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CARTAGENA PROTOCOL ON BIOSAFETY
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Item 4.8.4 of the provisional agenda*

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

Note by the Executive Secretary

I. INTRODUCTION

1. The Conference of the Parties to the Convention on Biological Diversity approved, at its fifth meeting held in Nairobi in May 2000, a work plan for the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP). One of the issues that have been identified in the work plan for consideration by ICCP during its second meeting refers to "modalities for a process for discussion on Article 18, paragraph 2 (a), by the first meeting of the Parties" (decision V/1, annex, section B, item 11). At its first meeting, ICCP considered Article 18 of the Protocol, on handling, transport, packaging and identification of living modified organisms and requested the Executive Secretary to undertake inter-sessional activities and to make more information available for its consideration at its second meeting. The ICCP also invited Parties to the Convention, Governments and relevant international organizations to provide to the Executive Secretary information on their existing practices, rules and standards relevant to Article 18 of the Cartagena Protocol on Biosafety. It further requested the Executive Secretary to prepare, based on the information provided by Parties, Governments and relevant international organizations, for its consideration at its second meeting:

(a) A synthesis of the existing practices, rules and standards; and

(b) Options for coordinating the work under Article 18 with the work of other relevant international bodies.

2. ICCP further requested the Executive Secretary to convene, subject to the necessary financial resources being made available, a meeting of government-nominated technical experts in handling, transport, packaging and identification that considers, based on the synthesis report, the needs and modalities for developing measures for Parties to the Protocol to meet their obligations under

* UNEP/CBD/ICCP/2/1.

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paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol, and to prepare a report on their deliberations and recommendations for its consideration at its second meeting.

3. Accordingly, the Meeting of Technical Experts on Handling, Transport, Packaging and Identification of Living Modified Organisms was convened in Paris from 13 to 15 June, following the generous offer made by the Government of France to host and Canada to co-host and with the financial support provided by the two countries, as well as the United Kingdom. The Meeting of Technical Experts discussed the issues relating to documentation accompanying the transboundary movements of living modified organisms destined for contained use (Article 18, paragraph 2(b)) and those intended for intentional introduction into the environment (Article 18, paragraph 2(c)). The report of the meeting is annexed to the present note. It contains the deliberations and recommendations of the meeting for consideration by the ICCP.

4. This document, therefore, presents the synthesis of information provided by Parties, Governments and relevant international organizations on their existing practices, rules and standards relevant to Article 18 of the Protocol (section II). It reviews latest developments in existing rules, practices and standards on handling, packaging, transport and identification (section III). The document suggests options for coordinating the work under Article 18 with the work of other relevant international bodies, including the modalities for a process for discussion on paragraph 2 (a) of Article 18 by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its first meeting (section IV). Finally, there are recommendations that ICCP may wish to consider (section V).

5. It should be noted that the following synthesis of information reproduces the terminology used in the original submissions to refer to products of modern biotechnology ("living modified organisms", "genetically modified organisms", "genetically engineered organisms", etc.).

II. A SYNTHESIS OF INFORMATION ON EXISTING PRACTICES, RULES AND STANDARDS RELEVANT TO ARTICLE 18

6. In response to the request made at the first meeting of the ICCP, and the notifications issued by the Executive Secretary to all Parties to the Convention, Governments and relevant international organizations to provide information on their existing practices, rules and standards relevant to Article 18 of the Cartagena Protocol, the following Parties and Governments submitted, as of 30 June 2001, information on their existing practices, rules and standards relevant to Article 18 of the Protocol: Argentina, Australia, Austria, Canada, Croatia, Cuba, Estonia, the European Community, India, Norway, the Republic of Korea, Slovenia, Sweden, Switzerland, the United Kingdom of Great Britain and Northern Ireland and the United States of America.

7. According to the Australian approach, there are various Government agencies that are involved in managing genetically modified organisms. These agencies establish, *inter alia*, requirements for handling, transport, packaging and/or identification based upon the potential risks by the individual or groups of genetically modified organisms, and this is conducted in a scientifically sound and transparent manner. The Australian submission contains also key points that Australia believes are relevant in the consideration of future elaboration of Article 18 of the Protocol.

8. Belarus informed the Executive Secretary that no information on existing practices, rules and standards relevant to Article 18 of the Biosafety Protocol is available.

9. Norway has generally indicated that it has established a comprehensive legislation for regulating, *inter alia*, risk assessments for releasing living modified organisms into the environment.

10. Croatia has been undertaking a number of activities since the last three years that mainly focus on filling the existing gap in legislation. Accordingly, Croatia has established an inter-ministerial commission responsible for preparing draft laws that regulate foodstuffs and food ingredients containing genetically modified organisms on the one hand, and the release of living genetically modified organisms into the environment, on the other. In the meantime, an Act to Ban Genetically Modified Organisms has been initiated and was expected to be completed in July 2001.

11. Similarly, Slovenia is in the process of preparing a draft Act in the field of gene technology in line with the relevant European Union directives.

12. Cuba indicated that it is using the existing international regulations such as that of the International Maritime Organization (IMO), the International Air Transport (IATA), the Universal Postal Union (UPU), and the Technical Instructions of the International Civil Aviation Organization (ICAO), as appropriate, for regulating the transportation of dangerous goods, including biological substances. There are also on-going activities in Cuba, as a project and a committee work, with regard to setting biological safety requirements, and standards for the safety of food produced through biotechnological means.

13. Austria also provided, without going into the details, the list of regulations in force in the country relevant to living modified organisms.

14. The Division of Environmental Conventions of UNEP has forwarded to the Executive Secretary information on the use of the World Custom Organization's Harmonized Commodity Description and Coding System.

15. The Global Industry Coalition also made submission of information as requested.

16. Following is the synthesis of the information received by the Executive Secretary from Parties and Governments other than those whose submissions are summarized in paragraphs 7-13 above.

*A. Living modified organisms intended for direct use as food or feed, or for processing**

1. Handling

17. European Community directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms has been in place since 1991 and provides a basis for handling provisions that exist under the legislation of member States. This directive has been recently revised and will be repealed by directive 2001/18/EEC. When this repealing directive comes into force it requires the conditions for placing a genetically modified organism on the market, including specific conditions of use and handling to form part of the information required in a notification.

18. The United Kingdom Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997, which mainly implement the Environmental Protection Act 1990, part VI, and

* Except for the inclusion of additional information provided by Canada, paragraphs 17-117 below reproduce paragraphs 11-106 of the synthesis of existing practices, rules and standards relevant to Article 18 of the Cartagena Protocol on Biosafety (UNEP/CBD/BS/TE-HTPI/1/2), which was prepared, in English only, for the Meeting of Technical Experts on Handling, Transport, Packaging and Identification of Living Modified Organisms that was held in Paris from 13 to 15 June 2001.

directive 90/220/EEC, requires the submission of information by applicants for the release of genetically modified organisms, to provide information on the labelling regarding measures that need to be taken in the event of escape of the organisms or in misuse and specific instructions or recommendations for storage and handling of the product.

19. Since the Swedish Ordinance (SFS 1994:901) on genetically modified organisms is meant to implement the directive 90/220/EEC, it may be assumed that the same requirements exist in Sweden.

20. In the United States of America, once the genetically engineered organisms (GEOs) destined for direct use as food or feed or for processing have successfully completed the federal review process they will be handled, transported, packaged and identified according to the same practices, regulations and standards that apply to their conventional counterparts. This is, in fact, true also for other GEOs, including those intended for intentional introduction into the environment. The agencies primarily responsible for regulating products of biotechnology, namely the United States Department of Agriculture (USDA), the United States Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) undertake their specific part of the review or evaluation of the product of the GEO prior to commercialization or importation, as appropriate, in accordance with the applicable regulations and guidelines. Once the product is found to comply with federal requirements that apply to conventional products, there will be no more requirements that exceptionally treat the GEOs.

2. Transport

21. On the basis of information received, no specific legislation that addresses the transport of living modified organisms intended for direct use as food or feed or for processing seems to exist in all the jurisdictions for which information was received.

22. At the European Community level, where there are laws on the transport of dangerous goods by road or by rail, no specific transport legislation exists for genetically modified organisms other than genetically modified micro-organisms (GMMs). European Union directive 94/55/EC on the approximation of the laws of the member States with regard to the transport of dangerous goods by road, and directive 96/49/EC on the approximation of the laws of the member States with regard to the transport of dangerous goods by rail, apply to the transport of genetically modified micro-organisms (GMMs). These directives require that transport operations involving GMMs, within or between member States, by road or by rail, to be in conformity with the European Agreement on the Transport of Dangerous Goods by Road (ADR) and the Agreement on the Transport of Dangerous Goods by Rail (RID), respectively. The provisions of the ADR and RID are, in turn, consistent with the United Nations Recommendations on the Transport of Dangerous Goods, as revised from time to time. The European Community directives provide for packing instructions and have special provisions for carriage, including operation, loading, unloading and handling of GMMs.

23. The Swedish regulation issued by the Swedish Board of Agriculture specifies the need to transport genetically modified animals in a cage, container or transport wagon. T here are also other regulations in Sweden issued for the purpose of implementing the European Union directives issued to implement the ADR and RID.

3. Packaging

24. In most of the cases, packaging is addressed indirectly in connection with transport criteria and/or labelling or identification requirements. The Estonian Release into the Environment of Genetically Modified Organisms Act 1999, for instance, talks about the label on the package.

25. European Union directives 94/55/EC and 96/49/EC on the transport of GMMs include packing instructions and mixed packaging. However, these directives do not seem to apply to LMO-FFPs. The proposed European Community directive 2001/18/EC that replaces directive 90/220 and which is believed to apply also to LMO-FFPs, requires packaging of GMOs as or in products to be specified when placed on the Community's market.

26. The United Kingdom Genetically Modified Organisms (Deliberate Release) Regulations, as amended, however, requires that applications for consent to market LMOs and LMO-FFPs to include proposals for appropriate safe packaging.

27. The Indian Environmental Protection Act 1989 also refers to labelling of packages and standards for packaging. But the requirements of the Act are confined only to GMOs for research purposes. In fact, the information provided gives the impression that the provisions of the Environment Protection Act of India that are relevant to GMOs address only GMOs destined for contained use or those imported for research purpose only.

4. *Identification*

28. In Argentina, there is a voluntary system of certification of the quality of grains under regulation No. 61/2000, which established a System for the Promotion and Certification of Grain Specialities. Argentina also believes that it has the capacity and the regulatory framework necessary to differentiate organic products from non-organic ones.

29. Austria has an Ordinance issued in 1998 on the labelling of products that contain or consist of GMOs. In 1998 the Austrian Codex Alimentarius Commission has also adopted a guideline on criteria for labelling food, where appropriate, as "gene technology free".

30. The Canadian Environmental Protection Act, 1999, requires microorganisms not regulated under product specific legislation to be notified and assessed prior to import. All imported feeds are also subject to registration under the Federal Feeds Act. Proper labelling information is required for feed ingredients, registered feeds, and feeds exempt from registration. As per directive D-96-13 on Import Permit requirements for Plants with Novel Traits (Including Transgenic Plants), and Their Products, importation into Canada of living modified plants including fruit, tubers and grain, require a permit. Under the Canadian Environmental Protection Act, 1999, LMO animals (including livestock and fish) must be notified and assessed prior to import. A phytosanitary certificate must accompany most Canadian exports of agricultural products. Under the authority of the Canada Grains Act, a Certificate Final, which indicates the weight and grade of the cargo as well as the dockage to be separated from the grain, and the country of origin, where the grain was not grown in Canada, is issued for exports of grains. As far as current practice is concerned, in sum limited cases, organisms intended for direct use as food or feed, or processing, including those which are LMOs, are produced and distributed as segregated or identity preserved product with a view to meeting contract specifications negotiated on a case-by-case basis between a buyer willing to pay the additional price and a seller prepared to incur the associated costs.

31. The Estonian 1999 Release into the Environment of Genetically Modified Organisms Act requires all products containing GMOs or consisting of GMOs to be labelled and specify on the package a text that reads: "This product contains genetically modified organism(s)". In case the presence of GMOs in the product is not certain, it should be stated that: "This product may contain genetically modified organism(s)". In addition, the Act requires the inclusion of the name of the genetically modified organism contained in the product, the name (company name) of the producer, and the properties of the product and information on the natural conditions suitable for the product.

32. In line with the European Community directive 2001/18 will impose labelling requirements on GMOs as or in products intended for the placing on the European Community market. The words "This product contains genetically modified organisms" must appear either on the label or on the accompanying document. According to the directive, there is a possibility of establishing a minimum threshold below which products do not have to be labelled when adventitious or technically unavoidable traces of authorized GMOs cannot be excluded. The directive contains also a requirement to ensure traceability at all stages of the placing on the market of GMOs.

33. According to European Community regulation 258/97 on novel foods, foods and food ingredients consisting of or containing GMOs have to be labelled. Regulation 1139/98 on the labelling of foods produced from a genetically modified soya and genetically modified maize and regulation 50/2000 on the labelling of GMO additives and flavourings, specify labelling requirements. These regulations require labelling on the belief that the consumer should be informed of the presence in the food or feed ingredient of GMOs, and in case the food or food ingredient is no longer equivalent to an existing food or feed ingredient, an indication of the characteristics or properties modified, together with the method by which that characteristic or property was obtained. If less than 1% genetically modified material is present in the authorized genetically modified soya or maize, the products, according to regulation 49/2000, may not have to be labelled.

34. The Ministry of Agriculture and Forestry of the Republic of Korea has issued Guidelines for Labelling of Genetically Modified Agricultural Products in accordance with the relevant provisions of the Presidential Decree on the Agricultural and Fishery Products Quality Control Act. The Guidelines provide for detail labelling standards for genetically modified agricultural products. The labels, "Genetically modified (the name of the agricultural product)", "Containing genetically modified (the name of the agricultural product)", and "It may contain genetically modified (the name of the agricultural product)" should be put on genetically modified agricultural products, on products containing genetically modified agricultural products, and on containers suspected to have genetically modified and non-genetically-modified agricultural products mixed. These labels must be shown on the packages, or when they are placed on the market without packages, at the sites where the genetically modified products are displayed for sale in a manner that can easily be read or recognized by the consumers, and should not easily be erased or detached. This labelling requirement is not applicable, for the time being, on agricultural products with less than 3% genetically modified content. This may be lowered to 1% taking into consideration the growing precision in the verification techniques and international trends. The Korean Food and Drug Administration also issued notification 2000-43 on labelling standards for genetically modified foods. The notification, which will come into effect on 13 July 2001, specifies foods and food additives that are subject to genetically modified labelling requirements.

35. The Swedish regulatory framework also requires GMOs intended to be released or placed on the market to be clearly labelled.

36. The Swiss Federal Law on Food Products and the related Ordinance regulate the identification or designation of food products. The Ordinance on Food Products regulates genetically modified organisms used as food products or for processing. Food products, additives or substances that are GMOs or that contain or are derived from GMOs must bear an indication that says, "made from X modified by genetic engineering" or "made from X genetically modified". "X" stands for the name of the GMO. No mandatory requirement exists for food products or derived food products with less than 1% of GMOs. The Federal Law on Agriculture and its related Ordinance on Feed Products regulate similarly the identification of genetically modified feed products. But the minimum threshold in the case of genetically modified feed products, in particular raw materials, single feed products, additives, and conservative agents is 3%.

37. The United Kingdom Genetically Modified Organisms (Deliberate Release) Regulations, as amended, requires labelling on the product or document supplied with the product. Adequate information on identification and detection is also required.

38. In the United States, a GEO product for food or feed is not required to be identified as a product of genetic engineering. If a living modified organism, as defined in the Cartagena Protocol on Biosafety, is imported for processing purposes, there is also no requirement for it to be identified as a product of genetic engineering unless it is subject to regulation under the Toxic Substances Control Act or the Federal Insecticide, Fungicide and Rodenticide Act, in which case EPA imposes labelling and other requirements on a case by case basis, in the same way that conventional chemicals are regulated.

B. Living modified organisms destined for contained use

1. Handling

39. In 1996, Austria issued the Ordinance on the Safety of Contained Uses of GMOs. Estonia is preparing a draft law that enables it to conform to directive 90/219/EEC on the contained use of genetically modified micro-organisms (GMMs).

40. The Canadian Health of Animals Act and Regulations require permits for the importation of all animal or zoonotic pathogens into Canada. Each import permit has specific conditions for handling and, disposal and transport. These conditions specify the containment level for the imported material, and that the material must be handled in the appropriate containment facilities as described in the Containment Standards for Veterinary Facilities. For work with recombinant organisms, an additional condition may be added to the permit that prohibits the manipulation of the organism if those manipulations may result in the creation of a pathogen requiring a higher level of containment than that approved in the permit. Living modified organisms that are human pathogens are subject to the Human Pathogens Importation Regulations. The Regulations do not diminish the responsibility of the importer/supplier to comply with international and domestic regulations regarding the transportation of dangerous goods.

41. European Community directive 90/219/EEC provides for a wide range of specific requirements on contained use of genetically modified micro organisms based on the level of risk involved by the genetically modified microorganisms concerned. This directive has been amended by directive 98/81, which specifies requirements for the use of genetically modified micro organisms in containment facilities like glass-houses, growth rooms, animal houses, laboratories and industrial production facilities. The United Kingdom also has legislation, namely the Genetically Modified Organisms (Contained Use) Regulations 2000, that implements directive 90/219/EEC and which has extensive requirements for the handling of genetically modified micro organisms in contained -use activities. As mentioned earlier, directive 94/55/EC on the transport of dangerous goods by roads and directive 96/49/EC on the transport of dangerous goods by rail stipulate special provisions regarding loading, unloading and handling of genetically modified microorganisms, which may constitute handling requirements.

42. In the United States, certain genetically engineered organisms intended for certain specific uses, such as for pesticidal and for general commercial use are subject to EPA jurisdiction at the stage of laboratory research. Other laboratory research involving LMOs containing recombinant DNA is subject to the National Institutes of Health guidelines that require physical and biological containment. The level of containment increases based upon the risk that the release of the organism would pose for humans and the environment. The guidelines specify container requirements when LMOs are removed from physical containment in the course of an experiment but otherwise make reference to the applicable shipping requirements of the Centres for Disease Control and Prevention, the Department of Transportation and

the United States Department of Agriculture. In the case of importation of genetically engineered organisms that are considered regulated articles, the container used must ensure the secure containment of the article as specified in the Animal and Plant Health Inspection Service (APHIS) regulations in part 340.8 of Title 7 ("Agriculture") of the Code of Federal Regulations (7 CFR 340.8).

2. *Transport*

43. In the case of the European Community, directive 94/55/EC and directive 96/49/EC on the transport of dangerous goods by roads and by rail respectively apply to the transport of genetically modified microorganisms within the Community. Based on these directives, the United Kingdom also has issued the Carriage of Dangerous Goods (Classification, Packaging, and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996, as amended; the Carriage of Dangerous Goods by Road Regulations 1996; and the Carriage of Dangerous Goods by Rail Regulations 1996, as amended.

44. In Sweden, the transportation of GMOs, according to the Swedish Environment Code (SFS 1998:808), chapter 13, is generally regarded as contained use of GMOs. The Swiss Ordinance on the Contained Use of Organisms provides for the transport of GMOs and requires anyone involved in transporting GMOs to observe relevant national and international rules regarding labelling and packaging

3. *Packaging*

45. In Sweden a new law, [SJVFS 2000:xxx] is expected to be adopted soon on the contained use of genetically modified plants. The draft requires genetically modified plants to be packed and labelled during transportation. The United Kingdom regulations mentioned under paragraph 43 above on the transport of dangerous goods also require packaging of the genetically modified microorganisms. The Indian Environment Protection Act 1989 has also relevance, as mentioned in paragraph 27 above, since the requirements for packaging and labelling are attached with the import of GMOs for research purposes. As mentioned above, the Swiss Ordinance on the Contained Use of Organisms refers to national and international rules regulating packaging and labelling.

4. Identification

46. In Argentina, LMOs destined for contained use are clearly identified in that the importer or the producer is required to have authorization from the National Advisory Committee on Agricultural Biosafety and from the sanitary authority SENASA.

47. Under the Canadian Environmental Protection Act, 1999, micro-organisms not regulated under product specific legislation must be notified and assessed prior to import for contained use. Requirements for documentation, specifying identification and contact points may be imposed as a measure to mitigate an identified risk.

48. The proposed European Union directive 2001/18/EC requires the labelling of genetically modified microorganisms destined for contained use and GMOs other than genetically modified microorganisms destined for contained use. The legislation of member States is expected to incorporate this requirement. At least, the United Kingdom regulations that will be introduced later this year to implement this directive are expected to provide for this requirement.

49. As mentioned before, India and Sweden have also rules that require the labelling of GMOs for contained use.

50. Estonia does not yet have legislation that regulates contained use of GMOs. Preparation of such legislation in conformity with the European Community directive 90/219 on contained use of genetically modified microorganisms is under way.

51. In Sweden, regulations SFS 1982:821 and SFS 1982:923 issued to implement the two European directives on the transport of dangerous goods by road and by rail require the inclusion of a label on the consignment that reads: "Genetically modified organisms".

52. The Swiss Ordinance on the Contained Use of Organisms requires the provision of mandatory information during placing on the market of potentially harmful organisms, including information on the properties of the organisms, whether the organisms are genetically modified, and that the use of the organisms is subject to containment.

53. In the United States, there is no general requirement for LMOs destined for contained use to be identified as a product of genetic engineering. There is no also a general requirement for LMOs containing recombinant DNA and destined for contained use to be identified as a product of genetic engineering. The regulations in 7 CFR 340 detail the marking, identification and container requirements for the movement of genetically engineered organisms that are considered regulated articles into and through the United States. Containers must be marked with: the general nature and quantity of contents; the country and locality where the organism was collected, developed and produced; the name and address of shipper, owner, or person shipping or forwarding the organism; the name, address and telephone number of the consignee; and the number of the authorizing permit. Nevertheless, there is no requirement for the organism to be identified as a product of genetic engineering.

54. The labelling and identification of imports of veterinary biologics for research and evaluation in the United States must conform to APHIS regulations in 9 CFR 112, which do not distinguish between genetically engineered and non-engineered materials. An import permit is required and the copy of the permit must accompany the shipment. Again, there is no general requirement for the organism to be identified as a product of genetic engineering in the case of genetically engineered products for research and development for eventual use commercially or as a pesticide. However, for certain living microorganisms that fall under the Toxic Substances Control Act, EPA has established some requirements such as labelling the container as it may only be used for research and development where the distribution of the organisms goes beyond the employees of the manufacturer or the processor, and written notification of any health risk to all employees and to anyone receiving the chemical in case where the manufacturer, importer or processor has any reason to believe that a health risk may be associated with the organism. Such notification should be made through a container labelling system; conspicuous placement of written notices where exposure may occur; or some similar system. There are some labelling requirements for substances, including those products of genetic engineering meeting specified criteria and that are intended to be used as pesticides, without a general requirement for the organisms to be identified as products of genetic engineering.

C. Living modified organisms intended for intentional introduction into the environment

1. Handling

55. Austria issued an Ordinance on Deliberate Release in 1997. As mentioned in paragraph 17 above, European Union directive 2000/18, which will repeal directive 90/220 on the deliberate release into the environment of GMOs, provides for specific conditions of use and handling of GMOs. The 1992 Genetically Modified Organisms (Deliberate Release) Regulations of the United Kingdom, as amended,

require applicants for consent to supply information on appropriate storage and handling and on measures to be taken in case of escape or misuse of the organism.

2. Transport

56. Swedish regulation SJVFS 1995:33 on the use of genetically modified animals, as amended, requires such animals to be transported in a cage, container or transport wagon. Apart from this information, no specific legislation on transport other than those referring to transport of genetically modified microorganisms by road or by rail, is reported to exist.

3. Packaging

57. The Estonian 1999 Release into the Environment of Genetically Modified Organisms Act and the Seed Act presume the packaging of GMOs for release into the environment when addressing the question of labelling.

58. European Union directive 98/95, amending the directives on the marketing of different varieties of seeds and which has been in force since February 2000, requires packaging and sealing of the seeds. Directive 1999/105 on the marketing of forest reproductive material, and the proposed amendment to directive 68/193 on the marketing of material for the vegetative propagation of vine, also contain the same requirement of sealed packages.

59. The regulation by the Swedish Board of Agriculture, SJVSF 1999:122 on the release of genetically modified plants, demands packaging that must be designed to prevent spreading to the environment. The Swedish Board of Forestry has also detailed rules on genetically modified trees that require, among other things, that the packaging of the genetically modified forest trees or parts thereof to be designed as to avoid spill or gene spreading to the environment.

60. The 1992 United Kingdom Genetically Modified Organisms (Deliberate Release) Regulations, and their amendments of 1995 and 1997, demand safe packaging.

4. *Identification*

61. In Argentina, LMOs intended for commercialization are required, like any other seed, to follow the identification procedure of the Argentine seed legislation, is accordance with the International Convention for the Protection of New Varieties of Plants (UPOV). The information on the identification includes the relevant traits and characteristics, contact point, the name and address of importer and special requirements, if needed, for safe handling, storage, transport and use. There are also labels explaining that the seeds have been obtained through biotechnological methods.

62. Austria has an Ordinance issued in 1999 on the Labelling of Genetically Modified Plant Varieties and Seeds of Genetically Modified Plant Varieties.

63. In Canada, fertilizers and supplements, including naturally occurring or genetically modified organisms are required, under the Fertilizers Act and Regulations, to provide for proper identification. The Act requires supplements to conform to prescribed standards, be packaged and identified as prescribed. Similar requirements exist for microbial pest control products and microbial pest control agents under the Pest Control Products Act. The Application for Permit to Import Plants and Other Things Under the Plant Protection Act requires the applicant to indicate whether the product they wish to import has been genetically modified. Living modified plants that have been authorized for unconfined release under the Seeds Regulations, may be exempted from the requirement for a Permit to Import. Each seed lot that is

imported into Canada should be accompanied by a statement containing information as regards to the name of the kind or species of seed; the quantity of seed; the variety name of the seed for all kinds, species and varieties subject to registration; a lot designation of the seed, and the name and address of the exporter and importer. Seed exported from Canada must be appropriately identified under the Seeds Regulations. With regard to animals, export certificates are designed to be specific to the country importing the product.

64. As mentioned in paragraph 31 above, the Estonian Act of 1999 on the Release into the Environment of Genetically Modified Organisms requires a label on the package that reads: "This product contains genetically modified organism(s)". If the presence of GMOs in the product is not certain, the label must state that: " This product may contain genetically modified organism(s)". The Seed Act of Estonia also requires the labelling of genetically modified seeds and reproduction materials with the letters "GMO".

65. The European Community directive 90/220 on the deliberate release into the Environment of GMOs, and the directive 2001/18, which is going to replace it soon, require labelling for GMOs as or in the products intended for placing on the market that bears the words: "This product contains genetically modified organisms". This indication should appear either on the label or in accompanying document. There is a minimum threshold beyond which this requirement applies. Traceability should also be ensured at all stages of the placing on the market of GMOs. Labelling is required under the European Community regulation 258/97 on novel foods, regulations 1139/98 and 49/2000 on the labelling of food products produced from genetically modified soybean and maize, and under regulation 50/2000 on labelling of GMO additives and flavourings.

66. Directive 98/95/EC amending directives 66/400/EEC, 66/401/EEC, 66/402/EC, 66/403/EEC, 69/208/EEC, 70/457/EC, and 70/458/EEC on the marketing of specific varieties of seeds, requires marking and in the case of GMO seeds any label or document that is affixed or accompanies a seed lot shall clearly indicate that the variety has been genetically modified. Directive 1999/105, on the marketing of forest reproductive material, also requires that in the case of any such material derived from basic material that consists of a genetically modified organism, any label or document, official or otherwise, for the lot shall clearly indicate that fact. The same applies to the proposed amendment to directive 68/193 on the marketing of material for the vegetative propagation of vine.

67. The Republic of Korea has specific and detail requirements on the labelling of genetically modified agricultural products as referred to in paragraph 34 above.

68. Swedish regulation SJVFS 199:124 on the deliberate release of genetically modified plants requires every unit containing genetically modified plants or plant material to be labelled and to clearly state that the content is genetically modified plants. The species name, the genetically modified trait, and the names and addresses of the sender as well as the receiver should also be visible on the packaging. The new law [SJVFS 2000:xxx], which is ready for adoption, also requires, during transportation of GMOs for deliberate release, labelling on every unit clearly stating that it contains GMOs. The rules issued by the Swedish National Chemical Inspectorate, KIFS 1998:8 on biotechnological organisms (including GMOs), provide for labelling in consistent with European Commission directive 97/35/EC and directive 90/220/EEC on the deliberate release into the environment of GMOs. Genetically modified forest trees or their parts should also be labelled in a manner that clearly shows that the content is genetically modified trees.

69. In Switzerland, the Law on the Protection of the Environment and the related Ordinance on the Release of Organisms puts a mandatory requirement to designate or identify products containing GMOs. Any person who intends placing GMOs on the market must inform the recipient about the nature of the

organisms by an easily recognizable label or some other equivalent means. Products that contain GMOs in a negligible or trace amounts are not covered by this requirement.

70. As mentioned above, labelling of GMOs for deliberate release and of genetically modified foods and food ingredients is required in the United Kingdom under the Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997, and Novel Foods and Food Ingredients Regulations 1997. The Genetically Modified And Novel Foods (Labelling) Regulations 2000 go even further and require labelling of genetically modified foods in catering establishments. The Beet, Cereal, Fodder Plant, Oil and Fibre Plant, Potatoes and Vegetable Seeds Regulations of 1993, as amended by regulations 2000, demand labelling in an official certificate and in an attached or accompanying label or document.

71. In the United States of America, there are requirements for obtaining authorization from the appropriate agency, for packaging and identification before releasing GEOs for field-testing or for commercial uses. These requirements vary depending on the intended use of the organism. Once unregulated status is granted the requirements, including handling and identification requirements, do not make any distinction between genetically engineered and non-engineered organisms. In all cases, no indication of genetic engineering is required.

D. Observations that may be made from the above review

72. In most of the jurisdictions reviewed, there are some rules that regulate one or the other aspect of the elements addressed under Article 18 of the Cartagena Protocol on Biosafety. However, in some cases the rules are so general and inadequate to clearly and fully regulate the handling, transport, packaging and identification of LMOs. In other cases, such as in the case of the European Community, there exist relatively comprehensive regulations that specifically address genetically modified organisms.

73. Labelling or identification of GMOs is well addressed in most of the cases, whereas the treatment of transport of GMOs is very limited. In fact, no specific legislation regulating transport of GMOs by water or by air exists, and the existing regulations on transport by road or by rail are limited to genetically modified microorganisms, and do not cover other GMOs. Unlike elsewhere, there is no general requirement in the United States for identifying genetically engineered organisms as products of genetic engineering. Further information on this issue as well as on transportation documentation and other relevant United States practices and standards, is available in the text of the United States submission in the compilation of information received on the subject (UNEP/CBD/BS/TE-HTPI/1/INF/1).

74. The other observation that could be made relates to the fact that there is a general tendency to continue to have more new regulations in these areas. There is also an extensive process of making amendments to the existing ones. There are a number of laws in the pipeline in some cases. Interestingly, most of the recent amendments to existing laws or the undertaking to issue new ones, seem to be made, in particular, with regard to labelling or identification, with the primary objective of ensuring safety to the environment and human health, and respecting the right of the public to be informed. These undertakings appear to be more in line with the general spirit of the Cartagena Protocol on Biosafety and the particular intention of Article 18.

E. Information provided by the Global Industry Coalition

75. As far as the Global Industry Coalition (GIC) is concerned, there are no existing rules and standards, both at national and intergovernmental level, that provide for the documentary information described in paragraph 2 (a) of Article 18 of the Biosafety Protocol. For GIC, providing for such

documentary information is, in fact, not a matter of normal commercial practice. According to their information, the commercial trade, in the case of the majority of international shipments of bulk commodities, does not distinguish between those that may contain LMO-FFPs and those that do not. As a result, there is no requirement in the general practice to have indication on accompanying documentation that the shipment "may contain" LMO FFPs.

76. GIC believes that the transboundary movement of LMOs destined for contained use is currently well regulated through internationally accepted processes that fulfil the requirements under paragraph 2 (b) of Article 18 of the Protocol. One of such international rules is the United Nations Recommendations on the Transport of Dangerous Goods, which serves as the framework for various international industry and government modal transport organizations and agreements.

77. In the case of LMOs intended for intentional introduction into the environment under paragraph 2 (c) of Article 18, GIC submitted that existing standards and regulations guide the movement of seeds and satisfy the bulk of the informational requirements as provided for in that particular paragraph of the Protocol. Moreover, GIC provided extensive information on world trade seed and the existing practices and standards throughout the seed marketing process as can be seen in the compilation of all the information submitted (UNEP/CBD/BSP/TE-HTPI/1/INF/1).

F. The Harmonized Commodity Description and Coding System of the World Customs Organization

78. In response to the request made by the first meeting of ICCP and the subsequent notification of the Executive Secretary to relevant international organizations to provide information on existing practices, rules and standards relevant to Article 18 of the Biosafety Protocol, the Division of Environmental Conventions of UNEP, provided the Secretariat with information on the use of the World Customs Organization's Harmonized Commodity Description and Coding System.

79. The Harmonized System, as it is commonly known, is an application-based international numerical coding system for commodity governed by the International Convention on the Harmonized Commodity Description and Coding System. The system covers 98 per cent of the merchandise in international trade comprising more than 5,000 commodity groups and 200,000 commodities. The World Customs Organization overseas the implementation of the system, mainly through its Enforcement Committee that is responsible to monitor international efforts to eradicate illegal trade.

80. Traditionally, commodities have been listed under the Harmonized System according to criteria relating to the volume and monetary value in trade. However, this is now changing and new criteria that allow the inclusion of commodities of social or environmental concern are evolving.

81. A discussion paper prepared by the UNEP Division on Environmental Conventions and submitted for the ninth meeting on the Coordination of Convention Secretariats, held in Nairobi from 11 to 12 February 2001, refers to some multilateral agreements whose objective is to control import and export of various substances/commodities of environmental concern. These agreements include the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Montreal Protocol on Substances that Deplete the Ozone Layer, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Cartagena Protocol on Biosafety, and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction. The paper indicates that these multilateral environmental agreements have, in their efforts to control the transboundary movement of the

substances/commodities under their respective jurisdiction, the option of applying to WCO to use the Harmonized System. The principal advantage identified in using the System is the fact that customs officials are better positioned to control illicit transboundary movement since controlled commodities are coded in an internationally accepted way.

82. Although the identification requirements under paragraph 2 of Article 18 of the Protocol would be instrumental to control illegal transboundary movements of LMOs, the primary objective or concern behind the requirement to take measures to identify LMOs in the documentation accompanying them is to avoid or mitigate damage to the environment, taking also into account human health, due to mishandling or unintentional transboundary movement of the LMOs.

III. REVIEW OF LATEST DEVELOPMENTS IN EXISTING RULES, PRACTICES AND STANDARDS ON PACKAGING, HANDLING, TRANSPORT AND IDENTIFICATION (UPDATING DOCUMENT UNEP/CBD/ICCP/1/6, AS APPROPRIATE)

A. United Nations Recommendations on the Transport of Dangerous Goods

83. The note by the Executive Secretary on handling, transport, packaging and identification submitted to the first meeting of ICCP (UNEP/CBD/ICCP/1/6) had pointed out that the relevant parts of the United Nations Recommendations on the Transport of Dangerous Goods were an appropriate starting point in the process of considering modalities for developing standards in the context of Article 18 of the Protocol on Biosafety.

84. Pursuant to a resolution of the United Nations Economic and Social Council, the Recommendations are regularly amended and updated by the Committee of Experts on the Transport of Dangerous Goods, which prepared the initial recommendations that were first published in 1956 (ST/ECA/43-E/CN.2/170).

85. The Committee of Experts on the Transport of Dangerous Goods held its twenty-first session from 4 to 13 December 2000. The Committee discussed, among other things, its programme of work for the biennium 2001-2002 and agreed that the work programme should include a revision of division 6.2 provisions on "Infectious Substances" and miscellaneous proposals of amendments for the Model Regulations. In connection with the revision of division 6.2, Canada agreed to act as the lead country on behalf of the Committee in liasing with the World Health Organization, the Secretariat of the Basel Convention, the Secretariat of the Convention on Biological Diversity and others in developing a new basis for addressing division 6.2. The Secretariat of the Convention on Biological Diversity and ICCP may wish to utilize this opportunity and assess how much the revision of 6.2 or miscellaneous amendments to the Model Regulations could accommodate a basis for developing requirements or standards that apply to the packaging, handling, transport and identification of LMOs.

86. The Committee has also looked at the need for exploring how risk analysis could be used for rationalizing the Model Regulations. The expert from Germany was invited to provide examples in the next biennium. The methodologies that may emerge for rationalizing the Model Regulations could also offer experience in the development of rationalized standards based on risk analysis of GMOs under Article 18.

87. Following a resolution by the Economic and Social Council, the Committee has been reconfigured as of 2001, and will be a Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, with two sub-committees under it.

These are: the Sub-Committee of Experts on the Transport of Dangerous Good (TDG Sub-Committee), scheduled to have its next meeting from 2 to 6 July 2001, and the Sub Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS Sub-Committee), which will have its first session from 9 to 11 July 2001.

B. The IMO International Maritime Dangerous Goods Code (IMDG Code)

88. As indicated in the note by the Executive Secretary submitted to the first meeting of ICCP, the IMDG Code is one of the modal requirements developed within the framework of the United Nations Recommendations on the Transport of Dangerous Goods. The Model Regulations of the Recommendations are addressed to all modes of transport, and the IMDG Code, based on these recommendations, includes additional requirements that address the vast majority of shipments of hazardous materials by sea.

89. The IMDG Code is maintained and updated by the IMO Dangerous Goods, Solid Cargoes and Containers (DSC) Sub-Committee. The Code is recommended to Governments for adoption or for use as the basis for national regulations in conjunction with their obligations under the International Convention for the Safety of Life at Sea (SOLAS) and the International Convention for the Prevention of Pollution from Ships (MARPOL). The Code is currently updated every two years. The latest revision, Amendment 30, involves the complete reformatting of the Code, as well as revisions to its various sections and to transport requirements for specific substances. The amendment was adopted by the Maritime Safety Committee at its session in May 2000 where it was decided that the Code would enter into force on 1 January 2001, with a 12 months transitional period ending 31 December 2001.

90. The IMO Sub-Committee for Dangerous Goods, Solid Cargoes and Containers (DSC) proposed some amendments to the Code of Safe Practice for Solid Bulk Cargoes (BC Code) and submitted to the Marine Safety Committee in May 2000 relating to segregation and storage requirements for Ammonium Nitrates; segregation and classification for materials processing chemical hazards, specifically relating to seed cakes, description of the test of resistance to detonation; and ventilation requirements for solid bulk cargoes. The BC Code deals with three basic types of cargoes contained in appendices to the Code.

91. Appendix A refers to cargoes, which may liquefy; appendix B to materials possessing chemical hazards, and appendix C to other materials not falling within the other two categories. Appendix C is an open-ended category of bulk cargoes, the coverage of which may extend to LMOs in general, and to LMOs that are intended for direct use as food or feed or for processing in particular (Article 18, para. 2 (a) of the Biosafety Protocol), as these are, perhaps the only LMOs that are bound to move from place to place in bulk cargoes. The BC Code aims to promote storage and shipment by:

(a) Highlighting the dangers associated with the shipment of certain types of bulk cargoes;

(b) Giving guidance on the procedures to be adopted when the shipment of bulk cargoes is contemplated;

(c) Listing typical materials currently shipped in bulk, together with advice on their properties, handling, etc.; and

(d) Describing test procedures to be employed to determining various characteristics of the materials to be carried.

92. The Maritime Safety Committee, senior technical body of IMO, decided, at its 73rd meeting held from 27 November to 6 December 2000, to make, in principle, the IMDG Code mandatory, aiming at 1 January 2004 as an effective date, and instructed the Sub-Committee for Dangerous Goods, Solid Cargoes and Containers to prepare, in cooperation with the Secretariat, relevant documents including draft amendments to SOLAS, at its sixth session in July 2001.

C. The ICAO Technical Instructions and IATA Dangerous Goods Regulations

93. The International Civil Aviation Organization (ICAO) has used the United Nations Recommendations on the Transport of Dangerous Goods as the basis for developing regulations for the safe transport of dangerous goods by air. The ICAO regulations are codified in annex 18 of the Convention on the International Civil Aviation and in its Technical Instructions for the Safe Transport of Dangerous Goods by Air (Doc. 9284 – AN/905 as amended), known as "Technical Instructions" for short.

94. The IATA Dangerous Goods Regulations (DGR) is a field manual on the documentation, labelling and notification requirements for transporting dangerous goods by air. The Regulations are issued annually based on the ICAO Technical Instructions and remain valid from 1 January to 31 December of each year. The Regulations contain not only the current regulatory requirements as issued by ICAO and the United Nations but also the latest State and operator variations. Lists of product supplier are also provided and continuously updated so as to facilitate compliance with the Regulations.

95. As one of the modal requirements to the United Nations Recommendations on the Transport of Dangerous Goods, the Technical Instructions treat any genetically modified material that meets the definition of division 6.2 of the United Nations Recommendations as an infectious substance. In addition, these international standards classify a genetically modified material that does not meet the definition of a division 6.2 material, but is capable of altering animals, plants, or microbiological substances in a way not normally the result of natural reproduction, in hazard class 9 material. IATA has also developed guidelines on shipping infectious substances designed to provide a comprehensive source for shippers of infectious substances, diagnostic specimen and other biological material to ensure that these materials are shipped safely, efficiently and expeditiously. The first edition of these Guidelines was produced in April 2000.

D. Codex Alimentarius

96. The Ad Hoc Working Group established by the first session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology held from 14 to 17 March 2000, met twice in Tokyo, Japan, from 5 to 7 July and from 30 October to 1 November 2000. The Working Group reviewed a preliminary text of proposed draft General Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, and also considered the proposed draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant DNA Plants.

97. The Working Group agreed upon a number of amendments and appreciated the ongoing process to elaborate Codex-wide working principles of risk analysis, which once adopted, would be equally applicable to foods derived from biotechnology. It also looked at the opportunity for including the concept of post market monitoring in the proposed draft principles. The Working Group also reviewed a draft discussion document on the traceability of genetically modified organisms, introduced by France. France is requested to revise the draft discussion document for further consideration by the Working Group. The Ad Hoc Working Group has further reviewed the draft principles at its second meeting that took place from 30 October to 1 November 2000. Accordingly, it agreed upon, among other things, the proposed wording relating to post-market monitoring to be included in the draft principles under risk management.

Although the issue of traceability was discussed, it was agreed to put a short square bracket on the wording as reference to further discussion.

98. The draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology as proposed by the Ad Hoc Working Group uses the definition of the Cartagena Protocol on Biosafety to define the term "modern biotechnology".

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

99. In May 2000, the OECD Task Force for the Safety of Novel Foods and Feeds adopted a report as part of its continued efforts to promote international harmonization in the field of safety assessment of products of modern biotechnology. The report acknowledges food labelling as a valuable source of information for many consumers as they contain important information on ingredients. However, it suggests that given the small size of many labels, there are constraints on the amount of information that labels can provide. The report, therefore, concludes that food labelling would not be a practical way of communicating to the public information on approaches to food safety assessment (OECD, C (2000) 86/ADD1). According to the report, ways to make information electronically available to consumers are being considered. The main area of work for the Task Force, at the moment, is the development of consensus documents that provide information on criteria or parameters for food safety and nutrition for each food crop.

F. United Nations Economic Commission for Europe (ECE)

100. The Task Force on GMOs established by the first meeting of the signatories to the ECE Convention on Access to Information, Public Participation in Decision–making and Access to Justice in Environmental Matters (Aarhus Convention) held its second meeting, in Vienna from 4 to 5 December 2000. It considered, within three discussion groups, issues relating to the various procedural options for extending the application of the Convention in decision-making on GMOs; the definition of "deliberate release" and the question of how to deal with the contained use of GMOs under the Convention; and labelling and "non-living" products derived from GMOs.

101. The Task Force raised the issue of GMO product information that it recognized as a matter clearly linked to labelling. There were mixed feelings about the extent to which the labelling issue would be fully addressed under the Aarhus Convention, the Cartagena Protocol on Biosafety and the Codex Committee. For the further work of the Task Force, it was found necessary to establish what type of product information comprising labelling was required to be available under other international or regional agreements and it was recommended that a legal analysis of the relevant agreements and existing practices be undertaken for this purpose. The Task Force considered the need to define a set of "sufficient product information" as mentioned under paragraph 8 of Article 5 of the Aarhus Convention and the importance of clarifying which of this information was required to be provided to the public through the other international and regional agreements and which of this information might be required to be provided to the public under the Aarhus Convention in order to enable consumers to make informed environmental choices. It was also felt that links between the Cartagena Protocol on Biosafety and the Aarhus Convention should be established and it was recommended that the secretariats of the two instruments should explore possibilities on how to work together more closely and on a more formal basis.

102. The Task Force has also looked at the definitions of "contained use", "deliberate release" and "placing on the market" of GMOs as contained in the Common Position for the Revision of EU Directive 90/220. It was recommended that there should be no grey areas between "contained use" and "deliberate release" of GMOs, including for all potential "placing on the market". Reference was made, by way of

illustration, to the case of placing on the market of GMOs intended for direct use as food, feed or for processing where the placing on the market entailed some degree of containment. It was noted that this was not to be construed as contained use. The report of the second meeting of the Task Force is supposed to be submitted to the first meeting of the intergovernmental Working Group on Genetically Modified Organisms that will be held in Geneva from 10 to 12 October 2001.

G. The International Plant Protection Convention (IPPC)

103. The third meeting of the Interim Commission on Phytosanitary Measures (ICPM), the governing body of the Convention, took place in Rome from 2 to 6 April 2001. Under its agenda item on GMOs, Biosafety and Invasive Species, the ICPM acknowledged that LMOs/products of modern biotechnology and invasive species are covered by various international agreements and initiatives and, therefore, considered it necessary to strengthen the cooperation between the IPPC and the Convention on Biological Diversity in order to reach the objective of coherence and mutual support in the implementation of these agreements. Furthermore, the ICPM recommended also that an IPPC expert working group in cooperation with the experts working in the framework of the Convention on Biological Diversity and other relevant experts be established, as a matter of urgency, to develop a detailed standard specification for consideration at its fourth meeting.

H. The European Community

104. The two LMO-related major directives of the European Union, namely directive 90/219 on the contained use of LMOs and directive 90/220 on the deliberate release into the environment of GMOs and the subsequent Regulations on compulsory labelling of certain foodstuffs produced from GMOs, as amended, represent the most comprehensive regional regulatory framework on GMOs. Directive 90/220 is expected to be repealed soon and replaced by directive 2001/18. The objective of the latest directive is, in accordance with, the precautionary principle, to approximate the laws, regulations and administrative provisions of the European Union member States and to protect human health and the environment in carrying out intentional releases of GMOs for any other purpose than placing on the market, and placing on the market of GMOs as or in products within the European Community.

105. It is important to note that paragraph 2 of article 1 of directive 90/220 categorically excludes the carriage of GMOs by rail, road, inland water- ways, sea and air from its scope of application. The transport of GMOs within the Union should take into account other regional and national rules and standards such as those different directives issued to regulate the transport of dangerous goods as listed in document UNEP/CBD/ICCP/1/6. Directive 94/55/EC on the approximation of the laws of member States with regard to transport of dangerous goods by road, and directive 96/49/EC on the approximation of the laws of member States with regard to the transport of dangerous goods by rail are the two relevant laws available in the region.

106. The European Community is also looking forward to issue legislation on labelling and traceability of GMOs. Additional identification requirements are to be proposed in a new legislation on traceability and labelling of GMOs to complement existing requirements of information provision and labelling. Specific legislation on novel feeds, which is covered, at the moment, under directive 90/220 on the deliberate release into the environment of GMOs, is also in view.

I. The Australia-New Zealand Food Authority Standards

107. As the result of the Australian and New Zealand Health Council's agreement of July 2000 to extend the labelling requirements that previously existed with regard to foods that are substantially

different from their conventional counterparts, to all genetically modified foods, amendments to regulations, known as Standard A18, were made and gazetted on 7 December 2000. This gave effect to the Australia-New Zealand Food Authority's (ANZFA) resolution on labelling of genetically modified foods. The amendments will take effect as of 7 December 2001. An Intergovernmental Task Force has developed a draft Compliance Guide with the view to assist food businesses to comply with the new labelling requirements for genetically modified food. The Guide was open for public comment until 26 February 2001.

IV. FURTHER CONSIDERATION OF THE RELEVANT ISSUES

108. The review of existing practices, rules and standards reveals that, with the exception of few regional level experiences, there are no regulations or recommendations that specifically address the safe handling, packaging, transport and identification of LMOs at the international level. Nevertheless, quite a number of international instruments seem to be dealing with this issue, through incorporating these organisms into some broader definitions such as "dangerous goods," "infectious substances " or "biological materials".

109. At the domestic level, as we have seen from the synthesis of the information submitted, there is a good deal of regulations specifically designed to address LMOs and issues of their handling, transport, packaging and identification at different levels. Without ignoring the differences that exist in the approaches and contents of these national practices, rules and standards, some commonalities may be identified that could serve as a starting point for designing measures and standards in the context of Article 18 of the Cartagena Protocol on Biosafety.

110. The relevant directives of the European Union, the specific modal requirements developed by international organizations such as ICAO and IMO are based on a common basic text, the United Nations Recommendations on the Transport of Dangerous Goods and are further elaborations of these Recommendations. These regional and international rules and practices as well as the existing and emerging national laws that we have seen in the foregoing discussion may form good basis for examining the needs and modalities for developing measures necessary for meeting the obligations under Article 18 in general and for documentation accompanying LMOs in particular. In so doing, there is a need to take into account some important and relevant issues.

A. Relevant issues

1. Trade rules

111. The WTO Agreements define the rights and obligations of WTO members in international trade and provide the institutional setting for negotiating and enforcing global rules for trade and economic activity. The WTO works to remove trade barriers, prevent discrimination among participants in the world trading system, and resolve specific trade disputes. The undertaking to develop criteria or measures for handling, transport, packaging and identification of LMOs may require, as mentioned and extensively discussed in the note by the Executive Secretary on the subject prepared for the first meeting of the ICCP (UNEP/CBD/ICCP/1/6), account to be taken of at least two of the WTO Agreements, namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and Agreement on Technical Barriers to Trade (TBT Agreement).

112. The TBT Agreement aims at preventing arbitrary standards from being used to protect domestic industries. It encourages countries to use international standards where appropriate. The Agreement covers a wide range of domestic measures, including many taken to protect the environment. It divides

these measures into two categories: "technical regulations" and "standards". Technical regulations are laws requiring mandatory compliance, including regulations regarding product specifications, labelling, packaging and other "technical" issues. The SPS Agreement deals with the application of food safety and animal and plant health regulations. While allowing countries to set their own standards, it requires that regulations be based on science and applied only to the extent necessary to protect human, animal, or plant life or health.

113. The question of whether the TBT or the SPS Agreement applies to the packaging and labelling of genetically modified organisms may be controversial. Clearly, the relationship that exists between these agreements and the Biosafety Protocol is complex. However, any interpretation in determining whether the TBT or the SPS Agreement is more relevant to the issue at hand, should lead to a result that makes these two areas of international agreements mutually supportive.

2. Substantial equivalence

114. The TBT non-discrimination obligation requires that imported products must be given the same treatment as like products by domestic producers. Where products are like they must be given the same treatment. If a country gives like products different treatment, then they would stand against the non-discrimination obligation. Here, the question is whether GMO and non-GMO products are like products. This raises the concept of "substantial equivalence", which was developed way back before any GM foods came to the market.

115. If one looks at the report of the GATT Working Party on Border Tax Adjustment of December 1970, sets out the traditional test for determining the likeness of products, which focuses on: (i) consumers' tastes and habits; (ii) the products physical characteristics and end uses; and (iii) the products' properties, nature and qualities. In fact, the report suggests that the interpretation of the terms "like" or "similar" should be examined on a case-by-case basis.

116. The concept of "like product" and "substantial equivalence" is complex and evolving. To properly understand its exact meaning also requires that consideration be given not only to WTO policy, decisions and jurisprudence on the issue but also the work of other relevant agencies such as the OECD. The most recent legal interpretation on the issues can be found in the "asbestos case". In this case, the Dispute Panel (the court of first instance within the WTO) decided that in the case of asbestos fibres, "toxicity" was not a valid criterion by which to distinguish products. The Appellate Body of the WTO overturned this ruling on appeal. The contrasting approaches and decisions of the Dispute Panel and the Appellate Body indicate the complexity of the issue.

117. Substantial equivalence is claimed to be not a substitute for a safety assessment, but a part of the assessment process. In 1996, participants at an expert WHO/FAO consultation recommended that, "safety assessment based upon the concept of substantial equivalence be applied in establishing the safety of foods and food components derived from genetically modified organisms". Generally, the "substantial equivalence" test sets some thresholds for determining when GMO and non-GMO products are similar or like products.

B. Identification

1. General

118. Usually goods that cross the boundaries of two or more States are accompanied by transport documents. The transboundary movement of living modified organisms would necessarily involve certain

documentation accompanying each shipment. The question is therefore what and in what manner information should be provided through such accompanying documentation. Chapter 5 of the United Nations Recommendations on the Transport of Dangerous Goods provides for consignment procedures. According to section 5.4.1.11, the dangerous goods transport document shall contain the following information for each substance, material or article by any mode of transport:

(e) The proper shipping name, as determined by another section of the Recommendations (3.1.2);

(f) The class or, when assigned, the division of the goods, which for substances, and articles of class 1 shall be followed immediately by the compatibility group letter;

(g) The United Nations number preceded by the letters "UN" and where assigned, the picking group for the substance or article; and

(h) The total quantity of dangerous goods covered by the description (by volume, mass, or net explosive content, as appropriate).

119. The Recommendations require the information on a transport document to be legible and special provisions are also made for special goods such as wastes, elevated temperature materials, self-reactive substances and organic peroxides, infectious substances, and radioactive materials. There is also a certification requirement where the transport document needs in addition to carry, or be accompanied by a certificate or declaration by the shipper/exporter confirming that the consignment offered can be accepted for transport and that the goods are properly packaged, marked and labelled, and in proper condition for transport in accordance with the applicable regulations. The form for such declaration is:

> "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 labelled/placarded, are in all respects in proper condition for transport according to applicable international and national governmental regulations."

120. The IATA Dangerous Goods Regulations contain identification information that describes "genetically modified micro-organisms" as the proper shipping name for GMMs, with class or division 9 and UN/ID No. 3245.

2. Unique identification

121. Unique identifiers are commonly used in computer systems and publishing. There can also be unique health identifiers for individuals. Unique identification such as numbers may be important to be assigned so that no other person, object, substance or attribute type has same identifier. Computer systems, for example, require a way to identify the people associated with them. These identifiers are known as "user names" or "account names". The identifiers are typically short, alphanumeric strings.

122. In the case of a publisher item identifier, unique identification is being used as a means of document identification by describing the structure and assignment of an identification code for publication items. There are also object identifiers intended to ensure uniqueness among the attribute types that many different applications generate and use. Object identifiers are typically obtained from a hierarchy of allocation authorities, the highest being the International Organization for Standardization (ISO) and the International Telegraph and Telephone Consultative Committee (CCITT).

123. Unique identification is referred to in paragraph 2 (a) of Article 18 and in Annex II of the Protocol in connection with documentation and information requirements respectively, regarding living modified

organisms intended for direct use as food or feed, or for processing (LMO-FFPs) under Article 11. Careful consideration should be given to the question of whether information on any unique identification of the LMO-FFP that a Party is required to make available through the Biosafety Clearing-House when it makes a final decision regarding domestic use, including the placing on the market, of that LMO serves also the requirement of identification under paragraph 2 (a) of Article 18. However, unique identification in the sense of distinct symbol, mark or logo that distinguishes LMO-FFPs from other living organisms or from other LMOs intended for intentional introduction into the environment may be considered. Furthermore, unique identifier for different categories of LMOs may also be considered as an essential component of administrative simplification in managing the transboundary movement of LMOs in accordance with the Biosafety Protocol. It would have some benefits in terms of allowing improved handling of the LMOs and access to information. Nevertheless, the full implications of using unique identifiers in order to meet the identification obligation under paragraph 2 of Article 18 of the Biosafety Protocol need to be examined from both safety and trade perspectives.

3. Identification under paragraph 2 of Article 18

124. Identification under paragraph 2 of Article 18 refers to documentation that accompanies LMOs that are intended for direct use as food or feed, or for processing, LMOs destined for contained use and LMOs that are intended for intentional introduction into the environment.

125. According to paragraph 2 of Article 18 of the Biosafety Protocol, each Party is required to take measures with regard to documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed or for processing that clearly identifies:

(i) That they [LMO-FFPs] "may contain" living modified organisms; and

(ii) A contact point for further information;

(b) Living modified organisms that are destined for contained use:

(i) Clearly identifies them [LMOs for contained use] as living modified organisms; and

(ii) Specifies:

a. Any requirements for the safe handling, storage, transport and use;

b. The contact point for further information, including:

c. The name and address of the individual and institution to whom the LMOs are consigned;

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol:

(i) Clearly identifies them [LMOs intended for intentional introduction into the environment] as LMOs; and

(ii) Specifies:

a. The identity and relevant traits and/or characteristics;

b. Any requirements for the safe handling, storage, transport and use;

c. The contact point for further information; and, as appropriate,

d. The name and address of the importer and exporter; and

(iii) Contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

126. Paragraphs 2 (a), (b) and (c) of Article 18, already specify what major information should be included in the documentation accompanying LMOs of different categories. Taking the requirements of Chapter 5 on Consignment Procedures under the United Nations Recommendations on the Transport of Dangerous Goods into account, still more information such as proper shipping name, class, the division of goods, where established, etc, may be needed. The need for more information such as these ones and the modalities of setting and adopting them as international requirements in the case of LMOs might be considered by the present meeting of experts.

127. Chapter 5.5 of the United Nations Recommendations provides for special provisions. Section 5.5.1 specifies the special provisions applicable to the consignment of infectious substances. According to these special provisions, the transport of infectious substances requires coordinated action by the consignor, the carrier and the consignee to ensure safety and arrival in time and in proper condition. To this effect, necessary measures that need to be taken in the case of transport of infectious substances include:

(a) Advance arrangements between consignor, carrier and consignee;

(b) Preparation of dispatch documents;

(c) Routing (the quickest possible routing); and

(d) Timely notification of all transport data by consignor to consignee.

128. The transboundary movement of LMOs may also need to fulfil one or more of these measures in order to satisfy the major preoccupation (i.e., safety) of Governments and Parties to the Convention on Biological Diversity in developing the Biosafety Protocol in general and the provisions under Article 18 in particular. But it is important to note that there are as much distinctions of risks between infectious substances and LMOs as similarities. At least the primary concern that prompted the regulation of the transboundary movement of LMOs is their potential risk to cause damage to biological diversity whereas the primary concern in the case of infectious substances is health.

129. It should also be noted that the measures or standards that may be envisaged under Article 18 should take into account the distinction among LMOs based on the purpose that they are destined for and the level of risk associated with them. As we have seen in section II above, there are provisions in most national, as well as regional, regulations that distinguish LMOs destined for contained use and those intended for intentional introduction into the environment. In many of the national regulations, the level of risk posed by LMOs has also been one of the major considerations for making such distinction and for setting the corresponding handling requirements.

130. In view of the above, therefore, there may be a need to develop, based on the existing international standards and the national and regional experience, detailed requirements or measures with regard to the handling, packaging, transport and identification/documentation of LMOs as per Article 18 of the Biosafety Protocol. It is possible to take one or a combination of different approaches or modalities

for developing measures or standards that fulfil the obligations under paragraph 2of Article 18 of the Protocol.

V. OPTIONS FOR PROCESSES

A. Coordinating the work under Article 18 with the work of other relevant international bodies

131. The process of developing or specifying the special requirements (the modal requirements, according to the United Nations Recommendations) for packaging, handling, transport and identification of LMOs in the context of Article 18, could commence on a more focused manner by engaging the relevant international organizations such as the United Nations Committee of Experts on the Transport of Dangerous Goods, and the Interim Commission on Phytosanitary measures (ICPM), the interim governing body of the International Plant Protection Convention (IPPC). It is also possible and may be desirable to establish a clear need to use the Harmonized System (HS) of the World Customs Organization.

132. All of these organizations have expressed their willingness to work with the Convention on Biological Diversity with a view to sharing the possible benefits that the systems of their respective organizations offer with respect to the requirements for packaging, handling, transport and identification of LMOs as set by the Cartagena Protocol on Biosafety. In the comments that it submitted to the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety, held in Cartagena, Colombia, from 14 to 19 February 1999 (UNEP/CBD/BSWG/6/Inf.5), the United Nations Committee of Experts on the Transport of Dangerous Goods, stated that should there be a requirement to establish provisions for transportation of LMOs related to classification, documentation, safety marks and means of containment, this could rapidly be accomplished using the United Nations Recommendations on the Transport of Dangerous Goods without the need for a separate transport regulatory system.

133. The participation of IPPC is important since it is in the process of standard-setting that specifically addresses the plant pest risks of LMOs/products of modern biotechnology, which will be directly relevant to the standard-setting task under Article 18 of the Biosafety Protocol. The secretariats of IPPC and the Convention on Biological Diversity have already started consultations with regard to cooperation between the two processes, and ICPM has recommended, at its third meeting, held from 2 to 6 April 2001, that, as a matter of urgency, an IPPC expert working group in cooperation with the experts from the Secretariat of the Convention on Biological Diversity and other relevant experts is established to develop a detailed standard specification for the consideration by the ICPM at its fourth meeting.

134. The Meeting of Technical Experts on Handling, Transport, Packaging and Identification discussed issues relating to documentation requirements under paragraph 2 (b) and 2 (c) of Article 18 of the Biosafety Protocol. The Meeting identified three major options with a view to meeting those requirements, namely:

(a) Existing documentation practices supplied by the originator of the shipment;

(b) Existing international documentation systems; and

(c) A new documentation mechanism tailored on existing systems.

135. The Meeting recommended that ICCP should consider these options, and that Parties use an accompanying document provided by the originator and/or existing international documentation systems that incorporates the information required under paragraph 2 (b) and 2 (c) of Article 18, as relevant, to enable Parties to fulfil their obligations as required in the Protocol. This recommendation takes into

account the first two options identified. As regards the third option, the Meeting recommended that the need for the development of a new system of documentation under paragraph 2 (b) and 2 (c) of Article 18 of the Protocol should be kept under review and further discussed.

136. The Meeting also recommended that international organizations that administer IPPC, the Seed Certification Schemes of the OECD, division 6.2 and class 9 of the United Nations Recommendations on the Transport of Dangerous Goods, and other relevant organizations be invited to provide advice on their ability to assist Parties to meet the requirements of the paragraphs under consideration, as well as on their capacity to adjust their systems, should adjustment be necessary.

137. Taking into account the willingness of the relevant organizations to work closely with the Secretariat of the Convention on Biological Diversity, on the one hand, and the recommendations of the Meeting of Technical Experts on Handling, Transport, Packaging and Identification on the other, options to coordinate the work under Article 18 of the Biosafety Protocol with the work of the relevant international organizations may include:

(a) Inviting the relevant international organizations to provide advice, in writing, on their ability to assist Parties to meet the requirements of Article 18, and on their capacity to adjust their systems, should adjustment is necessary;

(b) Inviting experts from the relevant international organizations to participate and contribute in the meetings of the Convention on Biological Diversity that deal with Article 18 of the Biosafety Protocol and, similarly, requesting the relevant international organizations to invite experts from the Convention on Biological Diversity to participate in their meetings that deal with matters relevant to Article 18 of the Protocol; and/or

(c) Establishing a liaison group of experts consisting of representatives from the relevant international organizations and from ICCP/the Conference of the Parties serving as the meeting of the Parties to the Protocol with balanced regional representation, that will assess the extent of possibilities that existing systems within the relevant international organizations would offer to address the requirements under Article 18 of the Biosafety Protocol, identify gaps, and submit its recommendations to ICCP/ the Conference of the Parties serving as the meeting of the Parties to the Protocol.

B. Modalities for a process to consider the requirements under paragraph 2 (a) of Article 18

138. As indicated earlier, paragraph 2 (a) of Article 18 requires that documentation accompanying 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 paragraph further requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements, including specification of their identity and any unique identification, no later than two years after the date of entry into force of the Protocol. In view of this requirement, the work plan of the ICCP envisaged an approach that tends to address paragraph 2 (a) of Article 18 in a separate process.

139. One of the options to conduct discussion towards fulfilling the requirements of paragraph 2 (a) of Article 18 may possibly be, like what was done for the purpose of paragraph 2 (b) and 2 (c) of Article 18, convening a group of technical experts with balanced regional representation, which will explore the issues, and forward its recommendations with regard to the detailed requirements of Article 18 to the Conference of the Parties serving as the meeting of the Parties to the Protocol;

140. The other option or modality would be to have a technical expert meeting convened first, to look at the issue from the technical point of view, and then to convene an open-ended meeting of experts that should further consider the issue, elaborate the detail requirements, and submit recommendations to the Conference of the Parties serving as the meeting of the Parties for its consideration and decision.

141. Additionally, Parties, Governments and relevant international organizations may be requested to submit their views regarding the detailed requirements of paragraph 2 (a) of Article 18, and the Executive Secretary to compile the views and submit a synthesis report to the group of technical experts envisaged in paragraphs 139-140 above for its consideration.

VI. RECOMMENDATIONS

142. The ICCP may wish to further review the synthesis of the information provided by Parties, Governments and relevant international organizations regarding their existing practices, rules and standards relevant to Article 18 of the Biosafety Protocol, and, based on the synthesis, the other information included in this note, and the report and recommendations of the Meeting of Technical Experts on Handling, Packaging, Transport and Identification of Living Modified Organisms, held in Paris, from 13 to 15 June 2001, may wish to recommend to the Conference of the Parties serving as the meeting of the Parties:

(a) To request Parties to the Protocol to use an accompanying documentation provided by the originator and /or required by the existing international documentation systems that incorporates the information required under paragraph 2 (b) and 2 (c) of Article 18 of the Protocol, with a view to fulfil their obligations under the two paragraphs, until decided otherwise;

(b) To request Parties, Governments and relevant international organizations to provide their views to the Executive Secretary regarding the detailed requirements of paragraph 2 (a) of Article 18 of the Protocol, including specification of the identity of living modified organisms that are intended for direct use as food or feed, or for processing, and any unique identification;

(c) Request the Executive Secretary to prepare a synthesis report of the views submitted in accordance with subparagraph (b) above, and submit such report to the meeting of technical experts that will be convened in accordance with subparagraph (d) below;

(d) Request the Executive Secretary further to convene a meeting of technical experts in the identification of living modified organisms that are intended for food or feed, or for processing, taking into account the need for a balanced regional representation to consider the detailed requirements of paragraph 2 (a) of Article 18 of the Protocol, including specification of the identity of living modified organisms, that are intended for direct use as food or feed, or for processing, and any unique identification, and to submit recommendations to the Conference of the Parties serving as the meeting of the Parties;

(e) Invite the Sub-Committee of Experts on the Transport of Dangerous Goods of the United Nations, the Interim Commission on Phytosanitary Measures, the Organisation for Economic Co-operation and Development, and other relevant international organizations to provide advice, in writing, on their ability to assist Parties to meet the requirements of Article 18 of the Biosafety Protocol, and on their capacity to adjust their systems should adjustment be necessary.
