Biosafety Liability Legal Regime for East African Region Workshop
Whitesands Hotel, Mombasa 22-26 Sept 2003

The Cartagena Protocol on Biosafety: An overview for implementation

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Presentation Outline

- Brief background to the Protocol
- Current status of ratification
- Key provisions of the Protocol
- Summary of the general rights and obligations under the Protocol
- Conclusion

Brief Background

UNCED Earth Summit, June 1992

- Agenda 21, Chapter 16
- Rio Declaration on Environment and Development
  - Principle 15: Precautionary approach
- Convention on Biological Diversity article 8(g) and 19.3
- Protocol negotiations(Decision II/5 - six BSWG sessions)

Status Biosafety Protocol

- Adopted 29 January 2000
- 103 signatures, 49 + 1 Parties
- Entry into force - 90 days after 50th ratification- Sept. 11 2003
- Governing body is COP-MOP
- 3 ICCP meetings have been held preparing for the 1st COP-MOP

Objective & Scope

- Adequate protection in the safe transfer, handling and use of living modified organisms (LMOs) that may have adverse effects

Scope

- Transboundary movement, transit, handling and use of LMOs (Article 4)

Key Elements of the Protocol

- Objective and Scope
- Advance Informed Agreement
- LMO-FFPs
- Risk assessment and management
- Identification (labeling)
- Information-sharing and the Biosafety Clearing-House
- Capacity-building
- Socio-economic considerations
- Liability and redress
- Compliance

Main Pillars

Advance Informed Agreement

- Applies prior to first movement of LMOs for intentional introduction into environment
- AIA Procedure (Articles 7-10, 12):
  - Notification (with minimum details in Annex 1)
  - Acknowledgement by importer (90 days) – Art. 9
  - Decision procedure (Article 10)
  - Review of Decisions (Article 12)

Decision Procedure

- Importer asks exporter to do a risk assessment
- Importer submits risk assessment
- Importer communicates decision (+ reasons) to exporter & BCH in **270 days**
- Importer may review/change its decision in light of new information (Art. 12)
- Exporter may also request a review

Exceptions to AIA

- Pharmaceuticals covered by other
- LMOs in transit for a third party
- LMOs destined for contained use
- LMOs declared safe by COP-MOP
- LMOs for food, feed and processing subject to modified procedure

LMOs for Food, Feed, or for Processing

- LMO-FFPs not subject to AIA
- Decisions regarding domestic use and marketing must be notified through BCH in **15 days** – minimum info in Annex II
- Not applicable to field trials
- Avail to BCH applicable national laws
- Indicate need for assistance– LMO FFPs

Risk Assessment

- In accordance with the principles, methodologies & details in Annex III
- Identify/evaluate potential adverse effects - scientifically, case-by-case
- Minimum information, Annex 1
- Ensured by importer, cost by exporter
- Lack of knowledge, not lack of risk

Risk Management

- Measures to manage and control risks
- Prevent unintentional LMO movement
- Ensure that LMOs are observed for an appropriate period before use

Handling, Transport, Packaging and Identification

- Varying required details for shipment documentation accompanying different categories of LMOs
- LMO-FFPs - Art. 18.2 (a)
- LMOs for contained use – Art. 18.2 (b)
- LMOs for intentional introduction into the environment – Art. 18.2 (c)

Information Sharing

- Article 20 establishes BCH
- Facilitates information exchange on LMOs: scientific, technical, environmental and legal information
  and experience
- Assists Parties to implement the Protocol

Biosafety Clearing-House Information sharing

- BCH will contain:
  - National laws, regulations, guidelines
  - Bilateral, regional, multilateral agreements
  - Risk assessment summaries
  - Final decisions on importation or release
  - Reports
- Pilot phase of BCH is in operation

Capacity-Building

- Articles 22 and 28, paragraph 3
- Training in safe management of biotechnology, risk assessment and risk management
- Technological / institutional capabilities
- Roster of Experts
- Capacity-building Action Plan

General Obligations

Prior to entry into force of the Protocol:

- Designate NFP & CNA(s) and notify SCBD
- Avail to BCH contact point for receiving notifications under Art.17: unintentional LMO

After entry into force

- Legal, administrative and other measures to implement Protocol obligations (Art. 2.1)
- Ensure the development, handling, transport, use, transfer and release of any LMOs prevents risks to biodiversity (Art.

Obligations cont’

- Make available through the BCH copies of any laws, regulations and guidelines applicable to the import of LMOs-FFP (Art 11).
- In the absence of a domestic regulatory framework, declare through the BCH that decisions on import of LMO-FFPs will be taken following the procedure in article 11 paragraph 6 (i.e. using risk assessment)
- Identify transboundary movements of LMOs in accompanying documentary (Art 18)

Provisions to be Elaborated

- Liability and Redress (Art 27): Process to elaborate international rules and procedures to be defined by MOP
- Compliance (Art. 34): COP-MOP to approve procedures to promote compliance and to address on-compliance; objective is to assist Parties

Implementation in Kenya

- Signatory in May 2000
- Ratified January 2002
- Support for implementation by UNEP-GEF demonstration projects
  - Legal structures place
  - Policy
  - Regulations and Guidelines reviewed : Foods and feeds, (development within country).
  - Capacity building and establishment of biosafety authority
  - Establishment of biosafety clearing house node
  - Increased awareness
  - Publications

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