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OPEN-ENDED TECHNICAL EXPERTS GROUP ON IDENTIFICATION REQUIREMENTS OF LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING
First meeting
Montreal, 16-18 March 2005
Items 3 and 4 of the provisional agenda*

SYNTHESIS OF INFORMATION AND VIEWS REGARDING IDENTIFICATION REQUIREMENTS FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING (PARAGRAPH 2(a), ARTICLE 18)

Note by the Executive Secretary

I. INTRODUCTION

1. The first sentence of paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety provides for identification requirements of living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP) in accompanying documentation. The details of these requirements were, however, envisaged to be worked out at a later stage. According to the second sentence of the same paragraph, the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol (COP-MOP) has to take a decision on the details of these requirements and on other relevant issues no later than two years after the date of entry into force of the Protocol.

2. In order to fulfil this responsibility in a timely manner (i.e., no later than two years after 11 September 2003, the date when the Protocol entered into force), the Conference of the Parties serving as the meeting of the Parties to the Protocol decided, at its first meeting, to establish an open-ended technical expert group, which should examine the issues and submit a draft decision for consideration. The Conference of the Parties serving as the meeting of the Parties to the Protocol also requested Parties to the Protocol, other Governments and relevant international organizations to submit their views and information regarding their experience in the implementation of the requirements specified in the first sentence of paragraph 2 (a) of Article 18, the detailed requirements referred to in the second sentence of the same paragraph and related issues, and their experience with the use of unique identification systems. The Executive Secretary was requested to convene, subject to the availability of financial resources, the meeting of the Open-ended Technical Expert Group; to prepare a synthesis of the views and information for the consideration of the Technical Expert Group; and further to submit the report and draft decision of

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the group to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

3. The present note is, therefore, intended to convey a synthesis of views and information provided by Parties, other Governments and relevant international organizations for the consideration of the Open-ended Technical Expert Group on Identification Requirements of LMOs-FFP (section II). In addition to the present synthesis of views and information, the Open-ended Technical Expert Group is, in accordance with its terms of reference, expected to consider: (i) the report and recommendations of the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) of Article 18, which met in Montreal from 18 to 20 March 2002; (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 Intergovernmental Committee for the Cartagena Protocol on Biosafety; and the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (decision BS-I/6 A).

4. Section III of this note presents possible options of elements that the Open-ended Technical Expert Group may wish to consider in addressing the specific issues identified in its terms of reference and especially in preparing the draft decision regarding these issues as requested by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, for the consideration of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. These options of elements are essentially derived from the submissions synthesised herein below. Finally section IV submits a draft recommendation to the Technical Expert Group, for its consideration.

II. A SYNTHESIS OF VIEWS AND INFORMATION

5. As mentioned in paragraph 2 above, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested Parties, 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; (b) 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 LMOs-FFP (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 LMOs with non-LMOs; and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification; (c) experiences with the use of unique identification systems under the Protocol, such as the Unique Identifier for Transgenic Plants of the Organisation for Economic Co-operation and Development (OECD).

6. By 10 August 2004, submissions were received from Argentina, Australia, Bulgaria, Cameroon, Canada, Colombia, European Community and its member States, Guinea-Bissau, India, Japan, Liberia, Lithuania, Mali, Mauritius, Mexico, Norway, Romania, Sri Lanka, Switzerland, Togo, Uganda, United States of America, Global Industry Coalition and International Grain Trade Coalition. The full texts of the submissions have been compiled and made available in an information document (UNEP/CBD/BS/OETEG-HTPI/1/INF/1). The following is the synthesis of the information and views contained in the submissions.

A. Experience in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18

7. Paragraph 2(a) of Article 18 requires each Party to take measures towards identifying LMOs-FFP during transboundary movement. The first sentence of the paragraph describes the information that needs to be made available for the purpose of identification. Such information needs to be provided through documentation that should accompany the LMOs-FFP. The accompanying documentation is required to state: (i) that the shipment "may contain" LMOs-FFP; (ii) that they are not intended for intentional introduction into the environment; and (iii) contact point for further information.

8. The Conference of the Parties serving as the meeting of the Parties to the Protocol has, at its first meeting, elaborated more on these requirements. It requested Parties and urged other Governments to take measures: (i) to require the use of a commercial invoice or other appropriate document currently in use by other systems as documentation to accompany LMOs-FFP; (ii) to ensure that the documentation provides the details of the exporter, the importer, or any appropriate authority designated by a Government, as a contact point for further information; (iii) to require that the accompanying documentation specifies the common, scientific and, where available commercial names, and the transformation event code of the LMO or, where available its unique identifier, which would be a key to accessing information in the Biosafety Clearing-House (BCH). The Conference of the Parties serving as the meeting of the Parties to the Protocol also encouraged Parties to the Protocol and other Governments to require exporters of LMOs-FFP under their jurisdiction to declare, in accompanying documentation, shipments known to be LMOs-FFP, that they really contain LMOs-FFP, instead of specifying only that the shipment "may contain" LMOs-FFP as is the requirement currently in the first sentence of paragraph 2 (a) of Article 18

9. The experiences in the implementation of the requirements of the first sentence of paragraph 2 (a) of Article 18 are varied. In this regard, the submissions could be categorized into three major groups i.e.: (i) those submissions from developing countries and, in some cases, from countries with economies in transition; (ii) submissions from European countries; and (iii) submissions from North America and the industry groups. The common feature in the submissions of the first group is that while there are no practical experiences in the implementation of the documentation requirements specified in the first sentence of paragraph 2 (a) of Article 18 at present, there are ongoing processes to develop national biosafety frameworks, which are expected to include also documentation requirements as specified in the Protocol and further elaborated by the Conference of the Parties serving as the meeting of the Parties to the Protocol. The existence of comprehensive regulatory frameworks, which also deal with documentation requirements and other related issues as provided for in the Protocol, is the typical feature of the situation in the European Union and other European countries. When it comes to North America, the prominent experience mentioned by all countries of the region and the industry coalition groups alike is the trilateral arrangement made in October 2003 among Canada, Mexico, and the United States regarding documentation requirements for living modified organisms for food, feed, or for processing.

10. One submission mentioned the fact that the question of implementing the documentation requirements of the Protocol does not arise in the case of a non-Party. It also noted that by providing comments it is not intended to convey a view that documentation requirements are necessary for achieving the objective of the Protocol. The submission further commented that if these requirements are found to be necessary, they have to be simple, practical, and not unduly burdensome or costly to implement or understand, for the importer and the exporter.

11. Some submissions have made it clear that their domestic regulatory frameworks require exporters to state in the documentation accompanying LMOs-FFP that the shipment "contains LMOs-FFP" instead of "may contain" as specified in the first sentence of paragraph 2 (a) of Article 18 of the Protocol. In contrast, other submissions support the use of the "may contain" identification requirement in the document accompanying not only those shipments known to contain LMOs-FFP but also all shipments of agricultural commodities for which there are LMO varieties approved in the country of export.

12. One submission stated that the national regulations set the identification requirements as derived from the Protocol and failure to observe those requirements and exporting LMOs-FFP to Parties to the Protocol without attaching the necessary information on the package, or container, or on the consignment invoice, or providing false information, would result in fines.

B. 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 LMOs-FFP (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 LMOs with non-LMOs, and possible linkages of the issue with Article 17 of the Protocol; the "may contain" language; and any unique identification

1. Detailed requirements: extent of information on the identity of the LMOs-FFP

13. Some submissions recalled decision BS-I/6 A, in which the Conference of the Parties serving as the meeting of the Parties to the Protocol urged Parties to the Protocol and other Governments to require exporters to include the common, scientific and, where available, commercial names and the transformation event codes of the LMOs that are subject to transboundary movement. These submissions favoured further strengthening of the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in this regard. They argue that the detailed requirements on the identity of the LMOs should allow the importing countries to verify that the LMOs-FFP they are importing are those that they agreed to import.

14. Other submissions supported further the inclusion of taxonomic name, the gene modifications inserted and traits or genes changed, information on the host organism and the donor in accompanying documentation. In the case of one of these submissions, this information may not be necessary on the accompanying documentation as long as a unique identification code is provided, which would enable access to the required information at the Biosafety Clearing-House. One other submission favoured information as detailed as in paragraph 2 (c) of Article 18, which includes specifying the relevant traits and characteristics of the LMOs. A number of submissions have also made reference to information on any requirements for safe handling, storage, transport and use; a contact point for further information which may include the name and address of exporter, the importer or the consignee or a government body designated for this purpose. The need to have a declaration in the accompanying documentation indicating that the LMOs are not intended for intentional introduction into the environment, and that the shipments are in conformity with the requirements of the Protocol, was also mentioned.

15. On the other hand, other submissions made it clear that they do not believe more information on the identity of the LMOs is needed. They argued that requiring additional or more information about the genetic modifications goes beyond the purpose of Article 18. One of these submissions supported delaying any consideration of detailed requirements until more experience is gained on the implementation of the requirements in the first sentence of paragraph 2 (a) of Article 18. Some of these submissions pointed out that any requirement should be minimally disruptive to trade, and not unduly burdensome or costly. They favoured a restrictive application of the requirements that are specified in the Protocol in an explicit and direct manner. These submissions argued that anything beyond that would be duplicative of the information in the Biosafety Clearing House. The submission from the International Grain Trade Coalition stated that the information requirements that the Conference of the Parties serving as the meeting of the Parties to the Protocol included in decision BS-I/6 A, placed its industry in a position of meeting unreasonable expectations related to the identification of LMOs-FFP events in shipments. It further stated that factors beyond the control of the grain shipper severely limit the implementation of those requirements. Some of the factors mentioned as causing such difficulties are lack of internationally acceptable sampling and testing system, lack of a single test to identify all of the specific traits that might be in bulk shipments and lack of definition of an LMO shipment. The industry group believes that the content of the accompanying documentation should be viewed in the context of the information that is or should be made available in the Biosafety Clearing-House.

2. The "may contain" language

16. Some submissions are in favour of the use of "may contain" on accompanying documentation to meet the identification requirement for LMOs-FFP. They support the inclusion of a statement that reads: "Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment".

17. One of the submissions mentioned that the "may contain" language is not designed to be a tool for risk assessment, or to serve as a basis for regulatory decision taking on whether to import. The submission went further and described the situations where the "may contain" documentation should not apply. Accordingly, the submission excludes from the "may contain" documentation requirement LMOs present in non-LMO shipments in trace (adventitious) amount; commodities where no LMO varieties are authorized from the country of export; small-volume, high-value specialty-type shipments of non-LMO commodities that have LMOs in general "parallel" commerce (such as organic, food-grade soybeans); a shipment of non-LMO when the exporter and the importer have contractually defined so but with at least 95% purity or without prejudice to the requirements of the importing country. Otherwise, according to this submission, which is also generally consistent with the submissions of the industry groups, all shipments of commodities from an exporting country where LMO varieties of the commodity are widely grown are presumed to contain LMOs, and thus, eligible to bear the "may contain" identification in the document accompanying them. It was also mentioned that such view is in agreement with the trilateral understanding that Canada, Mexico and the United States entered into in October 2003 regarding documentation requirements for living modified organisms for food or feed, or for processing. The copy of the signed document is also attached to the submission under consideration.

18. Other submissions, on the other hand, do not see it appropriate to use "may contain" to identify LMO-FFP shipments. They rather suggest that these shipments should be accompanied by documentation that states that the shipments "contain LMOs" intended for direct use as food or feed, or for processing. These submissions are in favour of building upon the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, which encouraged Parties and other Governments to require exporters to declare, when shipments are known to contain LMOs-FFP, that they "contain LMOs", instead of "may contain".

19. One submission favoured the use of "may contain" identification requirement for the time being until the detailed requirements are clarified. It further stated that the "may contain" language could also be appropriate to identify shipments that are normally non-LMO, but may have unintentionally mixed or co-mingled with LMOs. The submission further clarified that documentation may not be necessary if the amount of the co-mingling meets the threshold levels that might have been set by the importing country. This same submission also recommends that the Biosafety Clearing-House must be expanded to include information on whether the LMO posted is commercially cultivated, area of cultivation, amount production, share of production, export share of the crop, etc. It suggests that the standard of demarcation between segregation and non-segregation should be determined by each importing country in the context of Article 11, not at international level.

3. The type of documentation that should accompany LMOs-FFP

20. Only a few submissions commented on the type of documentation that should accompany LMOs-FFP. Some of them reiterated their support to the use of commercial invoices to incorporate the information requirements of the Protocol in order to identify LMOs-FFP shipments. Others support stand-alone documentation. In the case of one submission all possibilities for, and content of, documents for LMOs need to be further explored.

21. One submission that supported a stand-alone documentation argued that the national competent authority responsible for biosafety does not have control over a commercial invoice, nor such invoice is under the supervision of the Protocol. The submission has also indicated that it would, however, remain

open to consider other existing systems, including the templates that the Conference of the Parties serving as the meeting of the Parties to the Protocol endorsed as examples, which might be customized to meet the identification requirements of the Protocol. Another submission resubmits templates of documentation that were submitted to previous processes.

4. Adventitious/unintended presence of LMOs: thresholds and possible linkages with Article 17

22. There are submissions that support the establishment of threshold levels for the purpose of determining what triggers the documentation requirement under paragraph 2 (a) of Article 18. Some submissions referred to the threshold levels adopted under their domestic regulations while others have indicated the threshold that they would like to see adopted under the Protocol. Some of those submissions that favoured the establishment of thresholds also believe that the scope of Article 17 of the Protocol on "unintentional transboundary movement of LMOs and emergency measures" is broad enough to cover all LMOs that are likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in affected or potentially affected States. These submissions, therefore, see some kind of linkage between unintended presence of LMOs in a non-LMO shipment in the context of paragraph 2 (a) of Article 18 and Article 17. In this regard, one submission stated that no threshold would be acceptable for unapproved LMOs. According to this submission, if unapproved LMO is found to be co-mingled and if the exporting country is aware of that, the exporting country has to take appropriate emergency measures in line with Article 17. This same submission, however, believes that threshold levels should be set at national level taking into account the conditions in the receiving environment or the risk profiles, and the type of LMO that is usually being imported into that environment. It also noted that there could be a possibility to set thresholds at national level for unapproved LMOs in limited cases, depending on the condition of transportation used and the natural environment of the importing country.

23. On the other hand, there are submissions that are opposed to any notion of thresholds under the Protocol, and that they do not believe that Article 17 has anything to do with adventitious presence of LMOs. One submission refers to the fact that the Protocol does not address adventitious/unintended presence of LMOs in a non-LMO shipment because non-LMO shipments fall outside of the Protocol. The submission, therefore, implies that the consideration of the issue under the Protocol would not be appropriate. It, in fact, proposes that the issue of thresholds be left to other appropriate standard-setting bodies such as the International Plant Protection Convention (IPPC), and the Codex Alimentarius Commission, which are undertaking relevant work.

24. Another submission considers the issue of thresholds as complex due to testing limitations and the nature of bulk grain production, handling and transportation systems. The submission describes the documentation requirement under paragraph 2 (a) of Article 18 and Article 17 as mutually exclusive. According to the submission, the "may contain" documentation is for identifying cargoes while Article 17 addresses unintentional transboundary movement of an LMO that is likely to have significant adverse effect to biological diversity. This view was supported by other submissions. The grain industry group reiterated the same. One submission stated that the obligation to notify in case of unintentional transboundary movement of LMOs under Article 17 does not appear to be pertinent to adventitious or technically unavoidable presence of LMOs given that LMOs-FFP are not intended for introduction into the environment. Another submission also mentioned that there is no direct linkage between the provisions of Article 18 and Article 17.

25. The submissions from the industry groups and some other governmental submissions also expressed their support to a 5 percent threshold for adventitious presence or a 95 per cent purity level as a temporary measure until specific thresholds are developed based on scientific risk analysis. In this context, the grain industry group encourages the Codex Alimentarius Commission and IPPC to speed up the development of science based risk management thresholds for LMO material in non-LMO products.

5. LMO sampling and testing techniques

26. One submission suggests that the Open-ended Technical Expert Group note that a range of sampling and testing technologies were currently available with each test having its own strengths and weaknesses. The submission, therefore, proposes that the most suitable method for each LMO must be determined on a case-by-case basis. It also referred to the works of other bodies in developing frameworks for harmonization of tests for LMOs, such as that of the Codex Committee on Methods and Analysis of Sampling. Other submissions emphasized the importance of establishing and standardizing methods for detection, sampling, analysis and verification of LMOs.

C. 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

27. Several submissions have favoured the use of unique identifier codes to identify LMOs-FFP in accompanying documentation. A number of these submissions welcomed the OECD unique identifiers (UIDs) for GMO plants. While some Governments have already begun requiring applicants to apply the UIDs and thus are gaining some experience, many, however, indicated, in their submissions that they have no experience in actually using these codes.

28. One submission indicated that the format developed by the OECD for unique identifiers for transgenic plants has already been adopted for implementation as part of its own regulatory framework. The submission further suggests that it might be helpful for documentation specifying the unique identifier also to quote the Internet address of the Biosafety Clearing-House so as to facilitate access to the additional information that may be available from the Biosafety Clearing-House. In case of a mixture of LMOs, the submission states that there is a need to provide a list of UIDs assigned to the GMOs that form the mixture. The submission also supports the provision of both the transformation event(s) and the UIDs on the accompanying documentation until the operators become more acquainted with the UID system. It points out that some national authorities are still more familiar with the transformation event than the UID, and may not also have access to the Biosafety Clearing-House in the short term.

29. Another submission, on the other hand, favours the use of only UIDs on accompanying documentation instead of technical information such as taxonomic name, gene modifications inserted and traits or genes changed. According to this submission the inclusion of such technical information on the accompanying documentation would complicate the whole purpose and operation of the documentation. It further argued that technical information is not always necessary for someone who does not have the necessary expertise and knowledge on GMOs. The submission suggests that in order to distinguish between LMOs that are approved and those that are not, the information that would be unlocked from the Biosafety Clearing-House using the UID should be the one listed in annex II of the Protocol. One submission indicated that it is in the process of implementing a UID, taking into consideration the OECD designation of UID codes and that relates for the time being only to experimental GMO seeds.

30. One submission expressed its concern that some Parties to the Protocol such as the Members of the European Union are requiring such codes before the existence of an international consensus on this matter under the Protocol. Another submission believed that the requirement for UID has yet to be demonstrated. According to this submission, it should be demonstrated whether UIDs are "necessary measures" in the words of paragraph 1 of Article 18. Even before resolving the issue of whether the use of UIDs was a necessary measure, the submission further argues that there is a need to take into account the experiences of countries in implementing the Protocol and a step-wise approach needs to be followed. The submission raises the questions as to what would happen if the identified list were inaccurate or incomplete, and whether and how any UID would be verified or subject to compliance, or liability-and-redress measure. It describes the UID system of the OECD as limited in scope as it focuses only on LMO plants; that the veracity and robustness of the information is not guaranteed; the use of the system is not standardized; and that the format of the use of the identifiers was not decided. The

submission further asserts that the UID system of the OECD is not sanctioned by a regulatory body and that it is voluntary and at an early stage of development. It also reminds that harmonizing the OECD system with other systems that cover LMO animals, microbes and viruses would be cumbersome and inefficient.

31. Another submission, on the other hand, considers that the OECD UID is a useful regulatory tool for accessing information within databases on a specific product. The submission states that the experience generally confirms that the UID system of the OECD for plants can be successfully implemented. It, however, highlights, on the basis of such early experience, some issues that still need to be resolved. These include: (i) UIDs are not always available for products that were reviewed a number of years ago; (ii) original applicants may no longer be in business or the business may be under new ownership; and (iii) how to handle products containing stacked events, an emerging issue, according to the submission.

32. The grain industry group generally supports the use of an internationally recognized and applicable UID system for commercially available products in order to remove confusion and facilitate improved understanding regarding commercial products. Their submission, however, states that the UID codes should be used within the Biosafety Clearing-House, and not on shipping documentation. They also mentioned, in this connection, that increased segregation is estimated to increase the costs in the order of 10-25 percent.

III. OPTIONS OF ELEMENTS FOR A DRAFT DECISION

33. The Open-ended Technical Expert Group may wish to consider the following options of elements with a view to elaborating a draft decision for the consideration of the Conference of the Parties at its second meeting as the meeting of the Parties to the Cartagena Protocol. These options are neither exhaustive nor put in any order of importance or preference. They are derived from the submissions synthesized in the preceding section, and 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 relating to paragraph 2(a) of Article 18. The structure of the options follows the structure of the issues identified in the terms of reference of the Group. Accordingly, the following options are presented in two parts in order to reflect the order of priority that the Conference of the Parties serving as the meeting of the Parties to the Protocol attached to the issues as stipulated in the terms of reference of the Group.

Part I

(a) The documentation to accompany LMOs-FFP

Option 1:

A commercial invoice.

Option 2:

A stand-alone document:

- Agreed under the Protocol; or
- Provided (as a template) by national authorities.

Option 3:

Other document required or utilized by existing documentation systems.

(b) The information provided in the accompanying documentation

Statement or elements of a statement*:*

Option 1:

"Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

Option 2:

"This shipment contains living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

Option 3:

A clear identification that the shipment contains "living modified organisms".

Contact information*:*

Option 1:

The details of the last exporter and the first importer as a contact point for further information;

Option 2:

The details of the exporter, the importer, or any appropriate authority, when designated by a Government as a contact point for further information.

Option 3:

The contact point for further information, including the name and address of the consignee.

Information on the LMOs*:*

Option 1:

No information about the LMOs is necessary to be provided on the accompanying documentation as long as information is available on the BCH regarding all relevant LMOs-FFP subject to transboundary movement.

Option 2:

- Common, scientific and, where available, commercial names of the LMOs; and
- The transformation event codes of the LMOs;

Option 3:

Taxonomic name, the gene modifications inserted, traits or genes changed, information on the host as well as the donor organisms.

Other information (this information may be provided in addition to the information under each option above regardless of which option would finally be chosen)*:*

- Any requirements for safe handling, storage, transport and use;
- Declaration that the transboundary movement is in conformity with the Cartagena Protocol on Biosafety.

(c) The extent and modality of using unique identifiers

Option 1:

No unique identifiers on accompanying documentation.

Option 2:

No unique identifiers until the need is established through further experience in the implementation of the other identification/documentation requirements under paragraph 2 (a) of Article 18.

Option 3:

- OECD Unique Identifier for Transgenic Plants and other unique identifiers, where available; and
- Internet address of the Biosafety Clearing-House.

Part II

(d) Thresholds for adventitious or unintended presence of LMOs to trigger identification requirements

Thresholds for approved LMOs:

Option 1:

Thresholds for particular LMOs based on scientific risk analysis shall be adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol. The thresholds could be developed by other relevant international organizations such as the Codex Alimentarius Commission and IPPC.

Option 2:

National thresholds may be adopted or applied on a case-by-case basis by national authorities for particular LMOs or groups of LMOs taking into account the characteristics of the receiving environment.

Option 3:

No thresholds.

Option 4:

A temporary 5 per cent threshold of all commodity shipments where the LMO varieties of the commodity are widely grown.

Thresholds for unapproved LMOs:

Option 1:

No thresholds shall be acceptable for unapproved LMOs.

Option 2:

Thresholds may be adopted for unapproved LMOs at national level.

(e) Harmonization of sampling and detection techniques

Option 1:

One or more techniques that are most suitable for any particular LMO shall be determined and adopted as the standard technique(s) for that LMO.

Option 2:

Criteria for acceptability of sampling and testing techniques for any particular LMO shall be determined and any technique that meets the criteria may be used for that LMO.

Option 3:

The selection of the techniques or the establishment of criteria of acceptability of the techniques may be undertaken by other competent international organizations, or such undertaking may benefit from existing work on harmonisation of LMO sampling and testing techniques by those competent bodies, such as the Codex Committee On Methods and Analysis of Sampling.

IV. RECOMMENDATIONS

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

(a) Review the synthesis of information and views on the requirements of paragraph 2 (a) of Article 18, and other documents referred to in its terms of reference;

(b) Consider the options of elements highlighted in the preceding section of the present note in preparing a draft decision on the detailed requirements of identification of living modified organisms intended for direct use as food or feed, or for processing, for submission to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.
