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INTERGOVERNMENTAL COMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
Third meeting
The Hague, 22-26 April 2002
Item 4.1.5 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS (ARTICLE 18)

Note by the Executive Secretary

I. INTRODUCTION

1. The Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) addressed, in accordance with its work plan, the issues of handling, transport, packaging and identification of living modified organisms at its two previous meetings. At its second meeting held from 1 to 5 October 2001 in Nairobi, the ICCP made a number of recommendations as regards Article 18 as part of its preparations necessary for enabling the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol to take measures required to implement the provisions of the Article. The discussions and recommendations of the ICCP were largely confined to paragraph 2 of Article 18 regarding documentation accompanying living modified organisms.

2. With regard to paragraphs 2 (b) and 2 (c) of Article 18, the ICCP, following the recommendation of the technical experts' meeting held in Paris from 13 to 15 June 2001 that dealt with the two paragraphs, invited the Sub-Committee of Experts on the Transport of Dangerous Goods of the United Nations, the Interim Commission on Phytosanitary Measures, the Organisation for Economic Co-operation and Development, Codex Alimentarius Commission and other relevant international organizations to provide advice, in writing, on their ability to assist Parties to meet the requirements of Article 18 of the Protocol, and on their capacity to adjust their systems should adjustment be necessary. The ICCP requested the Executive Secretary to develop a model template that could be used as a stand-alone template tailored on existing systems, or be integrated into existing international documentation. It further requested the Executive Secretary to convene a Government-nominated technical experts' meeting to consider and make recommendations on the modalities of information requirements under paragraphs 2 (b) and 2 (c) of Article 18 based on the recommendation of the Paris technical experts' meeting and the model template, and on linkages of the two paragraphs to paragraph 3 of the same Article.

* UNEP/CBD/ICCP/3/1.

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3. The ICCP had also made several recommendations as regards paragraph 2 (a) of Article 18. It made recommendations that it considered would, on the one hand, facilitate the immediate implementation of the requirement contained in the first sentence of the paragraph once the Protocol enters into force, and on the other, help contribute to the process of addressing the issues involved in the second sentence of the same paragraph. In that regard, it requested Parties, Governments and relevant international organizations to provide any views as well as relevant information to the Executive Secretary regarding (a) the appropriate implementation of the requirement contained in the first sentence of paragraph 2 (a) of Article 18, by the time of entry into force of the Protocol, and (b) the requirements of each element of paragraph 2 (a) of Article 18. The ICCP requested the Executive Secretary to prepare a synthesis report of the views and relevant information, and to convene another technical experts' meeting, back-to-back after any meeting of technical experts on paragraphs 2 (b) and 2 (c) of Article 18, that would consider, in a stepwise manner:

(a) First, the modalities, prior to entry into force, of the implementation of the requirement contained in the first sentence of paragraph 2 (a) of Article 18; and then

(b) The identification of issues to be addressed beyond entry into force, in preparation for the decision referred to in paragraph 2 (a) of Article 18.

4. Accordingly, the meeting of technical experts on paragraphs 2 (b) and 2 (c) of Article 18, and the one on paragraph 2 (a) of Article 18 were convened in Montreal from 13 to 15 March 2002 and from 18 to 20 March 2002, respectively to consider those issues identified to them by the ICCP.

5. The reports of the two meetings will be made available as addenda to the present document (i.e., UNEP/CBD/ICCP/3/8/Add.1 and UNEP/CBD/ICCP/3/8/Add. 2). The present document contains the large portions of the substantive sections of the notes prepared by the Executive Secretary for the purpose of the two meetings of technical experts for further consideration by the third meeting of the ICCP, as appropriate. In that regard, the synthesis of views and information concerning the requirements under paragraph 2 (a) of Article 18, and the note on the modalities of information requirements in accompanying documentation under paragraphs 2 (b) and 2 (c) of Article 18 are included in sections II and III below, respectively.

II. A SYNTHESIS OF VIEWS AND RELEVANT INFORMATION REGARDING THE REQUIREMENTS OF PARAGRAPH 2 (a) OF ARTICLE 18 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

6. In response to the request made at the second meeting of the ICCP, and the notifications issued by the Executive Secretary to all Parties to the Convention, Governments and relevant international organizations to provide views and information regarding:

(a) The appropriate implementation of the requirement contained in the first sentence of paragraph 2 (a), Article 18 by the time of entry into force of the Protocol; and

(b) The requirements of each element of paragraph 2 (a) of Article 18,

as at 10 February 2002, Argentina, Australia, Canada, Czech Republic, Equatorial Guinea, the European Union, the Republic of Korea, Norway, Slovenia, Switzerland, Tunisia, and the United States had submitted their views and information. Romania stated that it has not yet established a labelling system. Viet Nam indicated that it has no comments. The International Grain Trade Coalition also submitted its views and information as requested. Following is the synthesis of views and information received by the Executive Secretary and the full text of each submission is compiled and made available in document UNEP/CBD/ICCP/3/INF/5.

A. Implementation of the requirement contained in the first sentence of paragraph 2 (a) of Article 18

7. The submissions may generally be regarded as representing mainly two different approaches concerning modalities of implementation of the requirements contained in paragraph 2 (a) of Article 18 in general, and the requirement contained in the first sentence of the paragraph, in particular.

8. One of these two groups of submissions is generally in favour of implementing the requirement of identification of transboundary movements of living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs) contained in the first sentence of paragraph 2 (a) of Article 18, at the entry into force of the Protocol, by modifying, amending, or inserting language into existing commercial invoice or standard invoice or other documentation provided by the originator of the shipment or required by the existing international documentation systems. There is an indication made, in one of the submissions, that they would rather remain open in the future to consider the question of a Protocol-specific documentation.

9. Some of these submissions have gone further and proposed wording or language that may be specified in the accompanying documentation, including the following variants:

Suggested wording 1:

"This shipment may contain living modified organisms for direct use as food or feed, or for processing. This shipment is not intended for intentional introduction into the environment."

Suggested wording 2:

"Cartagena Protocol on Biosafety Information: This shipment is intended for direct use as food or feed, or for processing and may contain living modified organisms. This shipment is not intended for intentional introduction into the environment. Further information on this shipment may be obtained from the contact point(s) identified above."

Suggested wording 3:

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

10. According to this group of submissions, the use of such modified commercial invoice would meet the requirements contained in the first sentence of the paragraph in question while satisfying the principles of making the accompanying documentation simple, visible and legible. It is also pointed out that this modality would have less interference with existing commercial international grain trade, which is complex in terms of volume, operation, and parties involved. Should additional information be required regarding, in particular the specific LMO-FFP that may be contained in any particular shipment, or any specific handling requirements, these submissions suggest that it should be drawn from the Biosafety Clearing-House database. With regard to contact point, the proposals include to specify: (i) those who are responsible in a particular foreign trade operation (firms); (ii) be identified by the representative of the originating party; (iii) the exporter, as the generator of the accompanying documentation; or (iv) the last seller or the first buyer, as the most knowledgeable about the contents of the cargo.

11. One submission suggests that due to unavoidable adventitious presence of LMOs in bulk shipments, a non-LMO purity level of 95% be adopted and, as a temporary measure, shipments containing less than 5% of LMO-FFPs be exempted from the identification requirement of the Protocol. This submission has also indicated the importance of appropriate technology for sampling and testing in order to determine the presence of LMOs and suggested that testing protocols be developed outside of the Protocol through the use and cooperation of relevant international bodies. Another submission indicates a 1% and 3% thresholds of mandatory identification for genetically modified food products or derived food products, and for single feed products, additives, or conservative agents, respectively provided for in the relevant domestic law.

12. The other group of submissions generally supports the inclusion of more information in particular, the identity (the species, in case of a couple of submissions) of the specific LMOs contained within the LMO-FFP shipment and associated requirements, in accompanying documentation or in a label. In fact, according to one of these submissions, specifying the LMOs known to be present or may be present within shipments of bulk commodities is important, to allow importing countries to verify whether such LMOs have been approved and posted on the Biosafety Clearing-House and also whether they comply with the requirements of the domestic regulatory framework of the Party of import. According to this submission, the broad application of the wording "may contain" may not be the appropriate way to implement paragraph 2 (a) of Article 18 as such minimal wording may create uncertainty in certain cases. It is argued that the transboundary shipments known to contain LMO-FFPs can be identified as containing LMO-FFPs rather than merely "may contain".

13. The submission further argues that in the case of commingled bulk commodities where the maintenance of the original composition of the contents of the shipment cannot be assured, the determination of the identity of individual LMO-FFPs contained in the shipment would change from the list of LMO-FFPs "actually present" to the list of LMO-FFPs which are "known to be present" or "may be present" at the origin. Another submission suggests that if non-LMO products are likely to be mixed in the process, the shipment should be identified as "may contain", but when LMOs are included (knowingly?), in non-LMO products, the shipment should be identified as "contains LMOs". This submission further proposes that a certificate indicating the absence of LMOs prohibited in the Party of import be also included. Similarly, another submission supports a verification of the consent to import the specific LMO into the Party of import.

14. With regard to contact point for further information, it is suggested by one submission that such contact point should have an official character and its responsibilities, the type of information that may be considered as further required as opposed to that which should be made readily available, and the modalities how such information would be made available, need to be further clarified.

B. Requirements of each element of paragraph 2 (a) of Article 18

15. This aspect of the issue, which seems to deal with all the requirements of paragraph 2 (a) of Article 18, has been generally understood to mean addressing those elements of the second sentence of the paragraph. In the case of one submission, however, all elements of both sentences have been identified and discussed in the context of the linkages that exist among them.

16. Some of the submissions are of the view that the primary focus at this stage should be on creating a common and appropriate ground for the implementation of the requirement contained in the first sentence of paragraph 2 (a) of Article 18 at the time of entry into force of the Protocol. It is argued that some experience should be gained regarding the implementation of the requirement in the first sentence before considering the detailed requirements indicated in the second sentence.

17. One submission suggests that a process of feedback on the effectiveness of the implementation of the requirement in the first sentence might be constituted by the Conference of the Parties serving as the meeting of the Parties to the Protocol, to be used as a basis for considering the detailed requirements contained in the second sentence. The process of taking a decision under the second sentence is proposed to follow within the time frame specified, and on the basis of reviewing the effectiveness of measures taken in implementing the requirement in the first sentence. According to another submission, the Conference of the Parties serving as the meeting of the Parties to the Protocol, may consider, during the two year time following entry into force of the Protocol, through an expert committee, the effectiveness of the requirement in the first sentence to protect global biological diversity, and the operational and cost implications of different options to implement the unique identifier requirement contained in the second sentence of the paragraph.

18. Other submissions on the other hand argue that the implementation of the requirement in the first sentence is linked to the elements of the detailed requirements indicated in the second sentence. The need for specifying the identity and any unique identification of the LMO-FFP is emphasized. According to one submission, the question of specifying the identity of each LMO indicated in the second sentence is

linked to Article 11 of the Protocol in that, there is a need to ensure that only LMO-FFPs that are: (i) domestically approved; (ii) posted to the Biosafety Clearing-House; and (iii) those exclusively intended for direct use as food or feed, or for processing, and not those intended for intentional introduction into the environment, are contained in any transboundary shipment.

19. It is further suggested that for identity to be specified in an unambiguous manner, a global unique identification system need to be put in place taking into account the work of relevant international organizations, in particular that of the Organisation for Economic Co-operation and Development (OECD). According to this submission, unique identifier should be included as part of the accompanying documentation for each LMO-FFP which is known to be present or may be present, and this need to be implemented as soon as possible and ideally at the time of entry into force of the Protocol. The decision referred to in the second sentence required to be taken within two years after entry into force of the Protocol as regards detailed requirements, including unique identification is, therefore, suggested to be a priority item at this stage, so that it would be taken at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. In this regard, another submission highlighted that all the requirements of paragraph 2 (a) of Article 18 would remain unclear until the decision envisaged in the second sentence of the paragraph is made by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

20. There are also views suggesting that the Secretariat may be requested to prepare, on the one hand, a survey report on possible unique identification systems, and a template of documentation tailored to the requirements of paragraph 2 (a) of Article 18 on the other. It is suggested, in one other submission, that Parties to the Protocol need to get financial and technical assistance for taking measures and adjusting their systems, as appropriate, with a view to implement the requirements contained in the paragraph.

III. MODALITIES OF INFORMATION REQUIREMENTS FOR ACCOMPANYING DOCUMENTATION UNDER PARAGRAPHS 2(b) AND 2(c) OF ARTICLE 18, AND LINKAGES TO PARAGRAPH 3 OF ARTICLE 18

21. The Executive Secretary, with the assistance of Switzerland, has developed, in response to the request of the second meeting of the ICCP, model templates of accompanying documentation and submitted to the meeting of the technical experts as basis for its discussion. The model templates aim to incorporate the information requirements of the Protocol specified under paragraphs 2 (b) and 2 (c) of Article 18 for the purpose of identifying living modified organisms destined for contained use and those intended for intentional introduction into the environment. The proposed templates may be used as stand-alone documents or integrated into existing documentation, where appropriate.

22. The draft model templates as presented to the meeting of technical experts held in Montreal, from 13 to 15 March 2002, are contained in an annex to this note.

A. Linkages between paragraphs 2 (b) and 2 (c) of Article 18 and paragraph 3 of the same Article

23. Paragraphs 2 (b) and 2 (c) of Article 18 provide for the documentation requirements of those living modified organisms destined for contained use, and those intended for intentional introduction into the environment respectively, for the purpose of identifying the living modified organisms during intentional transboundary movement. According to paragraph 2 of Article 18, each Party, is obliged to take measures for the identification of LMOs by requiring that documentation accompanying the shipment provide information on the content, identity, and intended use of the LMOs, including contact point details. The modalities of taking such measures might include the adjustment of existing laws, regulations or guidelines or the adoption of new ones. These are measures that need to be established essentially at the national level, and implemented by all concerned parties that are involved in the export of living modified organisms destined for contained use or intended for intentional introduction into the environment.

24. On the other hand, in accordance with paragraph 3 of Article 18, the Conference of the Parties serving as the meeting of the Parties to the Protocol is required to consider whether the development of standards for the identification, handling, packaging and transport of living modified organisms would be necessary, and if so what the modalities of developing them would be. According to this paragraph, international standards, including standards for identification are envisaged presumably with a view to harmonizing national measures and other relevant practices.

25. A possible argument concerning the linkages between paragraphs 2 (b) and 2 (c) and paragraph 3 of Article 18 could, therefore, be that, to the extent paragraph 2 of Article 18 in general, and paragraphs 2 (b) and 2 (c) in particular, specify the basic requirements of documentation in accordance with the nature and intended use of the LMOs, they are providing the principal elements of standards for identification that otherwise would have been addressed under paragraph 3 of Article 18. The requirements of information set out in paragraphs 2 (b) and 2 (c) of Article 18, therefore, seem to constitute some kind of standards with regard to identification. The work relating to these paragraphs would eventually contribute to any work under paragraph 3 of Article 18 once the Conference of the Parties serving as the meeting of the Parties to the Protocol considers the modalities of information requirements for accompanying documentation under paragraphs 2 (b) and 2 (c) of Article 18 and arrives at a conclusion to develop more broadly applicable standards in consultation with other relevant international bodies. On the other hand, if standards for handling, packaging and transport of living modified organisms, were developed under paragraph 3, such standards would need to be observed during intentional transboundary movements and would presumably have to be specified on the accompanying documentation as provided in paragraphs 2 (b) and 2 (c) of Article 18.

26. It may be important to note that the modality of identification in the context of paragraph 2 of Article 18 may be limited only to conveying the information required using documentation accompanying consignments that involve the living modified organisms in question. But for the purpose of paragraph 3, it might be possible to envisage identification more broadly where Parties may wish to consider other modalities, including labelling in the sense of putting certain data on the product package or container for the purpose of providing others with a minimum knowledge about its contents.

27. An issue that would need to be borne in mind, when considering the development of standards for handling, transport, packaging and identification in the context of Article 18, is the extent to which such standards would be compatible with other international agreements, in particular those under the World Trade Organization (WTO). The first expert meeting found that there were existing agreements or arrangements of which rules or standards might have been relevant to the requirements of paragraphs 2 (b) and 2 (c) of Article 18. Following the recommendation of the experts' meeting, consultations have already begun, in particular with the United Nations Economic and Social Council (ECOSOC) Sub-Committee of Experts on the Transport of Dangerous Goods, through its Secretariat—the United Nations Economic Commission for Europe (ECE); the Interim Commission on Phytosanitary Measures under the International Plant Protection Convention (IPPC); the Organisation for Economic Co-operation and Development (OECD); and other relevant international organizations, with a view to exploring the potential of existing relevant rules and standards under their auspices to address the requirements of the Protocol. These consultations are bound to address not only issues and requirements under paragraphs 2 (b) and 2 (c) of Article 18 but also, albeit implicitly, those under paragraph 3 of the same article.

B. A summary of responses received from some international organizations

28. As indicated above, the first expert meeting recommended inviting relevant international organizations to provide advice on their ability to assist Parties to meet the requirements of Article 18 of the Biosafety Protocol. The recommendation was subsequently endorsed by the ICCP, at its second meeting, and conveyed by the Executive Secretary to relevant organizations. In response to the invitation, OECD, the ECOSOC Sub Committee of Experts on the Transport of Dangerous Goods, through ECE, and WTO have communicated to the Executive Secretary, their views and information regarding systems

under their auspices that are relevant to one or the other aspect of Article 18 of the Biosafety Protocol. There follows as summary of the views and information received by the Executive Secretary and the full text of each submission has been compiled and made available as an information document (UNEP/CBD/ICCP/3/8/INF/5). It should be noted that the following summary reproduces the terminology used in the original submissions to refer to products of modern biotechnology (for instance, "GMOs" for "genetically modified organisms").

1. Organisation for Economic Co-operation and Development (OECD)

29. OECD submitted, before the second meeting of ICCP, information about the OECD "seed schemes", which are reported to have been practically tested and broadly used even with the participation of non-OECD countries for shipping seed across borders. It is estimated that 90 per cent of the internationally recognized seed shipments are being made under these schemes. The OECD schemes were established in 1958 and they cover close to 25,000 varieties representing some 200 species. According to the submission, the schemes have, over time, demonstrated flexibility in responding to both the public and the private sector and forging the necessary coordination, and in using the OECD documentation as a support for other official information requirement purposes. It has been indicated that discussions are under way on the issues of advanced breeding methods, identification of genetically modified varieties as well as thresholds for the presence of GMOs in conventional seed. These issues are admittedly some of the difficult ones that are under consideration.

30. OECD has once again communicated to the Executive Secretary, in response to the notification on the recommendations of the second meeting of ICCP, and confirmed that the development of a unique identification system could be another area for possible cooperation. It has been pointed out that an OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology is in the process of developing a unique identification system for transgenic plants.

31. The OECD Working Group met from 14 to 16 January 2002 to continue discussing the issue of development and designation of the unique identifier. The Working Group has come up with a proposed "Guidance for the designation of the OECD unique identifier for transgenic plants". The purpose of the unique identifier, as indicated in the first item of the Guidance, is "for the use as a key to accessing information in the OECD product database and interoperable systems for the products of modern biotechnology which have been approved for commercial application". It is envisaged that the unique identifier should be a "key" to unlocking more detailed information in the OECD product database and other interoperable systems such as the Biosafety Clearing-House of the Protocol. It was also indicated that the desire has been to build the system in a flexible way with a view to potentially serve as the core unique identifier for future developments.

2. World Trade Organization (WTO)

32. In response to the ICCP request, WTO has submitted information, which might have a bearing on Article 18 of the Protocol, in particular its paragraphs 2 (b) and 2 (c). According to the submission, WTO members have obligations relating to "transparency" of their sanitary or phytosanitary measures under article 7 and annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

33. It has been pointed out that WTO members are required to notify newly proposed SPS regulations or changes to existing ones, in cases where there are no international standards, guidelines or recommendations, or where the proposed regulations tend to deviate substantially from the existing standards and may have significant effect on trade. It is also indicated that similar obligations of transparency and notification exist under the Agreement on Technical Barriers to Trade (the TBT Agreement) with regard to technical regulations. According to the submission, while it is a right to introduce technical regulations in case of emergency without prior notification, it is also a duty to notify such measures immediately after their introduction.

34. It has been reported that in complying with their notification requirements under both agreements, several WTO members have notified measures dealing with products derived from biotechnology.

Accordingly, as at the date of the submission, 55 GMO-related SPS notifications from 16 countries, and 43 TBT notifications from 16 countries were received by the WTO and circulated to members.

3. ECOSOC Sub-Committee of Experts on the Transport of Dangerous Goods

35. The Sub-Committee of Experts on the Transport of Dangerous Goods was immediately informed of the outcomes and recommendations of the first technical expert meeting and the second meeting of the ICCP. The Sub-Committee considered the matter on the basis of notes (UN/SCETDG/19/INF.20 and UN/SCETDG/20/INF.25) submitted to it by its secretariat at its nineteenth and twentieth sessions, held from 2 to 6 July 2001 and 3 to 11 December 2001, respectively.

36. At its nineteenth session, the Sub-Committee considered the results of the deliberations of the experts meeting on paragraphs 2 (b) and 2 (c), on the basis of a note submitted to it by its secretariat, and took note of the recommendation addressed to relevant international organizations, including the Sub-Committee, calling them to provide advice on their ability to assist Parties to meet the requirements under paragraphs 2 (b) and 2 (c) of Article 18 and on their capacity to adjust their systems, as appropriate, so as to allow the requirements of the Protocol to be integrated into existing systems. In particular, the secretariat's note highlighted, based on the discussions of the Paris experts meeting, the specific areas or provisions of the United Nations Recommendations on the Transport of Dangerous Goods (hereinafter "the Model Regulations") where possible adjustments could be considered in order to address cases of living modified organisms under paragraphs 2 (b) and 2 (c) of Article 18, as appropriate. After an exchange of views on the matter, the Chairman of the Sub-Committee requested the expert from Canada to continue in her role as a coordinator in that regard, in accordance with the mandate entrusted to her previously by the Sub-Committee, and invited all the other experts to reflect on the matter and consult with the expert from Canada.

37. The relevant recommendations from the second meeting of ICCP were brought to the attention of the Sub-Committee at its twentieth session. As indicated in the report of that session (ST/SG/AC.10/C.3/40), the Sub-Committee discussed the question of cooperation with ICCP. It noted the recommendations of the second meeting of the ICCP and reaffirmed that the transport of some genetically modified organisms, to which ICCP has appropriate expertise, was subject to the provisions of the Model Regulations on the Transport of Dangerous Goods. The Sub-Committee agreed to establish cooperation with ICCP on matters concerning handling, packaging, transport and identification, and indicated that the provisions of the Model Regulations may be amended to accommodate the transport regulatory needs of the Cartagena Protocol on Biosafety on the basis of concrete proposals. In other words, the Sub-Committee is advising, in response to the request made to it by the second meeting of ICCP, on the possibility of adjusting the Model Regulations in a way that would satisfy the requirements of Article 18 provided a clear proposal comes from the ICCP or the process under the Biosafety Protocol. The Sub-Committee is to have an informal working group meeting in Paris from 11 to 13 March 2002. The purpose of the meeting is to look at the requirements in the Model Regulations for transporting infectious substances, Class 6.2, to consider submissions for changing those requirements, and to develop a proposal regarding any changes to the Model Regulations for consideration by the Sub-Committee at its meeting scheduled for July 2002 in Geneva.

IV. RECOMMENDATIONS

38. The ICCP may wish to:

(a) Consider the report and recommendations of the meetings of technical experts on paragraphs 2 (b) and 2 (c) of Article 18, on the one hand, and paragraph 2(a) of Article 18, on the other, held in Montreal, from 13 to 15 March and 18 to 20 March 2002, respectively (UNEP/CBD/ICCP/3/7/Add. 1 and 2); and

(b) Make appropriate recommendations, taking into account the recommendations of the two technical experts' meetings, to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

Annex

CARTAGENA PROTOCOL ON BIOSAFETY: PROPOSED MODEL TEMPLATES FOR DOCUMENTATION UNDER PARAGRAPHS 2 (B) AND 2 (C) OF ARTICLE 18

Background

1. The Cartagena Protocol on Biosafety is an international agreement that aims to contribute to the safe transport, handling and use of living modified organisms (LMO) derived from modern biotechnology. It attempts to achieve a balance between the free flow of goods in international trade and the conservation and sustainable use of biological diversity, by regulating the movement of LMOs from one country to another. Adopted by Parties to the Convention on Biological Diversity (CBD) on 29 January 2000 in Montreal, Canada, it is currently in the process of ratification around the world. Much preparatory work is under way to ensure that the proper mechanisms and instruments are in place when the Protocol enters into force.

2. Article 18 of the Protocol provides for the requirements on **handling, transport, packaging and identification** of living modified organisms. Paragraph 2 of Article 18 specifies the identification requirements of living modified organisms in accordance with their intended use. Paragraphs 2 (b) and 2 (c) of Article 18, which are the subject of this note, specify the information requirements needed for documentation accompanying the transboundary movement of living modified organisms destined for contained use, and those intended for intentional introduction into the environment respectively (see table 1).. At its second meeting in Nairobi, Kenya from 1-5 October 2001, the Intergovernmental Meeting for the Cartagena Protocol (ICCP-2) requested the Executive Secretary to "develop a model template that could be used as a stand-alone template tailored on existing system, or be integrated into existing international documentation, to be considered as a basis for discussion by the meeting of technical expert" (UNEP/CBD/ICCP/2/15, annex, recommendation 2/10).

3. Switzerland, represented at the second meeting of ICCP by the Swiss Agency for Environment, Landscape and Forest (SAEFL), proposed to assist the Secretariat in developing model templates for the categories of LMOs described in Article 18.2 (b) and (c). The present version of the model templates have been finalized in the awareness that certain key issues regarding accompanying documentation, by their nature, still remain open at this point for further investigation and negotiation within the framework of the Cartagena Protocol implementation activities and/or other relevant international processes.

Comments to the Draft Templates (annexes I and II)

4. The proposed templates for Article 18.2 (b) and (c) may be used as stand-alone documents to accompany shipments of LMOs, or be integrated into existing international documentation, where appropriate

5. The following proposal includes not only blank templates but also examples of documentation:

(a) Examples for Article 18.2 (b):

(i) Virus-resistant papaya seeds;

(ii) Organisms falling into the definition of dangerous goods

(b) Examples for Article 18.2 (c) template

(i) Plant material for experimental field release

(ii) Seeds for commercial application

Table

INFORMATION REQUIRED BY THE PROTOCOL FOR DOCUMENTATION ACCOMPANYING TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS DESTINED FOR CONTAINED USE OR INTENDED FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT

Article	Information required in accompanying documentation
Article 18.2 (b) **Contained use**	• identification as LMOs • requirements for the safe handling, storage, transport and use • contact point for further information • name and address of the individual and institution to whom the LMOs are consigned (*consignee*)
Article 18.2 (c) **Intentional introduction into the environment**	• identification as LMOs • identity and relevant traits and/or characteristics specified • requirements for the safe handling, storage, transport and use • contact point for further information • name and address of importer and exporter (“as appropriate”) • declaration that “the movement is in conformity with the requirements of the Protocol applicable to the exporter”

Annex 1

Model Template for Article 18.2 (b)

- Blank form
- Examples
  - Virus-resistant papaya seeds
  - Organisms falling into the definition of dangerous goods

The following model templates may be used as stand-alone templates tailored on existing systems, or be integrated into existing international documentation.

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

COMPANY OR INSTITUTION LETTERHEAD

Pro Forma Invoice

Date _____

	Exporter	**Consignee – Contact Point***
Company or institution		
Contact person		
Street		
City, Postal Code		
Country		
Phone; Fax		
Email		

Shipping details	**Shipper reference number**	**Shipper contact details**

Item	**Amount**	**Weight/Volume**	**Description****	**Value**
			LMO*: Name Risk Group This LMO is for contained use and not for intentional introduction into the environment.	

Any requirements for safe handling, storage, transport and use*****	

I declare all the information contained in this invoice to be true and correct

Signature of exporter_____ Date_____

* *Information specifically required by Article 18.2 (b) of the Cartagena Protocol*

** *Based on information to be provided for standard commercial invoices. (see http://www.fedex.com/ch/tools/invoice.html?link=4)*

*** *Other international regulations may apply, as appropriate.*

EXAMPLE 1 FOR ARTICLE 18.2 (b) OF THE CARTAGENA PROTOCOL

COMPANY OR INSTITUTION LETTERHEAD

Pro Forma Invoice

Date _____

	Exporter	**Consignee – Contact Point**
Company or institution		
Contact person		
Street		
City, Postal Code		
Country		
Phone; Fax		
Email		

Shipping details	**Shipper reference number**	**Shipper contact details**

Item	**Amount**	**Weight/Volume**	**Description**	**Value**
1	1 Bag	500 g	**LMO:** Papaya, virus-resistant Seeds This LMO is for contained use and not for intentional introduction into the environment.	-

Any requirements for safe handling, storage, transport and use	**None**

I declare all the information contained in this invoice to be true and correct

Signature of exporter_____ Date_____

EXAMPLE 2 FOR ARTICLE 18.2 (c) OF THE CARTAGENA PROTOCOL

Shippers Declaration of Dangerous Goods

Shipper: Name Company or Institution Address Phone number	Air Waybill No: 123456789 Page 1 of 1 Pages Shipper's Reference Number sso (optional)
Consignee and Contact Point: **Company or Institution** **Contact Person** **Street, City** **Postal Code, Country** **Phone, Fax** **Email**	
Two Completed and signed copies of this Declaration must be handed to the operator	**WARNING**
TRANSPORT DETAILS Airport of Departure This shipment is within the limitations prescribed for: *delete non-applicable)* PASSENGER ~~CARGO~~ AND CARGO ~~AIRCRAFT~~ AIRCRAFT ~~ONLY~~ Airport of Destination:	Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent. Shipment Type: (*delete non-applicable*) NON-RADIOACTIVE ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

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Dangerous Goods Identification							
Proper-Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of Packing	Packing Instruction	Authorization
Infectious Substances Affecting Humans (Human Adenovirus serotype 2)	6.2	UN 2814			1 Fiberboard Box ("Safe-T-Pak") x 25.0 mL	602	
This LMO is for contained use and not for intentional introduction into the environment.							
Dry Ice	9	UN1845	III		1 x 12.4Kg 1 Overpack Used	904	

Additional Requirements for Safe Handling, Storage, Transport and Use

Prior Arrangements As Required By The IATA Dangerous Goods Regulations 1.3.3.1 Have Been Made. IATA/ICAO USED

This material should only be used in a certified Safety Level 2 Facility

24 hr. Emergency Contact Telephone No. Chemtrec 800/424-9300

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.	Name/Title of Signatory Name/Title of Signatory Place and Date City, State, Country Date Signature (*see warning above)*

/…

Annex II

Model Template for Article 18.2 (c)

- Blank form
- Examples:
  - Plant material for experimental field release
  - Seeds for Commercial application

The following model templates may be used as stand-alone templates tailored on existing systems, or be integrated into existing international documentation

BLANK TEMPLATE FOR ARTICLE 18.2 (c) OF THE CARTAGENA PROTOCOL

COMPANY OR INSTITUTION LETTERHEAD

Pro Forma Invoice

Date _____

	Exporter	**Importer – Contact point***
Company or institution		
Contact person		
Street		
City, Postal Code		
Country		
Phone; Fax		
Email		

Shipping details	**Shipper reference number**	**Shipper contact details**

Item	**Amount**	**Weight/Volume**	**Description****	**Value**
			LMO: **Identity, relevant traits and/or characteristics*** Harmonized code (where possible) Intended use: research or commercial Regulatory status in the importing country: authorized, submitted or other	

Any requirements for safe handling, storage, transport and use*	

I declare all the information contained in this invoice to be true and correct and that **this shipment is in conformity with the requirements of the Cartagena Protocol**.*

Signature of exporter_____ Date_____

* Information specifically required by Article 18.2 (c) of the Cartagena Protocol

** Based on information to be provided for standard commercial invoices. (See http://www.fedex.com/ch/tools/invoice.html?link=4)

EXAMPLE 1 FOR ARTICLE 18.2 (c) OF THE CARTAGENA PROTOCOL

COMPANY OR INSTITUTION LETTERHEAD

Pro Forma Invoice

Date _____

	Exporter	**Importer – Contact point**
Company or institution		
Contact person		
Street		
City, Postal Code		
Country		
Phone; Fax		
Email		

Shipping details	**Shipper reference number**	**Shipper contact details**

Item	**Amount**	**Weight/Volume**	**Description**	**Value**
1	2 bags	5 Kg	**LMO**: **Rice, fungal -resistance** Seeds Intended use: research Regulatory status in the importing country: authorized for experimental field release (Permit RICE3434-02)	-

Any requirements for safe handling, storage, transport and use*	**Not to be used for human consumption or animal feed, commercial sales or unauthorized transfers** **See also the conditions of Permit RICE3434-02**

I declare all the information contained in this invoice to be true and correct and that **this shipment is in conformity with the requirements of the Cartagena Protocol**.

***Signature of exporter*_____ *Date*_____**

EXAMPLE 2 FOR ARTICLE 18.2 (c) OF THE CARTAGENA PROTOCOL

COMPANY OR INSTITUTION LETTERHEAD

Pro Forma Invoice

Date _____

	Exporter	**Importer – Contact point**
Company or institution		
Contact person		
Street		
City, Postal Code		
Country		
Phone; Fax		
Email		

Shipping details	**Shipper reference number**	**Shipper contact details**

Item	**Amount**	**Weight/Volume**	**Description**	**Value**
1	1000 bags	50'000 pounds	**LMO**: **Soybeans, high oleic acid** Harmonized code: BI-ABC891-8* Intended use: commercial seeds Regulatory status in the importing country: authorized for planting (Permit #GM21345/2002)	22'000 $

Any requirements for safe handling, storage, transport and use	**See the conditions of Permit #GM21345/2002**

I declare all the information contained in this invoice to be true and correct and **that this shipment is in conformity with the requirements of the Cartagena Protocol.**

***Signature of exporter*_____ *Date*_____**

*See OECD Guidance for the Designation of Unique Identifier for Transgenic Plants, 2002 – key to accessing databases that provide additional information on the LMO
