UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/1/7
2 December 2003

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
Kuala Lumpur, 23-27 February 2004
Agenda item 6.4 of the provisional agenda *

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

Note by the Executive Secretary

I. INTRODUCTION

1. Article 18 of the Cartagena Protocol on Biosafety provides for handling, transport, packaging and identification of living modified organisms (LMOs). The first paragraph of this Article requires each Party to take necessary measures to enable it to handle, package and transport LMOs under conditions of safety during intentional transboundary movement. Under the second paragraph of Article 18, each Party is under obligation to take measures that require the identification of LMOs in accompanying documentation. Article 18, paragraph 3 provides an opening for possible development of standards by the Conference of the Parties serving as the meeting of the Parties to the Protocol in the future, as may be needed, with regard to identification, handling, packaging and transport of LMOs within the scope of the Protocol.

2. The work plan of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), adopted under decision V/1 of the fifth meeting of the Conference of the Parties, included issues pertaining to Article 18. In fulfilling the work plan, at its three meetings ICCP dealt with those issues that were deemed important for decision-making by the Conference of the Parties serving as the meeting of the Parties to the Protocol, or for the smooth implementation of requirements, as appropriate, upon entry into force of the Protocol. The preparatory deliberations with regard to Article 18 were mainly focused on the issue of identification in the context of paragraph 2 of the Article.

3. During the preparatory process, technical expert meetings were also convened by the Executive Secretary in accordance with requests and recommendations of ICCP, with a view to facilitate the consideration of the relevant issues by ICCP itself and, subsequently, by the Conference of the Parties

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serving as the meeting of the Parties to the Protocol. One of these expert meetings took place in June 2001, in Paris, and two more were convened back-to-back in March 2002, in Montreal. Those expert meetings considered issues under paragraphs 2 (b) and 2 (c) and paragraph 2 (a) of Article 18, in accordance with the mandates given to them by ICCP. The reports of the technical expert meetings were made available to ICCP at its second and third meetings.

4. The resolution of several issues remained difficult at the third and last meeting of ICCP. Accordingly, with regard to paragraph 2 (a) of Article 18, the Intergovernmental Committee agreed to forward the issues identified at the expert meeting and, with respect to paragraphs 2 (b) and 2 (c) of Article 18, to submit the elements derived from the recommendations of the second expert meeting to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The present note presents those issues relevant to Article 18 in general and paragraph 2 of the same Article in particular, as identified and reviewed by the meetings of technical experts and by ICCP itself, with a view to assisting the Conference of the Parties serving as the meeting of the Parties to the Protocol in its consideration of the agenda item on Article 18.

5. Attached to the present note, in accordance with the recommendation of ICCP, is the full text of ICCP recommendation 3/6, including recommendations regarding paragraphs 2 (a), 2 (b) and 2 (c) of Article 18; a summary of the Chair of the Working Group that addressed paragraph 2 (a) of Article 18 at that meeting; and the report and recommendations of the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) of Article 18 held in March 2002. The Chair's summary reflects the different views expressed during the third meeting of ICCP concerning the requirement under Article 18, paragraph 2 (a).

6. Following the request made by ICCP at its third meeting, section II of the present note outlines information on existing standards, rules and practices of relevance to handling, packaging, transport and identification, including the ongoing processes on these matters under relevant international organizations. That section presents a synthesis of information on existing standards, rules and practices further to what has already been collected and reviewed for the purpose of ICCP process. The synthesis focuses on existing standards, rules and practices regarding identification and/or labelling of LMOs because the discussions that took place during ICCP preparatory process were largely confined to trying to find common ground as to what the requirements of identification were under the Cartagena Protocol and how should they be implemented.

7. Section III highlights those issues that have arisen in relation to the requirements of paragraph 2 (a) of Article 18 with the ultimate aim of providing some pertinent information to the Conference of the Parties serving as the meeting of the Parties to the Protocol in its consideration of the paragraph in general, and its second sentence in particular, i.e. taking a decision on the detailed requirements of identification, including specification of the identity of LMOs intended for direct use as food or feed, or for processing and any unique identification. Section IV presents a synthesis of views submitted further by Parties, other Governments and relevant international organizations in preparing for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Section V provides a conclusion and background to the elements of a draft decision proposed in the subsequent section. Finally, section VI presents possible elements of a draft decision for the consideration of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

II. INFORMATION ON EXISTING STANDARDS, PRACTICES AND RULES RELEVANT TO HANDLING, PACKAGING, TRANSPORT AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

8. Over the past few years, and particularly after the adoption of the Cartagena Protocol, public discussions and, in some cases regulations, on how to handle living modified organisms and on whether there is a need to have a system of identification or labelling have been evolving in a number of countries. These discussions and regulations are focused almost exclusively on genetically modified foods. The review of current trends in that regard indicates that quite diverse policy options are being pursued. For example, the policy questions arising in relation to labelling include: (i) should the system be voluntary or mandatory; (ii) which LMOs or products of LMOs have to be labelled; (iii) when should the labelling requirements be triggered (the question of threshold); (iv) what should be the content of the statement(s) of identification or labelling; (v) what are the methods of detection and verification (sampling and testing methodology); and (vi) should a non-LMO ("LMO/genetically modified organism (GMO) free") labelling be used. This section synthesises existing standards, practices and rules at the national, regional and international levels in this regard. The synthesis focuses more on recent policy developments regarding identification or labelling of LMOs in some jurisdictions. 1/

National and regional level

9. A number of countries are introducing new rules or strengthening old ones regarding requirements to identify or label genetically modified organisms and products. The following paragraphs summarize these requirements, as included in existing or evolving laws of some national and regional jurisdictions. The summary is not exhaustive and in some cases covers only the latest developments in this area in some countries and regions.

9. The Australia-New Zealand Food Authority (now replaced by the new Food Standards Australia-New Zealand) brought into effect new labelling rules for genetically modified foods on 7 December 2001. According to these rules genetically modified food products placed on the market in Australia and New Zealand must have their genetically modified (GM) status identified if modified genetic material or protein is present in the final food. The Government of New Zealand has also organized an interdepartmental working group to facilitate the development of a voluntary "GM-Free" Labeling System. According to the Government, the purpose of introducing the system is to assist businesses to meet consumer demands for information by labeling their food as GM-free.

10. In April 2003 the Government of Brazil issued a Decree (no 4.680) requiring all genetically modified foods to bear labels. The Decree requires foods or ingredients of foods with more than 1 per cent genetically modified material to be labelled.

11. In China, a law that requires the labelling of genetically modified seeds was introduced in 2000. In March 2003, Regulations on the Administration of Genetically Modified Agricultural Organisms entered into force, requiring all genetically modified produce listed in the regulations to be clearly labelled.

12. The Biotechnology Advisory Committee of Canada has submitted its report of 26 August 2002, "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada", to the Government of Canada Biotechnology Ministerial Coordinating Committee, recommending a voluntary labelling system for genetically modified foods. The system is recommended, as a beginning, that time be

1/ The synthesis draws largely on information available on the website of the International Service for the Acquisition of Agri-biotech Applications.

allowed for testing the adequacy and efficiency of labelling requirements and developing accepted international standards.

13. In February 2001, the Government of Hong Kong proposed that food containing more than 5 per cent of genetically modified materials to be labelled.

14. The draft law of Indonesia on Safety of Living Organisms of Biotechnological Products Produced Through Genetic Engineering requires all processed products packaged and made from transgenic organisms to be labelled, indicating that the producer uses material from transgenic organisms.

15. Since April 2001 the Ministry of Agriculture, Forestry, and Fisheries of Japan requires the labelling of 24 types of foods derived from genetically modified corn and soybeans. In 2002, the biotechnology scheme was further revised to include potato products in which introduced DNA or protein can be found.

16. The Republic of Korea Food and Drug administration requires labelling on processed foods that use soybean, corn or soybean sprouts enhanced through biotechnology. The threshold level for unintentional contamination of those ingredients by genetically modified material is three per cent. Since March 2002, the Ministry of Agriculture and Forestry requires unprocessed potatoes enhanced through biotechnology to be labelled if the shipment contains three per cent or more of biotech-enhanced component.

17. In Mexico, the Senate has approved a biosafety bill establishing the conditions of commercialization of genetically engineered crops and authorizing the creation of a labelling regime. The bill states that labels must identify products that are bio-engineered and reveal the purpose for which they are intended.

18. An Administrative Order issued on 3 April 2002 by the Department of Agriculture of the Philippines requires the documentation accompanying a regulated article (a listed organism included in the Order) to indicate that it is or may contain a genetically modified organism. The regulated article shall be identified with a label showing the permit number, name of the regulated article and, where applicable, the date of importation. As of July 2003, shipments containing GMOs for food, feed or for processing are required to be declared and cargoes may also be subject to random inspection. The details are still being worked out.

19. The 1999 Decree No. 12 of the Russian Federation refers to labelling of GMOs. In September 2002, new food safety regulations entered into force. The regulations require mandatory labelling of GMO products or products with GMO components. A list of GMO food products subject to mandatory labelling and those that do not need mandatory labelling is provided for in the regulations.

20. In February 2003, the Ministry of Agriculture of Saudi Arabia issued Ministerial Decree number 88631, imposing labelling requirements on all imported and locally produced genetically modified animal feed, planting seeds, fruits, vegetables and other products which fall under the authority of the ministry.

21. In South Africa, the Department of Health, in cooperation with the Department of Agriculture, has established two legislative advisory groups on genetically modified food labelling. One group, to be run by the Bureau of Standards, is to develop an identity preservation system to track food ingredients and check label claims. Accordingly, draft Regulations Governing the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modifications were developed and, in May 2001, were submitted to the public for comment, in the form of a public notice.

22. A notification issued by the Ministry of Public Health of Thailand requires producers of food products (22 products) containing genetically modified soybean and corn and derived products to label their products, starting from May 2003. The requirement applies to products with 5 per cent DNA or protein derived from genetic modification.

23. The draft biosafety regulations of Viet Nam have a provision on transportation of GMOs and their products which requires adequate packaging and labelling or marking that should indicate the name and address of the sender and the receiver, the GMOs and their products, requirements for transport, storage, use and safe handling.

24. Denmark's Statutory Order No. 380 of 17 May 2000 on Transport and Import of GMOs specifies detailed requirements for packaging, transport and labelling of GMOs. According to the Order, each packaging unit shall be labelled in Danish or English in such a way that it clearly appears that the unit contains GMOs. The type of organisms as well as the name and address of the sender need to be clearly indicated on the packaging unit and, in the case of microorganisms, their class shall be stated. The Order also sets specific packaging and containment requirements (transport containers) during transportation, depending on the class of the GMO.

25. In several other European jurisdictions there are requirements to label or to provide information identifying GMOs destined for contained use. The European Community, Sweden and Switzerland have legislation in place that requires labelling or mandatory provision of information that reveals the fact that the organisms, which are subject to containment, are genetically modified.

26. The European Union has been considering some legislative proposals that are relevant to the implementation of Article 18 of the Protocol. Three different sets of regulations have recently been adopted. These are: (i) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (ii) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC; and (iii) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms. These regulations are expected to enter into force in November 2003.

27. The regulation on labelling and traceability of genetically modified material requires a mandatory labelling of food, food ingredients and feed produced from GMOs. The regulation, while it takes as a base or a framework the requirements of Directive 2001/18/EC on the deliberate release into the environment of GMOs, also amends this directive. The requirement to ensure traceability at all stages of the placing on the market of GMOs was introduced for the first time in Directive 2001/18/EC, which became effective as of 17 October 2002. Traceability is the retroactive tracking of the movement of GMOs and products produced from GMOs through the production and distribution chains, based on transmission and retention of relevant information for the GMOs and such products at all stages of their placing on the market. The regulation requires operators to: (i) put in place systems and procedures to identify to whom and from whom products are made available; (ii) transmit specified information; and (iii) retain specified information for a period of five years and make it available to competent authorities on demand. The specified information that needs to be transmitted to the operator receiving the product is: (i) that the product contains or consists of GMOs, and (ii) the unique identifier(s) assigned to those GMO(s). Information regarding the identity of GMOs in products should, according to the regulation, continue to accompany the product, whether it is subsequently placed on the market as a whole or divided into separate assignments.

28. The European Union regulation on labelling and traceability of genetically modified material requires that operators placing pre-packaged products consisting of or containing GMOs on the market, at

any stage of the production and distribution chain, have to ensure that such products are labelled with the words "This product contains genetically modified organisms" or "This product contains genetically modified [name of organism(s)]". In the case of non-pre-packaged products offered to the final consumer, those words are required to appear on, or in connection with, the display of the product. These requirements for the identification of LMOs are provided for without prejudice to specific requirements imposed by Community legislation and international identification requirements to be developed under Article 18 of the Cartagena Protocol.

29. The European Union rules address, *inter alia*, issues regarding co-mingling and adventitious presence of LMOs. The identification and documentation requirements of the EU are subject to review in two years time, so that any detailed requirements that may be adopted under Article 18, paragraph 2 (a) no later than two years after the date of entry into force of the Protocol could be taken into account.

International level

30. At the international level, a number of organizations and processes are undertaking activities which may be relevant to Article 18 of the Protocol. That includes the work of organizations such as, *inter alia*, Codex Alimentarius Commission (through its Committee on Food Labelling), International Plant Protection Convention (IPPC), World Animal Health Organization (Office International des Epizooties) and World Health Organization (WHO). A synthesis of information on the relevant activities of these organizations/processes had been made available to the meetings of ICCP. As no further significant developments with regard to the requirements of paragraph 2 of Article 18 of the Protocol have taken place, the synthesis presented in this section focuses only on the work of the United Nations Recommendations on the Transport of Dangerous Goods and its Model Regulations, with a view to presenting a clear picture of how those recommendations could be applicable to address the requirements under paragraph 2 of Article 18 of the Protocol.

31. The United Nations Recommendations on the Transport of Dangerous Goods and its Model Regulations perhaps represent the only requirements at the international level, apart from the Cartagena Protocol, providing for handling, packaging, transport and identification of GMOs. First established in 1957, the United Nations Recommendations apply to land, sea, and air transport. They form the basis for uniform national and international regulations for identifying, classifying and transporting dangerous goods.

32. The United Nations Recommendations cover goods that are considered to be dangerous, based on their associated risks and these are divided into nine Classes. Genetically modified micro-organisms (GMMs) and organisms (GMOs) are covered in Class 6 under "Toxic and infectious substances", and in Class 9 under "Miscellaneous dangerous substances". The following table describes the coverage and categories of GMMs and GMOs under the United Nations Recommendations.

Type of GMM or GMO	**Proper shipping name/description**	**Class/ Division**	**UN No. (Assigned to)**
GMMs which meet the definition of infectious substance 2/	Infectious substance	6.2	UN 2814 (those affecting humans), or UN 2900 (those affecting animals only)
GMMs which do not meet the definition of infectious substance, but which are	Genetically modified micro-organisms		

2/ For the purpose of the United Nations Model Regulations infectious substances are those substances known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms or recombinant micro-organisms that are known or reasonably expected to cause infectious disease in animals or humans.

capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction		9	UN 3245
GMOs which are known or suspected to be dangerous to humans, animals or the environment			Conditions specified by the competent authorities
Animals which contain or are contaminated with GMMs and GMOs that meet the definition of infectious substance			Conditions specified by the competent authorities

33. As described in the above table, the United Nations Recommendations apply only to the first two GMMs, i.e. those which meet the definition of infectious substance, and those which do not meet the definition of infectious substance but are capable of altering plants, animals and microbiological substances in unnatural way. It is, however, important to note that it is only the second category of GMMs (Class 9 GMMs), which are required to be identified as "genetically modified micro-organisms" during shipment. GMOs that are generally believed to be dangerous to humans, animals or the environment and animals, and which contain or are contaminated with GMMs and GMOs that meet the definition of infectious substance are left for conditions specified by competent authorities. The coverage of the United Nations Recommendations is therefore limited to GMMs, which in most cases are destined for contained use, and thus fall under paragraph 2 (b) of Article 18. The Recommendations also include procedures and requirements for marking (proper shipping name and United Nations number) and documentation.

III. SUMMARY OF MAJOR ISSUES ARISEN IN RELATION TO THE REQUIREMENTS OF PARAGRAPH 2 (a) OF ARTICLE 18

34. Paragraph 2 (a) of Article 18 provides for identification requirements for intentional transboundary movements of LMOs that are intended for use as food, feed or for processing. The first sentence of the paragraph describes the information that needs to be made available for the purpose of identification, through documentation that should accompany living modified organisms that are intended for use as food, feed or for processing during intentional transboundary movement. The accompanying documentation is required to state: (i) that the shipment "may contain" living modified organisms that are intended for use as food, feed or for processing; (ii) that they are not intended for intentional introduction into the environment; and (iii) a contact point for further information. This is a requirement that needs to be met by the Parties concerned as of the date of entry into force of the Protocol.

35. The second sentence of paragraph 2 (a) of Article 18 requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of the elements specified in the first sentence of the paragraph within two years after the date of entry into force of the Protocol. The second sentence also introduces the concept of specification of the identity of the LMOs that are intended for use as food, feed or for processing, and unique identification as referred to in Annex II to the Protocol. The paragraph as a whole reads as follows:

"Each Party shall take measures to require that documentation accompanying:

"(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose,

including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

36. ICCP considered the requirements of paragraph 2 (a) of Article 18 at its second and third meetings as part of its preparatory work to facilitate the work of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. As noted in paragraph 3 above, following a request by the second meeting of ICCP, a meeting of technical experts was convened from 18 to 20 March 2002 in Montreal to consider modalities of implementation of the requirement contained in the first sentence of paragraph 2 (a) of Article 18, and to identify issues to be addressed beyond entry into force, in preparation for the decision referred to in the second sentence of the paragraph. Although the expert meeting could not arrive at a consensus with respect to some of the issues that were addressed, it raised, identified and discussed a number of relevant issues as reflected in its report and recommendations, which the third meeting of ICCP decided, taking into account the divergent views still persisted, to submit to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol for its consideration.

37. Issues relating to the requirements of paragraph 2 (a) of Article 18 that have been raised, identified and deliberated upon at the technical experts as well as ICCP level include: (i) the type of documentation that should accompany LMOs; (ii) type and extent of information necessary to clearly identify LMOs that are intended for use as food, feed or for processing; (ii) the understanding or implications of the "may contain" requirement to identify LMOs that are intended for use as food, feed or for processing known to be present in a transboundary movement; (iii) the need for unique identification; (iv) adventitious/unintentional presence of LMOs in non-LMO shipments or unauthorized LMOs in authorized LMO shipments and the question of threshold; (v) identity preservation -- the need for such a system and associated costs; and (vi) standard methodology for sampling, detection and identification of LMOs that are intended for use as food, feed or for processing. The following is a brief description of each of these issues as presented by or gathered from submissions and discussions that took place in the context of the ICCP process.

The type of documentation that should accompany LMOs

38. The issue here is whether there is a need for a new and a stand-alone document or whether one of the existing documents that currently accompany commodity shipments could be used to integrate the information specified in paragraph 2 (a) of Article 18 and accompany LMOs that are intended for use as food, feed or for processing in order to meet the requirements of identification under that paragraph. A number of different certificates were recognized to accompany shipments in international trade, as appropriate. But a commercial invoice has been considered as the only document always accompanying every shipment, and it is therefore easy and less costly to use. On the other hand, it is argued that the use of a new document specifically designed for the purpose of the Protocol would provide more convenience for the users and regulators to distinctly verify whether the information requirements are met.

Type and extent of information required in the accompanying documentation

39. There has been a divergence of views regarding the type and amount of information required to be provided through accompanying documentation. On one hand, it is argued that more information should be provided to identify LMOs that are intended for use as food, feed or for processing that may be contained in a given transboundary movement. It is further argued that information on the specific identity of the LMOs that are intended for use as food, feed or for processing or, as a minimum, the unique identity, the host organism and the donor, the transformation event(s) involved, and a reference to accessing relevant information in the Biosafety Clearing-House should be supplied. It is also said that the need for specifying such information is already implied in the term "clearly identifies" as included in the first sentence of paragraph 2 (a) of Article 18.

40. On the other hand, no more or additional information than what actually is stated in black and white in the paragraph has been found acceptable. The suggestion is to follow the wording of the Protocol and to adhere to the information requirements directly stated in it, and it is argued that no more information would serve the general purpose of the Protocol, which is the conservation and sustainable use of biological diversity. Even where the provision of more or additional information were to be required or justified, it is further argued that its cost implications need to be studied first, and it should happen only after the detailed requirements referred to in the second sentence of paragraph 2 (a) are defined by the Conference of the Parties serving as the meeting of the Parties to the Protocol in a decision that needs to be made not later than two years after the date of entry into force of the Protocol.

The "may contain" language

41. At the meeting of technical experts convened in March 2002, as well as at the third meeting of ICCP, a number of perceptions were noted regarding the "may contain" language stipulated in the first sentence of paragraph 2 (a) of Article 18. It may be possible to divide those views or perceptions into two broad categories, i.e. between those favouring the use of the phrase for identification of LMOs that are intended for use as food, feed or for processing in accompanying documentation on the one hand, and those expressing concerns that such phraseology provides no clear and useful information to identify shipments of LMOs that are intended for use as food, feed or for processing, on the other. The core points made and the issues raised may be summarized as follows:

The "may contain" phrase has a problem	**The "may contain" phrase is appropriate**
1. The use of the phrase "may contain" misrepresents shipments, especially where the content of the shipment is known to be LMOs that are intended for use as food, feed or for processing and the identity of the specific LMOs is known and verified.	1. The use of the phrase is appropriate in the case of commodity shipments, especially in grain shipments, where co-mingling is commonplace and the assuring of purity is hardly feasible.
2. The phrase is too vague; it should be specified more precisely.	2. The use of the phrase is justified and useful if one focuses on the intent of the shipment. It denotes a recognition in the Protocol that LMOs that are intended for use as food, feed or for processing should be treated differently.
3. Where the shipment is known to contain LMOs, exporters should make a declaration to that effect.	3. The use of the phrase need to be seen as an interim measure and there is a need to adhere to the language of the Protocol.
4. It would be meaningless if the "may contain" language applies to every bulk commodity shipment.	4. The purpose of the "may contain" language is to highlight the fact that LMOs are likely to be part of any bulk shipments.
5. The phrase implies the need for setting thresholds.	
6. There is a need to clarify the application of the "may contain" language as a requirement for identification of LMOs that are intended for use as food, feed or for processing.	

Unique identification

42. There seems to be a consensus on the need for a unique identification system to identify LMOs that are subject to transboundary movement. It is generally appreciated that if the identity of LMOs that are intended for use as food, feed or for processing were to be specified in an unambiguous manner, a global unique identification system needs to be put in place, taking into account the work of relevant organizations. The point of difference, however, is whether a unique identifier, where it exists, should be included as part of the information required to be made available in accompanying documentation at this juncture.

43. It is argued that, since a unique identifier is not part of the identification requirement contained in the first sentence of paragraph 2 (a) of Article 18, any discussion and determination on whether to use one or the other unique identification system and to specify unique identifier codes in documentation accompanying LMOs that are intended for use as food, feed or for processing should be postponed to a later stage when the second sentence of the paragraph would be taken up by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

44. On the other hand, those who are in favour of indicating a unique identifier in accompanying documentation support a quick move towards the development or adoption of the system and putting the unique codes in place, and make a requirement to specify them in accompanying documentation as a means to ensure consistent access and retrieval of a broad range of additional information about the identity and characteristics of the LMOs that are intended for use as food, feed or for processing from the Biosafety Clearing-House. Annex II of the Protocol demands the submission of any unique identification of the LMO that is intended for use as food, feed or for processing as part of the information required for the purpose of Article 11. In this context, the adoption of the "Guidance for the designation of the OECD's Unique Identifier for Transgenic Plants", developed by the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology, was generally welcomed.

Adventitious/unintentional presence of LMOs and thresholds

45. It is generally acknowledged that no complete purity may be achieved in shipments of LMOs that are intended for use as food, feed or for processing, particularly in the case of bulk grain shipments. The grain marketing industry is of the view that in reality the sheer quantities handled in the process of production, storage, distribution and processing of bulk commodities make it impossible to segregate by individual variety and to ensure purity of cargoes. Not only co-mingling in the handling, storage and transportation process, but also cross-pollination in the field is considered to result in an unintended presence of genetically modified material. For this reason, it is argued that thresholds have to be established for ensuring the practicability and feasibility of identification or labelling of a shipment of LMOs that are intended for use as food, feed or for processing where adventitious or technically unavoidable traces of LMOs cannot be excluded, below which these LMOs would not have to be identified or labelled.

46. Whether unavoidable traces of LMOs that may be present in a given shipment are LMOs authorized or approved by the exporting or importing country, as appropriate, brings an additional dimension to the issue of adventitious/unintended presence of LMOs. There may be cases where the LMO of which the presence has been adventitious could be: (i) authorized by the Party of export for placing on the market, but not authorized for import by the Party of import; (ii) generally authorized by the Party of import, but not authorized for the specific shipment; or (iii) not authorized or approved by the Party of export in the first place for placing on the market. In some cases the same threshold levels may be accepted to apply for both authorized (by both Parties of export and import) and unauthorized (by the Party of import) LMOs. In many cases, however, the tendency is to have no tolerance for illegal LMOs, i.e. LMOs that are not approved for placing on the market, even if their presence is unavoidable and in

trace amounts. In accordance with Article 25 of the Protocol, illegal transboundary movements of LMOs are those carried out in contravention of each Party's domestic measures to implement the Protocol. In that regard, a question may arise whether transboundary movements of LMOs that have authorization from the Party of export for placing on the market but do not have a permit or approval from the Party of import, whose domestic measures require such approval, would be considered illegal.

47. In its contribution to the relevant discussions during the ICCP process, the International Grain Trade Coalition proposed a 95 per cent non-LMO purity level to be adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol as a temporary measure. In other words, the grain industry suggests that shipments containing up to 5 per cent LMOs be exempted from the identification requirements of the Protocol, as is the case in Japan, for instance.

48. The European Union has adopted a 0.9 percent labelling threshold for the adventitious presence of genetically modified material in food and feed, provided that this presence is adventitious or technically unavoidable.

49. For Switzerland, the threshold for genetically modified food products or derived food products is 1 per cent, and for raw materials, single feed products, additives and conservative agents, 3 per cent. One of the issues raised in this regard is which body would be appropriate to set the tolerance level for the adventitious presence of LMOs at the international level, including for the purpose of the Protocol.

50. Another relevant issue that has been raised in this connection was whether the situation of the adventitious/unintentional presence of LMOs also encompasses unintentional transboundary movements under Article 17 of the Protocol. Unintentional transboundary movement involves an occurrence under the jurisdiction of a Party resulting in a release that leads, or may lead, to unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on biological diversity. For the purpose of Article 17, there must be an "occurrence" causing a "release" of the LMO, and such release should actually or potentially lead to unwanted cross-border movement. Occurrence may mean any unforeseen event that would allow the LMO to escape. For instance, a laboratory or a containment where LMOs are kept could fall apart due to an accident or a disaster. This could be taken as an occurrence resulting in a release of LMOs. On the other hand, there is a potential for a transboundary pollen flow from genetically modified crops to non-genetically modified crops. In such a case, the cross-pollination may be considered as an occurrence that leads to unintentional transboundary movement. The issue is whether these kinds of incidents anticipated under Article 17 could also be regarded as incidents underlying any adventitious or unintended presence of LMOs that are intended for use as food, feed or for processing in a shipment that is not supposed to contain such LMOs, or may contain LMOs but not the adventitious materials.

Identity preservation

51. Identity preservation is a procedure used to maintain and track the identity of a particular quantity of a commodity throughout the production and distribution chains. It is relevant to consideration of the issues of unique identification and adventitious presence of LMOs, because it provides information on the specific varieties of a commodity (LMO or non-LMO) that could be expected to be present in a transboundary shipment.

52. The European Union regulation on traceability and labelling of GMOs defines the objective of traceability as the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market, thereby facilitating quality control and also the possibility to provide a safety net to withdraw products, should any adverse effects be observed.

53. Industry argues that identity preservation cannot be undertaken without causing a substantial increase in costs. It is reported that a system of identity preservation, including separation in the supply chain between genetically modified and non-genetically modified grain varieties would increase the United States' grain handling cost by $8 per tonne for corn and over $18 per tonne for soybeans. In Australia, it is estimated that, with the current technology, testing and identity preservation systems increase the cost by between $20 and $28 per tonne for bulk commodities.

Sampling and detection methodologies

54. As long as identification of LMOs is a requirement during transboundary movements, there is a need to determine the presence of LMOs. The application of appropriate sampling and testing techniques could help to determine the presence or absence of LMOs in a given shipment. If, for example, there is a mixture of LMOs in a shipment and the information on the identity of some of the LMOs that may be contained in the shipment is not made available by the exporters, or is not adequate or not reliable, then the relevant authorities or importers may have to determine this through sampling and testing. At present, there are no standard sampling and testing methodologies for LMOs. As a result, different countries use different sampling and testing methods, with no guarantee for comparable results. It is, therefore, indicated that there is a need to develop standard sampling and testing methods. There is a suggestion from the grain trade industry that testing protocols should be developed using international bodies that are working on the development of appropriate technology.

IV. A SYNTHESIS OF VIEWS SUBMITTED IN PREPARATION FOR THE FIRST MEETING OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE PROTOCOL

55. As pointed out above, at its third meeting ICCP had difficulty in resolving a number of issues relevant to paragraphs 2 (a), 2 (b) and 2 (c) of Article 18. As regards paragraph 2 (a), ICCP, in addition to forwarding the report and recommendations of the technical expert meeting to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, had invited Parties and other States to closely consider the issues and facilitate their resolution. With respect to paragraphs 2 (b) and 2 (c), ICCP essentially agreed to submit the recommendations of the relevant technical experts meeting to Conference of the Parties serving as the meeting of the Parties to the Protocol and requested the Executive Secretary to continue to collect and review existing information on relevant standards, practices and rules (see section II above), including the ongoing processes on these matters under relevant international organizations, and operational experience of movements of LMOs destined for contained use and for intentional introduction into the environment. ICCP also invited Parties and Governments to examine unique identification systems such as the OECD system, with a view to considering their applicability to the requirements of identification of living modified organisms, and their linkage to the Biosafety Clearing-House.

56. The present section presents a synthesis of information and views received by the Secretariat from Governments and relevant international organizations. By 22 October 2003, the Secretariat had received submissions from Australia, Canada, the European Community, Norway, Paraguay, Switzerland, and the United States of America; the Organization for Economic Cooperation and Development (OECD), the International Plant Protection Convention, World Organization for Animal Health (OIE); the International Grain Trade Coalition, the Global Industry Coalition, and WWF International. The full texts of the submissions have been compiled and made available as an information document (UNEP/CBD/BS/COP-MOP/1/INF/3).

57. The following synthesis has four sub-sections. The first two synthesize the views on Article 18, paragraphs 2 (a), 2 (b) and 2 (c). The third sub-section summarizes the views on the use of unique

identification system(s); and the fourth contains a suggestion regarding the whole of Article 18. Each of the first two sub-sections starts by presenting the synthesis of submissions from industry (private sector). That includes the highlighting of their understanding and the status of implementation of the requirements of the paragraphs that are relevant to them, and their specific proposals regarding the implementation of the requirements. That is followed by the views of Governments and other international organizations.

A. LMOs intended for direct use as food or feed, or for processing (Article 18.2(a))

58. The movement across borders of LMOs that are intended for use as food, feed or for processing is a recent phenomenon. According to the International Service for the Acquisition of Agri-biotech Applications (ISAA), commercial-scale production of transgenic crops began in 1995. By the year 2001, the major genetically modified crops that entered the international market were soybean, cotton, canola, and maize. Transboundary movements of LMOs that are intended for use as food, feed or for processing, including bulk shipments, have only recently become more visible internationally, partly as a result of controversies over genetically modified food aid. There is, therefore, limited operational experience in the field.

59. At this stage, the elaboration and implementation of the requirements of paragraph 2 (a) of Article 18 concerns more the international trade in agricultural crops such as grains, oilseeds, and pulses. In June 2001, a group of organizations involved in grain trade formed a coalition known as the International Grain Trade Coalition (IGTC), with a view "to advising governments on how to implement the Biosafety Protocol in a manner that does not compromise the need to protect the global biological diversity" on the one hand, and the interests involved in the smooth operation of the international grain trade, on the other.

60. Since its establishment, IGTC has tried, on a number of occasions, to demonstrate for governments and other interested parties how the grain trade industry operates. It has made its case before a number of intergovernmental forums by making presentations, providing information materials, participating in expert-level discussions, organizing live demonstrations of grain shipment operation at busy sea ports such as Rotterdam, and showing how the grain trade sector operates and how it may be impacted by the requirements of paragraph 2 (a) of Article 18. The existing operational experience in the transboundary movement of LMOs that are intended for use as food, feed or for processing may provide opportunities as well as constraints in the implementation of paragraph 2 (a) of Article 18.

61. In its submission, the IGTC recommends that the commercial invoice be named as the document to accompany LMOs that are intended for use as food, feed or for processing, carrying the identification requirements of the Biosafety Protocol under Article 18, paragraph 2 (a). It supports the language proposed by some experts at the technical experts meeting held in March 2002 in Montreal, which reads as follows:

> "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"

62. The IGTC is of the view that the invoice should also bear the names of the last exporter prior to the transboundary movement and the first importer after the transboundary movement as contact points for further information. It also suggests a tolerance level of 5 per cent for the unintentional presence of LMOs in a non-LMO shipment (or a 95 per cent purity level), beyond which the documentation requirement would be triggered. The IGTC believes that the documentation requirement should not apply to:

(a) Shipments for which the exporting country does not have in commerce any LMO of that species; or

(b) Shipments which the exporter and importer have contractually defined as a "non-LMO shipment", provided that such shipment achieves a minimum of 95 per cent non-LMO content, and that such definition does not conflict with regulations of the importing country.

63. The IGTC indicated that, at the time of its submission, exporters were engaged in discussions with major importers to arrive at mutual understanding on the documentation requirement of Article 18, paragraph 2 (a) and implementing it without causing any disruption to trade. It has also stated in its submission that it is encouraging major exporters to use Article 24 of the Cartagena Protocol, on non-Parties, to bring greater clarity to this requirement.

64. Among the submissions received from governments, two are essentially in line with the specific suggestions of the IGTC. They recommend the use of a commercial invoice that would incorporate the wording specified under paragraph 61 above; they agree that the documentation requirement should not apply to shipments for which the exporting country does not have in commerce any LMO of that species; and suggest that the last exporter and the first importer be identified as contact points for further information. These two submissions state further that the requirements of Article 18, paragraph 2 (a) apply only to intentional transboundary movements of LMOs and hence adventitious material has to be excluded from the scope of the Article and should not trigger the provision of Article 18, paragraph 2 (a). One of the submissions further argues that adventitious material does not fall under the scope of Article 17. It also submits the view that documentation requirements under Article 18 do not arise for transit Parties. For that purpose, the submission provides a definition of "transit" for consideration by Conference of the Parties serving as the meeting of the Parties to the Protocol. The definition reads:

> "LMO shipments shall be deemed to be in transit across the territory of a Party when the passage across such territory, with or without transhipment, warehousing, breaking of bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the Party across whose territory the LMO shipment passes."

65. There are two submissions that advise the Conference of the Parties serving as the meeting of the Parties to the Protocol to focus, at this stage, only on ensuring and facilitating the implementation of the requirements of the first sentence of Article 18, paragraph 2 (a), and postponing any consideration of the second sentence of that paragraph until the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, when some practical experience in the implementation of the requirements in the first sentence could be gained, and that could usefully be used to inform the decision to be made under the second sentence of the paragraph.

66. On the other hand, another submission makes reference to the report and recommendations of the technical experts meeting held in March 2002 in Montreal, and to the Chair's summary annexed to recommendation 3/6 of the third meeting of ICCP, which cover a number of issues relevant to Article 18, paragraph 2 (a) and contain numerous suggestions on how to move forward in resolving some of the divisive issues. The submission supports the idea of addressing the need for thresholds for adventitious/unintentional presence of LMOs, and the need to clarify how the "may contain" language in paragraph 2 (a) of Article 18 has to be applied, in particular where the presence and identity of specific LMOs that are intended for use as food, feed or for processing in a certain transboundary movement is known and verified.

67. WWF International suggests that information about LMOs known to be present in a given shipment has to be provided in accompanying documentation so that importing countries would be able to verify whether such LMOs have been approved and posted on the Biosafety Clearing-House and whether the shipment complies with their domestic regulatory frameworks.

B. LMOs destined for contained use and LMOs intended for intentional introduction into the environment (Article 18, paragraphs 2 (b) and 2 (c))

68. The Global Industry Coalition (GIC), a private sector group representing the biotechnology industry made in its submissions the following specific suggestions in order to meet the documentation requirements of Article 18, paragraphs 2 (b) and 2 (c) of the Protocol:

(a) LMOs destined for contained use (Article 18.2(b)): Include the following information on existing shipping documentation such as commercial invoices:

(i) A statement outlining the contents of the shipment:

"This shipment contains living modified organisms for contained use" (may specify contents of shipment here, such as "*Bacillus subtilis* containing the α-amylase gene from *B. stearothermophilus*");

(ii) The name and address of the exporter, importer or consignee, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;

(iii) A brief description of any requirements for the safe handling, storage, transport and use of the LMO when safe handling requirements under other international agreements (such as the International Plant Protection Convention, or in the case of movement of genetically modified microorganisms, the UN Recommendations on the Transport of Dangerous Goods) have not already been met. In the event that there is no requirement, indicate that there is no specific requirement; and

(iv) The name and address of the consignee;

(b) LMOs for intentional introduction into the environment (Article 18.2(c)): Include the following information on existing shipping documentation such as commercial invoices:

(i) A statement outlining the contents of the shipment:

(ii) "This shipment contains living modified organisms";

(iii) A brief description of the LMO, including category, name, relevant traits and/or characteristics;

(iv) A brief description of any requirements for the safe handling, storage, transport and use of the LMO as provided under applicable existing international requirements (such as the requirements under the OECD Seed Schemes), under domestic regulatory framework, under the advanced informed agreement procedure, or under any agreement by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;

(v) The name and address of the exporter and importer, including contact details necessary to reach them as fast as possible in case of emergency (designate which is to be used as the contact point for further information); and

(vi) The following declaration:

"The exporter declares that the transboundary movement of this LMO is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter."

C. Use of unique identification system(s)

69. The Global Industry Coalition is of the view that the language in paragraph 2 (c) of Article 18, which states that the documentation accompanying LMOs for intentional introduction into the environment has to specify "the identity and relevant traits and/or characteristics" of the LMOs, does not require the use of a unique identifier on the shipping documentation. They believe that unique identifiers are not available or appropriate to all transgenic material that may be subject to the Protocol. In their view, many of the LMOs could be shipped for the purpose of limited research use, or specific identification of the material such as transformation event-specific information, could be contained and made available through the operation of the advance informed agreement procedure. While they suggest that the use of a unique identifier should not be a mandatory requirement under Article18, paragraph 2 (c), they also confirm that they will remain open for discussions on how the unique identifier system, developed by the Organisation for Economic Co-operation and Development (OECD) with the support of the private sector, might be considered for use in some instances for the purpose of the Protocol.

70. One government submission makes it clear that a unique identification system for LMOs based on a transformation event is essential for the efficient functioning of the database in the Biosafety Clearing-House regarding decisions. The submission supports the use of the OECD unique identifier in the relevant Biosafety Clearing-House databases, as the internationally recognized identification code for transgenic plants approved for commercialization.

71. Another submission, welcoming the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants, which is now being used within the OECD and the European Union regulatory approval process, supports the adoption of the same unique identification system for the purpose of the Protocol as well. The submission specifically supports the development of a register for unique identification codes to be placed under the Biosafety Clearing-House. It is also in favour of further work towards developing unique identification systems for micro-organisms and animals, which are not addressed by the present Guidance. In that regard, the submission suggests the adoption of a decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol that would call for the process under the OECD to be enhanced and to be as comprehensive as possible by developing a system that covers genetically modified micro-organisms and animals too.

72. OECD indicated, in its submission, that 80 unique identifiers have been assigned for products covering the majority of plant products available in the organization's product database and, in effect, most of the LMO products that have received commercial approval around the world. OECD believes that these identifiers assigned for products that have already been approved, and those which are being assigned for products that are not yet approved and are under consideration by some authorities, clearly show that the "guidance" could be implemented widely and make an important contribution to the implementation of the Protocol. The OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology is also expected to consider whether and how the "guidance" could be extended to products of microbial and animal origin, which are not covered at the moment. Because of the extensive relevance of the information to the item on information sharing and the Biosafety Clearing-House, the full text of the OECD's submission is made available in the information document UNEP/CBD/BS/COP-MOP/1/INF/1.

73. The submission from WWF International underlines the need for a standardized and comprehensive system of identification of LMOs, including LMOs that are intended for use as food, feed or for processing. It suggests that the Conference of the Parties serving as the meeting of the Parties to the Protocol should decide on the use of a unique identification system for LMOs that are intended for use as food, feed or for processing and should consider extending the use of such a system to all LMOs that are subject to transboundary movement.

D. Other elements of Article 18

74. One submission suggests that the Conference of the Parties serving as the meeting of the Parties to the Protocol should address the issues of implementation of Article 18 by taking into account existing systems under other international organizations that may be relevant to one or the other aspects of the Article and that could contribute to the achievement of the objective of the Protocol. The submission further suggests to consider Article 18, paragraph 3 in the implementation of Article 18, paragraph 2, and to adopt, where appropriate, guidance on the implementation of Article 18, paragraph 1. The submission also suggests how the adoption of a decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol regarding the implementation of the requirements of Article 18, paragraph 2 would be appropriate and timely. According to this submission, it is possible to implement the requirements of paragraphs 2 (a), 2 (b) and 2 (c) by adopting the templates suggested during ICCP process (and also by Norway (see below)), and using them as stand-alone documentation, or by incorporating the required information in existing documentation.

75. Norway has submitted templates of transport documents which can be considered for use as stand-alone documents to meet the documentation requirements under paragraphs 2 (a), 2 (b) and 2 (c). The templates are included in information document UNEP/CBD/BS/COP-MOP/1/INF/3.

76. In its submission, WWF International suggests that the requirements and issues relating to paragraphs 2 (a), 2 (b), and 2 (c) should be considered by the Conference of the Parties serving as the meeting of the Parties to the Protocol in an integrated manner. WWF International also suggests that, if the requirements of paragraph 2 were to be effectively implemented by developing countries, there is a need for capacity-building and the financial mechanism need to provide financial resources to these countries, as appropriate.

V. CONCLUSION AND BACKGROUND TO THE PROPOSED ELEMENTS OF DRAFT DECISION

77. ICCP addressed the issue of Article 18, paragraph 2 (a), in a focused manner at its last two meetings with input from the meeting of technical experts. As mentioned in Introduction of the present note, at its third meeting ICCP, in its recommendation 3/6, decided to submit, taking into account the different views expressed at that meeting, the report and recommendations of the Meeting of Technical Experts on the Requirements of paragraph 2 (a) of Article 18 to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol for its consideration. It also agreed to transmit to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol a summary prepared by the Chair of the Working Group reflecting the different views expressed during the third meeting of ICCP. In the preceding sections of the present note the Executive Secretary has tried to put together the major issues and views expressed in this regard with a view to assisting the Conference of the Parties serving as the meeting of the Parties to the Protocol to take an appropriate decision. The Executive Secretary proposes elements of a draft decision, as contained in the following section of the present note, taking into account:

(a) The issues, suggestions, and recommendations reflected in the report of the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) of Article 18 held in Montreal in March 2002;

(b) The summary of the Chair of the Working Group that discussed the issue at the third meeting of ICCP;

(c) The submissions of Governments and relevant international organizations; and

(d) The provisions of paragraph 2 (a) of Article 18 itself.

78. Similarly, ICCP addressed the issues in paragraphs 2 (b) and 2 (c) of Article 18 at its meetings with input from the two above mentioned meetings of technical experts. ICCP, at its third meeting, agreed to submit a list of elements contained in recommendation 3/6 for the consideration of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The elements were basically taken from the recommendations of the second meeting of technical experts that took place in March 2002 in Montreal. In preparing the elements of the draft decision presented in the following section, the Executive Secretary has taken into account:

(a) The submission of the third meeting of ICCP to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(b) The overall direction that the discussions and recommendations of the two expert group meetings have taken;

(c) The submissions from governments and relevant international organizations;

(d) Existing international documentation systems of the United Nations Recommendations on Transport of Dangerous Goods, for the purpose of Article 18, paragraph 2 (b), and the OECD Seed Schemes, for the purpose of Article 18, paragraph 2 (c), and

(e) The basic requirements of the Protocol under paragraphs 2 (b) and 2 (c) of Article 18.

VI. DRAFT DECISIONS

A. Paragraph 2 (a) of Article 18

79. With regard to paragraph 2 (a) of Article 18, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider adopting the draft decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Protocol,

Noting the recommendations of the third meeting of ICCP regarding paragraph 2 (a) of Article 18,

Recognizing the difficulties involved in the efforts to arrive at common grounds by ICCP with regard to some of the issues encountered in relation to identification of living modified organisms for direct use as food, feed, or for processing,

Recalling the second sentence of paragraph 2 (a) of Article 18, which requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of those elements specified in the first sentence of the same paragraph, including specification of the identity of the LMOs in question and any unique identification, no later than two years after the date of entry into force of the Protocol,

Noting that any decision taken at this stage regarding the understanding and implementation of the requirements specified in the first sentence of paragraph 2 (a) of Article 18 would only be interim until the decision referred to in the second sentence of the same paragraph on the detailed requirements is taken,

1. *Invites* Parties to the Protocol and other Governments to take measures to ensure the use of [a commercial invoice] [other document provided by the originator and/or required by existing international documentation system] [a stand alone document] as documentation that should accompany

living modified organisms that are intended for use as food, feed or for processing for the purpose of identification by incorporating the information requirements of the first sentence of paragraph 2 (a) of Article 18 into such document, until decided otherwise;

2. *Requests* Parties to the Protocol and other Governments to take measures ensuring that documentation accompanying living modified organisms that are intended for use as food, feed or for processing states that the 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;

3. *Further requests* Parties to the Protocol and other Governments to provide, in the documentation accompanying living modified organisms that are intended for use as food, feed or for processing, information regarding the details of the last exporter and the first importer in the process of the transboundary movement [or any other appropriate authority], as contact points for further information;

4. *Urges* Parties to the Protocol and other Governments to encourage exporters of living modified organisms that are intended for use as food, feed or for processing under their jurisdiction to declare, in documentation accompanying transboundary movements known to intentionally contain living modified organisms that are intended for use as food, feed or for processing, that the shipment contains living modified organisms that are intended for use as food, feed or for processing;

5. *Decides* to establish an ad hoc technical expert group on identification requirements of living modified organisms that are intended for use as food, feed or for processing to assist the Conference of the Parties serving as the meeting of the Parties to the Protocol in taking the decision referred to in the second sentence of paragraph 2 (a) of Article 18 of the Protocol, on the basis of the terms of reference specified in the annex to this decision;

6. *Requests* Parties to the Protocol, 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; and

(b) Their 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 that are intended for direct use as food or feed, or for processing (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;

7. *Requests* the Executive Secretary to prepare a synthesis of the information and views referred to above, for the consideration of the ad hoc technical expert group mentioned in paragraph 5 above, and to convene, subject to the necessary financial resources being made available, the meeting of the ad hoc technical expert group, with due regard to geographical representation, and to submit the report and recommendations of the technical expert group to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

8. *Urges* developed country Parties and other donor Governments to make financial contributions necessary for the convening of the meeting of the ad hoc technical experts group established under paragraph 5 above, including financial support for developing country experts who will be selected to participate in the meeting.

Annex

DRAFT TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP ON IDENTIFICATION REQUIREMENTS OF LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

Taking into account the need for the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements of identification of LMOs that are intended for use as food, feed or for processing in accompanying documentation, including specification of their identity and any unique identification, no later than two years after the date of entry into force of the Protocol, and

Considering: (i) the report and recommendations of the Meeting of Technical Experts on the Requirement of Paragraph 2 (a) of Article 18; (ii) the Chair's summary of Working Group I of the discussion regarding paragraph 2 (a) of Article 18 at the third of ICCP; (iii) the decision of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol; and (iv) the information and views provided by Parties to the Protocol, other Governments and relevant international organizations in accordance with paragraph 6, of decision A above.

The Ad Hoc Technical Expert Group shall:

1. Examine the issues of specifying the identity of LMOs that are intended for use as food, feed or for processing and unique identification mentioned in the second sentence of paragraph 2 (a) of Article 18 in relation to the "may contain" language of the first sentence of the same paragraph, and any other issues that may be relevant to the elaboration of the detailed requirements of identification of LMOs that are intended for use as food, feed or for processing, including:

(a) What documentation may be appropriate to accompany LMOs that are intended for use as food, feed or for processing for the purpose of Article 18, paragraph 2 (a);

(b) What information should the accompanying documentation provide;

(c) Thresholds for adventitious or unintentional presence of LMOs that may be needed to trigger identification requirements;

(d) The extent and modality of using unique identifiers;

(e) Harmonization of sampling and detection techniques.

2. Propose recommendations regarding issues mentioned in paragraph 1 above, for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

3. Complete its work in time for the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

B. Paragraphs 2 (b) and 2 (c) of Article 18

80. With regard to paragraphs 2 (b) and 2 (c) of Article 18, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider adopting the draft decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Protocol,

Noting the recommendations of the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety regarding paragraphs 2 (b) and 2 (c) of Article 18;

1. *Invites* Parties to the Protocol and other Governments to use to take measures to ensure the use of [a commercial invoice] [other document provided by the originator and/or required by existing international documentation system] as proposed in the relevant templates [a stand alone document] as documentation that should accompany LMOs for contained use and for intentional introduction into the environment of the Party of import, incorporating the information required under paragraphs 2 (b) and 2 (c) of Article 18, as appropriate, with a view to fulfil the identification requirements of these paragraphs;

2. *Requests* Parties to the Protocol and other Governments to take measures ensuring that documentation accompanying LMOs contains the following information and declaration:

(a) LMOs for contained use (paragraph 2 (b), Article 18):

(i) Clear identification as "living modified organisms" including the name of the organisms and as "destined for contained use";

(ii) The name and address of the exporter, importer and consignee, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;

(iii) Any requirements for the safe handling, storage, transport and use of the LMOs when safe handling requirements under other international agreements such as the International Plant Protection Convention, or in the case of movements of genetically modified micro-organisms, under the United Nations Recommendations on the Transport of Dangerous Goods, have not already been met. In the event that there is no requirement, indicate that there is no specific requirement;

(b) LMOs for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol (paragraph 2 (c), Article 18):

(i) Clear identification as "living modified organisms" and a brief description of the organisms, including category, name, relevant traits, including transgenic traits and characteristics such as event(s) of transformation or, where available and applicable, a reference to a system of identification;

(ii) Any requirements for the safe handling, storage, transport and use of the living modified organisms as provided under applicable existing international requirements such as the requirements under the OECD Seed Schemes, domestic regulatory frameworks, or under any agreement entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;

(iii) The name and address of the exporter and importer;

(iv) The details of the contact point for further information, including an individual or organization in possession of relevant information in case of emergency;

(v) A declaration that the movement of the living modified organisms is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter.

3. *Invites* Parties, other Governments and relevant international organizations to make available to the Executive Secretary, not later than 5 months prior to the date of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information regarding their experience, if any, in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18;

4. *Requests* the Executive Secretary to prepare a synthesis report of information received from Parties, other Governments or relevant international organizations in accordance with paragraph 3 above and submit the report to the second meeting of the COP-MOP.

C. Unique identification system(s)

81. With regard to unique identification systems, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider adopting the draft decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Protocol,

Mindful of the consideration of the issue of unique identification in the context of paragraph 2 (a) of Article 18 by the ad hoc technical expert group established pursuant to paragraph 5 of decision A above,

Recognizing the need for a harmonized unique identifier codes for facilitating access to relevant information that may be available in the Biosafety Clearing-House regarding living modified organisms subject to transboundary movement,

Welcoming the development and adoption of the Organization of Economic Cooperation and Development (OECD) Guidance for the Designation of a Unique Identifier for Transgenic Plants,

Recognizing that unique identification is also required for genetically modified micro-organisms and animals,

1. *Invites* Parties and other government to take measures to apply the OECD Unique Identifiers for Transgenic Plants to plant living modified organisms under the Protocol;

2. *Requests* the Executive Secretary to develop or maintain, in the Biosafety Clearing-House, a register of unique identification codes to ensure harmonisation of such codes by all users;

3. *Encourages* the Organisation for Economic Co-operation and Development or other organizations involved in the development of unique identification systems for LMOs to initiate or enhance their activities towards the development of unique identifiers for genetically modified micro-organisms and animals.

Annex

ICCP RECOMMENDATION 3/6 ON HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

The Intergovernmental Committee for the Cartagena Protocol on Biosafety,

I. Paragraph 2 (a) of Article 18

Noting the report and recommendations of the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) Article 18, which took place in Montreal from 18 to 20 March 2002 (UNEP/CBD/ICCP/3/7/Add.1),

Recognizing that different views, as reflected in the report of the meeting of technical experts, as well as its recommendations, were expressed by a number of experts with regard to several aspects of the issues involved in paragraph 2 (a) of Article 18, in particular on the extent of information that may be necessary to be made available in the documentation in the context of implementing the first sentence of paragraph 2 (a) of Article 18,

Noting that a number of views have been expressed during the consideration of the recommendations of the meeting of technical experts with a view to providing alternative proposals and to resolve elements in the recommendations of the meeting of technical experts and that different views have been expressed, as reflected in the summary of the Chair of Working Group I at the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, which is included as annex II to the present recommendation to be transmitted to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol,

Recognizing that these different views remain difficult to resolve at this stage,

Further recognizing the requirements to meet the obligations specified in the first sentence of paragraph 2 (a) of Article 18 at the date of entry into force of the Protocol, the lack of consensus on the recommendations of the technical expert group does not set aside the obligation to implement Article 18.2 (a) of the Protocol,

1. *Submits* the report, including the recommendations, of the Meeting of Technical Experts on the Requirements of Paragraph 2 (a) Article 18, as contained in annex I to the present recommendation, for consideration by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

2. *Invites* Parties and other States to closely consider the issues and facilitate their resolution with a view to ensure the timely and effective implementation of the requirements contained in the first sentence of paragraph 2 (a) of Article 18;

II. Paragraphs 2 (b) and 2 (c) of Article 18

Noting the recommendations of the Second Meeting of Technical Experts on Handling, Transport, Packaging and Identification of Living Modified Organisms (paragraphs 2 (b) and 2 (c) of Article 18), which took place in Montreal from 13 to 15 March 2002 (UNEP/CBD/ICCP/3/7/Add.2),

Recognizing that different views, as reflected in the report of the Meeting, were expressed by a number of experts with regard to the extent of necessary information according to paragraphs 2 (b) and 2 (c) of Article 18 or the potential need for additional information that would assist further in the implementation of paragraphs 2 (b) and 2 (c) of Article 18,

Further recognizing that, except for those elements where unresolved issues were highlighted with an asterisk, the recommendations of the meeting of experts have not been fully reviewed at this meeting, and *noting* that reservations were expressed regarding issues that relate to the other elements of the recommendations of the meeting of technical experts, such as items (i)-(iv), and (i) –(v) of elements 1 (b) and 2 (c) of the recommendations, and the examples of templates respectively, and that suggestions were made to further consider these issues,

Noting also that these different views remain difficult to resolve,

Further recognizing the requirements to meet the obligations specified in paragraphs 2 (b) and 2 (c) of Article 18 at the date of entry into force of the Protocol, the lack of consensus on these recommendations does not set aside the obligations to implement paragraphs 2 (b) and 2 (c) of Article 18of the Protocol,

Submits the following for the consideration of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol:

1. That the following information be provided to meet the requirements for documentation under paragraph 2 (b) of Article 18:

(a) Clear identification as "living modified organisms":

[(i) As destined for contained use;

(ii) Name of the organisms;]

(b) Specification of requirements for the safe handling, storage, transport and use:

(i) As provided under applicable existing international requirements, such as the United Nations Model Regulations on the Transport of Dangerous Goods;

(ii) As provided under domestic regulatory framework, if any;

(iii) Any other requirements agreed to by the importer and exporter; or

(iv) In the event there is no requirement, indicate that there is no specific requirement;

(c) Contact point for further information:

An individual or organization in possession of relevant information such as the exporter, importer or consignee, as appropriate, including contact details necessary to reach them as fast as possible especially in case of emergency;

(d) Name and address of the individual and institution to whom the living modified organisms are consigned.

2. The following information be provided to meet the requirements for documentation under paragraph 2 (c) of Article 18:

(a) Clear identification as "living modified organisms";

(b) Specification of identity and relevant traits and/or characteristics as specified in the Protocol and as identified in common practices:

(i) A brief description of the organisms, including category, name, relevant traits including transgenic traits, and characteristics such as event(s) of transformation;

[(ii) Where available and applicable:

- A reference to a system of identification, for instance:
  - A reference may be made to harmonized code such as unique identifier;
  - Notification under the advance informed agreement procedure;
  - Final decisions;
  - Notifications to the Biosafety Clearing-House;
- Other requirements in accordance with the regulatory status of the LMO in the Party of import.]

(c) Any requirements for the safe handling, storage, transport and use:

(i) As provided under applicable existing international requirements, such as the requirements under the OECD Seed Schemes;

(ii) As provided under domestic regulatory framework, if any;

(iii) Any other requirements agreed to by the importer and exporter;

(iv) As provided under the advanced informed agreement procedure if applicable; or

(v) In the event there is no requirement, indicate that there is no specific requirement;

(d) Contact point for further information:

An individual or organization in possession of relevant information such as the exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible especially in case of emergency;

(e) Name and address of the exporter and importer;

(f) A declaration that the transboundary movement is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter.

3. In the context of the implementation of the provisions of paragraphs 2 (b) and 2 (c) of Article 18 as soon as the Protocol enters into force, the Intergovernmental Committee:

(a) Pending consideration of the need to develop a stand-alone template, *urges* Parties and Governments to take the necessary measures with a view to include information requirements pertaining to paragraphs 2 (b) and 2 (c) of article 18 indicated in recommendations 1 and 2 above, into existing documentation practices accompanying living modified organisms supplied by the originator of the shipment (e.g. commercial invoices). Examples of such possible integration are illustrated in the templates contained in annex III to the present recommendation;

(b) *Encourages* Parties to consider whether the provision of additional information, especially the intended use of the living modified organisms, e.g, "research" or "commercial", if relevant to biosafety, and if not already specified on the accompanying documentation, would facilitate implementation of paragraphs 2 (b) and 2 (c) of Article 18.

4. With regard to linkages of paragraphs 2 (b) and 2 (c) of Article 18 to paragraph 3 of Article 18, the Intergovernmental Committee:

(a) *Requests* the Executive Secretary to continue to collect and review existing information on standards, practices and rules relevant to handling, packaging, transport and identification of LMOs, including the ongoing processes on these matters under relevant international organizations, and operational experience of movements of LMOs under paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol, with a view to assisting consideration of this issue by the Conference of the Parties serving as the meeting of the Parties to the Protocol at the appropriate time;

(b) *Invites* Parties and other Governments to examine unique identification systems such as the one being developed by the Organisation for Economic Co-operation and Development with a view to considering their applicability to the requirements of identification of living modified organisms, and their linkage to the Biosafety Clearing-House.

Annex I to recommendation 3/6

REPORT OF THE MEETING OF TECHNICAL EXPERTS ON THE REQUIREMENTS OF PARAGRAPH 2 (a) OF ARTICLE 18 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

INTRODUCTION

A. Background

1. At its second meeting in Nairobi, Kenya, from 1 to 5 October 2001, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) recommended a number of actions relating to paragraph 2 of Article 18 with a view to facilitating the implementation of requirements contained in the paragraph once the Protocol enters into force. It invited, among other things, Parties to the Convention, Governments and relevant international organizations to provide the Executive Secretary with views and relevant information 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 of the Protocol.

2. ICCP also requested the Executive Secretary to prepare a synthesis report of the views and information and to convene a meeting of technical experts with broad expertise covering all relevant aspects and disciplines for the implementation of paragraph 2 (a) of Article 18, taking into account the need for balanced regional representation, transparency and a stepwise approach.

3. Accordingly, and with generous financial contributions by the Governments of Canada, Spain, Switzerland and the United States of America, a meeting of the technical experts was held at the premises of the International Civil Aviation Organization (ICAO) in Montreal, from 18 to 20 March 2002.

B. Attendance

4. Participants in the Meeting were selected from among Government-nominated experts from each geographic region with a view to achieving a balanced regional distribution. In addition, representatives of relevant intergovernmental and non-governmental organizations, as well as other stakeholders were invited to participate.

5. The Meeting was attended by experts nominated by the following Governments: Antigua and Barbuda, Argentina, Armenia, Australia, Belarus, Brazil, Cameroon, Canada, Croatia, Cuba, Democratic Republic of Congo, Denmark, Ecuador, Egypt, France, Germany, Ghana, Honduras, India, Iran (Islamic Republic of), Italy, Jamaica, Japan, Kenya, Lao People's Democratic Republic, Mexico, Mozambique, Namibia, Nepal, Niger, Nigeria, Norway, Pakistan, Palau, Poland, Republic of Korea, Spain, Sweden, Switzerland, Tunisia, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Venezuela, and Viet Nam.

6. A representative of the European Community also attended.

7. Representatives of the following intergovernmental and non-governmental organizations and other stakeholders also participated in the Meeting:

(a) *Intergovernmental organizations*: United Nations Environment Programme (UNEP)

(b) *Non-governmental organizations and other stakeholders*: International Grain Trade Coalition, Global Industry Coalition; International Seed Trade Federation (FIS/ASSINSEL); SOLAGRAL; Third World Network, Greenpeace International.

ITEM 1. OPENING OF THE MEETING

8. The meeting was opened by Mr. Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity, at 10 a.m. on Monday, 18 March 2002.

9. In his opening statement, Mr. Zedan welcomed, the participants to the meeting and expressed gratitude to the Governments of Canada, Spain, Switzerland and the United States of America for their support of participants from developing countries, and to the Government of Canada for hosting the Meeting. He noted that this meeting had been convened at the request of ICCP, to consider the appropriate implementation of the requirements contained in the first sentence of paragraph 2 (a) of Article 18, as well as the requirements of each element in that paragraph. He stressed that the recommendations from this meeting would contribute significantly to the preparations necessary for the implementation of the requirements of Article 18 upon entry into force of the Protocol.

10. An opening statement was also made by Mr. Barry Stemshorn, Deputy Assistant Minister of the Environment, Canada.

11. In his statement, Mr. Stemshorn welcomed the participants to Montreal and thanked the Secretariat for its work in preparing for the Meeting. He recalled the text of the Preamble to the Cartagena Protocol on Biosafety, and he stressed that trade and environmental agreements should be mutually supportive with a view to sustainable development. Mr. Stemshorn considered that this was probably the best general statement of the mission of this meeting of experts, which together with the themes of capacity development and system development, laid the groundwork for the strong challenge ahead of the meeting.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of officers

12. At the opening session of the Meeting, on 18 March 2002, the participants endorsed the nomination of the following officers for the Meeting:

Chair: Mr. Desmond Mahon (Canada)

Co-Chair: Ms. Audia Barnett (Jamaica)

Rapporteur: Ms. Nevenka Preradovic (Croatia)

2.2. Adoption of the agenda

13. The Meeting adopted the following agenda on the basis of the provisional agenda circulated as document UNEP/CBD/BS/TE-18.2a/1/1.

1. Opening of the meeting.

2. Organizational matters:

   2.1 Election of officers;

   2.2 Adoption of the agenda;

   2.3 Organization of work

3. Consideration of views and relevant information on requirements of paragraph 2 (a) of Article 18 of the Protocol:

   3.1. Consideration of the modalities of implementation of the requirements contained in the first sentence of paragraph 2 (a) of Article 18 at the time of entry into force of the Protocol;

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

4. Recommendations.

5. Other matters.

6. Adoption of the report.

7. Closure of the meeting.

2.3. Organization of work

14. Following a discussion, the Meeting agreed to consider the items of the agenda in their customary order, and hold an initial general debate on item 3, in plenary. It was decided not to break into two groups to consider issues under agenda item 3.1 and agenda item 3.2 unless such an arrangement proved necessary.

ITEM 3. CONSIDERATION OF VIEWS AND RELEVANT INFORMATION ON THE REQUIREMENTS OF PARAGRAPH 2 (a) OF ARTICLE 18 OF THE PROTOCOL

15. Agenda item 3 was taken up in plenary at 1st session, on Monday, 18 March 2002

16. A representative of the Secretariat introduced the note of the Executive Secretary (UNEP/CBD/BS/TE-18.2a/1/2. He explained that section II of the note contained a synthesis of views and information on how to deal with the requirements of paragraph 2 (a) of Article 18. He observed that it also included information on existing practices, rules and standards relevant to paragraph 2 (a) of Article 18. With the exception of those limited cases where updated or new information had been added, all of the information on existing practices, rules and standards contained in section III of the note had been submitted by Parties, Governments and relevant international organizations and synthesized earlier for the purpose of the second meeting of ICCP. Section IV of the note contained a list of some of the important issues that had been derived from the submissions, with a view to assisting the participants in focusing their deliberations. Finally, he explained that recommendations of a more general nature were suggested in section V, for the consideration by the participants. The representative of the Secretariat ended by explaining that full text of the submissions of the Parties, Governments and relevant international organizations had been circulated as an information document (UNEP/CBD/BS/TE-18.2a/INF/1).

17. The Chair thanked the Secretariat and asked the participants for general observations as to the elements involved in the consideration of the two sentences of paragraph 2 (a) of Article 18.

18. Opening statements were made by the experts from Argentina, Australia, Brazil, Canada, Egypt, India, Jamaica, Namibia, Nigeria, Norway, the Republic of Korea, Tunisia, the United Kingdom of Great Britain and Northern Ireland, and the United States of America, as well as a representative from International Grain Trade Coalition.

19. The following main points were raised:

(a) That if a shipment is known to contain living modified organisms (LMOs) then the nature of these LMOs should be described;

(b) That a distinction should be made between shipments with LMOs and those without LMOs;

(c) That LMOs for food, feed or processing (FFP) are best considered as commodities;

(d) That there is a clear linkage between paragraph 2 (a) and paragraph 2 (c) or Article 18;

(e) That there is a linkage between paragraph 2 (a) and Article 11 of the Protocol;

(f) That LMOs-FFP have already been approved for intentional introduction into the environment;

(g) That there was a need to respect the wording of paragraph 2 (a);

(h) That if a shipment is known to contain LMOs, then there is no reason not to state this on any accompanying documents;

(i) That there was a need to identify the LMOs so that the Party of import could identify them and undertake testing to verify the contents of a shipment;

(j) That there was no need to undertake such testing, as a risk assessment would have already been done;

(k) That there was a need for a unique identifier linked to the Biosafety Clearing-House (BCH) to accomplish this;

(l) That the phrase "may contain" might be too vague;

(m) That the use of the phrase "may contain" might misrepresent the nature of a shipment of LMOs;

(n) That to avoid such misrepresentation there should be a threshold level established so that a developing country could perform the risk assessment under paragraph 6 of Article 11;

(o) That bulk commodities were at issue in consideration of paragraph 2 (a) of Article 18 and such was not the case with Article 11;

(p) That there was a need to protect biodiversity in a way that allows the movement of commodities in the least costly ways;

(q) That the transboundary movement of grain occurs on a large scale, and such trade is important in providing for the world's food requirements.

20. The Chair thanked the participants for their general interventions. He noted that there was a need to proceed in a stepwise manner in consideration of some of these issues.

21. Statements were then made by the experts from Argentina, Australia, the Islamic Republic of Iran, Jamaica, Norway, the United Republic of Tanzania, as well as a representative from the International Grain Trade Coalition.

22. The following main points were raised:

(a) That there was a need to establish a relatively low threshold level for LMOs to protect biodiversity;

(b) That bulk commodities moved to certain grade specifications;

(c) That there can be no zero-tolerance with bulk shipping;

(d) That even a threshold of 5% adventitious material would involve increased costs;

(e) That there was a need to establish what threshold levels would be appropriate;

(f) That commodities shipped for one purpose, such as food or feed or for processing, are often used for another, such as planting;

(g) That the identification "may contain" living modified organisms could appear on a commercial invoice;

(h) That a decision to use a commercial invoice ought to depend on whether it were linked to a unique identifier and the Biosafety Clearing-House;

(i) That documents should be clear, simple and not misleading;

(j) That there was a need to state the contents of the LMOs to ensure that exporters were in compliance with the domestic law of the importer;

(k) That any documents should be easy to handle by those who would have to use them;

(l) That if commercial documents are used then they should state which LMOs are in the shipment and that this should be connected to a harmonized code with a linkage to the Biosafety Clearing-House.

23. The Chair noted that this discussion had raised several issues. He observed that the information to be included in shipping documents had been directly provided by the Protocol, although this information could be further refined by ICCP or the Conference of the Parties.

24. Further statements were then made by the following experts from Brazil, Cuba, Egypt, the European Commission, France, Ghana, India, the Islamic Republic of Iran, Mexico, Namibia, Norway, Palau, Switzerland, Tunisia, the United Republic of Tanzania, and the United States of America, as well as representatives from the International Grain Trade Coalition and Third World Network.

25. The following additional points were made:

(a) That transhipment of bulk cargo meant that it was impossible to ensure cargo purity;

(b) That in the case of transhipment of bulk cargo, if all LMOs, including those that are unintentionally present, were required to be named then every subsequent country would also have the responsibility for accuracy of the description of the cargos leaving their borders;

(c) That the description of the contents of a cargo was not simply of use to port authorities but was also of use to the competent national authorities;

(d) That the environment should not have to support trade but that each should support the other;

(e) That the costs of trade should not be externalized on to the environment;

(f) That the costs should not be externalized on to the small producers and place them at a trade disadvantage;

(g) That those who cannot afford certified seed could use LMOs intended for FFP instead;

(h) That LMOs-FFP had already been in circulation for the past eight years;

(i) That if more detailed information was required in the shipping documents for all LMOs, including those that were unintentionally present, then all countries would have to adopt that requirement and shoulder the associated costs;

(j) That any further requirement for a description of the LMOs would be burdensome and stretch the capacity of the bulk trade system;

(k) That it was possible to assure a reasonable level of purity in shipments of grains;

(l) That documents should be clear and simple but also include the notification that the FFP was not intended for release into the environment;

(m) That additional information was not needed as such information was already with the Biosafety Clearing-House;

(n) That information was required for those LMOs-FFP that could spread and establish themselves in the environment;

(o) That LMOs were a fact of life for major exporters;

(p) That there was a need to discuss operational realities as the Protocol could be in force within six months;

(q) That, given the variety of documents in use, the commercial invoice that always accompanies a shipment should be used;

(r) That it was not clear that the commercial invoice was the best choice of documentation;

(s) That the generalized use of the term "may contain" LMOs would be too vague;

(t) That the burden should be on the exporter and grower to identify the LMOs, if Article 11 was to be implemented;

(u) That the term "may contain" was useful if one focused on the intent of the shipment;

(v) That recommendations had to be made to ICCP and that the recommendations of the previous week could be a starting point.

26. The Chair observed that many ideas had been laid out which related to: the first sentence of paragraph 2 (a), the second sentence of paragraph 2 (a), Article 11 of the Protocol and the discussions of the previous week. He thanked the participants for their contributions and suggested that the Meeting could continue by discussing those elements essential to the first sentence and suggested that the participants wait to, to discuss in greater detail those elements appropriate to the second sentence, until after a consensus had been reached on the first sentence.

27. At the start of the second plenary session, the Chair summarized the work of the first session. He noted that the issue of the documentation had been discussed and that there seemed to be general agreement on the use of existing forms of documentation accompanying shipments, such as commercial invoices, with the caveat that we might revisit this in light of further comments, which may be made. He observed that that the issue of the Contact Point had not been raised and he noted that the requirement that a reference in a document that the shipment "may contain LMOs" needed to be discussed as statement of some form would have to appear in documents. He suggested that the participants address the first two points and then deal with the central issue of what "may contain" might mean later.

Documents to accompany LMO for food, feed and processing

28. Statements were made by the experts from Australia, the European Community, Namibia, and Norway, and by representatives from the International Grain Trade Coalition and Third World Network.

29. The following main points were raised:

(a) That commercial invoices could be used pending consideration of the need to develop stand alone documentation;

(b) That the use of a commercial document will depend upon the creation of a unique identifier;

(c) That commercial documentation was not controlled by national authorities or was not under the supervision of the Cartagena Protocol;

(d) That no unique identifier was as yet in operational existence;

(e) That the use of existing documentation was the only course currently open;

(f) That if the Conference of the Parties later revisited the issue, it would run up against a system of documentation already in place;

(g) That there were a number of certificates in international trade, but that the only document always accompanying a shipment was the commercial invoice;

(h) That the Secretariat was in contact with relevant international organizations about their systems of documentation;

(i) That while the Protocol created obligations between the Parties, a commercial invoice only bound the exporter and importer.

Contact point

30. The Chair then asked the participants to address the issue of the second element in the first sentence of paragraph 2 (a) of Article 18, the contact point. On the suggestion of one participant that the Meeting could adopt language along the lines of the recommendation on the issue approved by the Second Meeting of Experts on Paragraphs 2 (b) and 2 (c) of Article 18, the Chair asked the Secretariat to read to the participants the relevant recommendation.

31. Statements were made by the experts from Australia, Brazil, Canada, Ecuador, France, Germany, Ghana, India, the Islamic Republic of Iran, Jamaica, Namibia, Norway, Palau, Pakistan, Switzerland, Tunisia, and the United States of America, and by representatives from Third World Network and Greenpeace International.

32. The following main points were raised:

(a) That the contact point should be the exporter;

(b) That the contact point could be the exporter, the importer or any other person sufficiently knowledgeable about the shipment;

(c) That the most important issue was not which person but which person had the most knowledge;

(d) That the person or the institution with the most knowledge should be the contact point;

(e) That the Biosafety Clearing-House could be a contact point;

(f) That there could be more than one contact point;

(g) That the exporter and a competent authority should be contact points;

(h) That as the invoice always had both the exporter and importer listed, the best contact point was those directly involved in the shipment;

(i) That the contact point should be related to the elements in the documentation otherwise the Contact Point would be vague;

(j) That the contact point should lead to information at the Biosafety Clearing-House;

(k) That paragraph 2 (a) referred to commodities and trade and thus commercial invoices were the best documents and pointed to the importer and exporter;

(l) That the primary contact point should be the exporter with a competent authority as a secondary contact point;

(m) That a reference to national authorities as a contact point would rectify a weakness in using commercial invoices;

(n) That the language of paragraph 2 (a) did not refer to certification or competent authorities;

(o) That developing countries were not always easily able to access information at the Biosafety Clearing-House;

(p) That the contact point should be easily accessible in an emergency;

(q) That the contact point should be someone intimately involved in the shipment, such as the exporter or importer otherwise the discussion becomes one of import permit;

(r) That a contact point meant a national authority;

(s) That countries needed as much information as possible to make informed decisions about the import of LMOs-FFP;

(t) That the reference to a contact point should be read in light of Article 11 and Annex II of the Protocol;

(u) That there was a need for reliable information and that the exporter and the importer were those best placed to give such information.

33. The Chair noted that while the text of the provision required that there be a Contact Point, another consideration was whether it would be possible to have a primary Contact Point and secondary Contact Points. The Chair then asked the participants to begin to consider the issue of the statement that a shipment "may contain" living modified organisms. To this end he asked the participants to consider the case where an entire shipment would be comprised of living modified organisms.

Identification of living modified organisms intended for direct use as food or feed, or for processing

34. Statements were made by the experts from Argentina, Australia, Brazil, Cameroon, Canada, Croatia, Denmark, Egypt, the European Community, France, Ghana; Germany, India, Iran (Islamic Republic), Italy, Jamaica, Kenya; Mexico, Namibia, Nigeria, Norway, Pakistan, Palau, Poland, the Republic of Korea; Sweden; Switzerland, Tunisia, the United States of America, and Viet Nam; and by

representatives from the International Grain Trade Coalition, Global Industry Coalition, Third World Network, and Greenpeace International.

35. The following main points were raised:

(a) That there was a need to take into consideration levels of literacy and establish an easily identifiable sign or logo; that there was a need to look for a standard threshold level;

(b) That the simple reiteration of the language of the Protocol would misrepresent the shipment in this case;

(c) That there was a need to be able to trace the shipment and know what it contained;

(d) That if the shipment were only of LMOs then the shipping document would say this anyway;

(e) That Article 18 of the Protocol had to be read in light of Article 11 and Annexes II and III to the Protocol in order to provide a link to the Biosafety Clearing-House;

(f) That the phrase "may contain" is a recognition in the Protocol that LMOs for FFP should be treated differently from those in paragraphs 2 (b) and 2 (c);

(g) That in the case of a known shipment of LMOs , then the nature of the LMOs should be stated;

(h) That there was a need to follow the language of the Protocol;

(i) That while the shipment may be known to contain LMOs the nature of the specific transformations would probably not be know;

(j) That consumers would have more confidence if tests were done on imported shipments and the results were known;

(k) That with bulk handling it was impossible to rule out the importation of any particular LMO;

(l) That where this information is available it should be given;

(m) That the LMOs had to be identified to ensure that they complied with those approved by the importing country;

(n) That where the shipment is known to contain LMOs countries should make a voluntary declaration to this effect;

(o) That there would never be a pure shipment of an LMO and that all bulk shipments of LMOs are, for all practical purposes, always commingled with other LMOs and non-LMOs;

(p) That because of the above-mentioned problem some countries refused to import certain produces;

(q) That the phrase "may contain" is an interim measure pending decision by the COP/MOP as provided for by the second sentence of paragraph 2 (a) of Article 18;

(r) That where material is transhipped that everyone must understand that LMOs might be involved;

(s) That where LMOs were known to be in a shipment the words "may contain" should be followed by a description of the LMOs involved;

(t) That there was a need to seek legal advice for clarification of the apparent contradictions in the first sentence of paragraph 2 (a) of Article 18;

(u) That there was a need for a precautionary approach;

(v) That there was a need to identify the LMOs including a reference to the transformational event and a unique identifier if available;

(w) That there was a need to protect biological diversity in a way which did not interrupt trade;

(x) That the listing of specific LMOs was needed to be able to reference these at the Biosafety Clearing-House;

(y) That the effect of some of the proposals was to shift the burden of verification on the developing countries which had no easy access to the Biosafety Clearing-House;

(z) That brokers and exporters would not, for all practical purposes, ship to those countries that would refuse a shipment of LMOs and that such information was at the Biosafety Clearing-House;

(aa) That there is a problem of the costs associated with having to withdraw products for circulation after they have entered a country;

(bb) That the problem of the centre of origin had to be considered and that consideration should be given to the problem of what threshold to establish, bearing in mind the increasing costs involved with lower thresholds.

36. The Chair noted that this was clearly a complex issue, but that there was general agreement that with bulk grain shipments there will be a mixture of varieties, and that it might be impossible to guarantee the absence of LMOs. He summarized the discussion and noted that the language "may contain" might be a useful starting point, which could cover a number of events, and that such information is useful to the recipient. However there was also a need to connect the "may contain" of paragraph 2 (a) to the Biosafety Clearing-House, and that while the "may contain" language might not work, it would be for the Conference of the Parties serving as the meeting of the Parties to the Protocol to correct this.

37. At the beginning of the 3rd session, the Chair circulated a status report of the discussion by the participants at the 1st and 2nd sessions. He stressed that the text was not intended to be a draft recommendation and that it was simply a summary of his understanding of the issues, as they had been expressed by the participants, and on which there seemed to be a high degree of clarity. He asked the participants for their comments, of a general nature, on the status report.

38. Statements were made by the experts from Argentina, Australia, Brazil, Cameroon, Canada, Denmark, Ecuador; Egypt, the European Community, France, Ghana, India, Italy, Jamaica, Japan, Kenya, Mexico, Namibia, Norway, Pakistan, Palau, the Republic of Korea, Spain, Sweden, the United States of America and Viet Nam, and by representatives from the International Grain Trade Coalition, Greenpeace International, Third World Network.

39. The following main points were raised:

(a) That references for LMOs-FFP should also include a reference to the transformation event;

(b) That documentation should be clear, informative, simple, precise and easy to use, and not misleading;

(c) That documentation should also be adequate and affordable;

(d) That any "may contain" language should be more precisely specified;

(e) That the "may contain" language is not strong enough;

(f) That "may contain" language was an interim measure and there was a need to stick to the language of the Protocol;

(g) That there was a need for a harmonized international approach;

(h) That such a harmonized approach did not yet exist;

(i) That there is at present no good way to detect the presence of adventitious/unintentional LMOs in a bulk shipment;

(j) That a simple approach is therefore needed for the first sentence of paragraph 2 (a) of Article 18 and that a reference to "may contain" is the best way to do this;

(k) That there was a need that information be informative to those who will use it;

(l) That it was not certain that the importer would be able to provide adequate information on LMOs-FFP and so the exporter or the exporter's agent ought to be the Contact Point;

(m) That there was a need for recommendations which either suggested that the "may contain" language be addressed and/or clarified;

(n) That it should be noted that LMOs-FFP were for food, feed and processing only;

(o) That there was a need to capture the language of Article 11 with reference to LMOs-FFP;

(p) That there needed to be a linkage to the Biosafety Clearing-House;

(q) That a linkage to the BCH would not be useful;

(r) That there should be a transfer of technology to those who would need it, but did not yet have it;

(s) That existing commercial documents already indicated the country of origin together with a description of the material being shipped;

(t) That the description ought to include a description of the transformation event;

(u) That it was possible to include a reference to the transformation event at this time;

(v) That there was a need to boost consumer confidence and that the disclosure of such information would help;

(w) That it was the importers who needed such information;

(x) That there was a need for the name of the variety of the LMO to be specified in the documentation;

(y) That there was need for information on the host organism and the donor as well;

(z) That there was a need for thresholds;

(aa) That there was a need for the Conference of the Parties serving as the meeting of the Parties to establish threshold values to set baselines;

(bb) That it was not useful to go down this route;

(cc) That in the case of the specificity of the LMOs-FFP in a shipment, the lack of a threshold could be a problem;

(dd) That there should not be an unnecessary increase in the costs of commodities in bulk trade;

(ee) That no transboundary shipment could take place without a contract between the importer and exporter in which each of them would verify that the contract could be completed by the importer taking delivery of the shipment;

(ff) That there was a link between the elements to be flagged in a document and the need for development of internationally accepted standards;

(gg) That importers were better contact points as they would be certain to speak local languages and also be aware of the contents of the shipments;

(hh) That bulk commodities can contain LMOs with a number of different transformation events.

40. The Chair synthesized the discussion to this point. He thanked the participants for their observations on his status report and recalled that the participants could only make recommendations to ICCP. He then asked the participants for their views on the linkage between the "may contain" language and the elaboration of the additional information that this might contain. He noted that a connection to the Biosafety Clearing-House could occur at this point, which could in turn lead to the competent national authorities. There was, however, also a need to examine the concept of thresholds; and while thresholds, were problematic, there was a need to explore this issue in order to make recommendations to ICCP so that preparations could go ahead for the first meeting of the Conference of the Parties serving as the meeting of the Parties. The Chair then asked the participants for their views.

The issue of thresholds relating to the adventitious/unintentional presence of LMOs

41. Statements were made by the experts from Australia, Cameroon, Canada, the European Community, Norway, the United States of America, Venezuela, and Viet Nam, and by representatives from the International Grain Trade Coalition and Greenpeace International.

42. The following main points were raised:

(a) That the quality of commodities was controlled all along the line;

(b) That with bulk shipments there was generally an allowance for tolerances for adventitious/unintentional materials;

(c) That a lower level of tolerance would lead to a more expensive product;

(d) That the European Commission was investigating standards of tolerance for LMOs;

(e) That a five per cent threshold as suggested by the grain industry representative would be too high;

(f) That some domestic laws currently specified a 2 per cent or 3 per cent threshold;

(g) That there was a need to wait and see what experience had been gained before recommending a threshold to ICCP;

(h) That ICCP should request a synthesis of the international practices on thresholds;

(i) That there was a need for the Meeting to stick to its mandate and that the discussion of thresholds was not within that mandate.

43. At the 4th session of the meeting, the Chair asked the participants to address two further issues: the adventitious/unintentional introduction of LMOs into a shipment that should not contain them, and the consideration that the "may contain" language of Article 18 paragraph 2 (a) might affect technical ability of the Parties to implement the Protocol.

Adventitious/unintentional presence of LMOs in non-LMO shipments

44. Statements were made by the experts from Argentina, Brazil, Cameroon, Egypt, the European Community, Germany, India, the Islamic Republic of Iran, Jamaica, Namibia, Norway, Pakistan, Palau, Sweden, Switzerland, Tunisia, the United Republic of Tanzania, and the United States of America and representatives from the International Grain Trade Coalition and Third World Network.

45. The following main issues were raised:

(a) That the Protocol did not apply to cases of non-LMO shipments;

(b) That the above-mentioned issue was one that needed to be addressed under domestic legislation;

(c) That thresholds should be linked to the "may contain" language, and this should be linked to the Biosafety Clearing-House so as to not overload documents;

(d) That too much responsibility was being put on exporters when they could not assure that there would be a non-LMO shipment would be free of LMOs;

(e) That exporters had no control over the actual shipment once it had left their hands and could face liability for small amounts of unintentional presence of LMOs in shipments;

(f) That commingling could occur in the preparations for shipment;

(g) That there might be a disclaimer on documents that the exporter was not responsible for the consequences of contamination during shipment;

(h) That exporters should be expected not to violate the objectives of the Protocol;

(i) That if the exporter is not to be liable for the presence of the LMOs in a shipment, then the Party to the Protocol ought to be instead;

(j) That it might not be possible to assure that a shipment of non-LMO-FFP, such as wheat, was free of other LMOs from other species;

(k) That the purpose of the "may contain" language was to highlight that the LMOs are likely to be part of any bulk shipment;

(l) That as an interim measure a 5 per cent threshold ought to be considered, and that such a level would not be too costly;

(m) That the term "GMO-free" is a misnomer;

(n) That there was a premium to be paid for lower tolerances;

(o) That it was a practical impossibility to avoid contamination in a non-LMO shipment by LMOs;

(p) That there were no adequate tests to establish the extent of all the different kinds of contamination which might occur in a single shipment;

(q) That where mixing was unintentional, it would be uncontrollable, while if it were intentional then it would be controllable;

(r) That the documentation should state the level of uncertainty as to whether the shipment contained LMOs;

(s) That the problem was really a question of what balance should be struck between the exporter and importer, especially when the importer is in the developing world;

(t) That although there were different levels of risk, a baseline had to be established;

(u) That there should be zero tolerance of contamination by LMOs;

(v) That it was possible to indicate the transformation event;

(w) That the purpose of a threshold was to help encourage trade;

(x) That a blanket 5 per cent threshold could not be accepted;

(y) That thresholds should be decided between the buyer and the seller;

(z) That the exporter should not be blind to the likely presence of LMOs in a shipment;

(aa) That there should be sampling to verify compliance with national laws and an indication of the transformation events would help in this;

(bb) That there should be precautionary measures to isolate LMOs from non-LMOs;

(cc) That there was a need to use the "may contain" wording in combination with a list of transformation events;

(dd) That thresholds should only apply when there had been an intentional inclusion of LMOs in a shipment;

(ee) That the purpose of the Protocol was to protect biodiversity;

(ff) That industry should be encouraged to improve its practices;

(gg) That industry should not be intentionally blind to the effect of its practices;

(hh) That it was important to protect biodiversity, and exporters should give standardized data on any detected LMOs in a shipment;

(ii) That a study should be done of the threshold issue.

46. The Chair noted that a number of important elements had been aired. These included the implementation of the first sentence of paragraph 2 (a) of Article 18, and issues to be considered by the Conference of the Parties serving as the meeting of the Parties to the Protocol, including ongoing work in preparation for the Conference of the Parties, such as studies.

47. Statements were then made by the experts from Australia; Brazil, Denmark; Egypt, the European Community, France, Ghana; India, the Islamic Republic of Iran; Jamaica, Japan; Mexico, Namibia Spain, and a representative from the International Grain Trade Coalition.

48. The following additional points were raised:

(a) That a shipment might contain LMOs that were not authorized for import, or authorized ones but over a certain threshold and that they could be refused entry;

(b) That there may be LMOs authorized for one purpose, such as feed, which were not authorized for another, such as food;

(c) That the Secretariat ought to research the issue of thresholds;

(d) That a threshold of 5% seemed too high;

(e) That there was a need for industry to re-evaluate its practices;

(f) That a recommendation should be made to Industry to review its practices;

(g) That there should flexible thresholds;

(h) That most developed countries have a zero tolerance to unapproved LMOs;

(i) That zero tolerance was the only tolerance acceptable for the environment;

(j) That there should be a recommendation to ICCP that it request more information on thresholds;

(k) That the exact transformation event in a shipment can often be stated;

(l) That not all shipments were bulk cargo such as grain;

(m) That the Meeting did not have a mandate to consider the unintentional transboundary movement of LMO-FFP;

(n) That LMOs-FFP would be useful to the economies of the developing world;

(o) That LMOs-FFP present different levels of risk, and that the risks increased when cross pollination was involved;

(p) That pending the development of standards for scientific sampling and detection techniques, there was a need for agreed tolerance levels;

(q) That adequate testing technologies were being developed.

Issues that may affect the technical ability of Parties to implement paragraph 2 (a) of Article 18

49. The Chair then asked the participants to consider what policy issues affecting the technical ability of the Parties to implement paragraph 2 (a) of Article 18 ought to be drawn to the attention of ICCP.

50. Statements were made by the experts from Australia, Germany, India and Norway,

51. The following issues were raised:

(a) That any recommendations made on this issue be for consideration by ICCP in preparation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(b) That there was a need to develop a unique identifier connected to the Biosafety Clearing-House;

(c) That there was a need to get the advice of industry on the sampling of adventitious LMOs;

(d) That there was a need to get the advice of Governments and industry;

(e) That the “may contain” phrase involved thresholds;

(f) That the “may contain” phrase presented difficulties in identifying shipments known to contain LMOs-FFP; and

(g) That, while industry ought to develop methods of scientific methods of sampling and identification, transformational traits associated with LMOs that are subject to transboundary movement had to be disclosed as well, bearing in mind the need for the Conference of the Parties serving as the meeting of the Parties to the Protocol to develop scientific standards.

ITEM 4. RECOMMENDATIONS

52. At the 5th session of the meeting, on Wednesday, 20 March 2002, the experts considered the draft recommendations, prepared by the Chair on the basis of the discussions.

53. Following a discussion, in which a number of experts participated, the Chair informed the experts that he would redraft a part of the preamble to the recommendations.

54. At the 6th session of the meeting, the experts continued their discussion of the revised text of the recommendations, as amended to include a proposal of the expert from Egypt.

55. The experts approved the draft recommendations, as amended in the course of discussion, for transmission to ICCP at its third meeting. The text of the recommendations is annexed to the present report.

56. The expert from Namibia expressed his view that there should be a reference to the final destination of shipments in paragraph 1 (f) of the recommendations.

57. The expert from India expressed his view, in connection with paragraph 3 (a) of the recommendations, that future consideration of the identification requirement contained in the first sentence of paragraph 2 (a) of Article 18 should be put in context in that the phrase "clearly identifies them as they 'may contain' " needed to be looked at, not merely the "may contain" portion of it.

58. The expert from Australia expressed his view that the introductory sentence, or chapeau, of recommendation 3 should read "With regard to implementation of paragraph 2 (a) of Article 18, the Meeting of Technical Experts identified the following issues that may warrant future consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol".

ITEM 5. OTHER MATTERS

59. No other matters were raised for discussion.

ITEM 6. ADOPTION OF THE REPORT

60. The present report was adopted on 20 March 2002, on the basis the draft report presented by the Rapporteur.

ITEM 7. CLOSURE OF THE MEETING

61. Following the customary exchange of courtesies, the meeting was closed at 8:30 p.m. on Wednesday, 20 March 2002.

Annex to the report of the Meeting of Technical Experts

RECOMMENDATIONS OF THE OF THE MEETING OF TECHNICAL EXPERTS ON THE REQUIREMENTS OF PARAGRAPH 2 (a) OF ARTICLE 18 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

The Meeting of Technical Experts on the Requirements of Paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety,

Noting the urgent need to provide guidance to Parties and States on the modalities for the implementation of the first sentence of paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety,as a requirement for Parties upon entry into force of the Protocol,

Noting also the linkage between the implementation of Article 11 and implementation of paragraph 2 (a) of Article 18, and, further, that the operation of the Biosafety Clearing-House and the capacity to utilize it is essential for the effective implementation of paragraph 2 (a) of Article 18, especially for developing countries, in particular the least developed and small island States among them, and countries with economies in transition,

Noting further:

(a) The complexity of the issues involved in the implementation of paragraph 2 (a) of Article 18 of the Protocol;

(b) The information provided by industry on the transboundary movement of agricultural commodities including bulk grains, whilst recognizing that this is only one example of transboundary movements that may contain living modified organisms intended for direct use as food or food, or for processing;

(c) The current state of methodology for identification of LMO content in shipments; and,

(d) The challenges in implementing the "may contain" provision and the second sentence of paragraph 2 (a) of Article 18 of the Protocol,

Acknowledging that the recommendation on implementation of the first sentence of paragraph 2 (a) of Article 18 in no way affects the right of Parties:

(a) To reach a decision, under their domestic legislation and consistent with their other obligations under international law, regarding the import of living modified organisms intended for direct use as food or feed, or for processing;

(b) To take further measures consistent with Article 2, paragraph 4, and Article 11, paragraph 4, of the Protocol, including on identification,

Recognizing that implementation of the requirements contained in the first sentence of paragraph 2 (a) of Article 18 is on an interim basis, pending the decision referred to in the second sentence of paragraph 2 (a) of Article 18,

Further recognizing that, as reflected in the report of the meeting, different views were expressed by a number of experts with regard to the extent of necessary information according to the first sentence of paragraph 2 (a) of Article 18 or the potential need for additional information (in sections highlighted by an * in the text) that would assist further in the implementation of the first sentence of paragraph 2 (a) of Article 18,

Aware that the Conference of the Parties serving as the meeting of the Parties to the Protocol shall take a decision on the detailed requirements of documentation accompanying living modified organisms intended for direct use as food or feed, or for processing, including specification of their identity and any unique identification no later than two years after the date of entry into force of the Protocol,

Submits the following for consideration by the Intergovernmental Committee for the Cartagena Protocol on Biosafety:

1. Regarding modalities for the implementation of the requirements for the documentation accompanying transboundary movements of living modified organisms intended for direct use as food or feed, or for processing, contained in the first sentence of paragraph 2 (a) of Article 18, required upon the entry into force of the Protocol, the Meeting of Technical Experts recommends that:

(a) Pending consideration of the need to develop stand-alone documentation accompanying living modified organisms intended for direct use as food or feed, or for processing, measures should be taken by Parties and Governments to require integration of the information requirements of the first sentence of paragraph 2 (a) of Article 18 into existing documentation supplied by the originator of the shipment;

(b) The documentation should accompany all shipments for food or feed, or for processing, that intentionally contain LMOs;

(c) The documentation should be informative, clear, precise and easy to use;

(d) The documentation should state that the shipment "may contain LMOs intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment, * and that additional information on the living modified organisms intended for direct use as food or feed, or for processing, is available through the Biosafety Clearing-House";

(e) *In order to facilitate access to the information in the Biosafety Clearing-House, exporters be encouraged to provide additional information on the specific living modified organisms in the shipment if known and not already provided elsewhere on the accompanying documentation, to facilitate implementation of paragraph 2 (a) of Article 18;

(f) The documentation should include information on a contact point for further information, who should be an individual or organization in possession of relevant information. The information should include contact details necessary to reach them as fast as possible especially in case of emergency. The contact point may be the exporter, importer, or any other appropriate individual, authority, or organization.

2. Regarding the issues to be addressed in preparation for the decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol referred to in the second sentence of paragraph 2 (a) of Article 18, the Meeting of Technical Experts identified that the following issues need to be considered, and recommends that Parties, Governments, and other relevant stakeholders including industries and non-governmental organizations should be requested to submit information, views and advice on:

(a) Operational experience, including the relevance and usefulness of other international systems, standards and provisions, on the effectiveness and efficiency of the implementation of the first sentence of paragraph 2 (a) of Article 18 with regard to achieving the objective of the Protocol;

(b) The need for and the development of a harmonized/unique identification system applicable to LMOs under paragraph 2 (a) of Article 18 as a means to provide direct access to pertinent information;

(c) The need for and the development of affordable, accessible, internationally accepted standard methodology for the sampling, detection and identification of LMOs intended for direct use as food or feed, or for processing;

(d) Any linkages between paragraph 2 (a) and paragraph 3 of Article 18.

3. With regard to the implementation of paragraph 2 (a) of Article 18, the Meeting og Technical Experts identified the following issues that may warrant future consideration:

(a) Clarification/elaboration on the application of the language in paragraph 2 (a) of Article 18, specifically the "may contain" phrase, where the identity of the specific LMO(s) in a transboundary movement is known and verified;

(b) The issue of unintentional/adventitious presence of LMO(s) in the context of paragraph 2 (a) of Article 18;

(c) The lack of and possible need for an independent report on current practices in the handling and trans-boundary movements of products for food or feed, or for processing, as they impact on implementation of paragraph 2 (a) of Article 18, including an assessment of the possible costs of implementation including Identity Preservation systems for living modified organisms intended for direct use as food or feed, or for processing.

Annex II to ICCP recommendation 3/6

SUMMARY BY THE CHAIR OF WORKING GROUP I OF THE DISCUSSION UNDER ITEM 4.1.5: HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18, PARAGRAPH 2 (a))

1. The following is a summary of the points made by various delegations during the consideration by Working Group I of the agenda item on handling, transport, packaging and identification:

(a) A step-by-step approach over the two-year interim period to Article 18 is warranted.

(b) There is a need for reference to unique identification in the documentation.

(c) There is a need for accompanying documentation to clearly identify LMO-FFPs.

(d) There is a need to further clarify the application of the "may contain" provision, particularly when it is known that shipments will contain LMOs.

(e) Additional information requirements should not go beyond the negotiated text of the Protocol.

(f) There is a need to implement an international system of transparent and continuous flow of unambiguous information.

(g) Care must be taken not to duplicate existing standard-setting efforts.

(h) Article 18.2 (a) is also intended to protect gene pools.

(i) There is a need for an independent study on the costs that would be incurred for separating LMOs and non-LMOs.

(j) Documentation requirements should not impede commodity trade.

(k) Accompanying documentation is intended for safe shipping and transport, not risk assessment.

(l) There is a need to focus on the necessary requirements at the time of entry into force, to allow time for industry to comply with the recommendations.

2. On this basis, a contact group was established to focus on the elements of the technical expert group recommendations that were preceded by an asterisk, as well as some of the elements of paragraph 3. The following is a summary of the outcomes of their deliberation.

3. In the contact group there was considerable discussion. Some views and concepts were discussed in attempting to improve the level of agreement. No agreed text was adopted. The following indicative list of further elements are presented for further consideration of the issues at a later stage:

(a) The acknowledgement that the decisions made in relation to paragraph 1 of Article 11, including placing on the market, will be available on the Biosafety Clearing-House and that this information will facilitate Parties' ability to initiate decisions regarding import under their domestic regulatory framework, or according to paragraph 6 of Article 11, fully and early, and that those decisions also will be made available on the Biosafety Clearing-House,

(b) The acknowledgement that the information to be provided pursuant to Annex II, along with the decisions referred above, will be a requirement by the time of entry into force.

(c) The recognition that if complete and accurate information on the accompanying documentation were not made available to Parties which are potential importers and which ask for it, it may impact on the import of the LMO shipments;

(d) The recognition of the absence of consensus, at this stage, on certain issues that may have implications on the implementation of obligations under paragraph 2 (a) of Article 18

(e) The recognition that any unresolved text (i.e., bracketed text) in ICCP recommendations does not affect the obligation of Parties to meet the requirements specified in the Protocol, including the first sentence of paragraph 2 (a) of Article 18, at the date of entry into force of the Protocol;

(f) The recognition that different views were expressed by a number of delegates with regard to the extent of necessary information according to the first sentence of paragraph 2 (a) of Article 18 or the potential need for additional information that would assist further in the implementation of the first sentence of paragraph 2 (a) of Article 18,

(g) The submission of the TEG recommendation and further elements of recommendation for consideration by the first Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, to take a decision on the implementation of paragraph 2 (a) of Article 18 in a step-wise approach.

(h) The possibility to revisit the issue of LMOs being "intentionally" contained in shipments may be envisaged in light of the outcome of an information gathering exercise on the issue of unintentional/adventitious presence of LMOs. The issues of trace amounts/ unintentional /adventitious presence of LMOs are however not referred to in paragraph 2 (a) of Article 18.

(i) The operative element that, without prejudice to more precise information, the documentation should state that the shipment "may contain" LMOs intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment.

(j) The operative element that, the documentation could/should also include any available identification to facilitate access to the information on these LMOs in the Biosafety Clearing-House according to Article 11 and Annex II.

(k) Regarding issues to be addressed in preparation for the decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol referred to in the second sentence of paragraph 2 (a) of Article 18, the issue of whether it would be suitable that, where the identity of specific LMO(s) in a transboundary movement is known and verified, exporters shall be encouraged to state on the documentation that the shipment contains LMOs intended for direct used as food or feed or for processing and to include any available unique identification, where not already clearly indicated elsewhere in the accompanying documentation, in order to specify the identity of these LMOs, needed to be considered, and information, views and advice of Parties, Governments, and other relevant stakeholders including industries and non-governmental organizations be collected.

(l) Regarding issues to be addressed in preparation for the decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol referred to in the second sentence of paragraph 2 (a) of Article 18, the issue of the identity of the LMOs in the shipment, including the taxonomic name, the gene modification inserted and traits or genes changed needed to be considered, and information, views and advice of Parties, Governments, and other relevant stakeholders including industries and non-governmental organizations be collected.

(m) The submissions on issues to be addressed in preparation for the decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol referred to in the second sentence of paragraph 2 (a) of Article 18 should be forwarded to the Executive secretary no later than one month after the depositing of the fiftieth instrument of ratification or accession, in order to be compiled in an information document to be circulated to all Parties to the protocol and governments, for their consideration prior to the first meeting of the Conference of the Parties serving as the meeting of the Parties.

(n) The request to Parties, Governments and relevant international organizations to submit their views and information to the Executive Secretary, for further consideration on the issue of unintentional/adventitious presence of LMO(s) in the context of paragraph 2 (a) of Article 18, and its linkages to Article 17 of the Protocol.

(o) The request to Parties, Governments and relevant international organizations to submit their views and information to the Executive Secretary, for further consideration on the issue of current practices in the handling and transboundary movements of products for food or feed, or for processing, as they impact on implementation of paragraph 2 (a) of Article 18, including an assessment of the possible costs of implementation including Identity Preservation systems for living modified organisms intended for direct use as food or feed, or for processing.

(p) The request to the Executive Secretary to prepare a synthesis report of the views and information submitted on the issues of unintentional/adventitious presence of LMO(s) in the context of paragraph 2 (a) of Article 18, and its linkages to Article 17 of the Protocol and to submit it to the meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, in order to reach a decision within two years after entry into force.

(q) The request to the Executive Secretary to prepare a synthesis report of the views and information submitted on the issues of current practices in the handling and transboundary movements of products for food or feed, or for processing, as they impact on implementation of paragraph 2 (a) of Article 18, including an assessment of the possible costs of implementation including Identity Preservation systems for living modified organisms intended for direct use as food or feed or for processing and to submit it to the meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, in order to reach a decision within two years after entry into force.

(r) The need to develop a template for a stand-alone document accompanying shipments of living modified organisms intended for direct use as food or feed or for processing under paragraph 2 (a) of Article 18.

Appendix 1/

EXAMPLES OF INTEGRATION OF INFORMATION REQUIREMENTS INTO EXISTING DOCUMENTATION

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

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date _____

	EXPORTER	**IMPORTER/CONSIGNEE**	**CONTACT POINT** **Exporter** ☐ **Importer/Consignee** ☐ **Other** ☐
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**
			Living modified organisms: Destined for contained use Name of the organisms Intended use e.g. research, others	

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	• **As provided under applicable existing international requirements,** • **As provided under domestic regulatory framework, if any,** • **Any other requirements agreed to by the importer and exporter, or** • **In the event there is no requirement, indicate that there is no specific requirement**

1/ Information in the shaded portions of the present annex represent the wording of the Protocol stipulated in the respective paragraphs.

B. Example 1 of template for Article 18.2 (b) of the Cartagena Protocol

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date

	EXPORTER	**CONSIGNEE**	**CONTACT POINT** **Exporter** ☑ **Consignee** ☐ **Other** ☐
COMPANY OR INSTITUTION	**XXXX**	**YYYY**	
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	bag	50 g	**Living modified organisms**: Destined for contained use Papaya Research material seeds, PRSV (Papaya Ring Spot Virus) resistant	none

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	**Should only be used in registered facilities**

C. Example 2 for Article 18.2 (b) 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 : **Company or Institution** **Contact Person** **Street, City** **Postal Code, Country** **Phone, Fax** **Email**	Contact Point Shipper ☐ Consignee ☑ Other ☐ **Company or Institution** **Contact Person** **Street, City** **Postal Code, Country** **Phone, Fax**
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

-

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 HIV gene bank in E.coli K12 Living modified organisms	6.2	UN 2814			1 Fiberboard Box ("Safe-T-Pak") x 25.0 mL	602	
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 is for contained use only 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)*

D. Blank Example Template for Article 18.2 (c) of the Cartagena Protocol

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date

	EXPORTER	IMPORTER	CONTACT POINT Exporter ☐ Importer ☐ Other ☐
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**
			• **Living modified organism** • **Brief Description of the organisms including category, name, relevant traits including transgenic traits and characteristics such as event(s) of transformation** • Where available and applicable: ❖ Reference to a system of identification such as: o Harmonized code such as unique identifier o Notification under AIA o Final decisions o Notifications to the BCH ❖ Other requirements in accordance with the regulatory status of the LMO in the Party of import	

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	• **As provided under applicable existing international requirements,** • **As provided under domestic regulatory framework, if any,** • **Any other requirements agreed to by the importer and the exporter,** • **As provided under the advance informed agreement procedure if applicable, or** • **In the event there is no requirement, indicate that there is no specific requirement.**

I declare that this transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter_____ Date_____

E. Example 1 Template for Article 18.2 (c) of the Cartagena Protocol

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date

	EXPORTER	IMPORTER	CONTACT POINT Exporter ☐ Importer ☑ Other ☐
COMPANY OR INSTITUTION	**XXXX**	**YYYY**	
CONTACT PERSON			
STREET			
CITY, POSTAL CODE			
COUNTRY			
PHONE; FAX			
EMAIL			

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

Item	Amount	Weight/Volume	Description	Value
4	Bags	1 Kg	**Living modified organism**: **Rice, resistance against Xanthomonas campestris pv. Orizae , RI323, 327, 432 &726** Permit **RICE3434-02** for experimental release Research material	none

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	• **See permit RICE3434-02**

I declare that this transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter_____ Date_____

F. Example 2 Template for Article 18.2 (c) of the Cartagena Protocol

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date

	EXPORTER	IMPORTER	CONTACT POINT Exporter ☐ Importer ☐ Other ☑
COMPANY OR INSTITUTION	**XXXX**	**YYYY**	***ZZZZ***
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	**Living modified organism**: **Soybean WSD 432, high oleic acid, HOA** Permit #GM21345/2002 for planting OECD UI: BI-ABC891-8 1/ Commercial seeds material	22’000 €

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	**NO SPECIFIC REQUIREMENT**

I declare that this transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter_____ Date_____

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