

Committee on Trade and Environment

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

DRAFT PROTOCOL ON BIOSAFETY

Recent Developments

Note by the Secretariat

An Extraordinary Meeting of the Conference of Parties to the Convention on Biological Diversity (CBD) was convened in Cartagena, Colombia, from 22-24 February 1999, in order to adopt a Protocol on Biosafety.¹ As consensus on the draft Protocol could not be achieved at the meeting, it was not adopted.² This Note reproduces for Members some of the articles of the draft Protocol that may be of interest.³

ARTICLE 5 APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Article 4, paragraph 2, the advance informed agreement procedure in Articles 6, 7, 8 and 9 shall apply prior to the first intentional transboundary movements of living modified organisms for intentional introduction into the environment of the Party of import.
2. "Intentional introduction into the environment" in paragraph 1 above does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. The parties may, under their respective domestic laws, require procedures consistent with advance informed agreement for living modified organisms other than those specified in paragraph 1 above.
4. Subject to paragraph 3 above, the advance informed agreement procedure shall not apply to the intentional transboundary movements of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to

¹ Article 19.4 of the CBD provides for parties to consider the need for and modalities of a protocol addressing concerns about the potential risks to biodiversity and human health posed by living modified organisms.

² Document UNEP/CBD/ExCOP/1/L.2/Rev.1 entitled *Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity*, contains the full text of the Draft Protocol on Biosafety. Copies of it may be obtained from the WTO Secretariat.

³ A number of other articles could also be of interest to Members, such as article 6 on Notification, article 19 on Capacity Building, article 26 on Financial Mechanism and Resources, article 33 on Compliance, and Annex II on Risk Assessment, but were not reproduced in this document for brevity.

have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

ARTICLE 8 DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 12.
2. The Party of import shall, within the period of time referred to in Article 7, inform the notifier, in writing, whether the intentional transboundary movement may proceed:
 - (a) After no less than ninety days without a subsequent written consent;
 - (b) only after the Party of import has given its written consent.
3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (b) above:
 - (a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;
 - (b) prohibiting the import;
 - (c) requesting additional relevant information in accordance with its domestic legal framework or Annexes I and II. In calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account;
 - (d) informing the notifier that the period specified in this paragraph is extended by a defined period of time.
4. Except in a case in which consent is unconditional, a decision under paragraph 3 above shall set out the reasons for the decision.
5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.
6. Parties concerned shall cooperate with a view to identifying, as soon as possible, the extent to which in relation to the procedures, and the cases in which, an intentional transboundary movement may not proceed between them without explicit consent.
7. Lack of full scientific certainty or scientific consensus regarding the potential adverse effects of a living modified organism shall not prevent the Party of import from prohibiting the import of the living modified organism in question as referred to in paragraph 3 (b) above.
8. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

ARTICLE 11 MULTILATERAL, BILATERAL AND REGIONAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into multilateral, bilateral and regional agreements and arrangements with Parties or non-Parties regarding intentional transboundary movements of living modified organisms, consistent with the objectives of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.
2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after entry into force of this Protocol.
3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.
4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

ARTICLE 12 RISK ASSESSMENT

1. Risk assessments conducted pursuant to this Protocol shall be undertaken in a scientifically sound manner in accordance with Annex II and taking into account recognized risk assessment techniques. Such risk assessments shall be based at a minimum on information provided in accordance with Article 6 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 8. It may require the exporter to carry out the risk assessments.
3. Financial responsibility for conducting risk assessments shall rest with the notifier.

ARTICLE 13 RISK MANAGEMENT

1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.
3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring risk assessments to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party, in order to ensure genomic and trait stability in the environment, shall endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes a period of observation commensurate with its life-cycle or generation time as the case may be before it is put to its intended use.

5. Parties shall cooperate with a view to:

- (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
- (b) Taking appropriate measure regarding the treatment of such living modified organisms or specific traits.

ARTICLE 18 CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the importing Party as part of the advance informed agreement process of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision providing reasons on request and an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall, in accordance with its national legislation, protect confidential information received under the Protocol, including any confidential information received in the context of the advance informed agreement process of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically-produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of all information identified as confidential, including information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

- (a) The name and address of the notifier;
- (b) A general description of the living modified organism or organisms;
- (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account human health;
- (d) Any methods and plans for emergency response.

ARTICLE 21 NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective and principles of this Protocol. The Parties are encouraged to conduct such transboundary movements in accordance with multilateral, bilateral and regional agreements and arrangements with non-parties under Article 11.
2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, their territory.

ARTICLE 22 NON-DISCRIMINATION

1. The Parties shall ensure that measures taken to implement this Protocol, including risk assessment, do not discriminate unjustifiably between or among imported and domestically-produced living modified organisms.
2. The Parties shall also ensure that measures taken to implement this Protocol do not create unnecessary obstacles to international trade.

ARTICLE 24 SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

ARTICLE 31 RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.
