *The Wingspread Statement:*

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically (Raffensperger & Tickner 1999).

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### *2.1 Implementation of the Precautionary Principle as a Response to the Threat of Harm*

The implementation of the Precautionary Principle requires that indications of adverse impacts are being documented in some way, and that risk-associated research is initiated (Myhr & Traavik 1999; Foster et al. 2000). First of all, the sources and types of scientific uncertainties should be identified. At present, scientific information on environmental and health effects is limited, both from the industry and from public research institutions, due to lack of biosafety related research. Several aspects of scientific uncertainty in regard to GMO use and release are presented elsewhere in this book: see Chapters 8–15.

When one is making decisions the presence of scientific uncertainty complicates the weighing of benefits against both immediate and long-term costs. Technological and economical approaches, such as risk-cost-benefit analyses, may be used to specify the uncertainties within a reduced scientific framework. However, such approaches cannot cope with complex biological and ecological processes that, for instance, GMOs are going to be used and released into. The decision makers might be prone to rely on short-term considerations of risk, and thereby not include adverse effects with a low probability or long-term hypotheses of risk in the decision. Hence, both technological and economical approaches tend to function as less restrictive standards of safety, in so far as risk and uncertainty are being permitted as long as there are benefits. In this context, uncertainty is often defined simply as lack of knowledge that can be reduced by further research.

Recognising that uncertainty is more than unknown probabilities or insufficient data, different taxonomies of uncertainty have been developed (Wynne 1992; Dovers et al. 1996):

Hazard can be related to a specific adverse event. Risk represents the relationship between probability and consequences, hence a condition where the possible outcomes are identified and the relative likelihood of the outcomes is expressed in probabilities.

Uncertainty refers to situations where we do not know or cannot estimate the probability of hazard, but the hazards to be considered are known. The uncertainty may be due to the novelty of the activity, or to the variability or complexity involved. For instance, even if the frequency of horizontal gene transfer has been studied extensively before the use and release of GMOs, there will be selective forces influencing the outcome and causing different results than that obtained in laboratory experiments.

Ignorance represents situations where the kind of hazard to be measured is unknown, i.e. completely unexpected hazards may emerge. This has historically been experienced with BSE or mad-cow disease, dioxins and pesticides, among others. With regard to GMOs, there may emerge, for instance, unprecedented and unintended non-target effects. Non-target effects include the influence on and interactions with all organisms in the environment, and may be either direct or indirect. Direct effects concern eco-toxic effects on other organisms, for instance, adverse effects on insects resulting from larval feeding on insect-resistant plants, or effects on soil organisms. Indirect effects concern effects on consumer health, contamination of wild gene pools or alterations in ecological relationships (see Chapters 8–15 in this book for further elaboration). Indeterminacy, or 'great uncertainty', describes the inevitable gap between limited experimental conditions and reality, where the consequences of an activity can never be fully predicted. The structures and dynamics of biological systems cannot be described by their parts solely, as genes and proteins, but concern interactions with each part of the system and the composite effects from abiotic (non-living) factors as well (Kitano 2002). Therefore, it is crucial that methods for detection and monitoring are initiated with the purpose of following up the performed risk assessment, to map the actual health and environmental effects, and to identify unexpected adverse effects. Long-term monitoring provides baselines against which to compare future changes, and it gives input data to improve regulation systems (Cranor 2003).

### *2.3 Implementation of the Precautionary Principle Involves Acknowledgement of Scientific Uncertainty*

The first step for scientists is to become aware of the role they play in the production of information and the subsequent political use of this information (Myhr & Traavik 2002). At present, the proponents, sceptics and opponents use different evidence to describe or interpret the data (or lack of data) with regard to the potential consequences of GMO use and release in various ways. Such factual divergences cause disagreement about which facts are relevant, and what research needs to be initiated (Levidow 2003). In addition, in most cases proponents of an activity will challenge the significance of evidence and argue that the opponents have a credibility problem. Consequently, there is a need to consider how to deal with the present uncertainty accompanying the use and release of GMOs. For instance, how to approach statistics (see Chapter 17 and approaches that define and systematise the uncertainty involved, such as the W&H (Walker and Harremoes) framework), may help to use scientific knowledge more efficiently in directing further research and in guiding risk assessment and management processes.

### *3. Threshold for evidence*

A threshold of scientific plausibility of potential harm must exist before a precautionary measure can be initiated. For instance, Article 15(1) of the Cartagena Protocol on Biosafety states:

*Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.*

The references to ‘available scientific evidence’ and ‘scientifically sound manner’ can be seen as a predetermined qualitative term, while, for instance, the EC communication on the Precautionary Principle (EC 2000) and the Report of the Expert Group on the Precautionary Principle of the World Commission on the Ethics of Scientific Knowledge and Technology (UNESCO 2005) have chosen to focus on the quality of the information. By demanding scientific evidence before employing the Precautionary Principle, the Biosafety Protocol requires documentation indicating that the GMO causes harm to health or the environment. Does this mean that one needs scientific evidence for lack of scientific certainty?

There is an important difference between demanding scientific evidence for potential harm versus only focusing on scientific uncertainty. Strong versions of the Precautionary Principle as well as the UNESCO version allow that presence of scientific uncertainty and indications of harm are enough for acceptance of employment. Hence, the demand for ‘scientific evidence’ represents an ambiguity in the formulation of the Protocol, especially if one compares this with what is stated in Article 10 of the Protocol:

*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.*

The demand for ‘scientific evidence’ and risk assessments to be undertaken in a ‘scientifically sound manner’ involves a misrepresentation of the current lack of knowledge and may cause uncertainty to be downplayed, especially if these terms have implications for how to interpret Article 10. This ultimately raises the question: What will be the role of lack of scientific certainty when risk assessment is going to be carried out in a scientifically sound manner?

For instance, the different scientific disciplines that are involved in the epistemic debate employ competing models or different analogies for basic assumptions to frame the scope for further research. Molecular biologists would refer to the practice and precision of doing laboratory research, and plant biologists would compare safety with the history of conventional plant breeding, while ecologists would refer to the adverse experiences based on the introduction of novel species into new environments. Such factual divergences cause disagreement about which facts are relevant and what research needs to be initiated (Levidow 2003).

A reference to qualitative terms may also cause non-mainstream arguments to be downplayed. For instance, not many years ago horizontal gene transfer (HGT) was considered to have such low a frequency that it was regarded as insignificant. However, it is now gaining increased attention and has become an important topic for risk-associated research related to GMO use and release.

### *3.1 The ‘Familiarity Principle’ and Substantial Equivalence versus the Precautionary Principle*

The OECD (1993a) introduced the ‘Familiarity Principle’, stating that GE used in order to produce new agricultural strains ‘does not exceed the risk of conventional techniques’. Criteria for determining familiarity include knowledge of and experience with any or all of the following: the crop plant, the environment, the trait, pleiotropic genetic modification of the crop or trait, and interactions among the crop, the trait, and the release environment. The Familiarity Principle is founded on the assumption that there does not seem to be any reason to expect more serious problems arising from GMOs in agriculture than from conventional agricultural practice. This principle has been criticised with regard to its underlying assumptions and its narrow framework (Barret & Abergel 2000). For instance, the decision thresholds for the extrapolation of safety that are supposed to ensure that adverse effects do not exceed those of the non-GM counterpart will vary significantly, depending on the nature of their subject, i.e. organic versus chemical-intensive agriculture. Furthermore, the argument of analogy to the safety of conventional agriculture is not a valid comparison and cannot be extrapolated to GM crops, because no similar conventional crops have been commercialised. Conventional breeding involves using natural plant reproductive methods which is only possible between closely related species, or breeding methods that introduce new traits into plants via chemical or radiation mutagenesis of the plant’s genome. GE, on the other hand, involves the exchange of genes from both distantly related and non-related species, which in many cases would never breed with each other, by using gene guns or microinjections in order to transfer the genes.

To assess the safety of GM food, the concept of ‘Substantial Equivalence’ was introduced by the OECD in 1993 and later affirmed by the FAO (OECD 1993b; FAO 1996; 2000). Substantial Equivalence is considered by some as a guiding principle for risk assessment with the intention to consider whether a GM food product is as safe as its traditionally bred counterpart. For example, in the US, GM food and GM products that are considered substantially equivalent, i.e. as safe as their non-GM counterparts, are being commercialised without labelling requirements and post-market monitoring (see Chapters 32 and 33).

The Expert Panel of the Royal Society of Canada (2001) identified two different uses of the concept of Substantial Equivalence: the decision threshold interpretation and a safety standard interpretation. The panel accepted the validity of the safety standard, but expressed that its validity as a decision threshold interpretation was restricted. The safety interpretation requires rigorous scientific analyses with the purpose of identifying all changes being introduced to the organism. At the same time, the panel raised the question of how to define ‘rigorous demonstration’ and suggested that an integrated approach is needed to consider changes in the GMO (The Expert Panel of the Royal Society of Canada 2001).

Inevitably, it has been argued that the application of Substantial Equivalence does not ascertain the problem that needs to be solved, and that the adequate assessment of ecological effects requires a broader basis. The narrow focus on risk has caused an extensive debate among regulators and scientists, leading to both support (Gasson & Burke 2001) and criticism (The Expert Panel of Royal Society of Canada 2001; Myhr & Traavik 2003). The issue of novelty of GE has been central in these discussions. It has been argued that there does not seem to be any reason to expect different impacts from genetically modified organisms than from traditional agricultural products.

On the other hand, as has been argued in Chapters 4, 8 and 9, the present methods for genetic modification entail a lack of precision and control over insert integration. The Codex Alimentarius Commission has suggested that risk assessments of GM foods need to be broadened in order to encompass not only health related effects of the food, but also to include unintended effects (Haslberger 2003). For instance, there is growing awareness that unintended effects in GMOs might arise as a result of gene or base pair/gene fragment insertion. The expression level of a gene rather than the amino acid sequence of the protein product can determine phenotypes that will contribute to natural varieties which can be influenced both by climatic and environmental conditions. Consequently, the significance of the genetic modification process needs to be elaborated at several levels: see Chapters 3, 4, 8, and 9 in this book.

Contrary to the use of the Familiarity Principle and the concept of Substantial Equivalence, the employment of the Precautionary Principle may initiate debate concerning the quality of risk-related scientific advice and the identification of areas where scientific understanding and knowledge is lacking, and perhaps most importantly increase recognition of the extent of ignorance (i.e. accept that we do not know that we do not know). A precautionary approach might, therefore, be seen as more scientific since it depends on broader judgements and involves initiation of basic research that either concedes or rules out risks of harm to human and animal health or the environment.

#### *4. The Need for Proactive Measures*

The level of precaution to be implemented will depend on the probability of harm, the level of uncertainty, the seriousness/irreversibility of the potential harm, and the availability of alternatives. Within GMO use and release, precautionary action might vary from restricted use (based on required monitoring of impacts) to labelling of the products, to a banning of a GM product or moratorium on action. Implementation of precautionary measures entails more science, since it depends on broader judgements and involves initiation of basic research that either concedes or rules out risks of health and environmental harm. The determination of a country’s chosen level of protection needs to be a political decision, where ‘consistency’ and ‘non-discrimination’ have, for instance, been relevant guidelines for employment of the Precautionary Principle in the EU (see Table 29.1).

**Table 29.1. Guidelines for implementation of the Precautionary Principle (EU 2000).**

<b>Proportionality</b>	‘measures ... must not be disproportionate to the desired level of protection and must not aim at zero risk’
<b>Non-discrimination</b>	‘comparable situations should be treated differently and ... different situations should not be treated in the same way’
<b>Consistency</b>	‘measures ... should be comparable in nature and scope with measures already taken in equivalent areas’
<b>Scientific research</b>	‘The measures must be of a provisional nature pending the availability of more reliable scientific data ... scientific research shall be continued with a view to obtaining more complete data’
<b>Demonstrated benefit</b>	‘examination should include an economic cost/benefit analysis when this is appropriate and feasible’

The types of precautionary measures that are considered acceptable by the international community under some multilateral agreements such as the World Trade Organization are (so far) unclear. For instance, the Biosafety Protocol may set a new precedent with regard to the relationship between environmental protection and the international trade regime. Other international treaties involving the Precautionary Principle focus on environmental problems and the conflicts have centred on the significance of scientific understanding and the uncertainty involved. The Biosafety Protocol is concerned with both environmental impacts and food safety, where trade issues may be a reason for conflicts.

Accordingly, countries may face the threat of a WTO complaint such as the one that the USA, Canada and Argentina have submitted to the WTO over the EU’s alleged failure to apply its authorisation system for GMOs. According to WTO rules, an importing country needs to prove scientifically that a particular product is unsafe in order to implement a legal ban on the import of that food (although in the case of insufficient scientific evidence, temporary precautionary measures may be applied). Hence, the demands of the WTO may come into conflict with the degree of scientific evidence necessary to trigger action under the application of the Precautionary Principle in the Cartagena Protocol on Biosafety (Helmuth 2000).

##### *5. The Precautionary Principle and the burden of proof*

Within the general use of technology it has been those who claim an existence of yet unproven effects who have had the burden of demonstrating that the activity in question is causing harm to health or the environment. With employment of the Precautionary Principle, the burden of proof is shifted to the proponent (notifier or exporter) which now needs to demonstrate that the activity is necessary and that it will not harm health or the environment. This is reflected in the Cartagena Protocol on Biosafety and in the EU and Norwegian regulatory frameworks.

The proponent has the responsibility to demonstrate that the GMO in question is reasonably safe. Most countries have therefore implemented a case-by-case and step-by-step approach. The case-by-case procedure entails a mandatory scientific evaluation of every notification of a GMO. The step-by-step procedure facilitates a progressive line of development of GMOs by evaluating the environmental impacts of releases in decreasing steps of physical/biological containment (from greenhouse experiments, to small-scale and large field tests to market approval). The purpose of the case-by-case and step-by-step procedures is also to establish a learning practice that enables the authorities and the notifiers to collect information. In addition, in the EU, the proponents have also to submit a well-designed monitoring programme for how environmental monitoring is to be

carried out after commercialisation. It has also been suggested that assigning liability or financial bonds together with conditional approval and broad-scale testing might be means to ensure the GMO developers' responsibility.

#### *6. The Precautionary Principle and the influence of normative standards*

Risk assessment and management strategies are developed within particular regulatory frameworks, including normative standards and preferences regarding our relation to the natural environment and the preservation/promotion of human health. For instance, in the EU Directive 2001/18/EC it is stated that an environmental risk assessment needs to consider direct and indirect effects, immediate and delayed effects, as well as potential cumulative and long-term effects due to interaction with other GMOs and the environment. Article 1 of the Cartagena Protocol specifies that the entire objective of the document is to protect and conserve biodiversity according to a precautionary approach. One of the purposes of the Norwegian Gene Technology Act is that use of GMOs shall be in accordance with the principle of sustainable development (see Chapter 24). Normative standards may affect the scope of risk management of GMO use and release, and affect legal interpretations about the acceptable risks, thereby function as guidance for when and how to apply the Precautionary Principle.

#### *Conclusions*

The challenge of implementing the Precautionary Principle in proper ways involves both taking into account scientific and value uncertainty. A change to more integrative risk assessment and management, where the Precautionary Principle has an important role in situations of scientific and moral uncertainty may make science more accountable to public concerns. The ultimate objective is to find the right balance between too little and too much precaution.

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