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

Second meeting

Montreal, 30 May-3 June 2005

Item 12 of the provisional agenda *

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Synthesis of information regarding experience in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18

Note by the Executive Secretary

I. INTRODUCTION

1. At its first meeting, the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol considered several issues related to Article 18 of the Protocol. With respect to paragraphs 2 (b) and 2 (c) of Article 18, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopted decision BS-I/6 B, in which it, *inter alia*, invited Parties, other Governments and relevant international organizations to submit to the Executive Secretary information regarding their experience, if any, in the implementation of the requirements specified in those paragraphs. It also requested the Executive Secretary to prepare a synthesis report of the information that might be received, and to submit the report to its second meeting.

2. Section II of the present document, contains a synthesis report of the information that the Executive Secretary has received in accordance with the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Section III suggests some elements of a draft decision for consideration by the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

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II. SYNTHESIS OF INFORMATION REGARDING EXPERIENCE IN THE IMPLEMENTATION OF THE REQUIREMENTS OF PARAGRAPHS 2 (b) AND 2 (c) OF ARTICLE 18

3. In paragraph 4 of its decision BS-I/6 B, the Conference of the Parties serving as the meeting of the Parties to the Protocol invited Parties, other Governments and relevant international organizations to make available to the Executive Secretary, not later than six months prior to its second meeting, information regarding their experience, if any, in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18. Accordingly, submissions were received, by 10 January 2005, from Australia, from the European Community and its member States, Japan, Lithuania, Slovenia, Switzerland, the United States, the Global Industry Coalition, and the World Trade Organization. The full texts of the submissions have been compiled and are available as an information document (UNEP/CBD/BS/COP-MOP/2/INF/4). The following is the synthesis of the information contained in the submissions.

4. Australia indicated that although it is not a Party to the Protocol, and hence not under any direct obligation to implement its requirements, there was a practical necessity for its agricultural exporters to comply with the requirements of the Protocol in order to export to Parties. In that spirit, Australia suggests that Parties to the Protocol could implement the requirements of paragraphs 2 (b) and 2 (c) of Article 18 in a manner that: (i) is minimally disruptive to trade; (ii) is consistent with other international obligations; (iii) will not be unduly burdensome or costly; (iv) allows the use of existing accompanying documentation; (v) does not go beyond the requirements explicitly set out in the Protocol; (vi) does not present the Protocol as an arbitrary threshold setting instrument; and (vii) avoids duplication of efforts in relation to work being undertaken by other international organizations. The submission enlists the specific elements of information requirements provided for in paragraphs 2 (b) and 2 (c) of Article 18. Australia expressed the view that any requirement beyond the explicit requirements of the Protocol in the case of living modified organisms for contained use would cause an unnecessary burden on importers and exporters, many of whom are researchers. The documentation that may be used to incorporate the information should, according to the submission, be existing documentation, and that could include bills of lading and letters to the recipient, in the case of living modified organisms for contained use, and a commercial invoice, in the case of organisms for intentional introduction into the environment.

5. The submission from the European Community and its member States makes reference to several Community laws that are relevant to the export and import of genetically modified organisms (GMOs). It mentions that the legislative framework on GMOs fulfils the documentation requirements of the Protocol both for movements of GMOs between member States and imports of GMOs into the European Union. As far as exports are concerned, the submission states that regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms implements the specific requirements, which include the information requirements of paragraphs 2 (b) and 2 (c) of Article 18. The submission reproduces the relevant provision of the Regulation, which requires exporters to ensure that a set of information specified therein is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO. The provision contains two sets of information, which are almost identical with the information required under paragraphs 2 (b) and 2 (c) of Article 18 as regards living modified organisms for contained use, and living modified organisms for intentional introduction into the environment, respectively. The submission indicates that requirements in Regulation 1946/2003 are provided for without prejudice to other specific requirements that may be imposed by Community legislation or result from developments at international level in the context of Article 18 of the Protocol. The submission attaches also, as an annex, a note regarding the experience of one member State in relation to identifying living modified organisms for intentional introduction into the environment.

6. Japan's Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, which came into force in February 2004, implements the requirements of paragraphs 2 (b) and 2 (c) of Article 18. According to the submission,

there is a provision in the Regulations that prohibits exporters from exporting living modified organisms for contained use and living modified organisms for intentional introduction into the environment to Parties to the Protocol without fulfilling the requirements stipulated in paragraphs 2 (b) and 2 (c) of Article 18, respectively. In that regard, exporters have to provide the required information using the appropriate forms provided in the Regulations, or on the packaging or the container of the living modified organisms, or on the consignment invoice. Anyone who violates this provision of the law or one who provides false information is, according to the submission, liable to a fine.

7. The submission from Lithuania indicates that their Order on the Regulation of Contained Use of GMOs, which was adopted in August 2003 and amended in April 2004, provides for requirements on containment and safety measures, a clear definition of genetic modifications, specifying detailed contents and descriptions of the contained use, identifying elements and extent of risk assessment for GMOs in contained use.

8. Slovenia indicated that it has no experience yet that it gained in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18. But the submission points out that the rules adopted by the European Union in these areas also apply to Slovenia.

9. Switzerland has an ordinance concerning the transboundary movement of genetically modified organisms, known as the 'Cartagena Ordinance'. The objective of the ordinance is to implement the Biosafety Protocol on the basis of the federal law on genetic engineering issued in 2003, which regulates, among other things, the import, export and transit of genetically modified organisms. According to the submission, the requirements of the ordinance to provide information in documentation accompanying GMOs for contained use and GMOs for intentional introduction into the environment, are based on the requirements of paragraphs 2 (b) and 2 (c) of Article 18 of the Biosafety Protocol. The submission indicated, that the only difference to exist between the requirements of the Protocol and those of the ordinance is that the Ordinance makes it unnecessary to specify the identity of the organism in terms of its traits or other relevant characteristics in the event where a unique identification of the GMO is provided on the accompanying documentation. The submission further indicates that operators were invited to comment on the templates attached to decision BS-I/6 B of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol as examples of possible forms and contents of accompanying documentation. The operators, according to the submission, were satisfied with the templates, especially with the ones for living modified organisms destined for contained use as provided for under paragraph 2 (b) of Article 18 of the Protocol.

10. The United States expressed its belief that the documentation in common commercial practice for shipment of living modified organisms for contained use or living modified organisms for intentional introduction into the environment was sufficient to ensure the safety of the environment in general and biological diversity in particular. The United States also believes that current practices in the transboundary movement of living modified organisms are consistent with the guidance provided by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol on the implementation of the paragraphs 2 (b) and 2 (c) of Article 18 as contained in decision BS-I/6 B. According to the submission, shipments of seed or preparative material are normally accompanied by information that complies with national regulations that govern the safe handling of living modified organisms destined for contained use or for intentional introduction into the environment. Therefore, no additional requirement is, justified as it would have the potential to create a needless burden and would likely compromise existing and well functioning procedures that are already Protocol-compliant. On the other hand, the submission emphasizes the importance of education of, and communication with, stakeholders, including Parties, non-Parties, importers, and exporters of any potential change in obligations due to the Biosafety Protocol. In this regard, the submission indicates how communication between national authorities and those entities that are shipping living modified materials would greatly be facilitated by taking the full advantage of the Biosafety Clearing-House to make available national

laws, regulations and guidelines concerning requirements for living modified organisms destined for contained use and for intentional introduction into the environment.

11. The submission from the World Trade Organization generally describes the distinction between the requirements that fall under the Sanitary and Phytosanitary (SPS) Agreement on the one hand, and the Agreement on Technical Barriers on Trade (TBT), on the other. It states that most labelling requirements, nutrition claims and concerns, quality and packaging regulations are not considered to be SPS measures; they normally fall under the TBT Agreement.

12. The Global Industry Coalition (GIC) pointed out that it revised its guidelines that it had issued for its members after the entry into force of the Protocol in order to reflect the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol as regards the implementation of the documentation requirements under paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol. According to its submission, the guidelines remind those entities shipping living modified organisms to ensure, among other things, the inclusion of appropriate information on the shipping documentation specific to a shipment of living modified organisms for contained use or for intentional introduction into the environment. The Global Industry Coalition, on behalf of the private sector, suggests specific sets of information to be included on existing shipping documentation such as pro forma invoices or commercial invoices in order to meet the requirements of paragraph 2 (b) and paragraph 2 (c) of Article 18. The specific list of information by the Global Industry Coalition reproduces, more or less, all the information listed in decision BS-I/6 B, except the items (in paragraphs 3 (a) (iv) and 3 (b) (vi)). The submission contains, as annex, templates of documents to demonstrate how the language required by paragraphs 2 (b) and 2 (c) of Article 18 could be formulated and incorporated into existing documentation.

13. The Global Industry Coalition said that it had conducted an informal survey of its members to determine their experiences with shipments of living modified organisms under paragraphs 2 (b) and 2 (c) of Article 18. The survey showed, that guidelines provided by the Coalition to its members based on the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, in conjunction with other country-specific information, were working satisfactorily in identifying transboundary movements of living modified organisms that fall under paragraphs 2 (b) and 2 (c) of Article 18. The submission mentions the lack of information in the Biosafety Clearing-House as regards domestic requirements on imports of living modified organisms as an ongoing concern for its members. It therefore suggests that potential delays in the transboundary movement of living modified organisms would be avoided if each country provides, through the Biosafety Clearing-House, a clear indication as to what its requirements for import are, including its shipping documentation requirements, with regards to living modified organisms for contained use and for intentional introduction into the environment.

III. ELEMENTS OF A DRAFT DECISION

14. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements in adopting a decision under this item:

(a) Recall paragraph 2, of decision BS-I/6 B, in which it requested Parties and invited other Governments to submit to the Executive Secretary, not later than six months prior to the third meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol, information on their experience gained with the use of commercial invoices or other documents required or utilized by existing documentation systems, with a view to the future consideration of a stand-alone document.

(b) Recall further that the Executive Secretary was also requested, in the same decision, to compile the information received and 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;

(c) Take note of the efforts, with appreciation, that exporters of living modified organisms are making to implement the requirements specified under paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol in accordance with the provisions of the Protocol as further elaborated by decision BS-I/6 B, other existing international or national requirements, and established practices;

(d) Urge Parties to the Protocol and invite other Governments to take further measures to make sure that those requirements of paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol as elaborated by decision BS-I/6 B are fully complied with;

(e) Urge Parties, especially those Parties of import, to make available to the Biosafety Clearing-House information on their domestic requirements concerning imports of living modified organisms in general, and documentation requirements in particular, with respect to living modified organisms for contained use and for intentional introduction into the environment, as part of the requirement set out in paragraph 3 (a) of Article 20 of the Protocol, for each Party to make available its laws, regulations and guidelines relevant to the implementation of the Protocol.
