UNEP/CBD/BS/COP-MOP/1/15 Page 53

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 stand-alone 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:
- (a) Information on their experience, if any, in the implementation of the requirements of the first sentence of paragraph 2(a) of Article 18; and
- (b) 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;
- (c) 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 with economies in transition in the open-ended technical expert group referred to in paragraph 6 above.

Annex

TERMS OF REFERENCE FOR THE OPEN-ENDED TECHNICAL EXPERT GROUP ON IDENTIFICATION REQUIREMENTS OF LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

Taking into account the need for 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 living modified organisms that are intended for direct use as food or feed, or for processing in accompanying documentation, including specification of their identity and any unique identification, no later than two years after the date of entry into force of the Protocol, and

Considering: (i) the report and recommendations of the Meeting of Technical Experts on the Requirements of Paragraph 2(a) of Article 18; (ii) the Chair's summary of Working Group I of the discussion regarding paragraph 2 (a) of Article 18 at the third meeting of the Intergovermental Committee for the Cartagena Protocol on Biosafety; (iii) the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol; and (iv) the information and views provided by Parties to the Protocol, other Governments and relevant international organizations in accordance with paragraph 7 of decision BS-I/6 A above,

Understanding that composition of the open-ended technical expert group shall be designed for effective participation, inclusiveness, transparency, and technical expertise relevant to the issues specified in this terms of reference, and that it will be composed of experts, nominated by Parties to the Protocol and other Governments and relevant international organizations, with technical expertise relevant to the issues specified in the terms of reference,

The Open-Ended Technical Expert Group shall:

- 1. Examine the issues of specifying the identity of living modified organisms that are intended for direct use as food or feed, or for processing and unique identification mentioned in the second sentence of paragraph 2(a) of Article 18 in relation to the "may contain" language of the first sentence of the same paragraph, and any other issues that may be relevant to the elaboration of the detailed requirements of identification of living modified organisms that are intended for direct use as food or feed, or for processing, including:
- (a) The documentation to accompany living modified organisms that are intended for direct use as food or feed, or for processing for the purpose of Article 18, paragraph 2 (a);
 - (b) The information provided in the accompanying documentation;
 - (c) The extent and modality of using unique identifiers; and, if possible,
- (d) Thresholds for adventitious or unintentional presence of LMOs that may be needed to trigger identification requirements;
 - (e) Review available sampling and detection techniques, with a view to harmonization.
- 2. Prepare a draft decision regarding issues mentioned in paragraph 1 above, for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol.
- 3. Complete its work in time for the Conference of the Parties serving as the meeting of the Parties to the Protocol to take this decision at its second meeting.

B. Paragraphs 2 (b) and 2 (c) 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 paragraphs 2 (b) and 2 (c) of Article 18 of the Cartagena Protocol on Biosafety,

- 1. Requests Parties to the Protocol and urges other Governments to take measures to ensure the use of a commercial invoice or other documents required or utilized by existing documentation systems, with consideration given to the formats outlined in the example templates annexed hereto, as documentation that should accompany living modified organisms for contained use and living modified organisms for intentional introduction into the environment of the Party of import, incorporating the information required under paragraphs 2(b) and 2(c) of Article 18 of the Protocol, as appropriate, with a view to fulfil the identification requirements of these paragraphs;
- 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, with a view to the future consideration of a stand-alone document, to fulfill the identification requirements of paragraphs 2(b) and 2 (c) of Article 18, and requests the Executive Secretary to compile the information received and to prepare a synthesis report presenting options for stand-alone documentation for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

- 3. Requests Parties to the Protocol and urges other Governments to take measures ensuring that documentation accompanying living modified organisms contains the following information and declaration:
 - (a) Living modified organisms for contained use (Article 18, paragraph 2 (b)):
 - (i) Clear identification as "living modified organisms" including common and scientific names of the organisms and as "destined for contained use";
 - (ii) The name and address of the consignee, and exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;
 - (iii) Any requirements for the safe handling, storage, transport and use of the living modified organisms under applicable existing international instruments, such as the United Nations Recommendations on the Transport of Dangerous Goods, the International Plant Protection Convention and the Organisation Internationale des Epizooties, domestic regulatory frameworks or under any agreements entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
 - (iv) Where appropriate, further information should include the commercial names of the living modified organisms, if available, new or modified traits and characteristics such as event(s) of transformation, risk class, specification of use, as well as any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House;
- (b) Living modified organisms for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol (Article 18, paragraph 2 (c)):
 - (i) Clear identification as "living modified organisms" and a brief description of the organisms, including common and scientific name, relevant traits and genetic modification, including transgenic traits and characteristics such as event(s) of transformation or, where available and applicable, a reference to a system of unique identification;
 - (ii) Any requirements for the safe handling, storage, transport and use of the living modified organisms as provided under applicable existing international requirements, domestic regulatory frameworks, or under any agreement entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
 - (iii) The name and address of the exporter and importer;
 - (iv) The details of the contact point for further information, including an individual or organization in possession of relevant information in case of emergency;
 - (v) A declaration that the movement of the living modified organisms is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter;
 - (vi) Where appropriate, further information should include the commercial name, risk class, and import approval for the first transboundary movement of living modified organisms;
- 4. *Invites* Parties, other Governments and relevant international organizations to make available to the Executive Secretary, not later than six months prior to the date of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information regarding their experience, if any, in the implementation of the requirements of paragraphs 2(b) and 2(c) of Article 18:

5. Requests the Executive Secretary to prepare a synthesis report of information received from Parties, other Governments or relevant international organizations in accordance with paragraph 4 above and submit the report to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

C. Unique identification system(s)

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

Mindful of the consideration of the issue of unique identification in the context of paragraph 2 (a) of Article 18 by the open-ended technical expert group established pursuant to paragraph 6 of decision BS-I/6 A above.

Recognizing the need for harmonized unique identifier codes for facilitating access to relevant information that may be available in the Biosafety Clearing-House regarding living modified organisms subject to transboundary movement,

Welcoming the development and adoption of the Organisation of Economic Co-operation and Development (OECD) Guidance for the Designation of a Unique Identifier for Transgenic Plants,

Recognizing that other unique identification systems may be developed, and that a unique identification system is also required for genetically modified micro-organisms and animals,

- 1. *Invites* Parties and other government to take measures to apply, as appropriate, the OECD Unique Identifiers for Transgenic Plants to living modified plants under the Protocol, without prejudice to the possible development and applicability of other systems;
- 2. Requests the Executive Secretary to develop or maintain, in the Biosafety Clearing-House, a register of unique identification codes to ensure harmonisation of such codes by all users;
- 3. Encourages the Organisation for Economic Co-operation and Development and other organizations involved in the development of unique identification systems for living modified organisms to initiate or enhance their activities towards the development of a harmonized system of unique identifiers for genetically modified micro-organisms and animals.

D. Capacity-building

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

Recognizing the urgent need to address the critical capacity-building requirements of developing country Parties, in particular the least developed and small island developing States among them, and Parties with economies in transition, regarding the implementation of the requirements of Article 18, in particular the documentation requirements under paragraph 2;

Requests the Executive Secretary to convene, prior to the meeting of the open-ended technical expert group mentioned in paragraph 6 of decision BS-I/6A above, subject to the necessary financial resources being made available, a workshop on capacity-building and exchange of experiences on the safe handling, transport, packaging and identification of living modified organisms, as related to the implementation of paragraph 2 of Article 18 of the Protocol.

Annex

EXAMPLES OF INTEGRATION OF INFORMATION REQUIREMENTS INTO EXISTING DOCUMENTATION

A. Blank example of template for Article 18.2 (b) of the Cartagena Protocol

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B. Example 1 of template for Article 18.2 (b) of the Cartagena Protocol

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C. Example 2 for Article 18.2 (b) of the Cartagena Protocol

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UNEP/CBD/BS/COP-MOP/1/15 Page 61

(see warning above)

D. Blank Example Template for Article 18.2 (c) of the Cartagena Protocol

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E. Example 1 Template for Article 18.2 (c) of the Cartagena Protocol

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F. Example 2 Template for Article 18.2 (c) of the Cartagena Protocol

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^{*/} See OECD Guidance for the Designation of Unique Identifier for Transgenic Plants, 2002 – Key to accessing databases that provide additional information on the LMO.

III/10. Handling, transport, packaging and identification of living modified organisms: paragraph 2 (a) of Article 18

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 entry into force of the Protocol,

Also recalling 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,

Recalling 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 the Protocol, provided that such action is consistent with the objective and the provisions of the Protocol and in accordance with that Party's other obligations under international law,

Understanding that Parties may, in the context of Article 14 and Article 24, enter into bilateral, regional and multilateral agreements and arrangements regarding requirements for the identification of living modified organisms intended for direct use as food or feed, or for processing,

Recalling Article 11 of the Protocol on the procedure for living modified organisms intended for direct use as food or feed, or for processing,

Stressing the need to promote the broadest possible participation in the Protocol, by countries exporting and importing living modified organisms intended for use as food or feed or for processing, in order to ensure the broadest possible implementation of identification requirements,

Convinced that capacity-building in developing countries is essential for the effective implementation of the documentation requirements under Article 18, paragraph 2 (a), of the Protocol,

- 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 and/or administrative frameworks, as documentation that should accompany living modified organisms that are intended for direct use as food or feed, or for processing. Such documentation should include the information in paragraph 4 below and allow for easy recognition, transmission and effective integration of the information requirements, with consideration of standard formats;
- 2. Requests Parties to the Protocol and invites other Governments to submit to the Executive Secretary, no later than six months prior to the fifth 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, with a view to further harmonization of a documentation format to fulfil the identification requirements set out in paragraph 4 below, including consideration of the need for a stand-alone document, and requests the Executive Secretary to compile the information and to prepare a synthesis report for consideration by the fifth 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 exporter, the importer, and/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 ensuring that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing, in commercial production and authorized in accordance with domestic regulatory frameworks, is in compliance with the requirements of the country of import, and clearly states:
- (a) In cases where the identity of the living modified organisms is known through means such as identity preservation systems, that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing;
- (b) In cases where the identity of the living modified organisms is not known through means such as identity preservation systems, that the shipment may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing;
- (c) That the living modified organisms are not intended for intentional introduction into the environment;
- (d) The common, scientific and, where available, commercial names of the living modified organisms;
- (e) 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;
- (f) The Internet address of the Biosafety Clearing-House for further information; and *notes* that in accordance with Article 24 of the Protocol, transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of the Protocol, and *further notes* that the specific requirements set out in this paragraph do not apply to such movements. In addition, in accordance with paragraph 2 of Article 24, Parties shall encourage non-Parties to adhere to the Protocol;
- 5. *Invites* Parties to the Protocol and other Governments to make available to the Biosafety Clearing-House the following:
- (a) The transformation events that are commercially produced for each planting cycle in the exporting country;
- (b) The geographical area within the exporting country where each transformation event was cultivated:
- (c) The common, scientific and, where available, commercial names of the living modified organisms;
- (d) The transformation event code of the living modified organism or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;
- 6. Acknowledges that the expression "may contain" does not require a listing of living modified organisms of species other than those that constitute the shipment;
- 7. Decides to review and assess, at its fifth meeting, experience gained with the implementation of paragraph 4 above, with a view to considering a decision, at its sixth meeting, to ensure that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing covered by paragraph 4 clearly states that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing, and includes the detailed information in items (c) to (f) of that paragraph;
- 8. *Decides* that the review referred to in paragraph 7 above shall include an examination of capacity-building efforts in developing countries;
- 9. Recalls the updated Action Plan for Building Capacities for the Effective Implementation of the Protocol adopted at the present meeting (decision BS-III/3, annex) and requests the Executive Secretary to mobilize funding from all available sources for the purpose of supporting implementation of Article 18, paragraph 2 (a), of the Protocol;

UNEP/CBD/BS/COP-MOP/3/15 Page 62

- 10. 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;
- 11. 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 its fourth meeting, information on experience gained with the use of sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques and requests the Executive Secretary to compile the information received 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;
- 12. Requests Parties to the Protocol and urges other Governments and relevant international and regional organizations to take urgent measures to strengthen capacity-building efforts in developing countries, in order to assist them in the implementation of and benefit from documentation and identification requirements for living modified organisms intended for direct use as food or feed, or for processing.