Book - Unit 2 - Major Components of the Cartagena Protocol

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Book: Book - Unit 2 - Major Components of the Cartagena Protocol

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1. Objective and Scope

The objective of the Protocol is to contribute to ensuring an adequate level of safety in the transfer, handling, and use of LMOs.

Generally, the Protocol applies to all LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, except LMOs that are pharmaceuticals for humans and addressed in other international agreements or by other international organizations.

2. Advance Informed Agreement Procedure

Central to the Protocol is the Advance Informed Agreement ("AIA") procedure. Article 7 of the Protocol defines the scope of the AIA procedure and the actual procedural rules are described in articles 8 to 10 and 12 of the Protocol. The AIA procedure applies prior to the first import of an LMO destined for intentional introduction into the environment of the Party of import.

According to these rules, the Party of export or the exporter is obliged to notify in writing and to provide a minimum set of information to the party of import, prior to the first shipment of any given type of LMO intended for introduction into the environment of the party of import.

The party of import then has to acknowledge receipt of the notification within 90 days. The party of import also has to inform the notifier, whether it intends to proceed according to the decision procedure specified in Article 10 of the Protocol, or according to its domestic regulatory framework.

The decision procedure specified in the Protocol is as follows: a risk assessment must be carried out in accordance with Article 15 and Annex III of the Protocol before a decision is made on the import of an LMO. The exporter has to carry out the risk assessment or bear its cost if the party of import so requires. Within 90 days of notification, the party of import must inform the notifier in writing whether it will have to wait for written consent, or that it may proceed with the import without written consent. If the requirement is to wait for written consent, the party of import has 270 days from the date of receipt of notification to communicate, in writing, its decision. The decision could be either to:

- Approve the import with or without conditions as appropriate, including how the decision would apply to future imports of the same LMO
- Prohibit the import;
- Request additional information; or
- Extend the deadline for response by a defined period.

A party of import may, in light of new scientific information, review and change a decision at any time. Also a party of export or a notifier (exporter) may request the party of import to review its decisions in light of a change in circumstances or availability of additional relevant scientific information.

The purpose of the AIA procedure is to ensure that importing countries have the opportunity to to receive and consider relevant information and assess risks associated with the LMO before taking a decision to approve or prohibit its import.

The importing country may also take into account socio-economic considerations as specified by the Protocol, when making its decision on import. Some countries consider this as important. They believe that the introduction of some LMOs might result in considerable risks for local farmers and national economies dependant on agriculture and biodiversity. Taking into account socio-economic considerations also allows for the recognition of the value of biodiversity to indigenous and local communities and the protection of traditional knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity as provided for under article 8(j) of the Convention.

Exclusions

The Protocol's AIA procedure does not apply to:

- Pharmaceuticals for humans that are addressed by other relevant international agreements or organizations;
- LMOs in transit to a third party;
- LMOs destined for contained use (in a laboratory or other containment facilities only);
- LMOs intended for direct use as food, feed or for processing (LMO-FFP);
- LMOs that have been declared safe by a meeting of the parties to the Protocol

3. Procedure for LMOs intended for Direct Use as Food, Feed or for Processing

LMOs intended for direct use as food, feed or for processing ("LMOs-FFP") represent a large category of agricultural commodities. They are not subject to the AIA procedure but are covered by a separate, less rigorous procedure outlined in article 11 of the Protocol.

A Party making a decision approving for domestic use, including releasing it into the market, an LMO-FFP that may be subject to transboundary movement, must inform others through the Biosafety Clearing-House (BCH) within 15 days of its decision. Other Parties may take decisions regarding whether or not to import such LMO under their domestic regulatory framework that is consistent with the objective of the Protocol.

A developing country Party or a Party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the BCH that its decisions on the first import of the LMO-FFP on which information has been made available to the BCH will be taken in accordance with a risk assessment as set out in the Protocol and within 270 days. In case of insufficient relevant scientific information and knowledge, the party of import may apply the precautionary approach in making its decision on the import of LMOs-FFP.

4. Risk Assessment and Risk Management

Article 10 of the Protocol requires that decisions regarding the import of LMOs for introduction into the environment are taken the Party of import based on risk assessment carried out in a scientifically sound manner, in accordance with Annex III of the Protocol and recognized risk assessment techniques. The objective of risk assessment is to identify and evaluate the possible adverse effects of an LMO on biological diversity, taking also into account risks to human health, to enable competent authorities to make informed decisions.

Parties to the Protocol are also required to establish and maintain appropriate mechanisms, measures and strategies to manage and control risks identified in the risk assessment, taking into account article 8(g) of the CBD. They are also required to take measures to prevent unintentional transboundary movements of LMOs. Risk management measures based on risk assessment should be imposed to the extent necessary to prevent adverse effects of LMOs on biological diversity and human health.

5. Unintentional Transboundary Movement of LMOs

When a party knows of the occurrence of an unintentional transboundary movement of LMOs that is likely to have significant adverse effects on biodiversity and human health, it must notify affected or potentially affected states, the BCH and relevant international organizations and give information on the unintentional release. Parties must start immediate consultation with the affected or potentially affected states to enable them to determine response and emergency measures.

6. Identification of LMOs

The Biosafety Protocol obliges Parties to take measures to require that LMOs subject to export or import are handled, packaged and transported in safe manner. Each party is required, among other things, to take measures to clearly identify LMOs destined for contained use and those intended for intentional introduction into the environment as “LMOs” in documentation accompanying transboundary shipments.

The specific documentation requirements for different categorised of LMOs are defined in Article 18 of the Protocol. In this regard, it is important to note that there are existing documentation requirements under other regimes that are relevant to some types of LMOs. For example, the United Nations Model Regulations on the Transport of Dangerous Goods specify documentation requirements for certain categories of genetically modified micro-organisms.

7. Confidential Information

Each party is required to protect confidential information received under the Protocol and identified as such by the notifier. Each party has to put in place procedures to protect and treat such information in no less favourable manner than it treats confidential information in connection with domestically produced LMOs. The party of import must not use confidential information for commercial purposes without the written consent of the notifier.

The Protocol does not allow the notifier to identify or withhold, as confidential, any information relating to:

1. the name and address of the notifier;
2. general description of the living modified organism;
3. summary of risk assessment; and
4. methods and plans for emergency response.

8. Capacity Building

The Protocol recognizes the fact that many countries, particularly developing countries have limited capabilities to cope with the nature and scale of known and potential risks associated with LMOs. In that regard, Parties are required to cooperate to help developing countries and countries with economies in transition to strengthen their human resources and institutional capacities in biosafety. Parties are particularly encouraged to assist with scientific and technical training and enhancement of technological capacity and to promote access to and transfer of technology, know-how and financial resources. Cooperation in capacity building could be existing institutions and organizations and, as appropriate, through private sector involvement.

9. Public Awareness and Participation

The Protocol requires and encourages Parties to inform and involve their public in matters relating to living modified organisms. More specifically, parties are required to promote and facilitate public awareness, education and participation, including access to information concerning the safe transfer, handling and use of LMOs. The public has to be consulted in the decision-making process and the results of such decisions should be made available in accordance with domestic legislation and with a respect to confidential information as provided for in the Protocol. The Protocol further requires parties to promote and facilitate public access to information on LMOs that may be imported, as well as access to the Biosafety Clearing-House.

10. Transboundary Movement of LMOs with Non-Parties

The Protocol provides that transboundary movements of LMOs between Parties and non-Parties to the Protocol must be consistent with the objective of the Protocol. Parties are required to encourage non-parties to adhere to the Protocol and to provide relevant information to the BCH.

11. Compliance Procedures and Mechanisms

In accordance with Article 34 of the Protocol the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol adopted procedures and institutional mechanisms to promote compliance and to deal with cases of non-compliance.

A Compliance Committee was established to implement or oversee the procedures. The procedures are facilitative, non-adversarial and cooperative in nature and include provisions to offer advice or assistance for those parties that may be faced with difficulties in complying with the obligations of the Protocol. The compliance procedures are separate from, and without prejudice to, the dispute-settlement procedures and mechanisms established by the Convention.