

# Risk Assessment and Risk Management in the Context of the Cartagena Protocol on Biosafety

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Convention on Biological Diversity





## Presentation Outline

- Context for risk assessment and risk management under the Protocol
- Article 15 and Annex III - risk assessment principles and methodology
- Article 16 on risk management
- COP-MOP programme of work and decisions on risk assessment and risk management



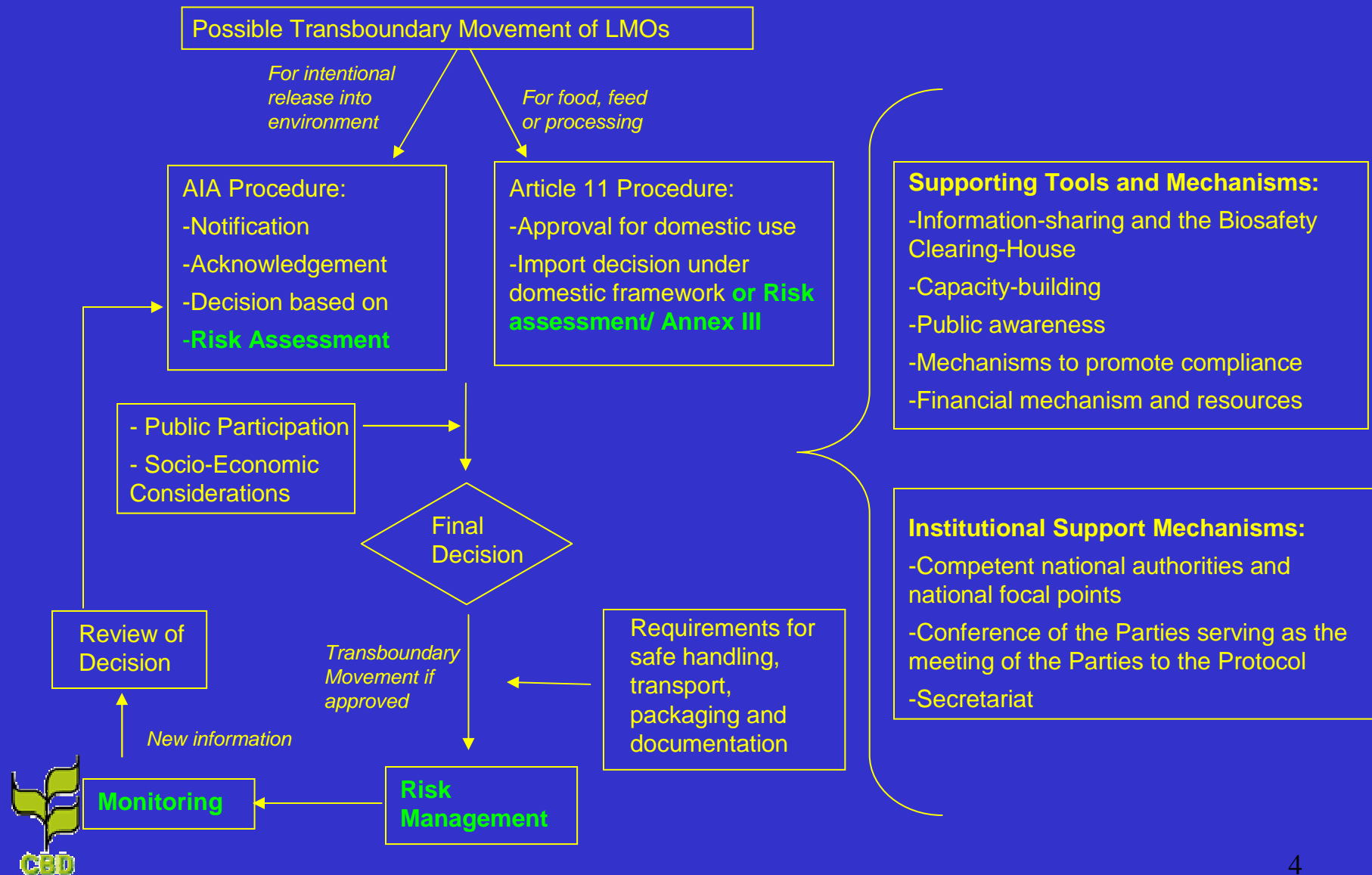


## Context - Objective of the Protocol

- “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, ... to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”



# Risk Assessment, the Decision-Making Process and other Elements of the Biosafety Protocol





## Risk Assessment under the Protocol

- Risk assessments are used by Competent Authorities to make informed decisions regarding LMOs
- Decisions on LMOs for intentional release into the environment must be taken by in accordance with Article 15 on risk assessment (Article 10.1)
- Developing country Parties without a domestic framework may base import decisions for LMOs-FFP on a risk assessment undertaken in accordance with Annex III (Article 11.6)
- Parties also have a right to subject LMOs destined for contained use to a risk assessment prior to taking decisions on their import (Article 6.2)



## Article 15 - Risk Assessment

- Risk assessments under the Protocol should:
  - Be carried out in a scientifically sound and transparent manner, in accordance with Annex III
  - Be carried out on a case-by-case basis
  - Take into account recognized assessment techniques
  - Provide, at a minimum, information specified in Annex I
- A Party of import has to ensure that risk assessments are carried for LMOs for intentional release into the environment
- A Party of import may require the exporter to carry out the risk assessment or to bear the cost of the assessment



## Annex III of the Protocol

Annex III specifies:

- The objective and use of risk assessments
- General principles of risk assessment
- Methodology/ steps of risk assessment
- Technical and scientific points to consider in carrying out a risk assessment

(details to be provided in the next presentations)



## Risk Assessment Methodology (Annex III, Paragraph 8)

- a. Hazard identification – what could go wrong?
- b. Evaluation of the likelihood of adverse effects
- c. Evaluation of consequences if those effects occur
- d. Estimation of overall risk – as a function of likelihood and consequences of the identified effects
- e. Recommendation if risks are manageable, if so how?
- f. Proposing appropriate risk management strategies and field monitoring

(see Protocol text for exact language)







## Risk Management (Article 16)

- Risk management under the Protocol covers management that arises as a result of risk assessment (paragraphs 1 and 2), as well as broader risk management activities

Parties are required take measures to:

- Regulate, manage and control risks identified in risk assessments carried out under the Protocol
- Prevent adverse effects of LMOs
- Prevent unintentional transboundary movements
- Ensure that LMOs undergo appropriate periods of observation prior to their intended use
- Cooperate in identifying, and in taking appropriate measures to manage, LMOs or specific traits that may have adverse effects





## Relationship Between RA and RM

- Risk assessment and risk management are interlinked

### Article 16.1

- Parties must take measures to manage risks identified in risk assessments carried out under the Protocol

### Para. 8 of Annex III - steps of risk assessment include:

- (e) Making a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, **identification of strategies to manage these risks**; and
- (f) Addressing, where it exists, uncertainty regarding the level of risk, by ... **implementing appropriate risk management strategies and/or monitoring** the LMO in the receiving environment.

- Mitigation measures/ options are thus considered as part of both risk assessment and risk management





## COP-MOP Programme of Work

- In its medium-term programme of work (decision BS-I/12, annex), COP-MOP decided to consider:
  - Clarification of the issues involved in RA and RM;
  - Development of guidance and a framework for a common approach in RA and RM;
  - Cooperation in identifying LMOs or specific traits that may have adverse effects, and taking appropriate measures regarding their treatment
- MOP-1 requested the Secretariat to collect and collate existing guidance materials
- Governments & relevant organizations were invited to provide relevant information





## COP-MOP 2 Decision (BS-II/9)

- MOP-2 considered a synthesis of the submissions document UNEP/CBD/BS/COP-MOP/2/9) and the full compilation (UNEP/CBD/BS/COP-MOP/2/INF/2) - available on the CBD website.
- MOP-2 considered the possible development of guidance and a framework for a common approach and requested further collection of existing guidance materials
- MOP-2 established an Ad Hoc Technical Expert Group (AHTEG) on risk assessment which met in Rome, 15-18 November 2005 – its report (UNEP/CBD/BS/COP-MOP/3/INF/1) is available)





## AHTEG on Risk Assessment

- The AHTEG was mandated to:
  - Consider the nature and scope of existing approaches to risk assessment,
  - Evaluate the relevance of, and identify gaps in, existing approaches and guidance materials to risk assessment.
  - Identify specific areas where limitations in capacity is an impediment to implementation of the risk assessment provisions and where capacity-building may be particularly important
- AHTEG made several observations and proposed a number of follow-up actions – see report
- In particular it noted that there are potential gaps in the guidance for risk assessment particularly for emerging applications of modern biotechnology
- It also identified a number of areas where capacity-building activities may be particularly important





## COP-MOP 3 Decision (BS-III/11)

### Parties and Governments:

- Provide to BCH links to databases and info on RA & RM
- Submit to BCH risk assessment summaries including and how challenges have been addressed and how existing information has been used to support risk assessments
- Put in place mechanisms to share RA&RA information
- Promote South-South, North-South coop. for capacity-building
- Invite universities to develop/expand programmes in biosafety

### Secretariat:

- Provide overview of the scope and applicability of existing guidance materials





## Upcoming Work (including COP-MOP 4)

- Regional workshops on capacity-building and exchange of experiences on RA & RM prior to COP-MOP 4
- COP-MOP 4 to consider the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for development of such guidance
- The ES, with inputs from Parties and Governments, will expand the compilation of guidance materials in the BCH
- COP-MOP 4 will consider potential mechanisms for provision of scientific and technical advice to the COP-MOP (such advice may cover, identifying LMOs or traits thereof that may have adverse effects on biodiversity, and taking appropriate measures regarding treatment of such LMOs or traits (reference Article 16.5)).





## Further Information

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