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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
Seventh meeting
Pyeongchang, Republic of Korea, 29 September - 3 October 2014
Item 10 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Synthesis of information on experience gained with the implementation of requirements related to paragraph 2 (a) of Article 18

Note by the Executive Secretary

I. INTRODUCTION

1. According to Article 18 of the Cartagena Protocol on Biosafety, each Party to the Protocol has to take measures to require the identification of transboundary movements of living modified organisms (LMOs) in accompanying documentation. At its third meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) decided, under paragraph 4 of decision BS-III/10, to take measures to ensure that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP), 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 LMOs-FFP;

(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 LMOs-FFP;

(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.

* UNEP/CBD/BS/COP-MOP/7/1.

2. At the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, Parties were expected to review and assess experience gained with the implementation of paragraph 4 of decision BS-III/10, with a view to considering a decision, at their next 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.

3. However, noting the limited experience gained, the Parties decided, at their fifth meeting, to postpone this further decision-taking until their seventh meeting. It was further agreed that this decision-taking should also include consideration of the need for a stand-alone document, as referred to in paragraph 2 of decision BS-III/10. Paragraph 7 of decision BS-V/8 requested Parties, and invited other Governments and relevant organizations, to submit to the Executive Secretary, prior to the seventh meeting, further information on experience gained with the implementation of paragraph 4 of decision BS-III/10 as well as the implementation of decision BS-V/8, including any information on obstacles that are encountered in the implementation of these decisions as well as capacity-building needs to implement these decisions. The Executive Secretary was requested to compile the information and prepare a synthesis report for consideration by the Parties.

4. Accordingly, section II of the present document contains a synthesis of the information received by the Executive Secretary on experience gained with the identification and documentation of shipments of living modified organisms intended for direct use as food or feed, or for processing, as well as information on challenges and obstacles encountered, capacity-building needs and on whether to use a stand-alone document for identification. Section III suggests some elements of a draft decision for consideration by the Parties at their seventh meeting.

II. A SYNTHESIS OF SUBMISSIONS ON EXPERIENCE GAINED

(a) Experience in the implementation of identification requirements (Article 18.2 (a), decision III/10, paragraph 4)

5. By the extended deadline of 2 May 2014, the Executive Secretary had received thirteen submissions. These consisted of eight submissions from the following Parties: Brazil, China, the European Union, Malaysia, Mexico, Norway, Republic of Korea and South Africa; two submissions from other Governments, namely Australia and the United States of America; and three submissions from non-governmental organizations, namely the Global Industry Coalition (GIC), the International Grain Trade Coalition, and No! GMO Campaign. The full text of the submissions has been compiled and made available as an information document (UNEP/CBD/BS/COP-MOP/7/INF/2).

6. Six Parties, namely Brazil, China, the European Union, Norway, Republic of Korea and South Africa, stated that they have a fully functional regulatory system in place to address the handling, transport, packaging, and identification of living modified organisms intended for direct use as food or feed, or for processing, that satisfies the requirements in this regard. Two Parties, Malaysia and Mexico, stated that they have a relevant legal framework or law governing the import of LMOs, but are still in the process of formally putting in place the necessary regulations or mechanisms to operationalize it.

7. Brazil indicated, in its submission, that paragraph 4 of decision BS III/10 provides a balanced guide on how to implement Article 18.2 (a) of the Protocol. According to the submission, it is important that Parties continue to adopt, in accordance with their needs and in line with the objectives of the Protocol, appropriate domestic measures for the implementation of both Article 18.2 (a) and decision BS-III/4. Brazil also indicated that it is important for Parties to provide, through the Biosafety Clearing-House, the list of LMOs which are allowed in their jurisdiction for use as food, feed or for processing.

8. China stated, in its submission, that it regulates the transport, packaging and labeling of LMOs and that a series of inspection standards have been developed in line with related laws and regulations. It

notes that the General Administration of Customs and the General Administration of Quality Supervision, Inspection and Quarantine inspect imported and exported LMOs in accordance with the Regulations on Administration of Agricultural Genetically Modified Organisms Safety and related measures. China further notes, in its submission, that while it currently requires inspection of imports and exports of LMOs in accordance with relevant domestic regulations, it suggests that Parties provide detailed information and identify labels for exported LMOs-FFP, undertake gene tests before export and provide test certificates and reports for exported LMOs-FFP, and share information on identity preservation system through the Biosafety Clearing-House so that importing countries can have access to accurate information on the LMOs on the market.

9. The submission received on behalf of the European Union (EU) and its Member States provided detailed information on the comprehensive legal framework that exists within the EU which addresses handling, transport, packaging, and identification of living modified organisms. It stated that its requirements for the identification and documentation of genetically modified organisms (GMOs) are in line with Article 18.2 (a) of the Protocol and without prejudice to further specific requirements imposed by EU legislation, such as:

(a) Regulation (EC) No 1829/2003, which lays down rules on labeling of all genetically modified (GM) food and feed, dictating that GM food and feed has to be labeled as GM, except if they contain GM material in a proportion no higher than 0.9 per cent and if this presence is adventitious or technically unavoidable;

(b) Regulation (EC) No 1830/2003, which provides that business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market;

(c) Regulation (EC) No 65/2004, which establishes a system for the development and assignment of unique identifiers for genetically modified organisms. The Regulation adopts the format developed by the Organisation for Economic Co-operation and Development (OECD) for unique identifiers for transgenic plants, which in mid-April 2004 became mandatory for the EC's domestic regulatory framework for GMOs; and

(d) Regulation (EC) No 1946/2003, under Article 12, which provides that exporters are required to state in a document accompanying the GMO, which is to be transmitted to the importer receiving the GMO: that it contains or consists of GMOs, and the unique identification code(s) assigned to those GMOs if such codes exist.

10. The EU also explained that Article 12 of Regulation (EC) No 1946/2003 further stipulates that the identification statement must be supplemented, for GMOs intended for direct use as food or feed, or for processing, by a declaration by the exporter stating that the GMOs are intended for direct use as food or feed, or for processing, and indicating clearly that they are not intended for deliberate release into the environment; and giving details of the contact point for further information. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing, the above identification requirements may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for the GMOs used to constitute the mixture. In this regard, the EU explained how the format developed by the OECD for unique identifiers for transgenic plants is mandatory among member states and how it has extended the use of this format to unique identifiers for genetically modified microorganisms and animals pending the development and adoption of any other specific format at an international level. The EU considers the use of the unique identifiers as a key to accessing information available on the Biosafety Clearing-House.

11. Malaysia explained that the Government is currently engaged, with several agencies that are directly involved with trade activities, in the development of a mechanism to require all consignments for import that contain products which have been subjected to genetic modification to carry a declaration stating that the product is "genetically modified".

12. Mexico indicated that it is in the process of developing accompanying regulations through a working group to facilitate inter-agency coordination. In the meantime, however, it has put in place a process by which an authorization needs to be obtained from the Ministry of Health in order to import and commercialize LMOs. The Ministry lists several requirements which must be met when requesting the authorization. These include, but are not limited to, the identification of the LMO to be imported by scientific and common names, the type of event and its intended use.

13. Mexico stated that, in order to comply with Article 18.2 (a) of the Cartagena Protocol, it signed a Trilateral Agreement (the Agreement) with Canada and the United States of America, which are not Parties to the Cartagena Protocol. Mexico explained that a rigorous process of exchange of information and consultation was carried out among Mexican authorities concerned with international trade of agricultural products, with a focus on bulk commodities, and with the aim of establishing minimum acceptable conditions so as not to hinder trade, while ensuring compliance with the requirements of the Cartagena Protocol. The Agreement, entitled "Documentation requirements for LMOs intended for food or feed or for processing", was originally valid until October 2005, but was subsequently extended indefinitely. Following negotiations, it was agreed to include the following terms in the agreement:

(a) Incorporating, in the invoice, the text "may contain LMOs intended for direct use as food or feed, or for processing, and are not intended for intentional introduction into the environment";

(b) Identifying the last exporter and first importer of the shipment and granting exemptions from such requirements to shipments of products for whose species LMOs have not been developed (e.g. wheat and sorghum) or that are explicitly or implicitly referred to as free of LMOs (LMO-free soybeans or maize);

(c) The threshold to determine the absence of LMOs is 5 per cent maximum content, based on tolerance established through a great number and duration of experiences on cost correlation and viabilities of control and verification in the various business parameters.

14. Mexico further explained that a voluntary compliance scheme was developed for that agreement. A "Pilot Program for the documentation accompanying imports of yellow maize intended for direct use as food, feed, or for processing", was adopted, simultaneously implementing the terms of the Agreement described for yellow maize from the United States of America, and the relevant guidance under the Protocol. The programme identifies imports that may contain LMOs and tracks them from their entry into the country to their final destination. Mexico considers it a simple mechanism to monitor the consumables imported, while not generating technical barriers for trade in yellow maize.

15. In its submission, Mexico further explained that the programme had originally been presented to Parties at COP-MOP 3 and that the current submission provides an update on the ongoing programme. At the time of submission of the document, the following preliminary results could be noted: The report states that in 2013, 6,343,179.78 tons of yellow maize from the United States of America and Canada were imported, of which 2,894,798.51 tons (equivalent to 45.64% of the total volume of imports) were reported to have the label "may contain LMOs". The submission indicates, however, that reporting in 2013 was done by means of a new format which was only made available to operators in October of the same year, and thus, the completing of these formats was done in a retroactive fashion. Furthermore, one must take into account the unfamiliarity of operators with adapting internal programs and specific rules to the "new" mechanism for sharing information. Mexico's submission also states that it will present the latest figures for 2014 during the current meeting, including a more complete and realistic analysis of the possibility of compliance with Article 18.2 (a) without involving extra costs that may impact the final consumer and food security.

16. In its submission, Norway indicated that it has thus far not had any transboundary movement of LMOs-FFP, and consequently had not gained experience related to the implementation of the paragraph relevant to the notification.

17. Imports of LMOs-FFP into the Republic of Korea must, according to Article 8, Clause 1 of the "Act on Transboundary Movement of Living Modified Organisms", acquire approvals from the related central administrative authorities. The application must clearly indicate the common and scientific name of the LMO-FFP to be imported, as well as the transformation event code. Furthermore, it must also include the import quality and monetary amount of the respective events. The Republic of Korea further stated in its submission that, at present, exporters actually indicate that their LMOs-FFP shipments "may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing", and provide all codes of transformation events that may be included. According to the submission, exporters also declare in the commercial invoices that the LMOs are "not intended for intentional introduction into the environment". The submission states that the country is implementing or is ensuring the implementation of the requirements related to the import/export of LMOs-FFP in accordance with decision BS-III/10. In fact, the submission further indicates that while about 8 million tons of LMOs-FFP have been imported into the Republic of Korea every year since January 2008, no special difficulties regarding implementation of decision BS-III/10 have been experienced.

18. South Africa supports the use of relevant standards with regard to handling, transport, packaging and identification of living modified organisms, in line with existing standard-setting bodies such as Codex and the World Organisation for Animal Health (OIE) and has incorporated the information requirements necessary under its Genetically Modified Organisms Act of 1997 in the relevant export permit. South Africa indicated that it has incorporated the information requirements in the export permit and currently uses the "may contain" language accompanied by the list of LMO events commercially approved in South Africa.

19. Australia and the United States of America, non-Parties to the Cartagena Protocol on Biosafety, indicated in their submission that the use of "may contain" language in commercial invoices is sufficient and in line with commercial trade practices and the Protocol's environmental objectives with regards to the transboundary movement of LMOs for FFP. Australia also explained that any additional documentation requirements would increase the cost of trading grains. It suggested that any documentation regime that raises transaction costs is likely to distort world markets for grains and raise the cost of food to consumers by more that the "may contain" regime. Similarly, the United States of America concludes that there is no need for guidance and additional work to amend decision BS-III/10.

20. The Global Industry Coalition (GIC) indicated in its submission that Parties can implement, and in several cases have implemented, the requirements of paragraph 2 (a) of Article 18 as outlined in decision BS-III/10 in a way that achieves the objectives of the Cartagena Protocol on Biosafety, is minimally disruptive to trade and will not be unduly burdensome or costly for Parties. The GIC further stated that implementation is already occurring with existing documentation in a way that provides the importing country customs officials with the information they require to make an informed decision to allow import of the material. According to the GIC, Parties already have reliable information about the LMOs approved in exporting countries, in light of the requirement to make such information available on the BCH (decision BS-III/10, paragraph 5) and the information provided by the six largest technology providers on a public database (www.biotradestatus.org). The GIC expressed the view that making changes to the existing guidance will disrupt the process that is working and would require new training of customs officials and negate the progress made by Parties and other Governments in implementing decision BS-III/10 to date. The GIC thus confirms that it supports the continued use of the language in decision BS-III/10, underlining that it ensures continuity for those Parties and other Governments that have already implemented the decision and encourages other Parties who haven't implemented the decision to do so.

21. Similarly, the International Grain Trade Coalition (IGTC) maintained that in light of a significant percentage of the global grain trade now involving products produced through modern biotechnology, it is critically important that Article 18.2 (a) is implemented in a commercially accepted manner. It stated that highly efficient and low cost margin international trade is only possible when exporters and importers are able to define and manage their trade risks, including those due to living modified organisms, and that the

current widespread practice of documenting the possible presence of living modified organisms on existing commercial documents with a simple "may contain" clause has been shown to be practical and cost-effective for commercial grain trade parties. To illustrate this, IGTC noted that importers and exporters conducting business among and between the United States of America, Canada, and Mexico, have found the so called "Trilateral Accord" covering the commodities traded among the three countries, which may contain living modified organisms, to be extremely useful and favorable to efficient trade.

22. In its submission, IGTC stated that its members believe that existing standards and procedures for sampling grains and oilseeds for other analytical needs including quality and safety are sufficient to sample grains for LMOs. The IGTC noted that sound, commercially viable, and sufficient representative sampling methods have been used successfully for decades. Therefore, the IGTC felt that there is no need for a separate or unique sampling plan system for GMO analysis.

23. No! GMO Campaign, introducing itself as a Japan-based coalition of civic society organizations and non-governmental organizations that are actively investigating and educating the public as well as discussing with the Japanese Government the negative influence that living modified organisms (LMOs), such as genetically modified organisms, are having on biodiversity in Japan, noted that measures need to be put into practice so that contamination by GM seeds during transport and loading/unloading is prevented. The coalition further stated that measures are needed for LMO labeling to make it possible to access accurate and detailed information on any gene flow that may occur. The submission suggests the need to implement measures in order to ensure that the current case of GM canola that is growing in the wild in Japan and the further contamination of local crop varieties and weeds would not spread to the rest of the world.

(b) Capacity-building needs

24. It is important to note that only three submissions mentioned or addressed capacity-building needs. The EU notified that it did not have any specific capacity-building needs. Malaysia, however, noted that, although it has developed a domestic legal framework, more inter-agency coordination, capacity-building and awareness activities need to be done before the framework can be fully operationalized. It noted that priority should be given to build capacity among the developing country Parties and Parties with economies in transition with appropriate financial support in place. Brazil did not identify any particular needs, but it indicated that Parties and other organizations should continue to support countries in need of capacity-building support.

(c) Experience on the type of document: a stand-alone document

25. In postponing the decision-taking referred to in paragraph 7 of decision BS-III/10 to their seventh meeting, Parties to the Protocol had indicated, in paragraph 6 of their decision BS-V/8, that the need for a stand-alone document would also be considered at the present meeting. Parties further requested the Executive Secretary, at their sixth meeting (decision BS-VI/8, paragraph 3), to include a specific question in the format for the third national reports inquiring whether Parties require identification information for the transboundary movements of living modified organisms for food, feed or for processing (LMOs-FFP), to be provided in existing types of documentation or in a stand-alone document or both. In that regard, few of the submissions received expressed views on the matter.

26. South Africa indicated that the requirement for the issuance of a relevant permit for the import of LMOs-FFP eliminates the need for any additional stand-alone document, which in their view could be perceived as additional trade barriers.

27. The Republic of Korea stated, in its submission, that a stand-alone document is not required given that domestic regulation, such as the import approval procedure, was able to make up for any deficiencies. Through import contracts, importers demand that exporters indicate information necessary for such import approval in commercial invoices. Therefore, according to the Republic of Korea, experience shows that no additional type of accompanying document is necessary. However, the Republic of Korea

indicated that further review of the need for accompanying documents and identification may be needed some time in the future as the types or characteristics of LMOs-FFP become more diversified.

28. The Global Industry Coalition stated that all the information required by the Protocol can be and has been adequately conveyed using existing documentation for the past eight years of implementation of decision BS-III/10.

III. SUGGESTED ELEMENTS FOR A DRAFT DECISION

29. In light of the information synthesized in section II above, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to:

(a) Take note of the experience and views of Parties and other Governments and relevant international organizations, which support the continuation of implementing the existing requirements of paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety and paragraph 4 of decision BS-III/10;

(b) Recall paragraph 1 of decision BS-III/10 and paragraph 1 of decision BS-V/8;

(c) Request Parties to the Cartagena Protocol on Biosafety and urge other Governments to:

(i) Continue to take measures ensuring the implementation of requirements in paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety and paragraph 4 of decision BS-III/10;

(ii) Continue to identify transboundary movements of living modified organisms intended for direct use as food or feed, or for processing, by incorporating the information identified in paragraph 4 of decision BS-III/10 into existing documentation accompanying living modified organisms;

(iii) Cooperate with and support developing country Parties and Parties with economies in transition to build capacity to implement the identification requirements of paragraph 2 (a) of Article 18 and related decisions;

(d) Urge Parties and invite other Governments to make available to the Biosafety Clearing-House any domestic regulatory requirements related to the identification and documentation of living modified organisms intended for direct use as food or feed, or for processing;

(e) Decide to further review the need for a stand-alone document in light of responses to the relevant question in the third national report and any relevant outcomes of the third assessment and review of the effectiveness of the Protocol.

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