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ONLINE FORUM ON PARAGRAPH 3 OF ARTICLE 18
REGARDING THE NEED FOR AND MODALITIES OF
DEVELOPING STANDARDS FOR THE HANDLING,
TRANSPORT, PACKAGING AND IDENTIFICATION OF
LIVING MODIFIED ORGANISMS
Online, 18-29 May 2009

SUMMARY OF INFORMATION ON STANDARDS AND STANDARD-SETTING BODIES RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

I. INTRODUCTION

1. In their decision BS-IV/10, the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to, *inter alia,* organize an online conference (referred to herein as "forum") on paragraph 3 of Article 18. The online forum is intended to: (i) identify the relevant standards with regard to handling, transport, packaging and identification of living modified organisms; (ii) identify where gaps exist; and (iii) suggest possible modalities to fill the gaps.

2. The online forum is scheduled to take place from 18 to 29 May 2009. It will be conducted through the Biosafety Clearing-House (BCH) at the following website: http://bch.cbd.int/onlineconferences/forum_art18.shtml.

3. The Secretariat has prepared this document in order to provide background information that will aid in the deliberations of the online forum. The document draws on information that was put together for the Inter-governmental Committee for the Cartagena Protocol and previous meetings of the COP-MOP (see the summary of these documents in notification 2008-113 (Ref. No. SCBD/BS/CG/KG/jh/64834) issued on 11 September 2008.) It also adds to and updates this information as necessary.

4. Sections II through IX, below, cover the relevant standards and ongoing work of a number of intergovernmental organizations, namely: the Codex Alimentarius Commission; the International Plant Protection Convention; the World Organisation for Animal Health; the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations; the Organisation for Economic Co-operation and Development; the World Customs Organization; the United Nations Centre for Trade Facilitation and Electronic Business; and the United Nations Commission on International Trade Law. Finally, section X discusses standard form contracts for the shipment of grain.

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II. CODEX ALIMENTARIUS COMMISSION

5. The Codex Alimentarius Commission is a joint initiative of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) that was set up to establish international standards on foods. The Codex Alimentarius 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.

6. Standards adopted by the Codex Alimentarius Commission are not legally binding on Codex member states. Countries and organizations that are members the World Trade Organization (WTO), however, have an obligation under the WTO's *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) to base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, for the purpose of harmonizing these measures on as wide a basis as possible (paragraph 1 of Article 3). Annex A to the SPS Agreement defines the term 'international standards, guidelines and recommendations' to mean, in the context of food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission (paragraph 3(a)).

7. Work to develop Codex standards is conducted by a number of committees and task forces, six of which are particularly relevant here: the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology; the Codex Committee on Food Labelling; the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding; the Codex Committee on General Principles; the Codex Committee on Food Import and Export Inspection and Certification Systems; and the Codex Committee on Methods of Analysis and Sampling.

A. Codex Ad Hoc *Intergovernmental Task Force on Foods Derived from Biotechnology*

8. In June 1999, the Codex Alimentarius Commission established an *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology 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. The Task Force initially completed its work in 2003 and the Codex consequently adopted three documents: (i) "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology"; 1/ (ii) "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants"; 2/ and (iii) "Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms" 3/.

9. The Principles for the Risk Analysis of Foods Derived from Modern Biotechnology cover both risk assessment and risk management as well as risk communication, consistency, capacity building and information exchange, and review processes. The definition of 'modern biotechnology' in the Principles is the same as the definition in the Biosafety Protocol. The Principles also suggest that tools may be needed to facilitate the implementation and enforcement of risk management measures and that such tools

1/ CAC/GL 44-2003, adopted in 2003, amended in 2008.

2/ CAC/GL 45-2003, adopted in 2003, annexes II and III adopted in 2008.

3/ CAC/GL 46-2003.

may include appropriate analytical methods; reference materials; and product tracing. 4/ The Principles do not cover animal feed or animals fed such feed except when these animals have also been developed through the use of modern biotechnology.

10. As part of its work, the Task Force prepared a list of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology. The list includes the performance criteria and status of the validation of each method. At its 2002 meeting, the Task Force agreed to forward the list of methods to the Codex Committee on Methods of Analysis and Sampling for its consideration. The Codex Committee on Methods of Analysis and Sampling "noted that the List provided a very good review of methods currently used by Member Governments in the area of GM material analysis ... [h]owever the Committee agreed that the selection or endorsement of methods without appropriate provisions was not possible." 5/

11. At its twenty-session session, held in Geneva from 28 June to 3 July 2004, the Codex Alimentarius Commission agreed to establish a new *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology with the understanding that the Task Force's final report should be submitted to the Commission in 2009. Under its new mandate, the Task Force developed three documents: (i) the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals"; 6/ (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 or Health Benefits"; 7/ and (iii) an annex on "Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food" 8/. All three were adopted by the Codex Alimentarius Commission at its thirty-first session, in 2008, and the Task Force was dissolved.

B. Codex Committee on Food Labelling

12. 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 other Codex Committees as part of their work. The Codex Committee on Food Labelling has been considering food labelling provisions for foods derived from biotechnology since 1996. This work has taken the form of definitions and Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering. As they currently stand, the definitions and recommendations would take the form of amendments to the *General Standard for the Labelling of Prepackaged Foods*. However, these draft texts are still under discussion due to lack of consensus. The most controversial point is whether or not mandatory labelling provisions should be established for the case where the production method is the sole difference between original products and genetically modified products. The next meeting of the Committee is scheduled to be held from 4 to 8 May 2009 and the issue of the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering is on the agenda.

4/ CAC/GL 44-2003 at para. 21.

5/ "Report of the Twenty-Fourth Session of the Codex Committee on Methods of Analysis and Sampling", UN Doc. ALINORM 03/23 (November 2002) at para. 86.

6/ CAC/GL 68-2008.

7/ Became annex II to the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants", CAC/GL 45-2003.

8/ Became annex III to the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants", CAC/GL 45-2003.

C. Codex Ad Hoc *Intergovernmental Task Force on Animal Feeding*

13. The Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding met between 1999 and 2004 and developed a "Code of Practice on Good Animal Feeding" 9/. The Code provides guidance for developing a feed safety system for food producing animals. The Code focuses on consumer health issues in line with the Codex mandate, but it does also include animal health and environmental considerations.

14. An earlier draft of the Code had allowed for competent authorities to decide that feed and feed ingredients "consisting, containing or produced from GMOs" should be labeled. 10/ As finally adopted, the Code states that its section on labelling does not apply to the labelling of feed and feed ingredients derived from modern biotechnology (paragraph 11, sub-section 4.2). A footnote to the provision adds that "[w]hether and how to label animal feed and feed ingredients derived from modern biotechnology awaits developments on food labelling, being considered by the Codex Committee on Food Labelling." 11/

15. While GMOs are excluded from sub-section 4.2 of the Code, they are covered by the rest of the provisions in the Code. Section 4.3 of the Code covers traceability/product tracing and record keeping of feed and feed ingredients. It provides that proper record keeping should enable the traceability/product tracing of feed and feed ingredients in order to allow for the withdrawal or recall of products if known or probable adverse effects on consumers' health are identified. This includes maintaining records regarding the production, distribution and use of feed and feed ingredients "to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source and trace-forward to the next subsequent recipients if known or probable adverse effects on consumers' health are identified" (paragraph 12).

16. Sub-section 4.4 on inspection and control procedures states that the manufacturers of feed and feed ingredients as well as other relevant parts of industry should self-regulate to ensure compliance with required standards for production, storage and transport. Section 5 goes into more detail on production, processing, storage, transport and distribution of feed and feed ingredients. It states that these activities are the responsibility of all participants in the feed chain. More specifically, paragraph 37 provides that "[a]ll feed and feed ingredients should be stored and transported in a manner which minimizes deterioration and contamination and enable the correct feed to be sent to the right animal group."

17. Section 6 covers on-farm production and use of feed and feed ingredients. It advocates the application of good agricultural practices to all stages of the production of feed or feed ingredients for food producing animals. Sub-section 6.3 addresses good animal feed practice which is said to include "those practices that help to ensure the proper use of feed and feed ingredients on-farm while minimising biological, chemical and physical risks to consumers of foods of animal origin" (para. 68). Paragraph 74 states that "[p]rocedures to ensure that medicated feed are transported to the correct location and are fed to animals that require the medication should be followed. Feed transport vehicles and feeding equipment used to deliver and distribute medicated feed should be cleaned after use, if a different medicated feed or non-medicated feed or feed ingredient is to be transported next."

18. Finally, section 7 covers methods of sampling and analysis. The provisions speak to the need for good sampling protocols and laboratory methods as well as competent laboratories.

19. The Codex Alimentarius Commission will consider whether to undertake new work on animal feeding at its thirty-second session, to be held in June-July 2009.

9/ CAC/RCP 54-2004.

10/ "Report of the Fourth Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding", UN Doc. ALINORM 03/38A (March 2003) at para. 11 of Appendix II.

11/ CAC/RCP 54-2004 at footnote 5.

D. Codex Committee on General Principles

20. Consideration of the subject of traceability/product tracing was initiated at the eighteenth session of the Codex Committee on General Principles in 2003. At its twentieth session, the Committee agreed on the following definition: "Traceability / product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution." The definition was then forwarded to the Codex Alimentarius Commission at its twenty-seventh session, held in 2004, where it was adopted and included in the Procedural Manual.

E. Codex Committee on Food Import and Export Inspection and Certification Systems

21. Following the adoption by the Codex Alimentarius Commission of the definition of "traceability/product tracing", the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its thirteenth session, in December 2004, started new work to develop the principles on traceability/product tracing in the context of food import and export inspection and certificate systems. The "Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System" 12/ were subsequently adopted at the twenty-ninth session of the Commission, in July 2006.

22. At its sixteenth session, in November 2007, CCFICS discussed the need for further guidance on traceability/product tracing by Codex and agreed to continue discussion on this matter at its next session, to address the present gaps in the implementation of traceability/product tracing, the key elements that would address these gaps, and the technical and economical feasibility of countries to implement traceability/product tracing. An electronic working group gathered information on these points inter-sessionally and concluded that there was insufficient information to clearly identify gaps and needs in relation to the implementation of traceability/product tracing. The working group also recommended that the Codex Alimentarius Commission request the FAO/WHO Regional Coordinating Committees to discuss whether there is a need for further guidance on traceability/product tracing. This recommendation was endorsed by CCFICS at its seventeenth session, held in November 2008 and will be forwarded to the next session of the Codex Alimentarius Commission to be held in June-July 2009.

F. Codex Committee on Methods of Analysis and Sampling

23. The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing methods of detection and analysis for genetically modified foods since 2002. The work initially took the form of developing recommendations with respect to criteria for the methods for the detection and identification of foods derived from biotechnology as well as for quality control measures in laboratories offering analyses of genetically modified foods.

24. At the twenty-eighth session of CCMAS, in 2007, it was agreed that a project document would be prepared for a proposal for new work on Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology. At its twenty-ninth session, in 2008, the Committee agreed to the proposal for new work and agreed to submit the project document to the Codex Alimentarius Commission. The latter approved the new work at its thirty-first session, in 2008.

25. Also at its twenty-ninth session, CCMAS agreed to circulate at Step 3 the Proposed Draft Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology as they stood at that point in preparation for the Committee's thirtieth session. As circulated, the Proposed Draft Guidelines include a general section on "Guidelines for the Validation and Quality Control Requirements for the Analysis of Foods derived from Biotechnology" with six annexes that cover: the information to be provided when a method is to be considered for endorsement by

12/ CAC/GL 60-2006.

CCMAS; applicable Codex definitions; information for the validation of different detection methods; and proficiency testing of foods derived from biotechnology.

26. The thirtieth session of CCMAS was held from 9 to 13 March 2009. The agenda for the meeting included an item on the Proposed Draft Guidelines. 13/ The project document foresees that the Proposed Draft Guidelines will be adopted at Step 5 by the Codex Alimentarius Commission in 2010 and adopted in their final form in 2011. 14/

III. INTERNATIONAL PLANT PROTECTION CONVENTION

27. 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 the introduction and dissemination of plant pests. It addresses natural flora and plant products, is not solely concerned with transborder transfer, and covers direct and indirect damage by pests, including weeds.

28. Article IV of the IPPC contains "general provisions relating to the organizational arrangements for national plant protection". The Article requires Parties to the Convention to create a national plant protection organization with responsibilities that include: issuing phytosanitary certificates for the export of consignments of plants, plant products and other regulated articles; and inspecting consignments of plants and plant products moving in international traffic and, where appropriate, inspecting other regulated articles, particularly with the object of preventing the introduction and/or spread of pests. Article V sets out requirements in relation to phytosanitary certification. It requires Parties to make arrangements for issuing phytosanitary certificates for the export of plants, plant products and other regulated articles and consignments thereof. It also provides that phytosanitary certificates are to follow the wording of model certificates contained in the Annex to the IPPC. The Annex contains a model phytosanitary certificate and a model phytosanitary certificate for re-export. Both require a description of the consignment and they focus on certifying that the consignment is free of pests.

29. The IPPC is governed by the Commission on Phytosanitary Measures (CPM). The CPM adopts International Standards for Phytosanitary Measures (ISPMs). These standards are not legally binding on the Parties to the IPPC; however, in similar fashion to the Codex Alimentarius Commission, the WTO SPS Agreement requires WTO members to base their sanitary and phytosanitary measures for plant health on the standards, guidelines and recommendations of the IPPC.

30. ISPM No. 12 from 2001 (*Guidelines for phytosanitary certificates*) elaborates principles and guidelines for the preparation and issue of phytosanitary certificates following the model certificates contained in the Annex to the IPPC. The ISPM states that phytosanitary certificates "should include only information related to phytosanitary matters. They should not include statements that requirements have been met and should not include references to animal or human health matters, pesticide residues or radioactivity, or commercial information such as letters of credit" (section 2). The ISPM does allow for attaching a note to the phytosanitary certificate to associate the certificate with the symbol or code of other relevant documents in order to facilitate cross-referencing. The model phytosanitary certificates in the Annex to the IPPC include a line for identifying the name of the produce. The ISPM allows that international codes such as customs codes may be used to facilitate identification. See the section on the World Customs Organization, below, for more information.

13/ The report of the meeting was not available at the time of writing.

14/ "Proposals for New Work (Including Project Documents Submitted) and for the Discontinuation of Work", Codex Alimentarius Commission, 31st Sess., UN Doc. ALINORM 08/31/9 (April 2008) at p. 26.

31. Other ISPMs are also relevant to the handling, transport, packaging and identification of LMOs. ISPM No. 7 on *Export certification systems* (1997) describes the components of a national system for the issuance of phytosanitary certificates. It provides that each national plant protection organization (NPPO) should maintain guidance documents, procedures and work instructions covering every aspect of the certification system including sampling, inspection and verification procedures and consignment identification, traceability and security. Section 4.5 of the standard states that "[c]onsignments and their certification should be traceable as appropriate through all stages of production, handling and transport to the point of export."

32. ISPM No. 20 contains *Guidelines for a phytosanitary import regulatory system* (2004). The standard "describes the structure and operation of a phytosanitary import regulatory system and the rights, obligations and responsibilities which should be considered in establishing, operating and revising the system." According to section 1 of the ISPM, the objective of a phytosanitary import regulatory system is to prevent the introduction of quarantine pests or limit the entry of regulated non-quarantine pests with import commodities and other regulated articles. The NPPO is said to be responsible for the operation and oversight of the import regulatory system. Section 4.1 of the ISPM provides examples of articles that can be regulated under a phytosanitary import regulatory system including: plants and plant products used for planting, consumption, processing or any other purpose; storage facilities; packaging materials; conveyances and transport facilities; research and other scientific materials; and international mail including international courier services.

33. Section 4.2 covers phytosanitary measures for regulation articles. Within this, section 4.2.1 contains measures for consignments to be imported. These measures are broken down according to the measures that may be required in the export country, during shipment, at the point of entry, after entry and other measures. Examples of measures include inspection and testing of consignments prior to export; maintenance of consignment integrity; and documentation tests. Section 4.2.2 covers import authorization, which may be general or specific. The ISPM indicates that specific authorization of individual consignments or a series of consignments may be required for imports with "specific, individual requirements such as those with post-entry quarantine requirements or designated end use or research purposes"; or imports where the material needs to be traced after entry (section 4.2.2).

34. Section 5 covers the operation of an import regulatory system. Included among the management and operational responsibilities of the NPPO is compliance checking at the time of import. This checking is said to include three basic elements: documentary checks; consignment integrity checks; and phytosanitary inspection, testing, etc. The standard elaborates that testing may be required for, *inter alia*, verification of the declared product. Finally, on documentation, communication and review, ISPM No. 20 advises that NPPOs should maintain guidance documents, procedures and work instructions on all aspects of the operation of the import regulatory system including inspection, sampling and testing methodology. It also states that it may be appropriate to keep records of imported consignments including where these consignments have specified end-uses or will require follow-up action including traceback.

35. ISPM No. 23 on *Guidelines for inspection* (2005) is focused on determining compliance with phytosanitary requirements based on visual examination, checks of documentation and identity and integrity checks. It is linked to Article IV of the IPPC where, as described above, NPPOs are required to be responsible for the inspection of plants and plant products moving in international traffic as well as other regulated articles, where appropriate. According to the ISPM, the objective of inspection is to confirm compliance with import or export requirements relating to quarantine pests or regulated non-quarantine pests. The result of an inspection should allow an inspector to decide whether to accept, detain or reject the consignment or whether further analysis is necessary. The ISPM lists three procedures that are part of the technical requirements for inspection and need to be designed by NPPOs:

- Examination of documents associated with a consignment;
- Verification of consignment identity and integrity; and

- Visual examination for pests and other phytosanitary requirements (section 2).

In elaborating upon these three procedures, the ISPM states that the examination of documents requires verifying that documents are complete, consistent, accurate, valid and not fraudulent. Documents that may be associated with import and/or export certification include phytosanitary certificates, manifests (including bills of lading and invoices), import permits, producer/packing records and commercial invoices.

36. For the second step, inspection for identity and integrity involves checking to ensure that the consignment is accurately described in its accompanying documents. The visual examination includes both pest detection and verifying compliance with phytosanitary requirements such as consignment packaging and shipping requirements.

37. ISPM No. 3, *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms* (2005) provides additional guidance relevant to the transport, handling and documentation of living organisms that are biological control agents or other beneficial organisms. The ISPM includes the need to ensure that the regulations of the importing country are complied with and to provide and assess documentation relevant to the export, shipment, import, or release of these organisms. This ISPM specifically excludes living modified organisms from its scope, however.

38. ISPM No. 11 on *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms* (2004) provides guidance on pest risk analysis, including risk management, for organisms that can directly or indirectly cause harm to plants, in managed or unmanaged environments, and specifically includes potential effects on biodiversity. The ISPM includes within its scope LMOs that present a phytosanitary risk. Once an LMO has been identified as a pest or a pathway of quarantine concern, the pest risk assessment and pest risk management provisions of the ISPM apply. The pest risk management options for organisms determined to present a plant pest risk include handling, documentation, inspection or testing measures to ensure the integrity of consignments (section 3.4.1). The ISPM reiterates that information on phytosanitary certificates regarding LMOs should only be related to phytosanitary measures (section 3.5).

39. The fourth session of the CPM took place from 30 March to 3 April 2009. According to the "IPPC Standard Setting Work Programme" adopted during the meeting, ISPMs No. 7 and 12 are under review with revised versions projected to be adopted by the CPM in 2011. 15/

40. There are also a number of regional plant protection organizations under the IPPC that can develop their own Regional Standards for Phytosanitary Measures (RSPMs). Canada, the United States. and Mexico have formed the North American Plant Protection Organization (NAPPO) which, in 2003, adopted RSPM No. 14 on the *Importation and release (into the environment) of transgenic plants, in NAPPO member countries*. In its current form, the RSPM consists of three modules: one on importation into contained facilities, one on confined release into the environment and one on unconfined release into the environment. A fourth module on importation for uses other than propagation is said to be in preparation.

41. The RSPM focuses primarily on information that should be provided to regulatory authorities for their consideration in the authorization of the import and release of transgenic plants. In module 1 on importation into contained facilities this includes requirements for risk management measures. It states that "[w]here required, information related to risk management measures should include: adequate identification, packaging and segregation measures to prevent and/or minimize mixing, spillage and dissemination of viable transgenic plant material" (paragraph 1.1.3). Paragraph 1.3 on authorization requirements states that "[a]uthorization to import should be conditional on clear identification of the transgenic plant material during transit and in the receiving facility". Furthermore, material passing

15/ Document CPM 2009/CRP/17 (April 2009) at p. 2.

through customs should be subject to inspection or audit according to the commodity-specific instructions. Records of imports must be maintained. The RSPM provides that where consignments of transgenic plants do not meet the requirements for entry, they should be either confiscated and destroyed or removed from the country into which they were being imported, at the importer's expense (section 1.3).

42. The risk management measures in module 2 on confined release into the environment specify information requirements related to handling, disposal, record keeping and other considerations. These requirements should include adequate identification, packaging and segregation measures to prevent seed mixing, spillage and dispersal into the environment during transit; and the devitalization of surplus seed or seeds and any viable transgenic plant material remaining at the confined field site. Transgenic material harvested from the confined field site can only to be retained in an approved facility if this has been authorized by the regulatory authority. Such material should be clearly identified, securely transported and stored separately from other seed or plant material to avoid mixing (paragraph 2.1.6.3).

43. The Biotechnology Panel of NAPPO is currently considering whether to revise RSPM No. 14 and will be undertaking work in this regard in 2009.

IV. WORLD ORGANISATION FOR ANIMAL HEALTH

44. The World Organisation for Animal Health (OIE) is an intergovernmental organization created to provide information to ensure transparency regarding the global animal disease situation. The main normative works produced by the OIE are: the *Terrestrial Animal Health Code* ("Terrestrial Code"), the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Aquatic Animals*. The standards are aimed at preventing the introduction of infectious agents and diseases through international trade in animals. In similar fashion to the Codex Alimentarius Commission and the IPPC, WTO SPS Agreement requires WTO members to base their sanitary and phytosanitary measures in the area of animal health and zoonoses on the standards, guidelines and recommendations of the OIE.

45. The OIE is governed by an International Committee that meets in a General Session in May of each year. Different Specialist Commissions report to the International Committee and these generally meet biannually. The Specialist Commissions, in turn, frequently establish working groups and *ad hoc* groups to carry out detailed work on specific issues. There are currently four Specialist Commissions:

- the Terrestrial Animal Health Standards Commission (which develops the standards for the Terrestrial Code);
- the Scientific Commission for Animal Diseases;
- the Biological Standards Commission (which oversees the production of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals)*; and
- the Aquatic Animal Health Standards Commission (which produces the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Aquatic Animals*).

46. The standards set by the OIE do not, for the most part, make specific reference to living modified organisms but LMOs would fall within the scope of many the standards. The relevant work of the Terrestrial Animal Health Standards Commission and the Biological Standards Commission is described below.

A. Terrestrial Animal Health Standards Commission

47. As mentioned, the Terrestrial Animal Health Standards Commission is responsible for the Terrestrial Code. In recent years, the Terrestrial Animal Health Standards Commission carried out an extensive re-organization of the Terrestrial Code which was reflected in its 2008 version. The Terrestrial

Code has been divided into two volumes: volume one contains recommendations that apply to a wide range of species, production sectors or diseases ('horizontal standards') while volume two contains recommendations on specific diseases ('vertical standards').

48. A number of the sections and chapters in volume 1 of the Terrestrial Code are relevant to the handling, transport, packaging and identification of living modified organisms. These include:

- From section 4 on "General recommendations: disease prevention and control":
    - Chapter 4.1: General principles on identification and traceability of live animals;
    - Chapter 4.2: Design and implementation of identification systems to achieve animal traceability;
- From section 5 on "Trade measures, import/export procedures and veterinary certification":
    - Chapter 5.10: Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin;
- From section 7 on "Animal welfare":
    - Chapter 7.2: Transport of animals by sea;
    - Chapter 7.3: Transport of animals by land;
    - Chapter 7.4: Transport of animals by air; and
    - Chapter 7.5: Slaughter of animals.

Further information on these chapters and ongoing work under the Terrestrial Animal Health Standards Commission is provided below.

49. A number of working groups and *ad hoc* groups work under the auspices of the Terrestrial Animal Health Standards Commission.

50. The Working Group on Animal Production Food Safety was established in 2002 "with a view to strengthening the OIE's activities in the food safety area and further developing collaboration with the Codex Alimentarius Commission." 16/ The Working Group established an *ad hoc* Group on Identification and Traceability of Live Animals that has been meeting since June 2005. The *ad hoc* Group developed "General principles on the identification and traceability of live animals" that were adopted at the 74th General Session of OIE's International Committee held in May 2006 and are now chapter 4.1 of the Terrestrial Code. It also developed standards on the "Design and implementation of identification systems to achieve animal traceability" which were adopted at the 76th General Session in May 2008 and are now chapter 4.2 of the Terrestrial Code.

51. As its title suggests, the provisions in chapter 4.1 provide general principles on the identification and traceability of live animals. The chapter states that animal identification and traceability are tools for addressing animal health and food safety issues (paragraph 1 of Art. 4.1.1). Paragraph 3 provides that animal traceability and traceability of products of animal origin should have the capability to be linked to achieve traceability throughout the production and food chain.

52. The recommendations in chapter 4.2 "outline for Members the basic elements that need to be taken into account in the design and implementation of an animal identification system to achieve animal traceability" (Art. 4.2.1). In addition to an introduction and objectives, the chapter includes a glossary and sets out seven key elements of the animal identification system. One of the seven key elements is the definition of desired outcomes for the animal identification system. The paragraph provides that the desired outcomes may be defined in terms of, *inter alia*, public health, management of emergencies or trade, specifically support for the inspection and certification activities of veterinary services (paragraphs 1(b) - (d) of Art. 4.2.3).

16/ "Final Report 2008", OIE 76th General Session, Doc. 76 GS/FR (May 2008) at para. 227.

53. At its January 2008 meeting, the *ad hoc* Group on Identification and Traceability of Live Animals concluded that it had accomplished the mandate it had been given. The *ad hoc* Group did recognize, though, "that additional guidelines may need to be developed to address some specificities relevant to the issue of biotechnology derived animals." 17/

54. The OIE also organized an International Conference on Animal Identification and Traceability – "From Farm to Fork" – that was held in Buenos Aires, Argentina from 23 to 25 March 2009. The Codex Alimentarius Commission provided technical collaboration in the organization of the conference.

55. The International Committee of the OIE at its 74th General Session in May 2006 established an *ad hoc* Group on Revision of the OIE Model Certificates. The *ad hoc* Group is working to update, revise and harmonize the model certificates. One outcome of this work was chapter 5.10 of the Terrestrial Code containing "Model Veterinary Certificates for International Trade in Live Animals, Hatching Eggs and Products of Animal Origin" which was adopted by the 76th General Session of the OIE International Committee in May 2008 and replaced the previous model certificates that had been in place.

56. Chapter 5.10 of the Terrestrial Code contains four model veterinary certificates on international trade in live animals and hatching eggs; international trade in embryos, ova and semen; international trade in products of animal origin; and international trade in bees and brood combs. The model certificates follow a common format and the chapter includes guidance notes that elaborate on the information requirements of the certificates.

57. Box I.15 of the certificates asks for a description of the commodity. The notes suggest using the commodity titles as they appear in the Harmonized System of the World Customs Organization (see below.) Box I.22 requests information on the intended use of the commodity that is the subject of the certificate. Each certificate provides a range of options. For the certificate for international trade in live animals and hatching eggs, the options including breeding/rearing, slaughter, game restocking and other. Finally, box I.24 requests information on the nature of the commodity that will be sufficient to identify it. Each certificate has its own requirements for the answer. For live animals and hatching eggs, the requested identification details include the scientific name of the species, the identification system and identification number or other identification details.

58. In 2006, the OIE Director General established an *ad hoc* Group on Animal Feeding that reports to the Working Group on Animal Production Food Safety. This *ad hoc* Group has developed "Guidelines for the Control of Hazards of Animal Health and Public Health Importance in Animal Feed". An earlier draft of the Guidelines made reference to genetically modified organisms but this text was deleted in subsequent versions. In commenting on this draft of the Guidelines, the Working Group on Animal Production Food Safety noted that it is not within the OIE mandate to pursue work in relation to GMOs in animal feed. 18/ The Guidelines have now been amended to take the form of a draft chapter, which will be proposed for adoption as a new chapter of the Terrestrial Code at the 77th General Session of the OIE to be held in May 2009. In their current form following the March 2009 meeting of the Terrestrial Animal Health Standards Commission, the draft chapter states that its aim is to ensure "the control of animal and public health hazards through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm animal feed and feed ingredients for terrestrial animals" (Art. 2). Article 4 of the draft chapter sets out a number of general principles including one on labelling which states that "[l]abelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and

17/ "Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission", Doc. 76 SG/12/CS1 B, (March 2008) at p. 539.

18/ "Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission", Doc. 75 SG/12/CS1 B (March 2007) at p. 517.

section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storage and use" (paragraph 8 of Art. 4).

59. The Terrestrial Animal Health Standards Commission has also established a Working Group on Animal Welfare. This Working Group developed a number of standards including on the transport of animals by sea; the transport of animals by land; and the slaughter of animals all of which were adopted by the International Committee at its 73rd General Session in May 2005 and are now found in section 7 of the Terrestrial Code.

60. The standards in section 7 have some relevance to LMOs largely in their provisions concerning the handling and transport of live animals. The standards in section 7 are drafted in particular from the perspective of animal welfare and its close relationship with animal health.

61. Chapter 7.2 on the Transport of Animals by Sea states that it applies to live domesticated cattle, buffaloes, deer, camelids, sheep, goats, pigs and equines and may also be applicable to other domesticated animals while Chapter 7.3 on the Transport of Animals by Land states that it applies to live domesticated cattle, buffaloes, camels, sheep, goats, pigs, poultry and equines and will be largely applicable to some other animals such as deer, other camelids and ratites. The two chapters follow a similar structure. Their third articles (Articles 7.2.3 and 7.3.3) sets out the individual responsibilities of the people involved in the journey of live animals in order to secure the animals' welfare. Their fifth articles cover considerations in planning the journey including the design and maintenance of vehicles and containers used for the transport of animals and, for the transport of animals by land, rest, water and feed considerations for the animals during the journey.

62. The chapters' sixth articles address documentation. Both provide that documentation accompanying a consignment should include, amongst other things, animal identification in order "to allow animal traceability of animals to the premises of departure, and, where possible, to the premises of origin" (paragraph 2(f) of Art. 7.2.6; paragraph 2(e) of Art. 7.3.6). The chapters' seventh through tenth articles cover the pre-journey period and loading, travel and unloading and post-journey handling of animals being transported by land. Article 7.2.11 addresses actions to be taken in the event of a refusal to allow the importation of shipment. These actions speak primarily to animal welfare considerations.

63. Chapter 7.4 on the Transport of Animals by Air is based on the IATA Live Animal Regulations. The chapter includes provisions on the design for livestock containers, stocking density for the transport of animals by air and the preparation of livestock for air transport. The focus is on animal welfare rather than environmental or biodiversity concerns.

64. Chapter 7.5 on the Slaughter of Animals primarily addresses different methods for slaughtering animals. Article 7.5.2 does, however, address the moving and handling of animals although its focus is animal welfare rather than environmental or biodiversity concerns.

65. The Working Group on Animal Welfare is now working on standards related to the welfare of aquatic animals including the transport of live farmed fish and the slaughter of farmed fish for human consumption.

B. Biological Standards Commission

66. As described above, the Biological Standards Commission oversees the production of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* ("Terrestrial Manual"). The standards in the Terrestrial Manual cover laboratory diagnostic tests for OIE-listed animal diseases of mammals, birds and bees.

67. During the seventy-third annual general session of the OIE in May 2005, the International Committee passed a resolution on "Applications of Genetic Engineering for Livestock and Biotechnology Products" (resolution XXVIII). The resolution states that the 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. The resolution also provides that the OIE is to take into account a number of priorities including: the development and adoption of standards and guidelines for research on the use of live attenuated vaccines in animal health; the development of recommendations and guidelines for the use of DNA vaccines; policy guidelines for the exclusion of unapproved animals and products from the livestock population and segregation from the feed and food supply; and the development of identification, testing and certification guidelines for international trade in production animals and their products for which biotechnology procedures have been employed.

68. In the resolution, the OIE also constituted an *ad hoc* Group on Biotechnology to support the work of OIE specialist commissions and related working groups. The *ad hoc* Group on Biotechnology reports to the Biological Standards Commission. The *ad hoc* Group on Biotechnology developed recommendations on animal health risks arising from the somatic cell nuclear transfer cloning in livestock and horses that were adopted by the seventy-sixth general session and integrated into the Terrestrial Code as chapter 4.12. At its August 2008 meeting, the *ad hoc* Group on Biotechnology agreed on a new format for its work. Henceforth, there will be an *ad hoc* Group on Vaccines Related to New and Emerging Technologies and an *ad hoc* Group on Diagnostic Tests Related to New and Emerging Technologies.

69. Turning to the standards in the Terrestrial Manual, chapter 1.1.8 on "Principles of Veterinary Vaccine Production" covers, amongst other things, vaccines produced through modern biotechnology, including vaccines that are living modified organisms. The chapter includes a section on labelling which sets out recommendations for information to be included on labels for veterinary vaccines. The recommended information includes:

- the true name of the product;
- the name and address of the producer and the importer for imported products;
- the recommended storage temperature;
- a statement that the product is 'for veterinary (or animal) use only';
- full instructions for use, including all required warnings;
- the batch/serial number by which to identify the product in the producer's record of preparation;
- a licence number for the product; and
- a safety warning to the operator, if appropriate. 19

The section also states that the label should indicate special restrictions concerning the use or handling of the product, when applicable. For small containers, the section indicates that the label may refer to the carton label or to an enclosed package insert for some of the less prominent information.

V. UNITED NATIONS RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS, MODEL REGULATIONS

70. The *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations* ("Model Regulations", also popularly known as the "Orange Book") has been developed by the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling. The Committee is a subsidiary body of the Economic and Social Council. The United Nations Economic Commission for Europe (UNECE) provides the secretariat for the Committee. The first version of the document was published in 1956 and the current version is the 15th revised edition. The sixteenth revised edition will be published in 2009.

19/ *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2008*, 6th edition, Vol. 1 at p. 97-98.

71. The Model Regulations were created to facilitate direct integration of requirements into all modal, national and international regulation thereby enhancing harmonization, facilitating regular updating of all legal instruments concerned, and resulting in resource savings for the Governments of the Member States, the United Nations, the specialized agencies and other international organizations. 20/ 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 and, above all, the requirements to ensure the safety of people, property and the environment.

72. The Model Regulations address the following main areas:

(a) List of dangerous goods most commonly carried and their identification and classification (parts 2 and 3);

(b) Detailed packing instructions for the transport of individual substances and articles, as well as standards for the use of packagings, intermediate bulk containers and large packagings, (part 4);

(c) Consignment procedures: labelling, marking, and transport documents (part 5); and

(d) Detailed provisions concerning the construction, testing and approval of packagings, intermediate bulk containers, large packagings, portable tanks, multiple-element gas containers and bulk containers (part 6).

A. Classification system of the Model Regulations

73. Part 2 of the Model Regulations adopts a system that categorizes goods by the types of risk associated with their transportation. There are nine different classes. Each class contains recommended definitions and criteria which are intended to indicate which goods are dangerous. The classification system also assigns a United Nations serial number to different dangerous goods. Each serial number corresponds to a proper shipping name that helps to identify the article or substance being transported and also corresponds to a set of packing instructions.

74. The two most relevant classes in the context of LMOs are class 6 (“Toxic and Infectious Substances”) and specifically division 6.2 (“Infectious Substances”); and class 9 (“Miscellaneous Dangerous Substances and Articles”).

75. Infectious substances are defined as substances known or reasonably expected to contain pathogens. Pathogens, in turn, are defined as microorganisms and other agents that can cause disease in humans or animals. The Model Regulations divide infectious substances into two categories. Category A covers an “infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.” 21/ Infectious substances falling into this category are to be assigned to either UN 2814 or UN 2900. Category B covers infectious substances that do not fall into Category A. These infectious substances are to be assigned to UN 3373.

76. If a genetically modified organism (GMO) or a genetically modified microorganism (GMMO) meets the recommended definition of ‘infectious substances’ in the Model Regulations then it is also to be assigned to UN 2814, UN 2900 or UN 3373, as appropriate. The organism or microorganism is then subject to the recommended packing instructions in chapter 4 of the Model Regulations, specifically packing instructions P620 or P650.

20/ *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations*, 15th revised edition, UN Doc. ST/SG/AC.10/1/Rev.15 (Vol. I) at iii.

21/ *Ibid.* at para. 2.6.3.2.2.1.

77. Class 9 on "Miscellaneous dangerous substances and articles" covers substances and articles not covered under the other divisions. Genetically modified microorganisms and genetically modified organisms "which do not meet the definition of infectious substances … but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction" are included in Class 9 (paragraph 2.9.2.1(c)). GMMOs and GMOs of Class 9 are not subject to the Regulations, however, when they are "authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination." GMMOs and GMOs falling into Class 9 are to be assigned to UN 3245 and are then subject to packing instructions P904 or, for GMMOs or GMOs to be transported in intermediate bulk containers (IBCs), IBC99. The latter provides that only IBCs that have been approved by the competent authority for the transport of these goods may be used (see section II of the addendum to this document.) 22/

B. The Model Regulations and other international instruments

78. The Model Regulations provide a uniform regulatory framework that 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 a binding nature only once they have been transposed into national legislation or international legally binding instruments. In this respect, 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.

79. There are a number of international instruments dealing with the transport of dangerous goods that are regularly amended to follow updates to the Model Regulations. For maritime transport, these include chapter VII of the *International Convention for the Safety of Life at Sea* (SOLAS 74); and 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 IMO.

80. In the field of air transport, annex 18 to the *Convention on International Civil Aviation* (Chicago Convention), amplified by the ICAO *Technical Instructions for the Safe Transport of Dangerous Goods by Air* ("Technical Instructions") is kept aligned with the Model Regulations as far as possible. The International Air Transport Association (IATA) also publishes a manual called *Dangerous Goods Regulations* on the basis of the ICAO Technical Instructions. The Dangerous Goods Regulations require that shippers of various classes of microorganisms must be trained by IATA-certified and approved instructors. They also require shippers' declaration forms, which should accompany the package in duplicate, and specified labels are used for organisms in transit by air.

81. There are also a number of regional inland transport agreements that follow the Model Regulations. In Europe, these include the *European Agreement concerning the International Carriage of Dangerous Goods by Road* (ADR); the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 23/; and the *European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways* (ADN). Under directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008, Members States of the European Union are required to apply the provisions of ADR, RID and ADN to domestic traffic as well. ADR, RID and ADN specify that

22/ Note that for ADR, RID and ADN (see the full titles and descriptions in paragraph 81, below), packing instruction IBC99 has been replaced by IBC08, which allows the use of all types of IBCs authorized for the transport of dangerous goods.

23/ These Regulations form Appendix C to the *Convention concerning International Carriage by Rail*. The majority of member States to the Convention are European countries but there are a few non-European member States as well.

genetically modified organisms which are known or suspected to be dangerous to the environment are to be carried in accordance with conditions specified by the competent authority of the country of origin. Other agreements include the *Agreement on International Goods Transport by Rail* (SMGS); the ASEAN Framework Agreement on the Facilitation of Goods in Transit; and the 1994 *Acuerdo sobre Transporte de Mercancias Peligrosas en el MERCOSUR* for countries of the Southern Cone Common Market.

82. The Universal Postal Union (UPU) largely follows the ICAO Technical Instructions and the IATA Dangerous Good Regulations to govern the air carriage of mail containing infectious substances. Article 16.2.1 of the *Universal Postal Convention* states that infectious substances "may be exchanged through mail only between officially recognized qualified laboratories. These dangerous goods may be acceptable in mail for air carriage, subject to national legislation and current ICAO Technical Instructions and as reflected in the IATA Dangerous Goods Regulations." Furthermore, the admission of infectious substances is restricted to the member countries of the UPU whose postal administrations have declared their willingness to admit such items (Article 16.2.3).

83. Article RL 130 of the *Letter Post Regulations* to the Universal Postal Convention sets out the conditions of acceptance and marking of items containing infectious substances. The Regulation requires senders of infectious substances to follow the packing instructions in the ICAO Technical Instructions or the IATA Dangerous Goods Regulations, which, in turn, follow the Model Regulations. The Letter Post Regulations prohibit the international transport of category A infectious substances through the post.

The main international instruments that are currently applicable and legally binding (the IMDG Code, the ICAO Technical Instructions, ADR, RID and ADN) contain provisions reflecting those of the 15th revised edition of the Model Regulations (which, for GMOs and GMMOs, are the same as those in the 14th revised edition.) The relevant provisions for GMOs/GMMOs in Division 6.2 or Class 9 are summarized in annex I of the addendum to this document (UNEP/CBD/BS/ONLINECONF-HTPI/1/2/Add.1).

84. The 16th revised edition of the Model Regulations, to be published in 2009, will contain amended provisions for the transport of Class 9 GMOs and GMMOs (UN 3245.) The main change is that, for transport in packagings, only the conditions specified in packing instruction P904 will apply to the transport of Class 9 GMOs and GMMOs. In other words, when GMOs and GMMOs of Class 9 are packed and worked in accordance with the revised packing instruction P904, they will no longer be subject to any other requirements of the Model Regulations (notably Class 9 label and mention in the transport document will no longer be required). 24/ These new provisions are expected to be reflected in the different legal instruments from 1 January 2011. The previous conditions of transport remain unchanged, however, when GMOs and GMMOs are packed in IBCs.

VI. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

85. 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. The Working Group developed *Guidance for the Designation of a Unique Identifier for Transgenic Plants*, which was published by the OECD in 2002 and subsequently revised in 2006 to take into account the commercialisation of plant products having one or more traits obtained through the use of recombinant DNA techniques (often referred to as "stacked" transformation events).

86. The OECD Unique Identifier is a simple alphanumeric code that is given to each living modified plant that is approved for commercial use, including for use as food or feed. The OECD naming system has been designed so that developers of a new transgenic plant can generate an identifier and include it in the dossiers that they forward to national authorities during the safety assessment process. Once approved, national authorities can then forward the unique identifier to the OECD Secretariat for inclusion in the

24/ See UNEP/CBD/BS/ONLINECONF-HTPI/1/2/Add.1, annex II.

OECD's product database, from which the information is automatically shared with the Biosafety Clearing-House.

87. The unique identifier is a nine-digit code, composed of three elements that are separated by dashes (-). These elements are:

- 2 or 3 alphanumeric digits to designate the applicant;
- 5 or 6 alphanumeric digits to designate the transformation event; and
- 1 numerical digit for verification (this is intended to reduce errors by ensuring the integrity of the alphanumeric code.)

An applicant should use a combination of the unique identifiers assigned to products that were previously approved for commercialization where these products have been combined to create a plant with stacked transformation events.

88. Decision BS-I/6 invites Parties and other Governments to take measures to apply, as appropriate, the OECD Unique Identifiers to living modified plants under the Protocol. The Parties have also elaborated the documentation and identification requirements for different categories of LMOs through a combination of text from the Protocol and decisions adopted at meetings of the Parties. These requirements make reference to the use of unique identifiers. Specifically, Parties are also to take measures to ensure that:

- Documentation accompanying LMOs intended for direct use as food or feed, or for processing clearly states the transformation event code of the LMO or, where available, as a key to accessing information in the BCH, its unique identifier;
- Documentation accompanying LMOs for contained use include, where appropriate, any unique identification of the LMO; and
- Documentation accompanying LMOs for intentional introduction into the environment include, where available and applicable, a reference to a system of unique identification.

89. To date, the OECD unique identification system only applies to living modified plants. In its decision BS-I/6, COP-MOP welcomed the development and adoption of the OECD guidance on unique identifiers for transgenic plants and encouraged the OECD and other organizations involved in the development of unique identification systems for LMOs to initiate or enhance their activities towards the development of a harmonized system of unique identifiers for genetically modified micro-organisms and animals. The OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology is making efforts to develop a system of unique identifiers for transgenic micro-organisms. The Working Group is also considering undertaking a project on the low-level presence of transgenic seeds in bulk shipments of conventional seeds.

VII. WORLD CUSTOMS ORGANIZATION

90. The *International Convention on the Harmonized Commodity Description and Coding System* (HS Convention) falls under the auspices of the World Customs Organization (WCO). The Convention creates a Harmonized Commodity Description and Coding System ("Harmonized System" or HS) which is a numerical coding system or nomenclature for the international trade of goods. The Harmonized System was designed and is maintained by the WCO and is used, as of April 2009, by more than 200 countries and Customs or Economic Unions, 137 of which are Contracting Parties to the HS Convention, as the basis for customs tariffs and for the collection of trade statistics, but also for rules of origin and for all kinds of transactions in international trade (transport, insurance, etc.). Countries applying the HS account for more than 98 per cent of the merchandise trade.

91. The Harmonized System is a structured nomenclature comprising a series of 4-digit headings, most of which are further subdivided into 5- and 6-digit subheadings. For the purposes of tariff

classification, the Harmonized System also provides a legal and logical structure within which a total of 1,221 headings are grouped in 96 Chapters, the latter being themselves arranged in 21 Sections. Each heading of the HS is identified by a 4-digit code, the first two digits of which indicate the Chapter wherein the heading appears, while the latter two digits indicate the position of the heading in the Chapter. The HS Nomenclature 2007 Edition comprises a total of 5,051 separate groups of goods identified by a 6-digit code, the first four digits of which correspond to the relevant heading, while the fifth and sixth digits identify the one- and two-dash subheadings respectively (the absence of such subheadings being indicated by a zero). As an example, maize (corn) is included in Chapter 10 on cereals. The heading for maize is 10.05 and within that heading there are two subheadings, i.e., subheadings 1005.10 for "seed" and 1005.90 for "other".

92. Chapters of the Harmonized System that would include living modified organisms within their scope are as follows:

- Chapter 1: live animals;
- Chapter 3: fish and crustaceans, molluscs and other aquatic invertebrates;
- Chapter 4: dairy produce; birds' eggs; natural honey; edible products of animal origin, not elsewhere specified or included;
- Chapter 6: live trees and other plants; bulbs, roots and the like; cut flowers and ornamental foliage;
- Chapter 7: edible vegetables and certain roots and tubers;
- Chapter 8: edible fruit and nuts; peel of citrus fruit or melons;
- Chapter 9: coffee, tea, maté and spices;
- Chapter 10: cereals;
- Chapter 12: oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder;
- Chapter 21: miscellaneous edible preparations (includes yeasts, heading 21.02);
- Chapter 30: pharmaceutical products (includes vaccines, toxins, and cultures of micro-organisms, heading 30.02);
- Chapter 95: toys, games and sports requisites; parts and accessories thereof (includes travelling menageries, heading 95.08).

93. Living modified organisms are not provided for separately in the HS Nomenclature 2007 Edition, nor did they form part of the fourth general review of the HS which was completed in March 2009 (see hereafter).

94. The HS codes are frequently used on documentation accompanying the international movement of goods in order to help identify the contents of the shipment. The Harmonized System is used by other multilateral environmental agreements to help track and monitor trade in controlled substances such as hazardous wastes under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, endangered species under the Convention on International Trade in Endangered Species of Wild Fauna and Flora and ozone-depleting substances under the Montreal Protocol on Substances that Deplete the Ozone Layer.

95. The maintenance of the HS Nomenclature is a WCO priority. In order to keep the HS up to date and to take into account changes in technology and the development of new products, the HS Convention provides for periodic amendments. The WCO manages this process through the Harmonized System Committee (representing the Contracting Parties to the HS Convention), which, *inter alia,* prepares amendments updating the HS every five to six years. There have been four general reviews of the HS to date with the most recent review having been adopted by the Harmonized System Committee in March 2009. The amendments of the fourth general review will be forwarded to the WCO Council for approval at its session in June 2009 and will enter into force on 1 January 2012 (except those for which an objection has been timely notified to the WCO Secretariat.)

VIII. UNITED NATIONS CENTRE FOR TRADE FACILITATION AND ELECTRONIC BUSINESS

96. In 2004, the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) approved recommendation No. 33 – "Recommendations and Guidelines on establishing a Single Window to Enhance the Efficient Exchange of Information between Trade and Government". The Recommendation defines a single window as "a facility that allows parties involved in trade and transport to lodge standardized information and documents with a single entry point to fulfil all import, export, and transit-related regulatory requirements. If information is electronic, then individual data elements should only be submitted once." 25/

97. The Recommendation and the Guidelines focus largely on the form a single window might take, steps in establishing a single window and background information on existing single window systems. The Recommendation and the Guidelines do not prescribe how a country should standardize its information and documentation requirements for import, export and transit. The single window concept is of relevance here, though, as it will influence how shipments of LMOs are to be identified on the standardized documentation required by countries with a single window system. Examples of countries with single windows are Mauritius, Sweden, the Netherlands and the United States.

IX. UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW

98. On 11 December 2008, the United Nations General Assembly adopted the *Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea*. 26/ The Convention had been negotiated by a working group of the United Nations Commission on International Trade Law between 2002 and 2008. The Convention will be opened for signature in Rotterdam on 23 September 2009 and will be known as the "Rotterdam Rules".

99. It is intended that the Convention will replace the Hague Rules (the 1924 *International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading*), the Hague-Visby Rules (the *International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading,* as amended in 1968 and 1979) and the Hamburg Rules (the *United Nations Convention on the Carriage of Goods by Sea*, 1978). Until the Convention enters into force, however, these rules will continue to be in effect.

100. The Hague-Visby Rules address, amongst other things, the responsibilities of carriers of goods and to the extent that such responsibilities are relevant to the handling, transport, packaging and identification of LMOs, the Hague-Visby Rules are relevant here.

101. One responsibility of the carrier is to exercise due diligence, both before and at the beginning of the voyage, to "make the holds, refrigerating and cool chambers, and all other parts of the ship in which goods are carried, fit and safe for their reception, carriage and preservation" (Art. III(1)(c)). The carrier must also properly and carefully load, handle, stow, carry, keep, care for and discharge the goods carried (Art. III(2)).

102. The Hague-Visby Rules require the shipper to be issued a bill of lading. The bill of lading must show, among other things, the leading marks necessary for the identification of the goods and the apparent order and condition of the goods. The carrier, master or agent of the carrier is not, however, "bound to state or show in the bill of lading any marks, number, quantity, or weight which he has reasonable ground for suspecting not accurately to represent the goods actually received or which he has had no reasonable means of checking" (Art. III(3)).

25/ Document. ECE/TRADE/352 (2004) at p. 3.

26/ General Assembly resolution 63/122 of 11 December 2008.

103. Paragraph 4 of Article III of the Hague-Visby Rules provides that a bill of lading issued to the shipper serves as *prima facie* evidence of the receipt by the carrier of the goods described in the bill of lading. Furthermore, "[t]he shipper shall be deemed to have guaranteed to the carrier the accuracy at the time of shipment of the marks, number, quantity and weight, as furnished by him, and the shipper shall indemnify the carrier against all loss, damages and expenses arising or resulting from inaccuracies in such particulars" (Art. III(5)).

104. The definition of "goods" in the Hague-Visby Rules excludes live animals (Art. I(c)).

105. Turning to the Rotterdam Rules, which should eventually replace the Hague-Visby Rules, chapter 7 addresses the obligations of the shipper of the goods to the carrier. Within this chapter, Article 27 requires the shipper to deliver the goods to the carrier "in such condition that they will withstand the intended carriage, including their loading, handling, stowing, lashing and securing, and unloading, and that they will not cause harm to persons or property" (Art. 27(1)). Article 28 requires the shipper and the carrier to cooperate with each other in providing information and instructions concerning the proper handling and carriage of the goods.

106. Article 29 sets out a more detailed obligation on the shipper to provide to the carrier information, instructions and documents relating to the goods for their proper handling and carriage, including precautions to be taken, and for the carrier to comply with the law, regulations or other requirements of public authorities in connection with the intended carriage. Article 32 provides special rules on dangerous goods. It requires that, "when goods by their nature or character are, or reasonably appear likely to become, a danger to persons, property or the environment", the shipper must inform the carrier of the dangerous nature of the goods. The shipper must also mark or label dangerous goods in accordance with any law, regulations or other requirements that apply during any stage of the intended carriage of the goods.

107. Chapter 8 of the Rotterdam Rules covers transport documents and electronic transport records. Some of the articles in this chapter are akin to the provisions in Article III of the Hague-Visby Rules. Article 35 of the Rotterdam Rules states that the shipper, upon delivery of goods to the carrier, is entitled to obtain a transport document from the carrier. 27/ Article 36 sets out the contract particulars that must be included in the transport document. These particulars include a description of the goods, the leading marks necessary for identification of the goods and a statement of the "apparent order and condition of the goods" at the time the carrier receives them (Art. 36(2)(a)). Paragraph 4 of the Article elaborates on the latter phrase, stating that it means the order and condition of the goods based on:

(a) A reasonable external inspection of the goods as packaged at the time the shipper delivers them to the carrier or a performing party; and

(b) Any additional inspection that the carrier or a performing party actually performs before issuing the transport document or electronic transport record.

108. While the definition of 'goods' in the Rotterdam Rules does not exclude live animals as is the case in the Hague-Visby Rules, Article 81 of the Rotterdam Rules does allow the contract of carriage to exclude or limit the obligations or liability of the carrier and a maritime performing party where the goods to be carried are live animals.

27/ This entitlement is subject to exemptions in cases where the shipper and carrier have agreed not to use a transport document or it is the custom, usage or practice of the trade not to use one (Art. 35).

X. STANDARD FORM CONTRACTS FOR SHIPMENTS OF GRAIN

109. The international transport of grain is governed first and foremost by contracts between the buyer and the seller rather than by standards delineated in international conventions or by intergovernmental organizations. Most of a purchaser's requirements for a shipment of grain are negotiated with the exporter on a case-by-case basis and the details set out in the terms of the contract between the purchaser and the exporter. In many cases, the details of the commodity to be shipped will be inserted into a standard form contract that has been developed by a private industry organization. Some of these standard form contracts are described below.

110. Three of the most commonly used standard form contracts for grain are the London Corn Trade Association (LCTA) contract number 27, LCTA contract number 30 and the North American Export Grain Association (NAEGA) contract number 2. LCTA 27 and 30 cover cargo that is sold with the price including cost, insurance and freight (CIF). Both contracts are for shipments from Canada or the U.S., excluding Pacific and Hudson Bay ports. LCTA 27 covers full cargoes while LCTA 30 is for parcels. NAEGA number 2 is for cargoes or parcels that are sold free on board (FOB) vessels leaving from Canada or the U.S., excluding Pacific ports.

111. In the case of NAEGA number 2, 28/ the contract provides space for its parties to specify the commodity to be shipped. The specification of the commodity is to be "in accordance with the official grain standards of the United States or Canada, whichever applicable, in effect on the date of this contract." 29/ In Canada, grain standards are set by the Canadian Grain Commission, a body of the federal government, while in the United States, they are set by the Grain Inspection, Packers and Stockyards Administration (GISPA) of the United States Department of Agriculture. Grain standards include parameters on things such as the physical and chemical characteristics of the grain (e.g., oil level, moisture content) and maximum allowable levels of certain defects (e.g., damaged grains, sprouted grains) and contaminants (e.g., stones, other types of grain).

112. NAEGA number 2 also provides that the quality and condition of the commodity will be final at the port of loading "in accordance with official inspection certificates." 30/ The Canadian Grain Commission and GISPA inspect shipments prior to export and certify their contents in Canada and the U.S., respectively.

113. The advantage of using standard form contracts is that the meaning of the clauses in these contracts is well understood as they have been developed and clarified over time and through extensive use. As such, disputes and uncertainties can be avoided. While the LCTA and NAEGA contracts are for shipments from Canada or the U.S., some of their clauses have gained wide currency and are used in contracts for export from other countries as well.

114. There are a large number of other standard form contracts besides the LCTA and NAEGA contracts described above. The Grain and Feed Trade Association (successor to LCTA) maintains over 70 contracts for commodities such as grain, peas, seeds, barley, rye, manioc, cassava and rice from origins such as Australia, New Zealand, South Africa, Argentina, Uruguay, the United Kingdom and Ireland, the European Union and China. In Brazil, the National Association of Grain Exporters (*Associação Nacional dos Exportadores de Cereais*, ANEC) has standard form FOB contracts for Brazilian soybeans and yellow maize shipped as parcels or full cargo (ANEC contract numbers 41, 42, 43 and 44). The contracts

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28/ "North American Export Grain Association, Inc. Free on Board Export Contract U.S.A./Canada No. 2" (1 May 2000) available online: http://www.naega.org/images/naegacontract.pdf. The text of the LCTA contracts are only available to members of the Grain and Feed Trade Association, successor to the LCTA.

29/ *Ibid.* at section 6.

30/ *Ibid.* at section 7.

contain the specifications of the standards the commodity must meet. The Eastern Africa Grain Council maintains four standard form contracts with accompanying rules that are organized according to different international commercial terms (e.g. free carrier, delivered duty unpaid). Each contract leaves room for the parties to specify the quality characteristics that the grain must meet.

115. In Australia, Grain Trade Australia (formerly the National Agricultural Commodities Marketing Association) has developed NACMA contract number 1 for grain and oilseeds in bulk, FOB terms. In a similar manner to NAEGA number 2, the NACMA contract number 1 provides space for its parties to enter the commodity grade and specifications that are the subject of the contract. In Australia, it is private organizations that set the commodity standards that would be referenced in the contract. The National Agricultural Commodities Standards Manual includes a canola standard and a non-GM canola standard. The latter allows for the adventitious presence of up to 0.9% of GM events approved by the Office of the Gene Technology Regulator of the Australian Government.

116. The Australian Oilseeds Federation has developed a number of common declarations for growers and traders to use for identifying commodities in the supply chain. For growers, the common declaration states: "This commodity is of the declared variety, and as such, is not known to contain any approved genetically modified material in excess of the allowed adventitious presence of approved events of 0.9%." 31/ According to the information from the Australian Oilseeds Federation, the declaration should be made by growers when delivering crops such as canola where a declaration is required by industry in order to provide confidence to the receiver that the grower is aware of its responsibilities and the grain received is compliant with legislation.

117. Three possible declarations have been developed for traders. The first would be used by traders who have received the above declaration from growers for all the grain that is the subject of the consignment. The declaration reads: "This commodity is not known to contain any approved genetically modified material in excess of the allowed adventitious presence of approved events of 0.9%." 32/ The second declaration could be used where industry stakeholders are conducting their own testing in addition to grower declarations: "This commodity has been tested for the presence of genetically modified material, and no genetically modified material was detected in excess of the allowed adventitious presence of approved events of 0.9%." 33/ Finally, the third declaration would apply in situations where the company supplying the commodity has a quality assurance program in place to verify the variety or varieties of the grain in question. This declaration reads: "This commodity has been received into and stored in facilities run by a company which operates under an independently audited QA program. This commodity is of known varieties that are not known to contain any approved genetically modified material in excess of the allowed adventitious presence of approved events of 0.9%." 34/

118. Commercial production of genetically modified canola only began in Australia in 2008 so there is not yet a great deal of experience with the use of these declarations. The document from the Australian Oilseeds Federation also reports that stakeholders within the oilseed industry are reviewing how to implement the declarations. Possible options include printing weighbridge documents or contracts that contain the specific wording or writing the declarations into contracts or storage and handling agreements.

31/ Australian Oilseeds Federation, "Grains Industry Common GM Declarations" (November 2008), online: http://www.australianoilseeds.com/__data/assets/pdf_file/0020/5537/GM_Declaration_Update_Nov_08.pdf at p. 1.

32/ *Ibid.* at p. 2.

33/ *Ibid.*

34/ *Ibid.*