





# CONVENTION ON BIOLOGICAL DIVERSITY

Distr. GENERAL

UNEP/CBD/BS/COP-MOP/3/8 22 November 2005

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOASEFTY

Second meeting Curitiba, Brazil, 13-17 March 2006 Item 10 of the provisional agenda\*

TAKING A DECISION ON THE DETAILED IDENTIFICATION/DOCUMENTATION REQUIREMENTS OF LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING (ARTICLE 18, PARAGRAPH 2 (a) )

Note by the Executive Secretary

#### I. INTRODUCTION

- 1. The first sentence of paragraph 2 (a) of Article 18 contains requirements on how living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP) need to be identified in accompanying documentation. On the other hand, the second sentence of the same paragraph requires the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) to take a decision on the details of those requirements, including the specification of the identity of the LMOs-FFP and any unique identification. The decision was required to be taken no later than two years after the date of entry into force of the Protocol, i.e., no later than 11 September 2005.
- 2. The the Conference of the Parties serving as the meeting of the Parties to the Protocol took a decision (decision BS-I/6 A), at its first meeting, regarding the understanding and implementation of the requirements specified in the first sentence of paragraph 2 (a) of Article 18. Accordingly, the Conference of the Parties serving as the meeting of the Parties to the Protocol urged Parties to the Protocol and invited other Governments to: (i) use commercial invoice or other document required or utilized by existing documentation systems, to accompany LMOs-FFP that are subject transboundary movement; (ii) require exporters of LMOs-FFP to include, in the accompanying documentation, the common, scientific and, where available, commercial names and the transformation event codes of the LMOs, and their unique identifier codes as keys to accessing information about the LMOs in the Biosafety-Clearing House; and (iii) require exporters, when they know that shipments intentionally contain LMOs-FFP, to declare so in the accompanying documentation.

/...

<sup>\*</sup> UNEP/CBD/COP-MOP/3/1.

- 3. The Conference of the Parties serving as the meeting of the Parties to the Protocol has, however made it clear that the decision it has taken at its first meeting was only interim until the decision referred to in the second sentence of paragraph 2 (a) of Article 18 on the detailed requirements is taken. The copy of decision BS-I/6 A (excluding the terms of reference in the annex) is attached herewith as annex I for ease of reference.
- 4. Accordingly, the Conference of the Parties serving as the meeting of the Parties to the Protocol made several efforts, inter-sessionally and during the sessions of its second meeting, to come up with the detailed requirements as required by paragraph 2 (a) of Article 18 of the Protocol and to adopt appropriate decision before the lapse of the first two years after the entry into force of the Protocol. In this respect, the following processes would be worth mentioning.
- 5. The Conference of the Parties serving as the meeting of the Parties to the Protocol had established, at its first meeting, an Open-Ended Technical Expert Group on Identification Requirements of LMOs-FFP with a view to fulfil the task and facilitate the process of taking a decision on the detailed identification requirements of LMOs-FFP, before the expiry of the first two years after the date of entry into force of the Protocol. The Expert Group was entrusted with a responsibility to examine the relevant issues specified in its terms of reference and to develop the draft of the decision on the detailed requirements of paragraph 2 (a) of Article 18, that the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider and adopt, as appropriate. The Expert Group met from 16 to 18 March 2005 in Montreal. At the end of its deliberations, the Expert Group was not able to agree on a text of a draft decision. Instead, it was agreed to forward to the Conference of the Parties serving as the meeting of the Parties to the Protocol a revised Chair's text of a draft decision as an annex to its report, (UNEP/CBD/BS/COP-MOP/2/10). The revised Chair's text is attached herewith as annex II.
- 6. The Conference of the Parties serving as the meeting of the Parties to the Protocol continued, at its second meeting, with the effort of working out the details of requirements of identification for LMOs-FFP and taking the necessary decision. However, the negotiations remained difficult once again. As a last resort effort, one of the Co-Chair's of the contact group established by Working Group I to deal with Article 18.2 (a), presented a text of a draft decision as a compromise text. The text was eventually endorsed by the Chair of the Working Group who ultimately submitted it to plenary for adoption. However, in the end, it was not possible to adopt the text as a decision on the detailed requirements for the identification of LMOs-FFP due to lack of consensus among Parties. The text of the draft decision that was tabled to the plenary for adoption is attached to the report of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in document (UNEP/CBD/BS/COP-MOP/2/15 annex III). The text is also attached to the present document as annex III.
- 7. It is now more than two years since the Protocol entered into force, the decision on the detailed requirements of paragraph 2 (a) of Article 18 is still pending.
- 8. The present note is therefore intended to remind Parties of the fact that the provision in the second sentence of paragraph 2 (a) of Article 18 that requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of identification of LMOs-FFP, still awaits resolution. In that regard, section II of this document suggests elements of action that the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider with a view to resolving the matter.

#### II. SUGGESTED ELEMENTS OF ACTION

- 9. The Conference of the Parties serving as the meeting of the Parties to the Protocol has several texts for a draft decision that could serve as options to work on and finalize the matter. In this regard, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider:
  - (a) Using the two Chair's texts annexed hereto, one from the Open-ended Ad Hoc Technical Expert Group, and the other one from the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, as texts that provide elements for further consideration of the issues at the present meeting; or
  - (b) Using the Chair's text from the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol as a working document and further consider the issues with a view to reaching at consensus; or
  - (c) Using decision BS-I/6 A, which is the interim decision regarding identification requirements for LMOs-FFP, as a working document, and make changes as may be necessary and appropriate, with a view to preparing and adopting a final decision as required by the second sentence of paragraph 2 (a) of Article 18.

#### Annex I

### BS-I/6. Handling, transport, packaging and identification of living modified organisms (Article 18)

#### A. Paragraph 2 (a) of Article 18

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

*Noting* the recommendations of the Intergovernmental Committee for the Cartagena Protocol on Biosafety at its third meeting regarding paragraph 2 (a) of Article 18,

*Recognizing* the difficulties involved in the efforts to arrive at common grounds by Intergovernmental Committee with regard to some of the issues encountered in relation to identification of living modified organisms for direct use as food or feed, or for processing,

Recalling the second sentence of paragraph 2 (a) of Article 18, which requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of those elements specified in the first sentence of the same paragraph, including specification of the identity of the living modified organisms in question and any unique identification, no later than two years after the date of entry into force of the Protocol,

Noting that any decision taken at this stage regarding the understanding and implementation of the requirements specified in the first sentence of paragraph 2 (a) of Article 18 would only be interim until the decision referred to in the second sentence of the same paragraph on the detailed requirements is taken,

*Recalling* that a Party to the Protocol may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of the Protocol,

- 1. Requests Parties to the Protocol and urges other Governments to take measures to require the use of a commercial invoice or other document required or utilized by existing documentation systems, as documentation that should accompany living modified organisms that are intended for direct use as food or feed, or for processing, for the purpose of identification by incorporating the information requirements of the first sentence of paragraph 2 (a) of Article 18, and the requirements established under paragraph 4 below, pending a decision on detailed requirements for this purpose by the Conference of the Parties serving as the meeting of the Parties to the Protocol, which could include the use of a standalone document;
- 2. Requests Parties to the Protocol and urges other Governments to take measures ensuring that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing clearly identifies that the shipment may contain living modified organisms intended for direct use as food or feed, or for processing, and states that they are not intended for intentional introduction into the environment;
- 3. Further requests Parties to the Protocol and urges other Governments to take measures ensuring that the documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, provides the details of a contact point for further information: the exporter, the importer, or any appropriate authority, when designated by a Government as the contact point;
- 4. Further urges Parties to the Protocol and other Governments to require that the documentation referred to in paragraph 1 above includes: (i) the common, scientific and, where available,

commercial names, and (ii) the transformation event code of the living modified organisms or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

- 5. Encourages Parties to the Protocol and other Governments to require exporters of living modified organisms that are intended for direct use as food or feed, or for processing under their jurisdiction to declare, in documentation accompanying transboundary movements known to intentionally contain living modified organisms that are intended for direct use as food or feed, or for processing, that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing, the identity of the living modified organism, and any unique identification, where possible;
- 6. Decides to establish an open-ended technical expert group on identification requirements of living modified organisms that are intended for direct use as food or feed, or for processing to assist the Conference of the Parties serving as the meeting of the Parties to the Protocol in taking the decision referred to in paragraph 2 (a) of Article 18 of the Protocol, on the basis of the terms of reference specified in the annex to this decision;
- 7. Requests Parties to the Protocol, other Governments and relevant international organizations to provide to the Executive Secretary by 30 June 2004:
- (b) Information on their experience, if any, in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18; and
- (c) Their views regarding the detailed requirements referred to in the second sentence of paragraph 2 (a) of Article 18, including specification of the identity of the living modified organisms that are intended for direct use as food or feed, or for processing (whether the extent of information should include taxonomic name, the gene modifications inserted and traits or genes changed); threshold levels in the case of co-mingling of living modified organisms with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification;
- (d) Their experiences with the use of existing unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organisation for Economic Co-operation and Development;
- 8. Requests the Executive Secretary to prepare a synthesis of the information and views referred to above, for the consideration of the open-ended technical expert group mentioned in paragraph 6 above, and to convene, subject to the necessary financial resources being made available, the meeting of the open-ended technical expert group, and to submit the report and draft decision of the group to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol:
- 9. *Urges* developed country Parties and other donor Governments to make financial contributions necessary to facilitate the participation of experts from developing countries and countries with economies in transition in the open-ended technical expert group referred to in paragraph 6 above.

#### Annex II

## PREPARATION OF A DRAFT DECISION FOR THE CONSIDERATION OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE BIOSAFETY PROTOCOL

#### Revised Chair's text

The Open-ended Technical Expert Group on Identification Requirements of Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing,

Recalling the decision of the first meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol regarding the identification/documentation requirements of living modified organisms intended for direct use as food or feed, or for processing, as contained in decision BS-I/6 A,

Examining the issues specified in its terms of reference, contained in the annex to decision BS-I/6 A, that were relevant to the subject of identification of living modified organisms that are intended for direct use as food or feed, or for processing on the basis of, among other things, submissions received from Parties, other Governments and relevant international organizations,

*Recognizing* that there are different views which remain difficult to resolve at this stage, and that this text does not represent consensus,

Submits the following draft decision on the detailed requirements of identification of living modified organisms intended for direct use as food or feed, or for processing, to the Conference of the Parties serving as the meeting of the Parties to the Protocol to provide elements for further consideration of the issues at its second meeting:

"The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling the second sentence of paragraph 2 (a) of Article 18, which requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of those elements specified in the first sentence of the same paragraph, including specification of the identity of the living modified organisms in question and any unique identification, no later than two years after the date of entry into force of the Protocol,

*Recalling further* decision BS-I/6 A of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol,

*Noting* the recommendation of the Open-ended Technical Expert Group on Identification Requirements of Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing,

*Recognizing* the potential role of thresholds for adventitious or unintentional presence of authorized living modified organisms as a practical tool for implementing documentation requirements,

Acknowledging the role of sampling and detection techniques in implementing identification requirements, and the technical nature of the issues involved, and noting the

relevant work of competent regional and international organizations in developing such techniques,

*Recognizing* that, pursuant to Article 2 paragraph 4 of the Protocol, nothing in the present decision shall affect any right of a Party to regulate documentation requirements for living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework,

- 1. Requests Parties to the Protocol and urges other Governments to take measures to ensure the use of a commercial invoice or other document required or utilized by existing documentation systems, or documentation as required by domestic regulatory framework, as documentation that should accompany living modified organisms that are intended for direct use as food or feed, or for processing. Such documentation should allow for easy recognition, transmission, and effective integration of the information requirements;
- 2. Requests Parties to the Protocol and invites other Governments to submit to the Executive Secretary, not later than six months prior to the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information on experience gained with the use of documentation referred to in paragraph 1 above, including information on cost-benefit analyses, with a view to the future consideration of a stand-alone document to fulfil the identification requirements, and requests the Executive Secretary to compile the information and to prepare a synthesis report for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- 3. Further requests Parties to the Protocol and urges other Governments to take measures ensuring that the documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, provides the details of a contact point for further information: the last exporter, the first importer, or any appropriate authority, when designated by a Government as the contact point;
- 4. Requests Parties to the Protocol and urges other Governments to take measures to require that documentation accompanying transboundary movements known to intentionally contain living modified organisms that are intended for direct use as food or feed, or for processing:
- (a) Specifies that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing;
- (b) States that they are not intended for intentional introduction into the environment;
- (c) Includes the common, scientific and, where available, commercial names of the living modified organisms,
- (d) Includes the transformation event code of the living modified organisms and/or, where available, as a key to accessing information in the Biosafety Clearing-House, the OECD Unique Identifiers for Transgenic Plants or any other unique identifier codes registered in the Biosafety Clearing-House; and
  - (e) Provides the Internet address of the Biosafety Clearing-House;

- 5. In cases where it is not known whether or not the shipment contains LMOs, or it is not known which particular LMOs are contained in the shipment, *requests* Parties to the Protocol and *urges* other Governments to take measures to require that documentation accompanying transboundary movements of living modified organisms that are intended for direct use as food or feed, or for processing:
- (a) Clearly identifies that the shipment may contain living modified organisms of this commodity that have been approved in the country of origin, and specifies the country of origin;
- (b) Provides the Internet address of the Biosafety Clearing-House for further information; and
- (c) States that the organisms are intended for direct use as food or feed, or for processing, and are not intended for intentional introduction into the environment.
- 6. *Notes* that thresholds may be adopted or applied on a case-by-case basis by a national authority, under its domestic regulatory framework consistent with the objective of the Protocol, for the adventitious or technically unavoidable presence of particular living modified organisms or groups of living modified organisms that have been authorized for the placing on the market as living modified organisms for food, feed, or for processing in that country, taking into account the characteristics of the receiving environment;
- 7. Encourages Parties and other Governments to cooperate in exchanging experiences and building capacities in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for living modified organisms;
- 8. *Decides* to consider the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques at its fourth meeting, taking into account the work of other competent regional and international organizations with a view to avoid duplication of efforts."

#### Annex III

## DRAFT DECISION ON HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18, PARAGRAPH 2 (a)) SUBMITTED BY THE CHAIR OF WORKING GROUP I

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling the second sentence of paragraph 2 (a) of Article 18, which requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of those elements specified in the first sentence of the same paragraph, including specification of the identity of the living modified organisms in question and any unique identification, no later than two years after the date of entry into force of the Protocol,

*Recalling further* decision BS-I/6 A of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol,

*Noting* the revised Chair's text contained in the annex to the report of the Open-ended Technical Expert Group on Identification Requirements of Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing, convened from 16 to 18 March 2005,

Recognizing the potential role of thresholds for adventitious or technically unavoidable presence of authorized living modified organisms as a practical tool for implementing documentation requirements,

Recognizing that, pursuant to Article 2 paragraph 4 of the Protocol, nothing in the Protocol "shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and provisions of this Protocol and is in accordance with that Party's other obligations under international law",

- 1. Requests Parties to the Protocol and urges other Governments to take measures to ensure the use of a commercial invoice, or an annex to a commercial invoice, or a stand-alone document, or other document required or utilized by existing documentation systems, or documentation as required by domestic regulatory framework as documentation that should accompany living modified organisms that are intended for direct use as food or feed, or for processing. Such documentation should allow for easy recognition, transmission, and effective integration of the information requirements, with consideration of the use of standard formats;
- 2. Requests Parties to the Protocol and invites other Governments to submit to the Executive Secretary, not later than six months prior to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information on experience gained with the use of documentation referred to in paragraph 1 above, including information on cost-benefit analyses where possible or appropriate, with a view to the future consideration of a stand-alone document or further harmonization of a documentation format to fulfil the identification requirements, and requests the Executive Secretary to compile the information and to prepare a synthesis report for consideration by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- 3 (a). *Requests* Parties to the Protocol and urges other Governments to take measures ensuring that documentation accompanying intentional transboundary movements of LMOs-FFP:

- (i) Clearly identifies that the shipment may contain LMOs-FFP that have been approved in the Party of import;
  - (ii) States that the LMOs are not intended for intentional introduction into the environment;
- (iii) Includes the common, scientific and, where available, commercial names of the living modified organisms;
- (iv) Includes the unique identifier code of the living modified organisms if registered in the Biosafety Clearing-House, or in the absence of such code, the transformation event code of the living modified organisms;
  - (v) Provides the Internet address of the Biosafety Clearing-House for further information;
- (vi) Provides the details of a contact point for further information: the exporter and the importer in the supply chain, and/or appropriate authority, when designated by a Government as the contact point;
- 3 (b). *Requests* Parties to the Protocol and urges other Governments to take measures ensuring that documentation accompanying intentional transboundary movements known to intentionally contain LMOs-FFP:
- (i) Clearly states that the shipment contains LMOs-FFP and specifies the LMOs that are known to be in the shipment;
  - (ii) States that the LMOs are not intended for intentional introduction into the environment;
- (iii) Includes the common, scientific and, where available, commercial names of the living modified organisms;
- (iv) Includes the unique identifier code of the living modified organisms if registered in the Biosafety Clearing-House, or in the absence of such code, the transformation event code of the living modified organisms;
  - (v) Provides the Internet address of the Biosafety Clearing-House for further information;
- (vi) Provides the details of a contact point for further information: the exporter and the importer in the supply chain, and/or appropriate authority, when designated by a Government as the contact point;
- 4. *Notes* that thresholds may be adopted or applied on a national basis, by a national authority under its domestic regulatory framework consistent with the objective of the Protocol, for the adventitious or technically unavoidable presence of living modified organisms that have been authorized for the placing on the market as living modified organisms for food, feed, or for processing in that country;
- 5. *Encourages* Parties and other Governments to cooperate in exchanging experiences and building capacities in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for living modified organisms;

- 6. Decides to review, at its fourth meeting, available sampling and detection techniques, with a view to harmonization, taking into account the work of relevant regional and international organizations with a view to avoid duplication of efforts;
- 7. Requests Parties to the Protocol and invites other Governments, regional and international organizations and interested stakeholders, to submit to the Executive Secretary, not later than three months prior to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information on experience gained with the use of sampling and detection techniques, and requests the Executive Secretary to compile the information received and to prepare a synthesis report, including an analysis of existing gaps, for consideration by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- 8. *Decides* to further consider, at its third meeting, the documentation requirements contained in this decision, taking into account experience gained, with a view to further elaboration of detailed requirements.

\_\_\_\_