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SERVING AS THE MEETING OF THE PARTIES TO
THE CARTAGENA PROTOCOL ON BIOSAFETY
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Item 10 of the provisional agenda*

CONSIDERATION OF THE NEED FOR AND MODALITIES OF DEVELOPING STANDARDS WITH REGARD TO IDENTIFICATION, HANDLING, PACKAGING AND TRANSPORT PRACTICES IN THE TRANSBOUNDARY MOVEMENT OF LIVING MODIFIED ORGANISMS (PARAGRAPH 3, ARTICLE 18)

Note by the Executive Secretary

I. INTRODUCTION

1. Article 18 provides for handling, transport, packaging and identification of living modified organisms that are subject to intentional transboundary movement. Paragraph 3 of Article 18 requires the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol to consider the need for and modalities of developing standards with regard to identification, handling, packaging, and transport practices. In doing so, the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol is required to undertake consultation with other relevant international bodies. The medium-term programme of work of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol specifies that paragraph 3 of Article 18 of the Protocol will be considered by the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol at its third meeting (decision BS-I/12).

2. In this regard, at its second meeting, the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol included a specific request to the Executive Secretary to establish cooperation with the World Customs Organization, the International Organization for Standardization (ISO), the United Nations Transport of Dangerous Goods Sub-Committee, the International Air Transport Association and other relevant customs and transport organizations, with a view to developing harmonized approach for the packaging and transport of living modified organisms in preparation for the consideration

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of paragraph 3 of Article 18 by the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol at its third meeting (decision BS-II/6, paragraph (f)).

3. Section II of the present document summarizes the response that the Secretariat received to its request for an update of activities from some of the relevant international organizations with a view to considering the need for and modalities of developing standards in the context of paragraph 3 of Article 18 of the Protocol. Section III highlights the work of those international bodies and standard-setting processes pertaining to identification, handling, packaging and transport practices of living modified organisms. Finally, section IV provides some preliminary conclusions and suggests elements of a draft decision for consideration by the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol.

4. It should also be noted that the related issue of documentation and identification requirements under paragraphs 2 (a), 2 (b) and 2 (c) of Article 18 of the Protocol are addressed in detail in documents UNEP/CBD/BS/COP-MOP/3/8 and UNEP/CBD/BS/COP-MOP/3/8/Add.1.

II. CONSULTATION WITH INTERNATIONAL BODIES

5. There are a number of international organizations, agreements or arrangements, which in one way or the other address issues relating to the requirements of Article 18 of the Protocol regarding identification, safe handling, packaging and transport of living modified organisms, in particular. Further details regarding the relative purview of these bodies are covered in section III of the paper.

6. Relevant international customs and transport related organizations and regulatory agencies were invited to initiate or strengthen cooperation with the Secretariat, with a view to developing a harmonized approach for the handling and transportation of living modified organisms in preparation for the consideration of the need for and modalities of developing standards as specified under Article 18, paragraph 3 of the Protocol. Accordingly, the Executive Secretary also invited these organizations, *inter alia*, to provide their views on existing international rules, standards or practices applying for the packaging and transport of LMOs, and on the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices involving LMOs.

7. The organizations contacted directly in this regard were (i) the United Nations Economic Commission for Europe (UNECE), in its capacity as the Secretariat for the United Nations Transport of Dangerous Goods Sub-Committee; (ii) the International Organization for Standardization (ISO); (iii) the Universal Postal Union; (iv) the World Customs Organization; and (v) and the International Air Transport Organization.

8. UNECE provided an extensive response to the Secretariat, including details of the existing rules, standards and practices relevant to transport of dangerous goods, and noted that it would not be desirable for the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol to develop transport requirements or standards besides those existing requirements and standards regarding identification, handling, packaging and transport operations for all types of dangerous goods which are, at present, integrated in a well-functioning specific international transport regulatory framework. Full details of the response sent by UNECE is provided in an information document (UNEP/CBD/BS/COP-MOP/3/INF/3), and are elaborated further in section III.

9. In addition, the Secretariat also invited the Codex Alimentarius Commission, specifically its Committee on Methods of Analysis and Sampling, and the Joint Research Centre, Institute for Health and Consumer Protection of the European Commission, for cooperation and update of developments regarding

living modified organisms sampling and detection techniques. In its response, the Codex Alimentarius Commission expressed its willingness to strengthen cooperation with the Secretariat in areas of common interest, and informed the Secretariat of its current activities in this area. Full details of the Codex response are included in the information document (UNEP/CBD/BS/COP-MOP/3/INF/3), and are elaborated further in section III.

III. OVERVIEW AND UPDATE ON RELEVANT INTERNATIONAL BODIES AND PROCESSES

10. An overview of existing standards, practices and rules relevant to handling, packaging, transport and identification of living modified organisms was considered by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in a note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/1/7).

11. Accordingly, the present section provides a summary of the relevant international organizations, including rules and standards pertaining to the handling, transport, packaging and identification of LMOs. It does not purport to provide a complete overview of this complex field, but rather focuses on recent policy developments and upcoming activities that are relevant to consideration of this issue. It is possible that not all of these activities will necessarily develop international standards or rules of relevance. Nevertheless, issues relevant to handling, transport, packaging or identification fall within their mandate, albeit not always as the focus of their work, and consequently their activities may become relevant in the future.

A. World Trade Organization

12. Although the Cartagena Protocol and the World Trade Organization (WTO) treaty are mutually supportive, clarification of the requirements of Article 18 will nevertheless need to take into account the requirements of the WTO, so as to remain mutually supportive of these rules. In particular, rules or standards developed in this regard may specifically need to consider obligations under the General Agreement on Tariffs and Trade, the Agreement on Technical Barriers to Trade, and the Agreement on the Application of Sanitary and Phytosanitary Measures.

1. Agreement on Technical Barriers to Trade (TBT)

13. The Agreement on Technical Barriers to Trade (TBT) applies to technical regulations and standards, including packaging, marking and labelling requirements. Technical regulations should not create unnecessary obstacles to international trade and should not be more trade-restrictive than necessary to fulfil a "legitimate objective, taking account of the risks of non-fulfilment" (Article 2, paragraph 2, TBT Agreement). As far as determining legitimate objectives, the TBT Agreement recognizes that "no country should be prevented from taking measures necessary" to ensure the quality of its exports; to protect human, animal or plant life or health, of the environment; or prevent deceptive practices, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguized restriction on international trade, and are otherwise in accordance with the provisions of the Agreement (preamble, TBT Agreement).

2. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

14. Under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), members should ensure that any such safety measure is based on "scientific principles and is not

maintained without sufficient scientific evidence, except as provided for in paragraph 7 of article 5". Paragraph 7 of article 5 allows members to adopt measures provisionally "where scientific evidence is insufficient". Paragraph 5 of the same article provides also that each member shall "avoid arbitrary or unjustifiable distinctions" in its standards.

15. Article 3 of the SPS Agreement notes that "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994." Additionally, members are allowed to "introduce or maintain sanitary or phytosanitary measures which result in a higher level of ... protection than ... measures based on relevant international standards, guidelines or recommendations, if there is a scientific justification".

3. General Agreement on Tariffs and Trade (GATT)

16. The 1994 General Agreement on Tariffs and Trade (GATT) contains a further set of rules of relevance. In particular, article III of GATT provides that Members must not discriminate between imports from different sources or between like domestic and imported products. This provision is qualified by article XX, paragraphs (b) and (g), of GATT. Article XX, paragraph (b), allows a contracting party to take measures that are necessary to protect "human, animal or plant life or health". Under paragraph (g) of article XX, a party may take trade measures that are related to "the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption".

4. Disputes Settlement Understanding

17. In addition, the Disputes Settlement Understanding may also be relevant to consideration of Article 18 of the Protocol. In 2003, the United States, Canada and Mexico requested the creation of a formal WTO dispute panel over the issue of the *de facto* moratorium of genetically modified food and products within the European Union. The Panel in European Communities - Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291, WT/DS292 and WT/DS293) indicated in its communication of 11 August 2005 to the Dispute Settlement Body that it would issue its final report to the parties by the end of December 2005.

5. Standards-setting institutions under the WTO

18. Some of the more prominent organizations involved in setting relevant standards include the three institutions named in the WTO treaty as having responsibilities for setting standards – the Codex Alimentarius Commission, the International Plant Protection Convention (IPPC), and the World Animal Health Organization (OIE). Relevant activities under these organizations are examined in further detail in the sub-sections below.

B. Food and Agriculture Organization of the United Nations (FAO)

19. The Food and Agriculture Organization of the United Nations (FAO) is mandated to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy. FAO is consequently involved in producing publications related to norms, standards and conventions, some of which are relevant to the provisions of Article 18.

1. Codex Alimentarius

20. The Joint FAO/WHO Codex Alimentarius Commission is an intergovernmental body set up to establish international standards on foods. The Codex is a collection of internationally adopted food standards presented in a uniform manner. These are developed in order to attempt to ensure that products meet internationally accepted minimum acceptable quality levels, are safe and do not present a health hazard. Standards are prescribed for individual foods and food groups, and general standards have also been adopted, for example, for labelling pre-packaged foods. In addition to specific standards, the Codex also includes "related texts". Related texts include advisory instruments: statements of principle, codes of practice, guidelines and codes of technological practice. Some of these instruments apply to food and food products that have been derived from biotechnology.

21. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology was established to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. It completed its work in 2003 and the Codex consequently issued 3 relevant documents: (i) Principles for the risk analysis of foods derived from modern biotechnology; (ii) Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants; (iii) Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms.

22. At its 27th session (Geneva, 28 June – 3 July 2004), the Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology with the understanding that its final report should be submitted to the Commission in 2009. The first session of this new Task Force (i.e. the fifth session in total) took place in Chiba, Japan from 19 to 23 September 2005. The Task Force agreed to undertake work on two items (subject to approval by the Codex Alimentarius Commission): (i) A Guideline on the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals; and (ii) an annex to the existing Codex *Guideline on the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* on "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional and Health Benefits".

23. The Codex Committee on Food Labelling is responsible for, *inter alia*, drafting provisions on labelling applicable to all foods; and endorsing specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines. At the next session of the Codex Committee on Food Labelling, scheduled to take place in Ottawa, from 1 to 5 May 2006, the Committee will be considering the *"Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic engineering (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods): Definitions"*.

24. In its submission to the Secretariat, the Codex also noted that the Committee on Methods of Analysis and Sampling was currently working on Criteria for the Methods for Detection and Identification of Foods Derived from Biotechnology and a revised document on that subject would be prepared in early 2006 for consideration by the 27th session of the Committee, in Budapest, from 15 to 19 May 2006.

2. Plant Genetic Resources

25. The Global System on Plant Genetic Resources under the FAO aims to ensure the safe conservation, and promote the availability and sustainable use of plant genetic resources by providing a flexible framework for sharing the benefits and burdens.

26. The Global System comprises an international agreement (the International Treaty on Plant Genetic Resources for Food and Agriculture), a variety of codes of conduct, scientific standards, technical mechanisms and global instruments for plant genetic resources for food and agriculture.

27. The Plant Genetic Resources Treaty entered into force on 29 June 2004. The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. It aims to establish an efficient, effective and transparent Multilateral System to facilitate access to plant genetic resources for food and agriculture, and to share the benefits in a fair and equitable way.

28. Standards developed under the global system include a draft Code of Conduct on Biotechnology. A report on policy issues, gaps and duplications was made to the Tenth Session of the Commission on Genetic Resources for Food and Agriculture held in Rome, from 8 to 12 November 2004, which identified several gaps that might form the basis for the development of a code or codes of conduct, guidelines or other course of action, such as international voluntary certification schemes for products obtained through biotechnologies. The next session in 2006 will again discuss the draft Code of Conduct.

3. The International Plant Protection Convention (IPPC)

29. The International Plant Protection Convention (IPPC) was established to promote appropriate measures to prevent and control the spread and introduction of pests of plants and plant products. Its objectives include the development and application of international standards in international trade to prevent introduction and dissemination of plant pests. It addresses natural flora and plant products, not solely concerned with transborder transfer, and covers direct and indirect damage by pests, including weeds.

30. The Convention establishes international standards for phytosanitary measures (ISPM) that may be relevant to LMOs, such as ISPM No. 11 on *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*. Other codes of conduct developed under the IPPC may be relevant to the transboundary movement of LMOs to some extent, for example, the *Code of Conduct for the Import and Release of Exotic Biological Control Agents*.

C. World Organization for Animal Health (OIE)

31. The World Organization for Animal Health (OIE) is an intergovernmental organization created to provide information to ensure transparency regarding the global animal disease situation. Within its mandate under the WTO SPS Agreement, it also aims to guarantee the sanitary safety of world trade by developing rules for trade in animals and animal products that are recognized by the WTO as reference standards. The main normative works produced by the OIE are: the *International Animal Health Code*, the *Manual of Standards for Diagnostic Tests and Vaccines*, the *International Aquatic Animal Health Code* and the *Diagnostic Manual for Aquatic Animal Diseases*.

32. The 73rd Annual General Session of the OIE was held in Paris from 22 to 27 May 2005. The International Committee passed a resolution at that meeting on Applications of Genetic Engineering for Livestock and Biotechnology Products (Resolution No. XXVIII).

33. This resolution provides that OIE should continue to provide scientific advice and support to enable countries to develop harmonized technical standards for regulation of biotechnology-derived animal health products, and genetically modified production animals. OIE members created an Ad Hoc Group on

Biotechnology to, *inter alia*, support the work of OIE Specialist Commissions and related Working Groups; facilitate international collaboration; standardize the techniques of assessment of bioengineered animals or products, and training Member Countries to conduct risk analysis through the recognition of international collaborating centre(s).

34. These objectives are to be reached by the OIE taking into account, *inter alia*, the following priorities: development and adoption of standards and guidelines for research on the use of live attenuated vaccines in animal health; development of recommendations and guidelines for use of DNA vaccines; policy guidelines for exclusion of unapproved animals and products from the livestock population, and segregation from the feed and food supply; and development of identification, testing, and certification guidelines for international trade in production animals and their products for which biotechnology procedures have been employed.

35. The International Committee also asked its secretariat to develop and adopt standards and guidelines for: research and use of vaccines for animals produced through biotechnology; animal health risks linked to cloning; exclusion of unapproved animals and products from the livestock population and segregation from the feed and food supply; and animals that have been genetically engineered to produce medicines or chemicals. In order to address these concerns, the OIE will convene a group of scientists to discuss the issues and produce a document that the OIE's elected specialist and regional Commissions could then adopt in coming years into a draft standard.

E. World Health Organization (WHO)

36. The World Health Organization (WHO) has a constitutional responsibility to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products, as well as diagnostic procedures.

37. The Department of Food Safety, Zoonoses and Foodborne Diseases of the WHO finalized in June 2005 an evidence-based study of the implications of modern food biotechnology on human health and development. This report will be used directly by WHO in planning its future activities with regard to the use and application of modern biotechnology in human health and development.

F. United Nations Transport of Dangerous Goods Sub-Committee

38. As outlined in detail under the United Nations Economic Commission for Europe's (UNECE) submission to the Secretariat (UNEP/CBD/BS/COP-MOP/3/INF/3), identification, packaging and transport requirements for genetically modified organisms and genetically modified micro-organisms are addressed in the *United Nations Recommendations on the Transport of Dangerous Goods. Model Regulations*, also known as the "Orange book". The Model Regulations are addressed not only to member States of the United Nations for the development of their national requirements for domestic traffic of dangerous goods, but also to international organizations such as the International Maritime Organization (IMO), the International Civil Aviation Organization (ICAO) and regional commissions such as the UNECE for regulations and international or regional agreements or conventions governing the international transport of dangerous goods by sea, air, road, rail and inland waterways.

39. The Model Regulations provide a uniform regulatory framework which can be applied in all countries for national or international transport by any mode of transport. The Model Regulations are not binding *per se*. They become of binding nature only once they have been transposed into national legislation or international legally binding instruments. Therefore, enforcement is placed under the responsibility of the competent authorities of the member States.

40. The Model Regulations address the following main areas:

(a) List of dangerous goods most commonly carried and their identification and classification;

(b) Consignment procedures: labelling, marking, and transport documents;

(c) Detailed packing instructions for the transport of individual substances and articles, as well as standards for packagings, Intermediate Bulk Containers and large packagings, test procedures, and certification; and

(d) Detailed provisions for the use and operation of multimodal tank-containers (portable tanks) and standards for their construction, testing and approval.

41. The Model Regulations are amended every two years as necessary to take into account technological developments as well as the advent of new substances and materials, the exigencies of modern transport systems, the changing needs of users, and the safety requirements of regulators.

42. There are a number of international instruments dealing with the transport of dangerous goods (including transport of living modified organisms – referred to as genetically modified organisms and genetically modified micro-organisms) which are regularly amended to follow the 2 year updating of the United Nations Model Regulations, as follows:

(a) Maritime transport: chapter VII of the International Convention for the Safety of Life at Sea (SOLAS 74), annex III of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78), supplemented by the International Maritime Dangerous Goods Code (IMDG Code) published by the International Maritime Organization (IMO);

(b) Air transport: annex 18 to the Convention on International Civil Aviation (Chicago Convention), amplified by the International Civil Aviation Organization (ICAO)'s *Technical Instructions for the Safe Transport of Dangerous Goods by Air*. The International Air Transport Association (IATA) also publishes a manual called *Dangerous Goods Regulations* on the basis of the ICAO Technical Instructions;

(c) Inland transport (regional): European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR); Regulations concerning the International Transport of Dangerous Goods by Rail (RID); Convention concerning international goods transport by railway (SMGS); ASEAN Framework Agreement on the Facilitation of Goods in Transit; 1994 *Acuerdo sobre Transporte de Mercancias Peligrosas en el MERCOSUR* [Southern Cone Common Market countries]; Andean Community draft legislation.

43. The last edition of the United Nations Model Regulations (14th revised edition) takes account of all the amendments that were adopted by the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, at its second session (December 2004). The adopted set of amendments includes modifications to the requirements for the transport of infectious genetically modified organisms and genetically modified micro-organisms contained in the previous edition (13th revised edition) of the United Nations Model Regulations.

44. In its submission, UNECE noted that, although United Nations 3245 in the United Nations Model Regulations covers both genetically modified organisms and genetically modified micro-organisms, the major related international legal instruments (IMDG Code, ICAO Technical Instructions, ADR, RID and

ADN) cover only genetically modified micro-organisms under UN 3245. At present, how to transport genetically modified organisms of class 9 is unclear for maritime and air international transport. For international transport under ADR, RID and ADN, genetically modified organisms which are known or suspected to be dangerous to the environment shall be carried in accordance with conditions specified by the competent authority of the country of origin.

G. Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters

45. The second meeting of the Parties to the United Nations Economic Commission for Europe's Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters took place in Almaty from 25 to 27 May 2005, at which the Parties adopted an amendment to the Convention extending the rights of the public to participate in decision-making on GMOs. Future work under the Aarhus Convention may be relevant to, for example, considering the role of labels used to identify living modified organisms in informing the public.

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

46. In recent years the most directly relevant work of the Organisation for Economic Co-operation and Development (OECD) has been undertaken by the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, established in 1995 to manage the implementation of the OECD programme for harmonization of regulatory oversight in Biotechnology. The activities of Task Force for the Safety of Novel Foods and Feeds, established in 1998 to consider safety of foods and feeds derived from biotechnology, are also relevant.

1. Consensus documents

47. The Working Group has published 23 "consensus documents" to date, as well as an introductory guide to these documents (ENV/JM/MONO(2005)17). These consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognized among OECD member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits.

48. The Task Force has published 11 consensus documents, containing information for use during the regulatory assessment of a particular food/feed product. In the area of food and feed safety, consensus documents are being published on the nutrients, anti-nutrients or toxicants, information of the product's use as a food/feed and other relevant information. There is no consensus document dealing specifically with labelling.

2. Unique identification

49. In February 2002, the OECD published its *Guidance for the Designation of a Unique Identifier for Transgenic Plants*. A Unique Identifier is a nine-digit alphanumeric code that is given to each transgenic (or genetically engineered) plant that is approved for commercial use, including planting and food/feed use. In its decision BS-I/6, the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol welcomed the development and adoption of the OECD guidance a unique identifier for transgenic plants, and encouraged OECD and other organizations involved in the development of unique identification systems for living modified organisms to initiate or enhance their activities towards the development of a harmonized system of unique identifiers for genetically modified micro-organisms and animals. This work is ongoing under the auspices of the OECD Working Group.

3. Seed schemes

50. The OECD Seed Schemes were developed primarily to facilitate international trade in seeds, by harmonizing varietal certification procedures and identification labels, and they are implemented by member and non-member countries. Their essential purpose is to harmonize the assessment and certification of identity and purity of cultivated crop plant varieties – including those that are living modified organisms. The impact of biotechnology and advanced breeding methods on seed certification is currently under discussion, and the mandate of the Working Group on Genetically Modified Seed Issues, established some years ago, is being revised.

I. International Organization for Standardization (ISO)

51. The International Organization for Standardization (ISO) is a non-governmental organization whose principal activity is the development of technical standards, and it has published more than 15 000 International Standards since its inception in 1947.

52. A number of standards specifically relevant to detection and analysis of living modified organisms for food have been recently released, including ISO/TS 21098:2005 (*Foodstuffs -- Nucleic acid based methods of analysis of genetically modified organisms and derived products*), ISO 21569:2005 (*Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Qualitative nucleic acid based methods*), ISO 21570:2005 (*Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Quantitative nucleic acid based methods*). ISO 21571:2005 (*Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Nucleic acid extraction*) and ISO 21572:2004 (*Foodstuffs -- Methods for the detection of genetically modified organisms and derived products -- Protein based methods*). Others are under development, such as ISO/FDIS 24276 (*Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- General requirements and definitions*). Although these standards have been established for food matrices, they could also be applied to other matrices (e.g. seeds, feed and plant samples from the environment).

J. Additional guidance materials

53. In many cases, LMOs are either specifically covered or will fall within the general definitions of goods, and will therefore be subject to general rules governing the international movement of substances and goods. For some classes of goods, especially those that pose a special danger to human or animal health and the environment, specific or detailed requirements have been developed by various bodies, which to some extent will also cover LMOs. For example, in addition to those addressed above, international rules governing the transport of biological control agents, pests, alien and invasive species, bacteria, pathogens, biological waste products, and even animals will to varying extents cover the transboundary movement of LMOs. Examples of these include the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, the *Code of Conduct on Responsible Fisheries* of the FAO, and the FAO *International Code of Conduct on the Distribution and Use of Pesticides*. The Universal International Postal Union has also developed rules and standards for the shipment of goods by post (see, for example, the *Acts of the Universal Postal Union*, Beijing 1999) that may also be applicable to LMOs (for example, the sending of living modified micro-organisms by post).

54. Many of the regimes described previously that primarily relate to handling, transport and packaging also contain rules and standards with respect to documentation that is required to accompany

the relevant shipment, or labels that should be affixed to the goods or packaging. For example, the United Nations Model Regulations include packaging requirements, such as information required in the transport document (e.g. proper shipping name, including the technical name, class or division of goods) risk labels, or special marks to be displayed on the external surface of outer packagings, as appropriate.

55. Moreover, identification requirements that have been developed for safety reasons (e.g., veterinary products), quality considerations (e.g., geographical origin of production), control authority considerations (e.g., bills of lading), product-management considerations (e.g., bar codes) or to convey information factually (e.g., a list of ingredients) may also be relevant when considering the need for, or modalities of, developing standards with regard to identification.

56. A further layer of rules and standards of relevance are the international rules and standards for quarantine and customs procedures. One important set of rules in this regard is the system of harmonized customs codes developed pursuant to the International Convention on the Harmonized Commodity Description and Coding System administered by the World Customs Organization (WCO).

57. It is also necessary to take into account the various regional initiatives that have established, or are in the process of establishing, specific standards for the handling, transport and packaging of LMOs, such as the relevant European Community directives, as well as national requirements.

IV. CONCLUSIONS AND ELEMENTS OF A DRAFT DECISION

58. Despite the variety and array of existing rules and standards, none comprehensively cover the scope of Article 18. For example:

(a) Few of the rules deal with the range of LMOs covered by Article 18. For example, many of the rules and standards focus on requirements for pathogens or dangerous organisms. As a result many types of genetically modified plants, for example, may well not be covered by any existing rules and regulations;

(b) Those standards and rules that do exist differ in the use of terms, scope and requirements and provide for information to be channelled to different government agencies;

(c) The stated purpose of most of the existing rules and standards is to protect human, animal or plant health, not biodiversity *per se*;

(d) Many of the labelling requirements deal with food products (largely outside the scope of the Protocol), not living organisms;

(e) Many of the relevant rules governing transport of LMOs only apply within a certain geographical or political region (e.g., rules developed under the auspices of the OECD or European Union) – with the consequence that other regions may not be adequately covered.

59. It is also clear that the international regulatory framework is continuing to develop new guidance that will be relevant to Article 18 paragraph 3 of the Protocol; however, determining how these will affect future developments will be dependent upon the exact nature of these provisions.

60. Given the wide range of situations possible within the scope of Article 18, it is difficult to determine the adequacy of existing regimes in the abstract, especially because of the rapidly expanding nature of biotechnology and the emergence of new products and applications. Moreover, the further development of existing rules will be warranted only on the basis that the inherent risks associated with the

LMOs are different from those of the original organism. Again, it is difficult to generalize about the different risks associated with new products or applications.

61. It should also be noted in the context of this discussion that, in practice, regulatory requirements are often supplemented by commercial contractual requirements in the marketplace, and that current practices are likely to rely on such bilateral arrangements to achieve the requirements of importers and exporters of LMOs in addition to, or in the absence of, any applicable standards.

62. The legal and institutional complexity of the relevant international rules for Article 18 of the Protocol means that any standards developed pursuant to paragraph 3 of Article 18 would need to be considered carefully and precisely in the context of the existing international regulatory framework. For example, careful consideration needs to be given as to which rules and bodies are relevant and whether the relevant existing regulations are inadequate or could simply be amended to meet the purposes of the Protocol. Therefore, should the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol consider that existing provisions are not fully adequate for LMOs and should be amended, further expanded, or should it be of the view that gaps in the existing framework that need to be addressed, cooperation would need to be established with the relevant international bodies to ensure relevant concerns are addressed.

63. The Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol may wish, therefore, to invite Parties, other Governments and relevant international organization to submit views on any areas where they consider that existing provisions are not fully adequate for LMOs and should be amended, further expanded, or where they have identified potential gaps in the existing framework that need to be addressed, for consideration at its fifth meeting.

64. The Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol may also wish to continue to gain experience in the implementation of the Protocol's provisions regarding handling, transport, packaging and identification, and to request the Executive Secretary to continue to collaborate with relevant international organizations in this regard.
