



Transboundary Movements of Living Modified Organisms: The Cartagena Protocol on Biosafety

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Outline



- Introduction to the Biosafety Protocol
- Procedures for intentional transboundary movements of living modified organisms (LMOs)
 - Including risk assessment
- Unintentional transboundary movements



Introduction to the Cartagena Protocol on Biosafety



- Cartagena Protocol on Biosafety is an international, legally-binding treaty.
 - Only legally binding treaty dealing exclusively with LMOs
 - Part of the United Nations
- Subsidiary instrument to Convention on Biological Diversity.
- Protocol was adopted in 2000
- Entered into force on 11 September 2003
 - Currently 159 Parties to the Protocol



Introduction to the Cartagena Protocol on Biosafety



Objective (Art. 1):

“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.**”



Decision-making procedures



Two decision-making procedures at the heart of the Protocol:

- (a) Advance informed agreement (AIA) procedure for intentional transboundary movements of LMOs for intentional introduction into the environment;
- (b) Procedure for intentional transboundary movements of living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP).



AIA procedure (Art. 7-10 & 12)



- AIA procedure applies prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment
- Exporter or Party of export must notify the Party of import prior to the intentional transboundary movement of an LMO for intentional introduction into the environment
- Notification must contain at a minimum information in Annex I of Protocol

e.g. description of modification introduced, quantity of LMO to be transferred, risk assessment report consistent with Annex III, regulatory status of LMO in State of export



AIA procedure (cont.)



- Party of import must acknowledge receipt of notification
 - Acknowledgement must state whether to proceed according to domestic regulatory framework (that is consistent with Protocol) or procedure specified in Art. 10.
- Decisions taken by Party of import must be in accordance with Art. 15 (risk assessment)



AIA procedure (cont.)



Article 10:

- Within 270 days of date of receipt of notification, Party of import must communicate to notifier and the Biosafety Clearing-House (BCH) its decision to:
 - Approve the import with or without conditions
 - Prohibit the import
 - Request additional information
 - Extend the time period for its decision
- Precautionary decision-making is allowed
 - Where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge about the extent of the potential adverse effect



Procedure for LMOs-FFP (Art. 11)



- Separate decision-making procedure for LMOs that are traded in bulk as commodities and, as such, are not intended for introduction into the environment
- A Party that makes a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing shall inform the Parties through the BCH
- Party may take a decision on import of LMO-FFP under its domestic regulatory framework that is consistent with the Protocol



Procedure for LMOs-FFP (cont.)



- In absence of domestic regulatory framework, a developing country Party or Party with economy in transition may declare through the BCH that its decision prior to the first import of an LMO-FFP will be taken according to:
 - A risk assessment
 - A decision made within a predictable timeframe, not exceeding 270 days.
- Precautionary decision-making is also allowed for LMOs-FFP



Risk Assessment (RA)



- Party of import's decision on whether or not to allow import of LMO for intentional introduction into the environment must be in accordance with Art. 15 (risk assessment)
- Art. 15 & Annex III:
 - RA must be carried out in scientifically sound manner, taking into account recognized risk assessment techniques
 - RA should be carried out in a transparent manner & on a case-by-case basis



Risk Assessment (cont.)



- Purpose of RA is to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biodiversity, taking also into account risks to human health
- Annex III includes a general methodology for RA as well as a number of ‘points to consider’ such as:
 - Recipient organism or parental organism,
 - Information relating to intended use,
 - Likely potential receiving environment



Risk Assessment (cont.)



- At their last meeting (Bonn, 2008), Parties to the Protocol established an open-ended online forum through the Biosafety Clearing-House (BCH) and an *Ad Hoc* Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to identify major issues related to specific aspects of RA and risk management
- Also convened online forums and real-time online conferences to feed into the process



Risk Assessment (cont.)



- Outcome of AHTEG includes “Guidance on Risk Assessment of Living Modified Organisms”
- Guidance has 2 parts:

Part I: Roadmap for RA of LMOs

- Elaborates methodology for conducting RA contained in Annex III to Protocol
- Includes a flowchart for RA



START

Context and Scoping of the Risk Assessment

Setting the context and scope for a risk assessment that are consistent with policies, strategies and protection goals may involve a process that includes risk assessors, decision-makers and various stakeholders.

Aspects to be taken into consideration include, as appropriate:

- Existing policies and strategies;
- Protection goals, assessment endpoints, risk thresholds and management strategies;
- Framing the risk assessment process; identification of relevant questions to the protection goals and endpoints;
- Identification of methodological and analytical requirements, including reviewing mechanisms;
- Nature and level of detail of the information required;
- Experience and history of use of the non-modified recipient.

Overarching Issues in the Risk Assessment Process

Ensure the quality and relevance of the information used:

- Data relevancy: Data may be considered relevant if they can affect the outcome of the risk assessment;
- Establishment of scientifically robust criteria for information: Acceptable scientific quality of data and sound science;
- Identification and consideration of uncertainty: *Source(s)* and *nature* of uncertainty.

THE RISK ASSESSMENT (return to appropriate step in the Risk Assessment)

Step 1: “An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.”

Step 2: “An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism.”

Step 3: “An evaluation of the consequences should these adverse effects be realized.”

Step 4: “An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.”

Step 5: “A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.”

Evaluate whether the set objectives and criteria were met; consider new information or management options

NO
NO
NO

- Were the objective and criteria that were set at the beginning of the risk assessment met?
- Have new risk management options been identified that reduce or remove identified risks?
- Has new information arisen that could change the conclusions?

YES
YES
YES

Related Issues

Consideration of Risk Management Strategies, and Decision-making

Risk Assessment (cont.)



Part II (of flowchart): Specific types of LMOs and traits

- Guidance on RA for 3 specific areas including LM mosquitoes
- Development of LM mosquitoes is often based on genetic biocontrol strategies so this section of guidance document may be relevant to RA of LM fish using genetic biocontrol strategies.
- AHTEG also identified RA for living modified fish as priority for development of guidance but this topic did not form part of work undertaken at this time



Risk Assessment (cont.)



- Next meeting of the governing body of the Protocol (to be held in Nagoya, Japan in October 2010) will consider next steps on RA
- AHTEG has recommended further work on RA including developing additional guidance documents on the basis of the “Guidance on Risk Assessment of Living Modified Organisms” on specific types of LMOs and traits



Risk Management (Art. 16)



- Parties must establish & maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in RA
- Measures shall be imposed to extent necessary to prevent adverse effects of LMOs on conservation and sustainable use of biodiversity
- Each Party must take appropriate measures to prevent unintentional transboundary movements of LMOs



Decision-making for intentional transboundary movements



- In reaching a decision on import, Parties may also take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity (Art. 26).
- Applies to both LMOs for intentional introduction into the environment and LMOs-FFP



Unintentional transboundary movements (Art. 17)



- Notification obligation:
 - Each Party must take appropriate measures to notify affected or potentially affected States when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of an LMO likely to have significant adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health in such States.
- Consultation obligation:
 - Each Party under whose jurisdiction the release of an LMO referred to above occurs shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.





Open-ended Online Expert Forum on RA & RM:
http://bch.cbd.int/onlineconferences/forum_RA.shtml

“Guidance on Risk Assessment of Living Modified
Organisms” available as part of report via:

[http://bch.cbd.int/protocol/meetings/documents.shtml?event
id=3409](http://bch.cbd.int/protocol/meetings/documents.shtml?event_id=3409)

Thank you!

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