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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
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Item 10.2 of the provisional agenda*

SUMMARY OF DEVELOPMENTS ON RULES AND STANDARDS RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

I. INTRODUCTION

1. In decision BS-V/9, the Parties requested the Executive Secretary to continue following developments in standards related to the handling, transport, packaging and identification of LMOs, including information on developments in standard-setting on the sampling and detection of living modified organisms (LMOs), and to report to the Parties at their sixth meeting on any such developments.

2. The information below is based on the summary of standards and standard-setting bodies relevant to the handling, transport, packaging and identification of LMOs contained in issue 1 of the Biosafety Technical Series.[1] The information has been updated to take into account recent developments and expanded to include information on standard-setting in relation to the sampling and detection of LMOs.

3. Sections II through X, 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

* UNEP/CBD/BS/COP-MOP/6/1.

[1] Biosafety Technical Series No. 1, "Standards for Shipments of Living Modified Organisms: Outcomes of an Online Forum" (Montreal: Secretariat of the Convention on Biological Diversity, 2011) online: http://bch.cbd.ing/protocol.cpb_technicalseries/cpb-ts-01-en.pdf.

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for Trade Facilitation and Electronic Business; the United Nations Commission on International Trade Law and the International Organization for Standardization. Section XI summarizes some standards from Europe. Section XII discusses standard form contracts for the shipment of grain and section XIII addresses certain relevant private standards. New and updated sections have been marked to facilitate use by readers who are familiar with previous versions of this document.

II. CODEX ALIMENTARIUS COMMISSION

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.

4. Standards adopted by the Codex Alimentarius Commission are not legally binding on Codex member states. Countries and organizations that are members of 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)).

5. Work to develop Codex standards is conducted by a number of committees and task forces, six of which are particularly relevant here:

(a) the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology;

(b) the Codex Committee on Food Labelling;

(c) the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding;

(d) the Codex Committee on General Principles;

(e) the Codex Committee on Food Import and Export Inspection and Certification Systems; and

(f) the Codex Committee on Methods of Analysis and Sampling.

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

6. 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";[2] (ii) "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants";[3] and (iii) "Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms".[4]

7. 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 may include appropriate analytical methods; reference materials; and product tracing.[5] 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.

8. 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."[6]

9. At its twenty-seventh session (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";[7] (ii) an annex on "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits";[8] to be added to the existing Codex "Guideline on the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" and (iii) an annex on "Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food".[9] 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

10. The Codex Committee on Food Labelling (CCFL) is responsible for, *inter alia*, drafting provisions on labelling applicable to all foods and endorsing specific provisions on labelling prepared by

[2] CAC/GL 44-2003, adopted in 2003, amended in 2008.

[3] CAC/GL 45-2003, adopted in 2003, annexes II and III adopted in 2008.

[4] CAC/GL 46-2003.

[5] CAC/GL 44-2003 at para. 21.

[6] "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.

[7] CAC/GL 68-2008.

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

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

other Codex Committees. The Codex Committee on Food Labelling considered food labelling provisions for foods derived from biotechnology from 1996 to 2011. This work took 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. The most controversial point during the deliberations was whether or not labelling provisions should be established for the case where the production method is the sole difference between original products and genetically modified products.

11. **Update:** At CCFL's 39th session (May 2011), the Committee agreed to discontinue work on the definitions. Regarding the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering, the Committee agreed to a simplified document which took the form of a Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology. It advanced this text to the Commission for adoption at steps 5/8.

12. At its 34th session (July 2011), the Codex Alimentarius Commission agreed to discontinue the work on definitions and also adopted the Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology (CAC/GL 76-2011).

13. In its final form, a footnote to the title of the Compilation cross-references the definition of 'modern biotechnology' in the Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003), which is the same as the definition in the Biosafety Protocol. The Compilation states that the purpose of the document "is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology." Under the section on considerations, it states "[d]ifferent approaches regarding labelling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production." The third section then lists a number of Codex texts and the specific sections that are relevant to the labelling of foods derived from modern biotechnology.

14. The 38th session of the Codex Committee on Food Labelling also proposed that the Committee undertake work on organic aquaculture in order to include aquaculture animals and the collection and farming of seaweeds in the scope of the "Guidelines for Production, Processing, Labelling and Marketing of Organically Produced Foods" (CAC/GL32). The work was approved by the 33rd session of the Codex Alimentarius Commission (2010). As it stood going into the 40th session of the CCFL, the draft text on aquaculture animals indicated that genetically modified organisms must not be used in organic aquaculture.[10] During the 40th session (May 2012), a number of delegations expressed the view that the draft needed further elaboration. Accordingly, the Committee agreed to undertake further work through both an electronic working group and a physical working group.

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

15. 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".[11] 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.

[10] CX/FL 12/40/10 at para. 8.
[11] CAC/RCP 54-2004.

16. An earlier draft of the Code had allowed for competent authorities to decide that feed and feed ingredients consisting, containing or produced from genetically modified organisms (GMOs) should be labeled.[12] 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."[13]

17. 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).

18. 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."

19. 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."

20. 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.

21. **Update:** At its 33rd session, the Codex Alimentarius Commission re-established the *Ad Hoc* Intergovernmental Task Force on Animal Feeding but the current mandate of the Task Force does not appear to relate to living modified organisms.

D. Codex Committee on General Principles

22. 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

[12] "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.
[13] CAC/RCP 54-2004 at footnote 5.

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

23. 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 (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"[14] were subsequently adopted at the twenty-ninth session of the Commission, in July 2006.

24. 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 was forwarded to the Codex Alimentarius Commission. The Commission, at its thirty-second session held in June-July 2009, endorsed the recommendation and requested the Committee to report back to the 34th session of the Commission on this matter.

25. **Update:** The 34th Session of the Codex Alimentarius Commission referred the views of the FAO/WHO Regional Coordinating Committees on the need for further guidance on traceability to the CCFICS and recognized that Members may submit proposals for new work directly to the Committee. The issue of traceability/product tracing does not appear to have been considered at the 19th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (October 2011).

26. The next meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems will take place in February 2013.

F. Codex Committee on Methods of Analysis and Sampling

27. 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.

28. At the twenty-eighth session (2007) of CCMAS, 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.

[14] CAC/GL 60-2006.

29. At the thirtieth session of CCMAS in March 2009, the Committee agreed (with some reservations) to change the title of this item to "Proposed draft guidelines on criteria for methods for detection, identification and quantification of specific DNA sequences and specific proteins, in particular in foods derived from modern biotechnology". The draft guidelines were further revised and, at its 31st session (March 2010), CCMAS agreed to forward them to the 33rd session of the Codex Alimentarius Commission for adoption at Step 5/8.

30. The 33rd session (July 2010) of the Codex Alimentarius Commission adopted the proposed draft guidelines at Step 5/8 with the title "Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods".[15] The Guidelines include considerations for the validation of methods for the detection, identification and quantification of DNA sequences and proteins as well as a number of annexes with information on the validation of both qualitative and quantitative polymerase chain reaction methods and the validation of protein-based methods.

31. **New:** CCMAS also developed "General Guidelines on Sampling" which were adopted by the Codex Alimentarius Commission in 2004 as CAC/GL 50-2004. The Guidelines cover the sampling of food lots (both bulk and pre-packaged) to test for compliance with other Codex commodity standards. The Guidelines explain basic notions of sampling. They also cover the selection of sampling plans in different situations, namely single or isolated lots in international trade, a continuous series of lots from a single source and for the inspection by variable of bulk materials where the standard deviation is known.

III. INTERNATIONAL PLANT PROTECTION CONVENTION

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.

32. 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.

33. 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

[15] CAC/GL 74-2010.

SPS Agreement requires WTO members to base their sanitary and phytosanitary measures for plant health on the standards, guidelines and recommendations of the IPPC.

A. International Standards for Phytosanitary Measures relevant to the handling, transport, packaging and identification of living modified organisms

34. There are two ISPMs of most relevance to the handling, transport, packaging and identification of LMOs.

ISPM No. 12: *Phytosanitary certificates* (2011)

35. **Update:** A revised version of ISPM No. 12 was adopted at CPM-6 in 2011. The current text elaborates requirements for preparing and issuing phytosanitary certificates following the model certificates contained in the Annex to the IPPC. The ISPM states that the purpose of phytosanitary certification is to attest that consignments meet phytosanitary import requirements. To this end, phytosanitary certificates "should only contain information related to phytosanitary matters. They should not include statements related to non-phytosanitary requirements such as animal or human health matters, pesticide residues, radioactivity, commercial information (e.g. letters of credit), or quality" (section 4).

36. The ISPM does allow for notes to accompany phytosanitary certificates to associate the certificates with the symbol or code of other relevant documents such as bills of lading or certificates under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) 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 on customs codes. The ISPM also states that the intended end use or degree of processing of the product in the consignment should be specified in the phytosanitary certificate as different phytosanitary requirements may apply to different intended uses (e.g. consumption versus propagation) or different degrees of processing (e.g. fresh versus dried.)

37. The ISPM states that the national plant protection organizations (NPPOs) of importing countries may require phytosanitary certificates for regulated articles only. Regulated articles are usually plants and plant products but may also include such things as empty containers, vehicles and organisms other than plants where phytosanitary measures are technically justified (section 3).

38. ISPM No. 12 also contains guidance regarding the use of electronic phytosanitary certificates. A draft of a proposed appendix to the ISPM indicates that NPPOs that use electronic phytosanitary certificates should develop and use systems that generate certificates using standardized language, message contents and exchange protocols. It then provides guidance on these elements. It is also foreseen that the appendix to ISPM No. 12 will be based on the work of the United Nations Centre for Trade Facilitation and Electronic Business (see section VIII, below.) The appendix is still under development.

ISPM No. 7: *Phytosanitary certification system* (2011)

39. **Update:** A revised version of ISPM No. 7 was adopted at CPM-6 in 2011. This ISPM describes the components of a national system for the issuance of phytosanitary certificates. It provides that each NPPO should maintain guidance documents and work instructions covering all aspects of the certification system including inspection, sampling, testing, treatment and verification of the identity and integrity of consignments and "ensuring traceability of consignments, including their identification and phytosanitary security (as appropriate) through all stages of production, handling and transport prior to export" (section 4.2).

40. A number of other ISPMs are also relevant to the issue of the handling, transport, packaging and identification of LMOs.

ISPM No. 3: *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms* (2005)

41. This ISPM 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.

ISPM No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms* (2004)

42. ISPM No. 11 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 regarding LMOs that is included in the phytosanitary certificates should only be related to phytosanitary measures (section 3.5).

ISPM No. 20: *Guidelines for a phytosanitary import regulatory system* (2004)

43. This 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.

44. 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).

45. 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.

ISPM No. 23: *Guidelines for inspection* (2005)

46. ISPM No. 23 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).

47. 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.

48. 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.

B. Development of new standards

International movement of grain

49. **Update:** The issue of the development of a standard on the international movement of grain was added to the IPPC Standard Setting Work Programme at the third session of the CPM. An open-ended workshop on the topic was held in Vancouver, Canada in December 2011. The terms of reference for the workshop specify that it was to "collect information and provide clarity on the relevance and type of phytosanitary problems related to the international movement of grain. Furthermore the workshop should collect views and discuss options for the management of the risks identified that may require further action in the IPPC framework in order to minimize these risks and to protect countries from the introduction of quarantine pests associated with the international movement of grain."[16] A representative of the Secretariat of the Convention on Biological Diversity took part in the workshop.

50. A summary of the main results of the workshop was submitted to CPM-7 for its consideration. The results included a number of points relevant to the handling, transport, packaging and identification

[16] "Report of the Fifth Session of the Commission on Phytosanitary Measures", UN Doc. CPM-5 (2010)/REPORT (March 2010) at appendix 19.

of LMOs. In the context of quality versus quarantine issues, it was noted that there is a need to distinguish between quarantine issues, quality issues, food safety issues and approved LMOs (LMOs that have not been deemed to be a pest) to focus certification on phytosanitary issues. In the category of pest risk assessment (PRA), it was stated that the intended use of the grain should be considered in the PRA process and requirements for seeds need to be clearly distinguished from those of grains. Furthermore, consideration should be given to developing focused guidance for conducting PRAs for grains.

51. The third category of discussion points addressed pest risk management. It included the following relevant notes:

(a) Some importing countries have difficulty controlling the intended use of imported product;

(b) Managing risk at origin may be more effective than at destination and can help alleviate the burden of pest risk management in developing countries where there may be deviation from the intended use;

(c) Importing countries may have to safeguard transport to storage and processing facilities;

(d) Equivalent internationally accepted sampling procedures in the export and importing countries are needed for grain;

(e) Traceability may not be practical or feasible; and

(f) Guidance for situations in cases of potential deviation from intended use is needed.[17]

52. The results of the workshop also include three options for how work on the issue could proceed: developing an ISPM on the international movement of grain, developing a 'best practices' guide that could include industry practices, outline the roles and responsibilities of NPPOs and explain the applicability of existing ISPMs; or a combination of both.

53. CPM-7 requested the Standards Committee to develop a specification on the topic of the international movement of grain, which would then be submitted for member consultation and revised in light of the comments from members with a recommendation to be submitted to the CPM seeking guidance on how to proceed.

54. A draft specification was developed and submitted for member consultation in June 2012. The draft specification suggests that "[g]uidance is needed on the assessment of pest risks related to grain as a pathway for quarantine pests, and on technically justified phytosanitary measures to manage such pest risks. … Phytosanitary measures applied prior to export and at the time of import can be effective in pest risk mitigation and thereby help to improve food security, but international guidance is needed to ensure such measures are technically justified, commensurate with the level of risk, and the least trade restrictive." It indicates that it would not apply to seed nor would it consider issues related to LMOs that are not pests.

55. The standard would be drafted by an expert drafting group. The proposed tasks for the group include discussing the need for guidance related to specific concerns such as guidance on sampling or inspection protocols for pest detection, diversion of grain shipments from intended use, grain shipments

[17] "Report of the Open-ended Workshop on the International Movement of Grain", UN Doc. CPM 2012/19Rev1 (February 2012).

intended for food aid, risk mitigation for in-transit and trans-shipped grain, and risk mitigation of pests and soil present at low levels.

Minimizing pest movement by sea containers and conveyances in international trade

56. **Update:** A specification for the development of a standard on minimizing pest movement by sea containers and conveyances in international trade has been approved and an expert working group is drafting the standard.

57. The specification explains that:

> Sea containers (i.e. 20- and 40-foot intermodal freight or shipping containers) are a significant pathway for the potential entry of pests, as they are now the most common means of transfer of internationally traded goods and moving personal effects. Insects, snails, other invertebrates and vertebrates may contaminate containers during storage or packing ... Micro-organisms, seeds and other plant parts and plant debris may be present in contaminating soil, birds' excrement etc. on or inside containers. Some of these organisms may be pests. A country may already regulate some of the pests as quarantine pests, while others may not yet have been evaluated in a [pest risk analysis] but may be potential quarantine pests.[18]

The specification states that the reason for the standard is to provide guidance to countries on how to manage the phytosanitary risks associated with the movement of sea containers.

58. The expert working group is tasked with, *inter alia*, identifying and describing possible phytosanitary measures and best management practices to reduce pest risks including procedures for packing, storing, loading and transport of shipping containers to minimize contamination; and measures to be carried out in the area surrounding locations where packing, storage and loading of containers takes place to minimize pest occurrence and the probability of contamination. The expert working group is also to consider whether the standard could have a positive or negative effect on the protection of biodiversity and the environment. The impact should be identified, addressed and clarified in the draft standard.

59. The expert working group met in May 2012 and is developing a draft ISPM. The Secretariat of the Convention on Biological Diversity participates in relevant parts of the meetings of the expert working group.

International movement of seed

60. **Update:** A specification for the development of an ISPM on the international movement of seed was approved in 2011. The specification indicates that the standard would apply to seed moved internationally and would not apply to grain: "The standard should identify and describe specific phytosanitary measures that could be used to reduce pest risk associated with the international movement of seed, including phytosanitary measures that could be used to reduce pest risk associated with the international movement of seed, including phytosanitary measures that may be applied during growth, at seed harvest, seed extraction, during post-harvest seed processing, and on arrival, inspection and testing. ... This standard will help minimize the risk of the global spread of pests of plants including those which can be considered invasive alien species and other organisms whose pest risk has not yet been identified."[19]

[18] "Minimizing pest movement by sea containers and conveyances in international trade", Specification n. 51 (no date).

[19] "International movement of seed", Specification 54 (2011).

61. The specification also outlines tasks for an expert drafting group. These include:

- identifying any existing international guidance dealing with the international movement of seed and considering the extent to which these are relevant to the development and application of phytosanitary measures under the IPPC;
- considering the relationship between the potential for the establishment of pests and the intended use of seeds, "including whether different measures should be applied to seeds intended for unrestricted field sowing versus those seeds intended for research and development";
- making recommendations for information that may be included on phytosanitary certificates to allow for the international movement of seed; and
- considering whether the ISPM could have specific positive or negative effects on the protection of biodiversity and the environment. Specific impacts would need to be identified, addressed and clarified in the draft ISPM.

Other proposed standards

62. **Update:** Other standards that are proposed in the IPPC Standard Setting Work Programme from CPM-6 that could be of relevance to the handling, transport, packaging and identification of LMOs include:

- Movement of growing media in association with plants for planting in international trade;
- Guidelines for the movement of used machinery and equipment; and
- Minimizing pest movement by air containers and aircraft.

C. Regional phytosanitary organizations: the North American Plant Protection Organization

63. 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 has adopted two RSPMs related to LMOs.

RSPM No. 14: *Importation and release (into the environment) of transgenic plants, in NAPPO member countries*

64. NAPPO adopted RSPM No. 14 on the *Importation and release (into the environment) of transgenic plants, in NAPPO member countries* in 2003. 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.

65. 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 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).

66. 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 and any viable transgenic plant material remaining at the confined field site. Transgenic material harvested from the confined field site can only 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).

RSPM No. 27: *Guidelines for Importation and Confined Field Release of Transgenic Arthropods in NAPPO Member Countries*

67. **New:** NAPPO has also adopted RSPM No. 27 on *Guidelines for Importation and Confined Field Release of Transgenic Arthropods in NAPPO Member Countries*. Arthropods include insects, crustaceans and arachnids. The standard states that "NAPPO member countries should implement authorization systems for the importation of transgenic arthropods that provide procedures to assess the phytosanitary risk posed by the importation and to make decisions on requirements for movement and containment facilities such that unauthorized dissemination into the environment is prevented."

68. Section 2.1 of the standard outlines the information that should be provided by the applicant to enable the NPPO to make a decision on the import of the transgenic arthropod. This includes information on handling, disposal, record-keeping and other considerations (section 2.1.4.2) such as:

- Means of transportation of the transgenic arthropods between the containment facility and the confined field release site and vice versa;

- Technically justified identification, packaging and segregation measures to prevent unauthorized mixing, spillage and dissemination of transgenic arthropods during transit between the containment facility and the confined field release site; and

- Clear identification, secure transport and separate storage from other arthropods to avoid unauthorized or accidental mixing.

IV. WORLD ORGANIZATION FOR ANIMAL HEALTH

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* ("Terrestrial Manual"), 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.

69. In similar fashion to the Codex Alimentarius Commission and the IPPC, the 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. For this reason, the OIE considers the Codes and the associated Manuals to be legally binding standards.[20]

70. The OIE is governed by a World Assembly (formerly known as the 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).

71. 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 of 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

72. As mentioned, the Terrestrial Animal Health Standards Commission is responsible for the Terrestrial Code. The Terrestrial Code is 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').

73. 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

[20] "Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission", doc. 78 SG/12/CS1 B (February 2010) at p. 3 and "Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission" (September 2010) at p. 4.

- Chapter 7.5: Slaughter of animals.

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

75. As its title suggests, the provisions in chapter 4.1 provide general principles on the identification and traceability of live animals.[21] 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.

76. 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 definitions 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).

77. 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 the information requirements of the certificates.

78. 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.

79. The chapter states that its aim is to ensure "the control of animal and public health hazards through adherence to recommended practices during the production (growing, procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial animals" (Art. 6.3.2). Article 6.3.4 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 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).

[21] The summaries in this publication of the relevant provisions of the Terrestrial Code are derived from the 2010 edition of the Terrestrial Animal Health Code, available online: http://www.oie.int/international-standard-setting/terrestrial-code/access-online/.

80. 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.

81. 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) set 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.

82. 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.

83. Chapter 7.4 on the Transport of Animals by Air is based on the International Air Transport Association (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.

84. 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.

85. Chapter 7.8 of the Terrestrial Code addresses the "Use of Animals in Research and Education" The chapter forms section 7.8 of the Terrestrial Code. The chapter states that its purpose "is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live animals in research and education" (preamble). The chapter applies to "animals as defined in the Terrestrial Code (excluding bees) bred, supplied and/or used in research (including testing) and higher education. Animals to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered" (Art. 7.8.2).

86. In discussing the source of animals, the chapter states that relevant documentation related to the source of the animals, such as animal identification, should accompany the animals. This section also defines a genetically altered or cloned animal as being one that has "undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an animal(s), where they have inherited the modification" (para. 5 of Art. 7.8.7). It states that if genetically altered or cloned animals are used,

> such use should be conducted in accordance with relevant regulatory guidance. With such animals, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and welfare needs associated with abnormal phenotypes. Records should be

kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient (para. 5 of Art. 7.8.7).

87. The chapter defines biocontainment to mean the system and procedures designed to prevent the accidental release of biological material including allergens (Art. 7.8.1).

88. Paragraph 8 of Article 7.8.7 states that care should be taken in the transport of animals to ensure their appropriate physical containment and relevant documentation should accompany animals during transport. The chapter also provides that animal identification is an important component of record keeping and animals may be identified individually or by group (para. 9 of Art. 7.8.9).

89. A number of working groups and *ad hoc* groups fall under the auspices of the Terrestrial Animal Health Standards Commission and carry out work on specific sections of the Terrestrial Code.

90. 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 developed chapter 6.3 of the Terrestrial Code on "the control of hazards of animal health and public health importance in animal feed", which was adopted at the 77th General Session of the OIE in May 2009. An earlier draft of the chapter 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.[22]

91. 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. The conference included consideration of the identification and traceability of animals produced through biotechnology. The conference adopted a number of recommendations including recommending that OIE members establish a clear regulatory framework for animal identification and traceability.

B. Biological Standards Commission

92. 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.

93. During the 73rd General Session of the OIE in May 2005, the World Assembly 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.

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

94. 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 reported to the Biological Standards Commission. The *ad hoc* Group on Biotechnology developed recommendations on animal health risks arising from somatic cell nuclear transfer cloning in livestock and horses. The recommendations were adopted by the 76th General Session and integrated into the Terrestrial Code as chapter 4.11. 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.

95. The *ad hoc* Group on Vaccines Related to New and Emerging Technologies has been revising certain sections of the Terrestrial Manual in light of developments in biotechnology. These revisions deal primarily with the scientific aspects of biotechnology and the development of vaccines.

96. Chapter 1.1.8 of the Terrestrial Manual 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.[23]

97. 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

The *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations* ("Model Regulations", also 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 17th revised edition.

98. 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.[24] The

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

[24] *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations*, 17th revised edition (2011), UN Doc. ST/SG/AC.10/1/Rev.17 (Vol. I) at iii.

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.

99. The Model Regulations address the following main areas:

- List of dangerous goods most commonly carried and their identification and classification (parts 2 and 3);
- 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);
- Consignment procedures: labelling, marking, and transport documents (part 5); and
- 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

100. 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 that 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.

101. The two most relevant classes in the context of LMOs are class 6 ("Toxic and Infectious Substances"), specifically divisions 6.1 ("Toxic substances") and 6.2 ("Infectious Substances"); and class 9 ("Miscellaneous Dangerous Substances and Articles").

102. Under class 6, toxic substances are defined as substances liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact. 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.

103. 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."[25] 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.

104. 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.

[25] *Ibid.* at para. 2.6.3.2.2.1.

105. Class 9 on "Miscellaneous dangerous substances and articles, including environmentally hazardous substances" covers substances and articles not covered under the other divisions. It includes GMOs and GMMOs that do not meet the definition of toxic or infectious substances. GMOs and GMMOs of Class 9 are not subject to the Regulations, however, when they are "authorized for use by the competent authorities of the countries of origin, transit and destination." The Regulations also specify that genetically modified live animals shall be transported under the terms and conditions of the competent authorities of the countries of origin 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.[26] When GMOs and GMMOs of Class 9 are packed and marked in accordance with packing instruction P904, they are not subject to any other requirements of the Model Regulations (notably Class 9 label and mention in the transport document are no longer required).

B. The Model Regulations and other international instruments

106. 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.

107. 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.

108. 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. 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.

109. 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);

[26] Note that for ADR, RID and ADN (see the full titles and descriptions in paragraph 109, 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.

- the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) ; and
- the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN).

110. Under directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008, Member 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 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.

111. 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).

112. 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.

VI. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The mission of the Organisation for Economic Co-operation and Development (OECD) is to promote policies that will improve the economic and social well-being of people around the world. In the area of biotechnology, the main focus of the OECD's work is on international harmonization of regulatory oversight in modern biotechnology which will ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of the technology.

113. In recent years, the most directly relevant work of the 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).

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

115. 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.)

116. 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.

117. 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 (para. 4(e) of decision BS-III/10);

- Documentation accompanying LMOs for contained use include, where appropriate, any unique identification of the LMO (para. 3(a)(iv) of section B of decision BS-I/6); and

- Documentation accompanying LMOs for intentional introduction into the environment include, where available and applicable, a reference to a system of unique identification (para. 3(b)(i) of section B of decision BS-I/6).

118. 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 undertaking a project on the consequences of low-level presence of transgenic grains in conventional seeds or commodities.

VII. WORLD CUSTOMS ORGANIZATION

The World Customs Organization (WCO) is an intergovernmental organisation focused exclusively on customs matters. It is noted for its work in areas such as the development of global standards, the simplification and harmonisation of customs procedures and the facilitation of international trade.

119. 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 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.

120. 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 in which the heading appears, while the second 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. 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".

121. 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).

122. 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 below).[27]

123. 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 CITES and ozone-depleting substances under the Montreal Protocol on Substances that Deplete the Ozone Layer.

124. **Update:** 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 entered into force on 1 January 2012. They do not include references to LMOs.

VIII. UNITED NATIONS CENTRE FOR TRADE FACILITATION AND ELECTRONIC BUSINESS

The United Nations, through its Centre for Trade Facilitation and Electronic Business (UN/CEFACT), supports activities dedicated to improving the ability of business, trade and administrative organizations, from developed and developing countries and countries with economies in transition, to exchange products and relevant services effectively. Its principal focus is on facilitating national and international transactions, through the simplification and harmonization of processes, procedures and information flows, and so contribute to the growth of global commerce. UN/CEFACT is part of the UNECE.

125. In 1973, UN/CEFACT adopted Recommendation No. 1, "United Nations Layout Key for Trade Documents". The Layout Key is also a joint standard with ISO where it is referred to as ISO 6422. The main function of the Layout Key is to present a standard and universal design for any paper document that can be exchanged by parties in the international supply chain. The Recommendation includes a number of data elements or data field headings for the Layout Key along with descriptions of the information to be entered in the corresponding data fields. The data field headings include things such as consignor (exporter), consignee, description of goods, commodity number (e.g. customs code).

126. The Layout Key still plays an important role in facilitating international trade. Increasing attention is now also being paid to the development of standards for the electronic exchange of information in international trade. ISO is currently considering adopting a new work item to develop an equivalent standard for electronic international trade documents.

127. In 2004, 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

[27] Some countries do, though, use the HS codes for identifying and tracking shipments of LMOs. See p. 49 of issue 1 of the Biosafety Technical Series, *supra* note 1, for information on Mexico's use of HS codes to identify imports of genetically modified yellow maize intended for direct use as food or feed, or for processing.

import, export, and transit-related regulatory requirements. If information is electronic, then individual data elements should only be submitted once."[28]

128. The Recommendations and 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 Recommendations and 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.

129. UN/CEFACT has also developed a library of the core components of the international supply chain. This Core Component Library contains written descriptions of terms or data that are exchanged as part of international trade.[29] Work is done to ensure that the data definitions are harmonized across the different processes and entries are then developed for the Core Component Library. The Core Component Library is intended to cover the full range of data required by the commercial, transport and regulatory, and financial procedures of cross-border trade. UN/CEFACT describes this as the Buy-Ship-Pay model. See table 1 for examples of some of the terms and definitions contained in the Core Component Library.

Table 1. Examples of terms and definitions in the UN/CEFACT Core Component Library.

Dictionary Entry Name	Definition
Address. Building Name. Text	The name, expressed as text, of a building, a house or other structure on a street at this address.
Agricultural Process. Occurrence. Area	An area within which this agricultural process occurs.
Animal. Breed. Text	The breed of the animal expressed as text.
Crop Production Cycle. Used. Area	An area used for this crop production cycle.
Crop. Botanical Species. Code	A code specifying a botanical species for this crop.
Crop. Sown. Species Variety	A sown species variety for this crop.
Dangerous Goods. UNDG Identification. Code	The code specifying the unique United Nations Dangerous Goods (UNDG) number assigned to the dangerous goods.
Dangerous Goods. Handling. Instructions	Handling instructions for the dangerous goods.
Identity. Details	Information which uniquely identifies a person, organization, animal or object.

[28] Document ECE/TRADE/352 (2004) at p. 3.

[29] Version 12A of the Core Component Library is available from the UN/CEFACT website: http://www.unece.org/fileadmin/DAM/cefact/codesfortrade/unccl/CCL12A.zip.

Identity. Identification. Identifier	A unique identifier for an identity.

130. The data definitions found in the Core Component Library can be used as the basis of aligned paper documents, eXtensible Markup Language (XML) schemas or UN/EDIFACT[30] messages. XML is a common language that allows the sharing of information among different databases. It thus enables the exchange of trade information over the internet.

131. A number of countries are increasingly moving towards electronic and internet-based exchange of information as part of their trade processes. Understanding the ongoing standards development in this area is relevant if such exchange of information should also include the identification of LMOs. It may also be noted that CITES has taken action to have the language of its standard permit and certificate form included in the Core Component Library.

IX. UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW

The United Nations Commission on International Trade Law (UNCITRAL) is the central legal body in the field of international trade law within the United Nations. UNCITRAL works to modernize and harmonize the rules of international business.

132. 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*.[31] The Convention had been negotiated by a working group of the United Nations Commission on International Trade Law between 2002 and 2008. The Convention was opened for signature in Rotterdam on 23 September 2009 and is known as the "Rotterdam Rules".

133. 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.[32]

134. The Hague-Visby Rules address, among 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. It should be noted, however, that the definition of "goods" in the Hague-Visby Rules excludes live animals (Art. I(c)).

135. 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

[30] UN/EDIFACT stands for 'United Nations Electronic Data Interchange for Administration, Commerce and Transport'. It is a set of syntax rules that consists of internationally agreed standards, directories and guidelines for the electronic interchange of structured data, see UNECE, "UN/EDIFACT Draft Directory: Introduction and Rules", online: http://www.unece.org/trade/untdid/texts/d100_d.htm.

[31] General Assembly resolution 63/122 of 11 December 2008.

[32] As of 6 September 2012, there were 24 signatures and two ratifications of the Convention. The Convention requires 20 ratifications, acceptances, approvals or accessions in order to enter into force (Article 94(1)).

must also properly and carefully load, handle, stow, carry, keep, care for and discharge the goods carried (Art. III(2)).

136. 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)).

137. 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)).

138. 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.

139. 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.

140. 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.[33] 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

[33] 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).

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

141. 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.

X. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

The International Organization for Standardization (ISO) is a network of national standards institutes from over 160 countries. The organization develops voluntary international standards which provide specifications for products, services and good practice.

142. **New:** ISO has released a number of standards related to nucleic acid extraction and nucleic acid and protein-based methods of analysis as listed below. ISO standards in this area have been developed by technical committee 34 on 'food products' and its working group 7, 'Genetically modified organisms and derived products', which developed standards in the area of biomolecular testing.

143. ISO had adopted the following standards and specifications concerning the detection of LMOs:

- ISO 21569, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods;
- ISO 21570, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods;
- ISO 21571, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction;
- ISO 21572, Foodstuffs — Detection of genetically modified organisms and derived products – Protein based methods;
- ISO 24276, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions; and
- ISO/TS 21098, Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571.

144. ISO has also been active in developing standards related to sampling.

145. ISO 24333, "Cereals and cereal products – sampling", was adopted in 2009. According to the description on the ISO website, the standard "specifies requirements for the dynamic or static sampling, by manual or mechanical means, of cereals and cereal products, for assessment of their quality and condition. It is applicable to sampling for the determination of heterogeneously distributed contaminants, undesirable substances, and parameters usually homogeneously distributed like those used to assess quality or compliance with specification."[34] ISO also indicates that the standard is applicable to sampling for assessing the quality and condition of lots of GMOs but is not appropriate for determining the adventitious presence of GMOs in a non-GMO lot. The standard is also not applicable to seed grain.

146. ISO 542, "Oilseeds – sampling", was adopted in 1990. It specifies general conditions relating to sampling for the assessment of the quality of oilseeds purchased as industrial raw materials, including

[34] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=42165.

limitations of the lot size, methods for taking samples, packaging and labelling of samples, sample dispatch and the sampling report.

147. ISO has also been developing a standard on "Bulk commodities sampling" (NP IWA 7) but it has not yet been adopted.

148. ISO has also adopted a standard on "General requirements for the competence of testing and calibration laboratories" (ISO/IEC 17025: 2005).

149. The full text of all ISO standards is only available for purchase.

XI. EUROPE

150. **New:** Standards relevant to the handling, transport, packaging and identification of LMOs have been also been developed in Europe both in the context of the European Committee for Standardization (CEN) and the European Union. These are addressed here as they apply in a large number of countries.

151. In 2007, the CEN adopted a technical specification[35] on "Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Sampling strategies". The specification provides guidance on establishing valid sampling strategies for food products that are to be analysed for the presence of GMOs and derived products. While the technical specification has been established for food products, it could also be applied to other products such as animal feed and plant samples from the environment.

152. The European Commission also adopted *Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003*. The Recommendation addresses sampling protocols for (i) seed and other plant propagating material lots; and (ii) bulk agricultural commodities.

153. Regarding seed and other plant propagating material lots, the Recommendation states that the rules of the ISTA as well as a number of other Council Directives should be followed. For bulk agricultural commodities, the Recommendation provides guidance on protocols for sampling lots of bulk agricultural commodities, for the preparation of analytical samples, for estimating uncertainty and for sampling lots of food and feed products.

154. The Recommendation also addresses testing methods and analytical test protocols, in particular by referring to other ISO and ISTA standards.

XII. STANDARD FORM CONTRACTS FOR SHIPMENTS OF GRAIN

155. 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.

[35] In the context of the CEN, a technical specification is applied provisionally to gather experience to decide whether to convert the technical specification into a European Standard (an 'EN').

156. Three of the most commonly used standard form contracts for grain are the Grain and Feed Trade Association (GAFTA) contract number 27, GAFTA contract number 30 and the North American Export Grain Association (NAEGA) contract number 2. GAFTA 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. GAFTA 27 covers full cargoes while GAFTA 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.

157. In the case of NAEGA number 2,[36] 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."[37] 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).

158. 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."[38] The Canadian Grain Commission and GISPA inspect shipments prior to export and certify their contents in Canada and the U.S., respectively.

159. 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 GAFTA 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.

160. There are a large number of other standard form contracts besides the GAFTA and NAEGA contracts described above. The Grain and Feed Trade Association 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 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.

161. In Australia, Grain Trade Australia (GTA, formerly the National Agricultural Commodities Marketing Association) has developed GTA contract number 1 for grain and oilseeds in bulk, FOB terms. In a similar manner to NAEGA number 2, the GTA 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

[36] "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 GAFTA contracts are only available to members of the Grain and Feed Trade Association.

[37] *Ibid.* at section 6.

[38] *Ibid.* at section 7.

organizations that set the commodity standards that would be referenced in the contract. The Australian Oilseeds Federation Quality Standards 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.

162. 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%."[39] 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.

163. 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%."[40] 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%."[41] Finally, the third declaration would apply in situations where the company supplying the commodity has a quality assurance (QA) 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%."[42]

164. The Australian Oilseeds Federation indicates 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.

XIII. PRIVATE STANDARDS

165. Standards relevant to the handling, transport, packaging and identification of LMOs have also been developed by private (i.e. non-governmental) organizations. Three such standards are discussed below.

[39] 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.

[40] *Ibid.* at p. 2.

[41] *Ibid.*

[42] *Ibid.*

A. International Seed Federation

166. The International Seed Federation (ISF) is a non-profit organization which represents the seed industry. The ISF has developed "Rules and Usages for the Trade in Seeds for Sowing Purposes"[43] which are intended to clarify and standardize contractual relations between buyers and sellers.

167. The rules apply to trade in all categories of seeds for sowing purposes and can also apply to trade in reproductive plant material (Art. 1). The rules are incorporated by reference into contracts between buyers and sellers of seed. Certain sections of the rules are relevant to the handling, transport, packaging and identification of LMOs.

168. Section V addresses contracts subject to import or export authorization. According to the definitions in section III, the term "subject to import or export authorization" means that "the shipment of seed needs an authorization of the exporting or importing countries on aspects such as but not limited to phytosanitary regulations, genetically modified (GM) crops, access to genetic resources" (Art. 8(a)). If a contract is concluded subject to an import or export authorization, the party requiring the authorization is to take all reasonable steps to obtain the authorization from the relevant authorities without delay (Art. 14).

169. Section XII addresses packaging. Article 36(a) requires that the seeds be put in "single packages of good quality, sound, suitable for export". The packages must be closed in a way that it is impossible to open them without there being evidence that the contents could have been altered or changed (Art. 36(c)) and they must be labelled so that they can be identified based on the documents (Art. 36(d)). For shipment of GM seeds, the packages are to "comply with relevant additional national and international packaging requirements" (Art. 36(f)).

170. Section XIV concerns documents. Article 39 in this section states that the documents to be presented by the seller as part of the contract may include, in the case of GM seed, documentation required by the Biosafety Protocol according to national regulations in the country of the buyer.

171. The ISF has also developed examples of standard commercial and standard pro forma invoices that incorporate language to meet the identification requirements of LMOs for contained use and LMOs intended for intentional introduction into the environment (Art. 18.2(b) and (c)).[44]

B. International Seed Testing Association

172. **New:** The International Seed Testing Association (ISTA) develops, adopts and publishes standard procedures for sampling and testing seeds and promotes the uniform application of these procedures for the evaluation of seeds moving in international trade. It has member laboratories in over 70 countries.

173. ISTA publishes the "International Rules for Seed Testing", which is the organization's primary instrument to promote uniformity in seed testing. The full text of the International Rules must be purchased but ISTA indicates that the International Rules "provide definitions and standardized methods to be used in, for example, sampling, testing seed lot quality and reporting results for international

[43] International Seed Federation, "Rules and Usages for the Trade in Seeds for Sowing Purposes" (July 2009), online: http://www.worldseed.org/cms/medias/file/Rules/Trade/ISF_Trade_Rules_2009.pdf.

[44] ISF standard pro forma invoice: http://www.worldseed.org/cms/medias/file/TradeIssues/CartagenaProtocol/Standard_Pro_Forma_Invoice.pdf; ISF standard commercial invoice: http://www.worldseed.org/cms/medias/file/TradeIssues/CartagenaProtocol/Standard_Commercial_Invoice.pdf.

trade."[45] ISTA also issues certificates of seed quality. The ISTA International Seed Analysis Certificate of seed quality is widely accepted and used for transactions of seed in international trade.

174. ISTA established a GMO Task Force to work on issues associated with the adventitious presence of genetically modified seeds in non-GM seed lots. To date, the GMO Task Force has developed a chapter on the detection, identification and quantification of GMO in conventional seed to be included in the International Rules (see below), has organized proficiency tests on GMO testing, and conducted workshops on detection.

175. Chapter 8 of the International Rules was amended to cover the detection, identification and quantification of GMOs in conventional seed lots. The revised chapter was adopted in 2005 and came into effect on 1 February 2006. Since then, it has been possible for laboratories to become ISTA accredited for the testing of seeds with specified traits under the performance-based approach. Under this approach, laboratories are free to choose the methods they use but they must meet the minimum requirements in the International Rules for the performance of laboratories carrying out such tests.

176. ISTA also publishes the "ISTA Handbook on Seed Sampling". The Handbook is intended primarily as a practical guide and covers aspects such as sampling seed lots in containers and sampling the seed stream, descriptions of tools for collecting samples, methods for sample reduction, labelling and sealing methods for seed lots and seed samples, procedures for the submission of samples to the laboratory, and quality assurance.

177. Furthermore, ISTA distributes the application 'Seedcalc' that can be used to design seed testing plans, including testing for the adventitious presence of GMOs in conventional seed lots. The application is freely available.

C. Non-GMO Project

178. The Non-GMO Project is a non-profit collaboration of manufacturers, retailers, processors, distributors, farmers, seed companies and consumers whose mission is to ensure the sustained availability of non-GMO choices. The organization is based in the United States and has developed the "Non-GMO Project Working Standard". Participants that follow the standard are able to place a seal on their products stating the products to be 'Non-GMO Project Verified'.

179. A few key points of the standard may be noted.[46] The scope of the Product Verification Program of the Non-GMO Project covers a number of activities including handling, storage, distribution, packaging and labelling. The guidance notes to the standard explain that handling includes "any form of post-harvest movement, storage, transformation, or labeling of goods along the entire chain of custody from seed to consumer, except for products enclosed in final retail packaging" (s. 1.2.2.2).

180. The core requirements of the standard are set out in section 2. They include traceability, cleanout and segregation, specifications for inputs and products, specification of high risk inputs and action thresholds. For example, on cleanout and segregation, the standard provides that "[r]eceiving, production, processing, manufacturing, transfer, and storage facilities, as well as shipping and transportation conveyances, shall be inspected and cleaned/purged as needed to remove sources of GMO contamination, and all relevant cleaning, purging, and inspections shall be documented" (s. 2.2.1.1).

[45] http://seedtest.org/en/international-rules-_content---1--1083.html.

[46] The descriptions here are from the fall 2010 version of the standard: http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v7.pdf.

181. Concerning action thresholds, the guidance notes explain that the standard seeks to achieve the absence of all GMOs in the products it certifies: "Continuous improvement practices toward achieving this goal must be part of the Participant's quality management systems. A key requirement of such quality management systems is to establish an Action Threshold, which, if exceeded, triggers the Participant to investigate the cause of the contamination, and to correct that cause when identified. Inputs contaminated above the action thresholds may not be intentionally used" (s. 2.6). The action threshold for seed and other propagation material from certain crops is 0.1%. The action threshold for animal feed and supplements is 0.9% (s. 2.6).

182. The standard is open to public comments twice a year and revised accordingly.
