Cartagena Protocol on Biosafety

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Convention on Biological Diversity

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History of the Protocol

1992-2000: *Ad Hoc* Working Group on Biosafety

2000: Adoption of the Protocol

2003: Entry into force

2018: 171 Parties

Objective of the Protocol

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"

What is Biosafety?

Measures to regulate, manage and control risks associated with the use and release of LMOs resulting from modern biotechnology which may cause adverse environmental impacts on biodiversity and human health

What are living modified organisms?

The term "Living modified organism" refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

LMO = GMO = transgenic = genetically engineered

"Modern biotechnology" means the application of:
a. In vitro nucleic acid techniques, or
b. Fusion of cells beyond the taxonomic family,
that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

LMOs and their uses

- LMOs intended for introduction into the environment
- LMOs for food, feed or for processing
- LMOs in transit
- LMOs for contained use

Competent National Authorities

They perform the administrative functions required by the Protocol and are authorized to take decisions on the LMOs

One or more CNAs per Party!

Provisions of the Protocol

Risk Assessment (Art. 15 and Annex III)

Risk Assessment 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.

While the Party considering permitting the import of an LMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear its cost.

Who undertakes Risk Assessment?

It depends on each country regulations administrative functions.

For example, some countries have permanent bodies or committees who undertake risk assessment on regular basis, while others have ad-hoc groups who will support the local authorities in this respect.

Risk assessment is often done by multidisciplinary groups of experts who combine their expertise for the analysis of an application.

Risk assessment principles

What is risk assessment?

Risk assessment refers to the quantitative and qualitative evaluation of the risk posed to the environment and/or human health by the actual or potential presence of and exposure to a particular agent.

Risk assessment principles

Scientific soundness: Risk assessments are to be undertaken in a systematic way on the basis of verifiability and reproducibility of information

Transparency: Example "Applications for LMOs that can significantly affect the environment are publicly notified, and anybody can then make a written submission"

Case-by-case: A case-by-case approach is one where each release of an LMO is considered relative to the environment in which the release is to occur, and to the intended use of the LMO in question.

Risk Assessment (Annex III)

Annex III – general principles for risk assessment:

(i) Risk assessment must be carried out in a scientifically sound and transparent manner and on a case-by-case basis;

(ii) 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; and

(iii) Risks of LMOs should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

Risk management (Art16)

The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

Risk management strategies

Risk management strategies include:

►"*preventive measures*" aim at reducing the likelihood;

►"*mitigation measures*" aim at reducing the consequences.

Monitoring strategies

Aims at detecting changes (e.g. in the receiving environment(s) or in the LMO) that could affect the likelihood or consequences of one or more potential adverse effects.

Monitoring strategies

Monitoring strategies include:

- "*general surveillance*" to identify unexpected long-term effects of the LMOs or traits;
- "*case-specific*" to investigate potential adverse effects identified during the risk assessment.

Other provisions under the Protocol

- Biosafety Clearing-House
- Unintentional and illegal transboundary movements
- Public awareness and participation
- Socio-economic considerations

Supplementary Protocol on Liability and Redress entered into force on 5 March 2018

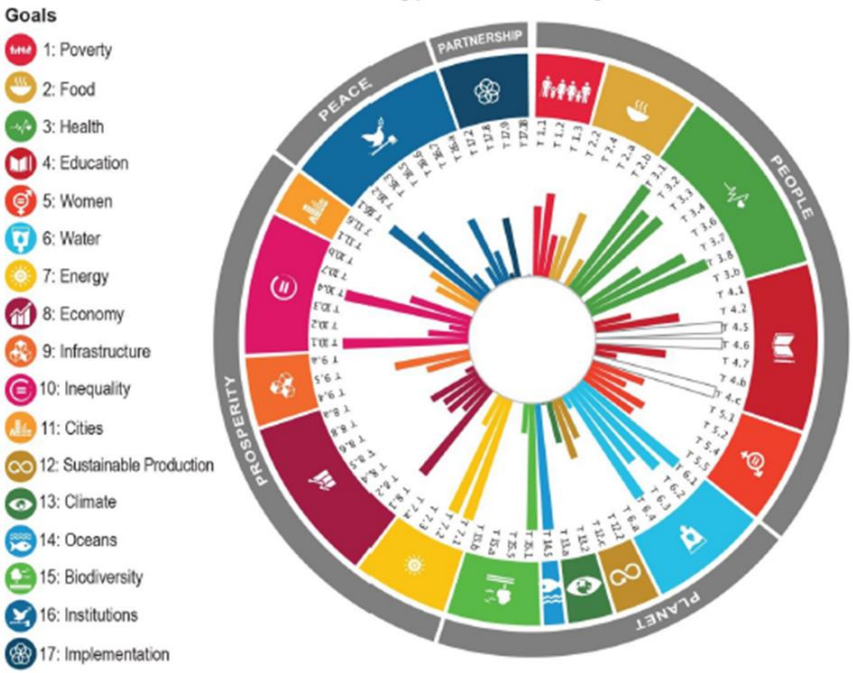
Cartagena Protocol & the Convention

- Genetic diversity of cultivated plants and farmed and domesticated animals and of wild relatives
- knowledge, the science base and technologies relating to biodiversity are improved, widely shared and transferred

Beyond the Convention

Biotechnology + Biosafety =
Biodiversity + Human Health + Economic Growth

SDGs



THANK YOU

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