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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

Sixth meeting

Hyderabad, India, 1-5 October 2012

Item 10.1 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

*Synthesis of the relevant information from the second national reports regarding
Articles 18.2 (b) and (c)*

I. INTRODUCTION

1. Paragraphs 2 (b) and (c) of Article 18 of the Cartagena Protocol on Biosafety place obligations on Parties to take measures to require that documentation accompanying (i) living modified organisms (LMOs) destined for contained use and (ii) LMOs for intentional introduction into the environment and any other LMOs within the scope of the Protocol clearly identifies them as living modified organisms; specifies any requirements for their safe handling, storage, transport and use; and provides other specific information.
2. At the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, the Parties adopted decision BS-III/8 on the "Handling, transport, packaging and identification of living modified organisms: paragraphs 2 (b) and 2 (c) of Article 18". This decision requested Parties and invited other Governments and relevant international organizations to submit to the Executive Secretary information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements with a view to future consideration of a stand-alone document (paragraph 1). The decision also requested the Executive Secretary to prepare a synthesis report of the information received for consideration in the context of the process of review of the implementation of the Protocol as provided for in Article 35 of the Protocol, which was to be undertaken at the fourth meeting of the Parties to the Protocol in 2008.
3. Accordingly, a synthesis of information on experience gained with the use of existing documentation to fulfil the identification requirements of paragraphs 2 (b) and (c) of Article 18 was included in the document on assessment and review prepared for the fourth meeting of the Parties to the Protocol (document UNEP/CBD/BS/COP-MOP/4/14).
4. At the fourth meeting of the Parties to the Protocol, the Parties noted the limited experience gained in the implementation of the Protocol and recognized that this did not provide a good basis for an effective assessment and review of the Protocol (decision BS-IV/15). The Parties thus decided, in

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decision BS-IV/8), to review the matter of paragraphs 2 (b) and (c) of Article 18 at their sixth meeting in light of the review of experience based on the analysis of the second national reports. The current document has been prepared in response to this decision.

5. The current document synthesizes the relevant information from the second national reports and also compares it to information provided in the first national reports from 2007. The document concludes with some possible elements for a draft decision.

II. SYNTHESIS OF INFORMATION FROM THE SECOND NATIONAL REPORTS

6. Question 111 in the reporting format for the second national reports asked whether countries had taken measures to implement the documentation requirements of Article 18.2 (b) of the Protocol. The analysis of the information in the second national reports (document UNEP/CBD/BS/COP-MOP/6/16) breaks down the responses to this question as follows:

(a) 61 Parties of the 143 who responded to this question (43%) reported that yes, they had taken measures to require that documentation accompanying LMOs that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned;

(b) 32 Parties (22% of the respondents to this question) responded that they had taken such measures to some extent; and

(c) 50 Parties (35% of the respondents to this question) reported that no, they had not taken such measures;

(d) The percentages of respondents within the different regions reporting that they had not taken such measures are as follows: 45% of the respondents in Africa, 37% in Asia-Pacific, 16% in Central and Eastern Europe (CEE), 57% in the Group of Latin American and the Caribbean countries (GRULAC) and 0% in the Western Europe and Others Group (WEOG).

7. Question 112 asked whether countries had taken measures to implement the documentation requirements of Article 18.2 (c) of the Protocol. The analysis of the information in the second national reports summarizes the responses as follows:

(a) 60 Parties of the 143 who responded to this question (42%) reported that yes, they had taken measures to require that documentation accompanying LMOs that are intended for intentional introduction into the environment of the Party of import, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter;

(b) 25 Parties (17% of the respondents to this question) reported having taken such measures to some extent; and

(c) 58 Parties (41% of the respondents to this question) reported that no, they had not taken such measures;

(d) The percentages of respondents within the different regions reporting that they had not taken such measures are as follows: 49% of the respondents in Africa, 43% in Asia-Pacific, 21% in CEE, 67% in GRULAC and 5% in WEOG.

8. Question 115 in the reporting format provided respondents with space to provide further details on the implementation of Article 18 in their country. A number of countries provided additional information regarding implementation of Article 18.2 (b) and (c). The relevant responses fall into four categories:

(a) Countries that have not yet implemented documentation requirements for LMOs for contained use or LMOs for intentional introduction into the environment:

- A few countries indicated that they still need to develop the necessary measures to implement paragraphs 2 (b) and (c) of Article 18;

(b) Countries that only have draft laws or have general provisions that need implementing regulations:

- A number of countries indicated that they have draft laws that, once promulgated, will set the details on the documentation required to accompany LMOs for contained use and LMOs for intentional introduction into the environment;
- Other countries stated that they have a general law but that specific implementing regulations are still needed to address documentation requirements;

(c) Countries where capacity-building is needed to implement existing measures:

- A few countries indicated that they need capacity-building in order to be able to implement Article 18.2 (b) and (c);

(d) Countries that have the necessary regulatory regime in place regarding Article 18.2 (b) and (c):

- A number of countries stated that they have the necessary regulatory regime in place;
- A few countries indicated that they have measures to implement Article 18.2 (b) and (c) partially in place.

9. For those countries that have the necessary regulatory measures in place, very little information was provided in the second national reports describing their experiences implementing their rules regarding Article 18.2 (b) and (c). Furthermore, most countries did not indicate whether their identification requirements could be included in existing types of documentation that would accompany shipments of LMOs or whether they must be in a stand-alone document. It may be noted, however, that there was no specific question in the format for the second national reports inquiring as to whether identification information is to be provided in existing types of documentation or as a stand-alone document.

10. Belgium stated that while it has the necessary regulatory measures in place to implement paragraphs 2 (b) and (c) of Article 18, its customs officials lack methods to distinguish genetically modified organisms (GMOs) from non-GMOs.

11. China stated that the owner or consignee of a shipment should, in the customs declaration, specify in the declaration form for import commodities whether the product is genetically modified. If the commodity is declared to be genetically modified, then other relevant documents such as the biosafety certificate for agricultural GMOs should be provided.

12. The Democratic People's Republic of Korea indicated that the country's checking and quarantine institutions require that importers and exporters must submit the correct declaration and the checking and quarantine institutions check the approved document of import and export, packages and marks. They also stated that the country's import and export checking institutions look at the different documents that may accompany LMOs, "such as certificates of freight, hygiene check, plant check, quality control, place of origin, fund and bill". They noted that import and export regulations are so strict and the checking procedures so complicated that most "importers and exporters are not inclined to treat LMOs".

13. The European Union (EU) recalled that its Regulation (EC) 1946/2003 on transboundary movements of GMOs requires:

(a) Exporters of GMOs destined for contained use to state in accompanying documentation that the shipment contains or consists of GMOs and the unique identification codes assigned to the GMOs if such codes exist. This information is to be supplemented by a declaration by the exporter which must specify any requirements for the safe handling, storage, transport and use of the GMOs, and the contact point for further information, including the name and address of the individual or institution to whom the GMOs are consigned;

(b) Exporters of GMOs for deliberate release into the environment to ensure that documentation accompanying the GMOs states that the shipment contains or consists of GMOs and the unique identification codes assigned to those GMOs, where these exist. The information is to be supplemented by a declaration by the exporter specifying the identity and relevant traits and characteristics of the GMOs, any requirements for the safe handling, storage, transport and use of the GMOs, the contact points for further information and, as appropriate, the name and address of the importer and exporter, and a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

14. This Regulation also applies to the 27 EU Member States.

15. India pointed to its “rDNA Biosafety Guidelines, 1990” which contain the procedure for importing LMOs for contained use, including the type of containment, packaging, labeling, contact point and documents to accompany shipments. It also noted that to import transgenic plant material for research purposes, the importer must furnish an appropriate phytosanitary certificate issued by the authority of the country of export. Finally, the country’s Directorate General of Foreign Trade requires that all consignments for import that contain products which have been subjected to genetic modification carry a declaration stating that the product is “genetically modified”.

16. According to Japan, “[t]he domestic law for the Protocol stipulates that the package, vessel and invoice, etc. of LMOs intended for export to a Party must be accompanied by the descriptions of the required specific matters. Their specific formats are set forth in the Regulations of the Law.”

17. Malaysia indicated that it has made initial efforts to design documentation to fulfil the requirements of Article 18. It noted, however, that without much experience from other sources to draw upon, the country would need a longer time frame. It noted that the legal mechanism for documentation requirements is already in place but more inter-agency coordination, capacity-building and awareness activities are to be done before it can be fully implemented.

18. Mexico stated that the notification that must be submitted by the applicant to the competent national authorities when applying to undertake activities involving the contained use of LMOs must also be used to fulfill the identification and documentation requirements of Article 18.2 (b). In the case of transboundary movements of LMOs for intentional introduction into the environment, the identification requirements for their importation are established in the relevant permits.

19. The Republic of Moldova stated that Article 24 of its Law on Biosafety requires the producer or importer to present to the National Commission information that includes the specific conditions of use and handling as well as recommendations related to packaging, labeling and identification. The report noted that the presence of GMOs must be clearly indicated on the label or accompanying documentation.

20. South Africa described its requirements for exports of LMOs to be accompanied by documentation identifying the LMOs.

21. Swaziland stated that consignments of LMOs imported into the country should be accompanied by appropriate documentation.

22. While the information from the second national reports is generally not very specific, it suggests that most countries do not require information identifying LMOs for contained use or LMOs for

intentional introduction into the environment to be provided in a stand-alone document that accompanies their shipment.

III. COMPARISON TO INFORMATION FROM THE FIRST NATIONAL REPORTS

23. The first national reports under the Biosafety Protocol were due on 11 September 2007. Questions 33 and 34 of the reporting format for the first national reports asked whether countries had taken measures regarding the documentation to accompany LMOs for contained use and LMOs for intentional introduction into the environment, respectively. The questions are the same as questions 111 and 112 in the reporting format for the second national reports although the possible answers are slightly different. In the first national reports, countries could respond “yes”, “not yet, but under development” or “no”. In the second national reports, countries could respond “yes”, “yes, to some extent” or “no”.

24. The revised analysis of the first national reports prepared in October 2008¹ found the following:

(a) A majority of respondents (62%) to question 33 reported that yes, they had taken measures to require that documentation accompanying LMOs that are destined for contained use clearly identifies them as LMOs and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned (Article 18.2 (b)).

(b) The same majority of respondents (62%) to question 34 reported that yes, they had adopted measures to require that documentation accompanying LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMO within the scope of the Protocol, clearly identifies them as LMOs; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter (Article 18.2 (c)).

25. If the countries that responded “yes” and “yes, to some extent” to questions 111 and 112 in the second national reports are combined, the figures are remarkably similar to those from the first national reports as summarized in table 1 below.

Table 1. Comparison of responses to questions concerning documentation accompanying LMOs for contained use and LMOs for intentional introduction into the environment in the first national reports versus the second national reports

First national report	Second national report
Question 33: Percentage of Parties responding “yes”	Question 111: Percentage of Parties responding “yes” or “yes, to some extent”
62%	65%
Question 34: Percentage of Parties responding “yes”	Question 112: Percentage of Parties responding “yes” or “yes, to some extent”
62%	60%

26. This suggests that there has been little change in the implementation of the documentation requirements in paragraphs 2 (b) and (c) of Article 18 of the Protocol between 2008 and 2011.

¹ Document UNEP/CBD/BS/CC/5/2, online: <http://www.cbd.int/doc/meetings/bs/bssc-05/official/bssc-05-02-en.pdf>.

IV. SUGGESTED ELEMENTS FOR A DRAFT DECISION

27. The information from the second national reports as synthesized in section II above indicates that many countries still need to develop measures to implement the documentation requirements of paragraphs 2 (b) and (c) of Article 18. This situation seems to have changed little since 2008. Furthermore, little information was provided in the second national reports on experience with the implementation of existing measures for those countries that already have them in place.

28. On this basis, the Parties to the Protocol may wish to consider the following elements in formulating and adopting a draft decision under this item:

(a) Urging Parties to expedite the implementation of their biosafety regulatory frameworks and make available to the Biosafety Clearing-House any laws, regulations and guidelines for the implementation of the Protocol, and any changes to their regulatory requirements related to the identification and documentation of living modified organisms destined for contained use and living modified organisms for intentional introduction into the environment;

(b) Requesting Parties and encouraging other Governments, relevant international organizations as well as the Global Environment Facility to cooperate with and support developing country Parties and Parties with economies in transition to build capacity to implement the identification requirements of paragraphs 2 (b) and (c) of Article 18 and related decisions;

(c) Deciding that the identification requirements in paragraphs 2 (b) and (c) of Article 18 should be fulfilled through the use of a commercial invoice or other documents required or utilized by existing documentation systems or pursuant to national requirements.
