

The Precautionary Principle and Modern Biotechnology

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Outline of Presentation

- Precautionary principle (PP) in international law
- Conditions for PP
- Precautionary Approach in the Rio Principles
- Precaution and Modern Biotechnology. Agenda 21, Convention on Biological Diversity, UNEP Guidelines, and Cartagena Protocol
- Risk Assessment and Precaution

Precautionary Principle in International Law

- Earliest explicit reference to precautionary principle (*Vorsorgeprinzip*) was in the German Program of Environmental Protection of 1971. It then spread to other European countries and applied also food safety and public health issues.
- In 2000, EU Heads of Government endorsed a Resolution which recognized that “the precautionary principle is gradually asserting itself as a principle of international law in the fields of environment and health protection”. Emphasis supplied; European Council, Council Resolution on Precautionary Principle, Paragraph 3.

It should be used “where the possibility of harmful effects on health or environment has been identified and preliminary scientific evaluation, based on available data, proves inconclusive for assessing the level of risk.” Emphasis supplied; Paragraph 7.

- Status in international law? Some believe it is already customary law but others don't.

Customary international law requires *usus* (the “quantitative” element of a stable and uniform international practice) and *opinio juris* (i.e., that States must act with the belief that the practice is undertaken to fulfill a legal duty).

- Precautionary Principle is no more than a guide to policy makers to act to anticipate problems before they occur.

Due to its flexible nature, the following conditions must be present:

1. **Uncertainty of risk.** – It is beyond preventive measures because it urges policy makers to anticipate problems before they arise or scientific proof of harm is established. Uncertainty of risks is a key element of PP; in preventive measures, harmfulness of the product or activity is well-known. Preventive measures are for situations of actual risk; PP measures respond to situations of potential risks.

2. Scientific assessment of risk. – While operating in the context of scientific uncertainty, PP should be applied only when, on the basis of the best scientific evidence available, there is good reason to believe that harmful effects might occur to public health or environment. Simple fear cannot justify precautionary measures.

According to EC, implementation of PP “should start with scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty”. European Commission, Communication on the Precautionary Principle,

2 February 2000, Para. 6.1.

Potential risks must be defined and likelihood evaluated by independent experts based on sound scientific principles.

3. Serious or irreversible damage. – The suspected damage should be significant enough to justify measures that may in some cases lead to restrictions. It requires a determination of “threshold of non-negligible damage”. This is culture-specific.

It is serious when it affects the life and health of individuals, vital natural resources, preservation of species, climate, and ecosystem balance.

It is irreversible when it involves natural resources that cannot be replaced or which could be restored but only in the long term or at great expense.

4. Proportionality of measures. - Takes into account the various precautionary measures available to the decision maker (e.g., monitoring, reduction of exposure, pre-market testing, labeling, and research to reduce uncertainty). Outright ban should be the last resort.

Decisions based on PP should always be provisional, i.e., subject to active review and modified when further information that reduces uncertainty becomes available.

5. Shifting burden of proof. - Burden of proof shifted to those whose actions may seriously threaten public health or environment. Since they will benefit from the products or activities and have more information on the product or activity, then they should at least assume the cost of risk assessment.

Not to be interpreted as requiring proponents of a technology to provide definite evidence that their products or activities are harmless (zero risk). Given the scientific uncertainty, it would be unreasonable to require one party to prove total absence of risk. The shift in onus is to make the hazard creators show that they have undertaken the necessary research to establish the nature of the risks.

Andorno (2004), Roberto, "The Precautionary Principle: A New Legal Standard for a Technological Age", Journal of International Biotechnology Law.

Rio Declaration on Environment and Development (Earth Summit, June 14, 1992)

Rio Principles

- Principle 15 (Precautionary Approach)

"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 uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Emphasis supplied.

Principle 15 links precautionary activities with cost-benefit considerations, a reflection of US environmental policy during the Reagan administration. Restrictions were required to be based on scientific evidence showing risks and proving damages. Role of scientists strengthened due to the importance of risk assessment and cost-benefit analyses. Meyer (2007), Hartmut, "The Precautionary Principle and the Cartagena Protocol on Biosafety: Development of a Concept", in Travik, T. and Lim, L.C. (eds.). Biosafety First.

Agenda 21 (June 1992)

- Non-binding, voluntarily implemented UN action plan adopted by 178 governments on June 13, 1992 at the UN Conference on Environment and Development held in Rio de Janeiro. Action agenda for the UN, multilateral organizations and individual governments.
- Established the nexus between biological diversity and biotechnology. Use of biotechnology seen as beneficial in protecting and sustainably utilizing biological diversity.
 - “Recent advances in biotechnology have pointed up the likely potential for agriculture, health and welfare and for the environmental purposes of the genetic material contained in plants, animals and micro-organisms.” Emphasis supplied, Chapter 15.3.
 - Hence, governments should “implement mechanisms for the improvement, generation, development and sustainable use of biotechnology and its safe transfer, particularly to developing countries, taking into account the potential contribution of biotechnology to the conservation of biological diversity and the sustainable use of biological resources.” Emphasis supplied, Chapter 15.4(h).

- Identified 3 program areas where use of biotechnology is useful:
 - Increasing the availability of food, feed and renewable materials. Increase the yield of major crops, livestock, and aquaculture species; reduce the need for volume increases of food, feed and raw materials by improving the nutritional value of source crops, animals and micro-organisms and reducing post-harvest losses of plants and animal products; increase the use of integrated pest, disease and crop management techniques to eliminate overdependence on agrochemicals; increasing yields and more efficient utilization of forest products; increase efficiency of nitrogen fixation and mineral absorption by the symbiosis of higher plants with micro-organisms. Chapter 16.3 (a)-(c),(e),(f)

- **Improving human health.** Help combat major communicable diseases; promote general good health among the people; assists in specific treatment of and protection from major non-communicable diseases. Chapter 16.12 (a),(b),(c)
- **Enhancing protection of the environment.** Prevent, halt and reverse environmental degradation in conjunction with other technologies. Use in bio-remediation of land and water, waste treatment, soil conservations, reforestation, afforestation and land rehabilitation. Protect environmental integrity with a long-term view of ecological security. Chapter 16.22 (b),(c).
- Agenda 21 even provides for an obligation to transfer biotechnology.
 - “Governments at the appropriate level, . . . should, as appropriate . . . facilitate the transfer of technologies relevant to the conservation of biological diversity and the sustainable use of biological resources or technologies that make use of genetic resources and cause no significant damage to the environment . . . and recognizing that technology includes biotechnology.” Emphasis supplied; Chapter 15.7(d)

Convention on Biological Diversity

- Opened for signature during the Earth Summit, on June 5, 1992, and entered into force December 29, 1993.
- More stringent version of the precautionary principle in the preamble, but not in the text. No link between precautionary activities and cost-benefit analyses.

“Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.” Emphasis supplied; Preamble Para. 9.

UNEP International Technical Guidelines for Safety in Biotechnology (1995)

- First international document which dealt with biosafety. Intended to implement Chapter 16 of Agenda 21.
- Its aim was to “assist Governments, intergovernmental, private sector and other organization in the establishment and maintenance of national capacities to provide for safety in biotechnology, to assist in developing expert human resources and for international exchange of information.”

Cartagena Protocol on Biosafety (2003)

- Entered into force on September 11, 2003.
- At the second CBD-COP (November 1995), a working group was established to start the negotiations on a Biosafety Protocol. US and Europe resisted.

Negotiations began in 1996 and text was finalized in January 2000 after 6 meetings of the BSWG, two ExCOP, and the intersessional informal meeting in Vienna.

Precautionary decision-making reflected in 5 paragraphs:

1. Preamble

“Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development;” Emphasis supplied; Preamble, Para. 3

Use of “Precautionary Principle” was blocked by US, Australia and other governments. Reason is that the Rio Declaration itself contains the word “Precautionary Approach” and “Precautionary Principle” is not an internationally recognized principle of law. The EU, through the EC, initially supported the inclusion of Precautionary Principle in the preamble and scope of the Protocol. EU’s support for inclusion in the operational text came only in the final negotiation round. Meyer (2007), Hartmut, “The Precautionary Principle and the Cartagena Protocol on Biosafety: Development of a Concept”, in Travik, T. and Lim, L.C. (eds.). Biosafety First.

No mention of Principle 9:

“States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies.” Emphasis supplied.

By failing to mention Principle 9, Cartagena Protocol departed from the spirit of the Rio Declaration where science and technology, including biotechnology, was seen as an instrument to protect biodiversity.

2. Article 1 (Objective)

“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. Emphasis supplied.

At the BSWG-6, the term Precautionary Principle was replaced by Precautionary Approach in the Preamble and Article 1. Does this mean that cost-benefit consideration under Rio shall apply?

3. Article 10 (Decision Procedure)

“6. 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 . . . in order to avoid or minimize such potential adverse effects.” Art. 10(6).

The Precautionary Principle was introduced into the operational part of the draft Protocol at the BSWG-4 in February 1998. This was supported by Peru, Thailand, Venezuela and Slovenia at the BSWG-5.

References to Precautionary Principle and Approach are common in international agreements. What is unique in the Protocol is that they are also found in the operative provisions. Hill (2004), R. , *et al.*, “Risk Assessment and Precaution in the Biosafety Protocol”, Review of European Community & International Environmental Law, 13:3.

4. Article 11 (Procedure for LMOs Intended for Direct Use as Food, Feed, or for Processing)

“8. 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 intended for direct use as food, feed and in question . . . in order to avoid or minimize such potential adverse effects.” Art. 11(8).

5. Annex III, Para. 4 (Risk Assessment)

“4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

The controversy about the use of Precautionary Principle was resolved at BSWG-6 when the delegates agreed to give up its use in this paragraph. Instead, they developed a definition of what they had in mind when they argued that the interpretation of the results of the risk assessments are subject to the concept of Precautionary Principle. Meyer (2007), Hartmut, “The Precautionary Principle and the Cartagena Protocol on Biosafety: Development of a Concept”, in Travik, T. and Lim, L.C. (eds.). [Biosafety First](#).

- Concept of precaution in the operative provisions is not clear. The Protocol allows the parties to consider undefined “socio-economic considerations”.
- In any case, the decisions must generally be taken in a scientifically sound and transparent manner, taking into account expert advice and relevant international guidelines.
- The Protocol merely gave the parties the right to take precautionary import decision in case of scientific uncertainty. It is not an obligation.
- One view: The difference between Precautionary Approach and Precautionary Principle is meaningless in the context of the Protocol. The language of Articles 10(6) and 11(8) can be said to *reflect* at least the concept of precaution in decision-making.

Hill (2004), R. , *et al.*, “Risk Assessment and Precaution in the Biosafety Protocol”, Review of European Community & International Environmental Law, 13:3.

Risk Assessment and Precaution

- Not incompatible.
 - *Risk assessment* is an approach for evaluating and characterizing risks while *precaution* is an attitude of decision makers, reflecting their values and/or the values they represent.
 - Risk assessors are capable of determining whether risks can be managed, but their role in determining the acceptability of risks is less clear. The value judgments lie with the decision makers. In reality, this involves a continuing dialogue between the two.
- While scientists who are responsible for risk assessment may have a role in decision-making, the Annex III language provides only for a “recommendation” from risk assessors on the acceptability of risks.

- No point in conducting a risk assessment if one insists on an extreme interpretation of precaution that requires no adverse effects. 100% certainty is impossible. Not appropriate to the Protocol because it negates its operational provisions which calls for risk assessment.
- Precaution is only operational if it is applied in a balanced way in the context of evaluating the positive and negative impacts of a decision. “The notion of decision making based on full consideration of benefits and risks, including their uncertainties, is simply common sense.”

Hill (2004), R. , *et al.*, “Risk Assessment and Precaution in the Biosafety Protocol”, Review of European Community & International Environmental Law, 13:3.

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