

Introduction to the Cartagena Protocol on Biosafety

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Convention on Biological Diversity

2011-2020 United Nations Decade on Biodiversity

OVERVIEW

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PART 1: BACKGROUND

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1992 UNCED, Agenda 21 (Chapter 16)

Negotiated under the Convention on Biological Diversity

- Article 19, paragraph 3, of the CBD
- Open-ended Ad Hoc Working Group on Biosafety (six meetings, July 1996 to February 1999)
- Adopted 29 January 2000 by CBD Ex-COP

Entered into force: 9 September 2003

- 162 ratifications/ accessions, latest Uruguay – November 2
- 5 meetings of the governing body (COP-MOP), COP-MOP 5 held October 2010 in Nagoya, Japan
- Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress adopted 15 October 2010

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General Context

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- CPB - tool for sustainable development – ensuring safe development and application of modern biotechnology
- CPB is the only international treaty that deals exclusively with LMOs
- Other international instruments and standard-setting processes addressing the safety of LMOs:
  - International Plant Protection Convention (IPPC) - GM plant pests
  - Codex Alimentarius - GM food safety
  - World Organization for Animal Health (OIE) - standards and guidelines, e.g. for GM vaccines
  - WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) measures

PART II: PROTOCOL OVERVIEW

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Objective

To contribute to ensuring the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the biological diversity, taking also into account risks to human health

*In accordance with the precautionary approach

Scope of the Protocol

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Applies to:

– Transboundary movement, transit, handling and use of all LMOs that may have adverse effects on biodiversity, taking also into account risks to human health (*Does not apply to domestically developed LMOs not intended for export*)

Exclusion:

– Pharmaceuticals for humans addressed by other international agreements or organisations (Art. 5)

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General Provisions

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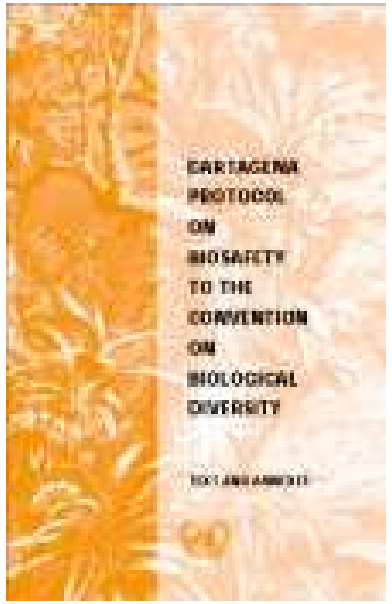
- Parties are required to take legal, administrative and other measures to implement the Protocol…

- The Protocol does not restrict the right of Parties to take actions more protective of biodiversity; provided such action is consistent with the objective and provisions of the Protocol

- Parties have a right to subject all LMOs to risk assessment prior to taking a decision on their import



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Main Provisions of the Protocol

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Precautionary Approach

Objective: Safe transfer, handling and use of LMOs

- Procedures:
  - AIA Procedure
  - Procedure for LMOs-FFP
- Decision -making

- Risk Assessment
- Risk Management

- Handling, transport, packaging and identification (HTPI):
  - Documentation for LMOs shipments
  - Standards for HTPI

- Information sharing
- Public awareness education & participation

Supporting mechanisms:

Biosafety Clearing-House (BCH) , Capacity-building, Financial mechanism, Compliance mechanism and COP-MOP

Procedures under the Protocol

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The Protocol establishes various rules and procedures for regulating the transboundary movement of LMOs

Advance Informed Agreement (AIA) procedure

Procedure for LMOs intended for direct use as food or feed, or for processing

Simplified procedure

Bilateral, regional and multilateral agreements and arrangements

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AIA Procedure (Art. 7-10)

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Applies to:

The first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import

Procedure:

- Notification by the exporting Party
- Acknowledgement of notification by Party of import (90 days)
- Decision-making (with 270 days) – the precautionary approach, risk assessments and socio-economic considerations
- Review of decision (new information/change in circumstances)

Exemptions:

- *LMOs in transit; LMOs for contained use and LMOs-FFP*

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Procedure for LMOs-FFP

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- A Party that approves for domestic use (and marketing) of an LMO-FFP must inform other Parties through the BCH within 15 days
- Any Party can subject an LMO-FFP import to its regulatory framework (consistent with the Protocol's objective). Copies of applicable laws, regulations & guidelines must be submitted to the BCH
- A Party without a regulatory framework has to declare, through the BCH, its intent to subject the first import of an LMO-FFP to a risk assessment and prior approval

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Other main provisions of the Protocol

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- Risk assessment (scientific, case by case) and risk management (Art. 15 & 16)
- Safe handling, transport, packaging and proper identification of LMO shipments (Art. 18)
- Information sharing and BCH (Art. 20)
- Capacity-building (Art. 22)
- Public awareness, education participation (Art 23)
- Socio-economic considerations (Art. 26)
- Financial mechanism and resources (Art. 28)
- Compliance procedures and mechanisms (Art. 34)
- Liability and redress (Art 27) ⟹ Supplementary Protocol

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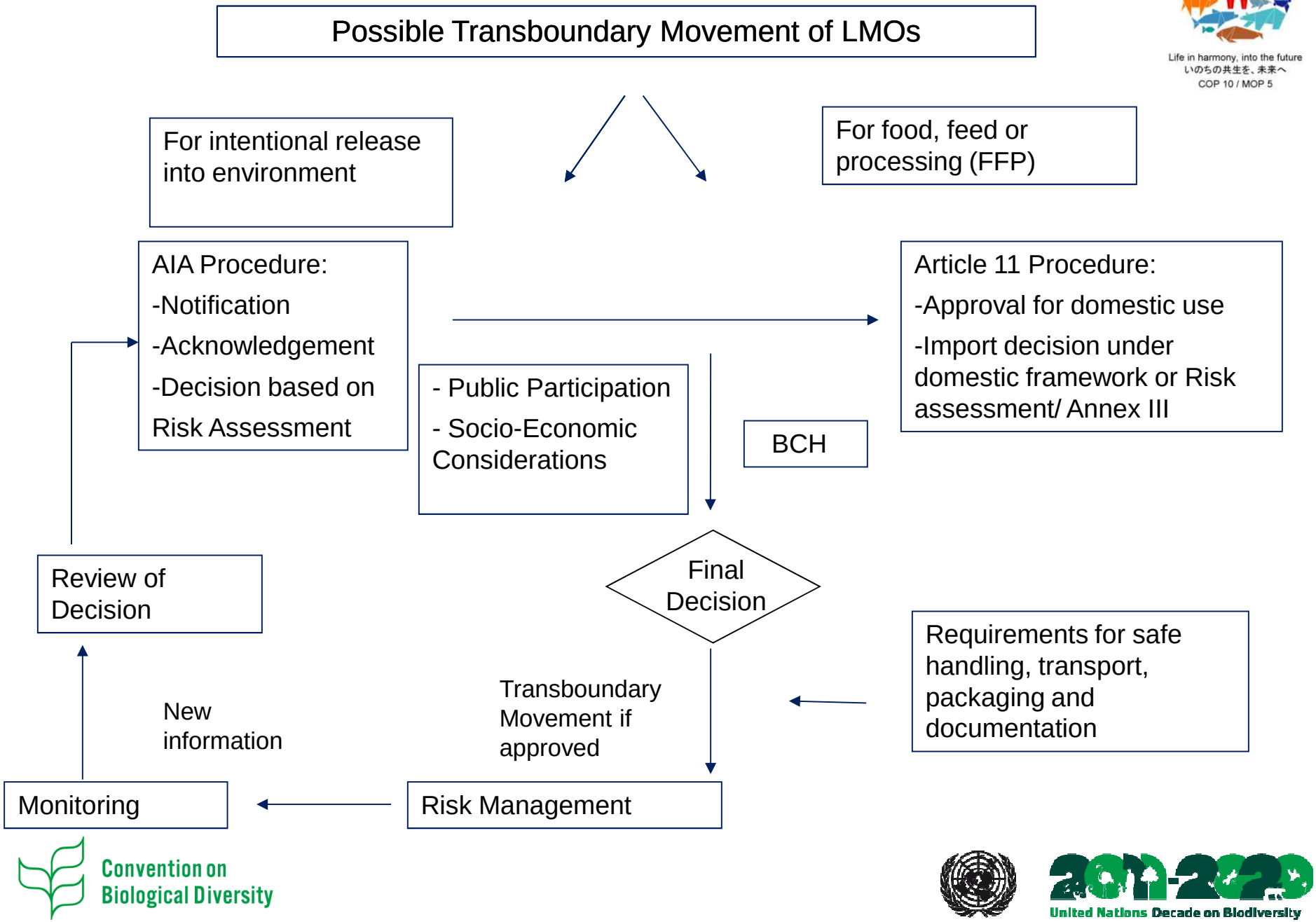
Summary of the key regulatory measures



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PART III: Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress

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- Adopted by COP-MOP 5 on 15 October 2010 in Nagoya (decision BS-V/11)

Objective:

"to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to LMOs"

- Open for signature: 7 March 2011 to 6 March 2012
- 36 signatures to date
- Entry into force: 90 days after deposit of 40th instrument of ratification

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Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress

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The N-KL Supplementary Protocol:

- Specifies response measures to be taken in the event of damage or sufficient likelihood of damage to biodiversity resulting from LMOs
- Obliges the competent authority to require the person in control of the LMO (operator) to take appropriate response measures or implement such measures itself and recover any costs incurred from the operator
- Provides essential elements that may be taken into account in developing or implementing national legislative, administrative or judicial rules or procedures relevant to liability and redress

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PART III: CONCLUDING REMARKS

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- The CPB recognises the potential of biotechnology to contribute to human well-being and sustainable development if developed and used with adequate safety measures
- The Protocol establishes procedures and mechanisms for ensuring that LMOs do not adversely affect biological diversity and human health
- The CPB aims to ensure the safety of LMOs, not to prohibit their trade

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Concluding Remarks

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- Not all LMOs inherently pose risks to the environment – case by case risk assessment is needed
- It is important to obtain relevant information and keep abreast with new developments
- The BCH is a key source for information on, and experience with, LMOs
- The Protocol has moved to a new phase of implementation to be guided by a Strategic Plan covering the period 2011-2012

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