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Standards for Shipments of Living Modified Organisms

Outcomes of an Online Forum

Convention on Biological Diversity

UNEP

United Nations Decade on Biodiversity

CBD BIOSAFETY TECHNICAL SERIES 01

Standards for Shipments of Living Modified Organisms

Outcomes of an Online Forum

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Standards for shipments of living modified organisms: outcomes of an Online Forum

I. Introduction

Article 18 of the Cartagena Protocol on Biosafety concerns the handling, transport, packaging and identification of living modified organisms (LMOs). Its paragraph 3 states that the Conference of the Parties serving as the meeting of the Parties (COP-MOP) "shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies."

As part of this process, the COP-MOP at its fourth meeting held in Bonn, Germany in May 2008, requested the Executive Secretary to organize an online conference. The terms of reference for the online conference are set out in box 1, below.

Accordingly, the Secretariat organized the "Online Forum on Standards for Shipments of Living Modified Organisms" which took place through the Biosafety Clearing-House (BCH) from 18 May to 5 June 2009.[1]

A report on the Online Forum was prepared for COP-MOP 5 (document UNEP/CBD/BS/COP-MOP/5/INF/23). The Parties requested the Executive Secretary to disseminate the results of the Online Forum, including information about potential gaps in international standards, to relevant organizations. This publication has been prepared to fulfil this request. The next section describes how the Forum was organized while section III summarizes the discussions during the Online Forum. Section IV contains a summary of the recommendations from the Online Forum that were presented to the Parties at COP-MOP 5 and section V reproduces decision BS-V/9, "Handling, transport, packaging

1 http://bch.cbd.int/onlineconferences/forum_art18.shtml.

BOX 1: Terms of reference for an online conference on paragraph 3 of Article 18

In its decision BS-IV/10, the COP-MOP requested the Executive Secretary to organize an online conference to:

(i) identify the relevant standards with regard to handling, transport, packaging and identification of LMOs;

(ii) identify where gaps exist; and

(iii) suggest possible modalities to fill the gaps (paragraph 4).

The decision invited Parties, other Governments and relevant international organizations to provide the Executive Secretary with guiding questions for the conference and requested the Executive Secretary to finalise the list of questions in consultation with the Bureau. The decision also requested the Executive Secretary to prepare a summary of the outcome of the conference, reflecting the full range of views expressed, for the consideration of the fifth meeting of the Parties to the Protocol.

and identification of living modified organisms: paragraph 3 of Article 18", that was adopted by the Parties at COP-MOP 5. Part B of the publication contains a summary of information on standards and standard-setting bodies relevant to the handling, transport, packaging and identification of LMOs. This updates information that was provided to both the Online Forum and COP-MOP 5.

II. Organization and structure of and participation in the Online Forum

The Secretariat solicited guiding questions for the Online Forum and also put forward three questions that it thought would facilitate discussions. The guiding questions were finalized in consultation with the Bureau and then made available on the Online Forum. The questions were grouped into four themes to help structure the discussions. The final set of guiding questions can be found in Annex I.

The Secretariat also prepared a background document to facilitate and inform the discussions. The document contained a summary of information on standards and standard-setting bodies relevant to the handling, transport, packaging and identification of LMOs. This information has been updated and provided in part B of this publication.

The Online Forum itself was divided into two main sections. One section contained discussion groups organized around the four themes of the guiding questions. The other was an 'Ask an Expert' section whereby experts from different organizations whose work has some relevance to the handling, transport, packaging and identification of living modified organisms were invited to participate in the Forum. They committed to being available online for one day to answer questions submitted by participants in the Forum. Representatives from the following organizations took part as experts:

- Codex Alimentarius Commission;
- International Plant Protection Convention (IPPC) Secretariat;
- Organisation for Economic Co-operation and Development (OECD);
- United Nations Economic Commission for Europe (UNECE);
- World Customs Organization (WCO);
- World Organisation for Animal Health (OIE); and
- Secretariat of the World Trade Organization (WTO).

The Forum was open to everyone but individuals needed to register in order to post messages. Eighty-one people registered for the Forum. See Annex II for more statistical information on participation in the Forum.

III. Summary of the outcome of the Online Forum

The summary below follows the four themes of the guiding questions. In addition, the discussions under the 'Ask an Expert' component of the Forum have been included under the theme to which they most closely relate. In accordance with the rules of the Forum,[2] the contributions of participants are considered to have been made in their personal capacity unless they stated otherwise. For this reason, only the intervenors who made clear that their comments represented the views of their Government or organization have been identified by name in the summary that follows.

THEME 1: EXISTING STANDARDS AND STANDARD-SETTING BODIES

Ten different discussion threads were created under this theme.

One intervention described the situation in Moldova where the Government is in the process of implementing the national biosafety framework and is preparing an enforcement regulation on the labelling, packaging and transport of LMOs. This intervention stated that it would be worthwhile developing a unified standard document for the identification, handling, transport and packaging of LMOs in accordance with Article 18 of the Protocol that would take into account all the types and uses of LMOs covered by the Protocol. A number of other interventions supported this suggestion. One intervention added that it would be very useful if countries' efforts on the handling,

2 http://bch.cbd.int/onlineconferences/participation_art18.shtml.

transport, packaging and identification of LMOs were included in the BCH. Another added that a special standard under paragraph 3 of Article 18 could take the form of a guideline on how to use the existing international regulations and standards and that such a guideline should be prepared by stakeholders in and experts on the Protocol.

One intervention noted the biotechnology-related standards of the International Organization for Standardization (ISO) and other regional and national organizations (such as the European Committee for Standardization (CEN)). It described ISO as having developed several standard test methods for the identification and detection of genetically modified organisms (GMOs) and stated that these test methods provide a uniform way for countries to detect or identify GMOs that are the subject of the Protocol. The intervention specifically referred to the ISO Technical Committee on Food Products and its Working Group 7 which has published five standards related to the detection and identification of GMOs. The intervention noted that the Working Group has transferred its tasks on GMO standardization to Subcommittee 16 on horizontal methods for molecular biomarker analysis. Regarding CEN, the intervenor commented that the Committee has developed many valuable standards for post-release monitoring of GMOs and assessing their effects on the environment.

The Secretariat agreed that there are a number of standards in the area of sampling and detection but remarked that it had made a conscious decision not to include information on sampling and detection standards in the background document. The representative of the Secretariat noted that access to many of these standards must be purchased. She reminded participants of paragraph 2 to decision BS-IV/9 in which Parties are requested and other Governments and relevant international organizations are encouraged to ensure that information related to rules and standards on the sampling of living modified organisms and detection techniques is made available via the BCH.

A participant suggested that the Secretariat enter into a memorandum of understanding (MOU) with ISO, CEN and the International Seed Testing Association in order to obtain observer status at their meetings, gain access to the standards and perhaps also be involved in the implementation of standards. He suggested that other benefits of such an MOU could include the integration of Protocol provisions into the implementation and amendment of the standards of these organizations, thus avoiding duplication. He commented that the costs would be the expense for representatives of the Secretariat to participate in these meetings but suggested that such costs could be minimized by restricting participation by Secretariat representatives to only a few key meetings.

Mr. Olivier Kervella from the UNECE added information based on their experience in relation to the use of ISO and CEN standards concerning the transport of dangerous goods. He described how ISO is in consultative status with the UN Economic and Social Council and so cooperates with the latter's subsidiary bodies including UNECE. He explained that the UN Sub-Committee of Experts on the Transport of Dangerous Goods has liaison status with a number of ISO Technical Committees and thus is able to obtain relevant information relating to the work of these committees. He added that the ISO Secretariat provides UNECE all relevant standards free of charge. Furthermore, ISO standards may be referred to in the UN Model Regulations on the Transport of Dangerous Goods (UNTDGs or 'Model Regulations') only when the Sub-Committee has checked that they meet the required safety level. He noted that normally, administrations can get copies of ISO standards from their national standardization bodies.

Mr. Kervella continued by stating that the fact that ISO and CEN standards are not publicly available free of charge may be a problem for those who have to apply regulations that require the application of a specific standard. He commented that UNECE is unable to get copies of final CEN standards free of charge and national administrations in European Union countries should be able to obtain them from their national standardizations body although in practice, it is not always so straightforward. He explained that, once adopted, CEN standards must be applied by all European Union countries so UNECE has established a process of cooperation with CEN to avoid contradictions between some of the latter's standards and legal instruments that apply to the transport of dangerous goods in Europe. Mr. Kervella remarked that copies of the draft standards are made available to the UNECE

and members of the Joint Meeting at the various stages of verification.

A second discussion thread under theme 1 concerned the *Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea* (Rotterdam Rules). An intervenor inquired whether the Rotterdam Rules would be relevant for the implementation of paragraph 3 of Article 18 of the Protocol.[3] Mr. Kervella replied by describing how the international carriage of goods is usually effected by a contract of carriage between the consignor and the carrier. He explained that these contracts of carriage may be established under the provisions of various international conventions and a contract of carriage is usually evidenced by a transport document which contains the information in accordance with the relevant convention. He noted that the information required under transport of dangerous goods regulations is usually included in or attached to this transport document. Mr. Kervella added that the Rotterdam Rules are intended to apply to transport operations which are effected wholly or partly by sea, i.e. in case of multimodal transport they would supersede the provisions of the current conventions that separately govern the contract of carriage on the different legs of the journey (sea and inland), but the convention is very recent and has not yet come into force.

The initiator of the discussion thread stated that cooperation with the secretariat for the Rotterdam Rules will ensure that the implementation of the Rules will take the provisions of the Protocol into consideration.

Another discussion thread raised a question about the London Corn Trade Association[4] and North American Export Grain Association (NAEGA) contracts as described in the background document for the Online Forum. Mr. Gary Martin from the NAEGA elaborated on some of the details of the NAEGA 2 model contract. He stated that the contract does not set a standard for quality or other attributes that are intrinsic to the grain in the shipment. Rather, these standards are normally created by governments or industry trade associations and shipments are inspected by governments or third party inspection companies. He described how the basic standards are established in countries of export as they reflect quality criteria inherent in specific geographic areas but the contracts also often incorporate specific quality requirements desired by the importer. He noted that products produced from modern biotechnology were incorporated into the international commercial grain standard/grading systems as they entered the commercial industry 15 years ago. Mr. Martin explained that the NAEGA 2 contract is a model and many of its provisions are used in free on board contracts around the world but parties have other options.

> products produced from modern biotechnology were incorporated into the international commercial grain standard/grading systems as they entered the commercial industry 15 years ago

The intervention went on to express concern that a lack of understanding of the practicalities of the development of a new international standard for products produced through modern biotechnology under paragraph 3 of Article 18 could create a regime that inhibits trade and the use of crop biotechnology as well as other production practices. The intervention concluded with an expression of willingness on the part of the NAEGA to participate in education and communications opportunities to provide information on the effectiveness and use of existing standards and practice employed within the international grain trading system.

One discussion thread began by examining the nature of existing standards. The initial intervention noted that the standards set by the Codex Alimentarius Commission and the International Plant Protection Convention are not legally binding on their Parties and the OIE only focuses on animal and not human health. The intervention stated that the lack of standards for shipments of LMOs will be a barrier to trade. The intervention advocated that standards should be set by a group of international experts in different LMO-related fields as well as the Parties to the Biosafety Protocol.

3 See part B of this publication for a discussion of the Rotterdam Rules as well as the Hague-Visby rules they are intended to replace.
4 The London Corn Trade Association is now the Grain and Feed Trade Association.

Another intervention agreed that the lack of standards for shipments of LMOs will be a barrier to trade as national standards may vary creating difficulties for suppliers. It stated that the most serious consequence is the threat to human health for countries that may not have the capacity to develop their own standards and so the intervenor advocated the need for binding international standards. A later intervention agreed that a special standard for the handling, transport and packaging of LMOs under paragraph 3 of Article 18 is needed. It stated that Parties and the Secretariat should provide guidance towards ensuring international harmonization.

Another participant in the Online Forum responded by agreeing that LMOs can represent a kind of danger especially during transportation but would not classify LMOs under either Class 9, 'Dangerous substances', or Class 6, 'Infectious substances', of the UNTDGs. Instead, the intervenor proposed giving LMOs a special status and specific labelling during packaging and transportation. The intervenor also stated that it is difficult for developing countries and countries with economies in transition to elaborate their own national standards that would be in line with international standards and so she supported the idea that it is necessary to elaborate comprehensive legally binding standards under the Protocol. She concluded by stating that synergies and cooperation among the international standard-setting bodies and the Secretariat of the Convention on Biological Diversity (CBD) are crucial for coordinating activities such as the elaboration of databases, information exchange systems such as the BCH, the development of standards and ensuring the segregation and traceability of LMOs that are the subject of transboundary movements. She stated that the creation of a special permanent working group responsible for cooperative relationships could become an instrument for achieving these activities.

Mr. Kervella responded by indicating that the suggestion that infectious LMOs should not be assigned to the class of infectious substances would not receive much support. He explained that when there is evidence that a microorganism, genetically modified or not, meets the criteria for an infectious substance, it must be carried in accordance with the requirements applicable to infectious substances. He added that for assignment to class 9, there are no criteria in the Model Regulations for deciding whether they are dangerous or not. LMOs are assigned to class 9 only if they are not authorized for use by one of the countries of origin, transit or destination since one of these countries has decided that a particular LMO is dangerous and should not be released accidentally during transport. He noted that when LMOs are authorized for use in all countries concerned by the international transport operation, they are not subject to transport regulations unless they possess other dangerous properties.

LMOs are assigned to class 9 of the UNTDGs only if they are not authorized for use by one of the countries of origin, transit or destination since one of these countries has decided that a particular LMO is dangerous and should not be released accidentally during transport.

Another intervention described how the international rules and standards for the movement of dangerous goods are implemented in the European Union. The intervenor highlighted that there is a working system to develop rules on the transport of dangerous goods. He referred to the existing classification system under the UNTDGs[5] which includes rules on handling, transport, packaging and identification. He concluded that if there is a need to develop further the rules on transport, there is an established system to work through. He felt that developing separate standards for the transport of LMOs would not only create confusion but would also be subject to all the teething problems that the existing systems have seen. He pointed out that law enforcement and civil protection organisations are well aware of the relevant international rules (the *European Agreement concerning the International Carriage of Dangerous Goods by Road*, the Regulations concerning the International Carriage of Dangerous Goods by Rail and the *European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways*) and know how to enforce those rules.

5 See section V of part B of this publication for more details on the classification system of the UNTDGs.

Mr. Kervella replied that the European Union's system is fully based on the UNTDGs which are developed by a specific Sub-Committee of the United Nations Economic and Social Council where all parts of the world, including developing countries and countries in transition, are represented. He added that the Model Regulations have no mandatory status but they become mandatory when they are transposed into national and regional regulations—such as those of the European Union and many other countries—or international legal instruments such as those for international transport by air and sea. He referred to the explanation in the background document.[6]

In another discussion thread, a participant asked whether, regarding standards or criteria for shipments of LMOs, it is better for each country to identify those standards that are in line with its situation or to set global standards agreed upon by all Parties. He also asked what standards may need to be consulted if each country has the right to develop its own standards. He felt that these issues should be taken into account at the next meeting of the Parties to the Protocol.

One participant pointed to ISO, the OECD, the International Seed Testing Association, the Codex Committee on Methods of Analysis and Sampling, CEN, the Global Industry Coalition, IPPC, WCO, OIE, the International Air Transport Association, the International Civil Aviation Organization and the International Maritime Organization as organizations with standards relevant to the handling, transport, packaging and identification of LMOs. He suggested that regional and sub-regional bodies may also be involved in the development of relevant standards. He felt that all types of LMOs could be shipped under the guidance or recommendations of the organizations listed in the guiding questions for this theme (see annex I). He pointed to the European Union, New Zealand and Australia as governments that have developed their own relevant standards and he indicated that countries have implemented the biosafety-related standards set by relevant organizations by incorporating the standards into their national regulatory systems. His suggestions for new topics of discussion included the following:

- where and when does a standard become operational?
- from among the existing standards, what should be applicable in the context of handling, packaging and transport?
- can the standards be harmonised to take care of handling, packaging and transport?
- what about coordination among the standard-setting bodies?
- can each Party's national laws/standards or the regional/sub-regional law be applied to address the issues?
- how do we address the global 'regulatory divide' due to political and economic factors in the handling, transport and packaging of LMOs?

A number of the questions posed in the 'Ask an Expert' section of the Forum were also relevant to the theme of existing standards and standard-setting bodies.

QUESTION to Ms. Gretchen Stanton, Secretariat of the World Trade Organization: the WTO recognizes Codex, IPPC, and OIE for standard setting with respect to food safety, and plant and animal health. The subject matters and responsibilities covered by these processes or organizations have some overlaps with the scope of Cartagena Protocol on Biosafety. In that regard, how does the WTO consider standards developed and adopted by multilateral environmental agreements such as the Protocol on Biosafety? Would you recommend harmonised biosafety standards across these global conventions to facilitate national and regional biosafety issues?

Ms. Stanton replied by noting that the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) was negotiated well prior to the existence of the Biosafety Protocol. She also explained that, in addition to identifying Codex, IPPC and OIE as relevant international standard setting bodies, paragraph 3(d) of Annex A to the SPS Agreement provides that the definition of the term 'international standards, guidelines and recommendation' includes "for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee." Ms. Stanton pointed out that, to date, no WTO

6 See section V of part B of this publication.

Member has suggested in the SPS Committee that there is a need to identify another international organization as relevant for this purpose. She further noted that only countries may be members of many international organizations whereas WTO membership includes some customs territories that are not recognized as states by the United Nations.

Ms. Stanton continued by describing how, in the GMO dispute case,[7] the WTO dispute settlement panel examined the applicability of the Cartagena Protocol. She explained that, according to the *Vienna Convention on the Law of Treaties*, a treaty can be interpreted only in the light of other rules of international law which are applicable to all the parties in the treaty being interpreted. She observed that since the US was not a signatory to the Biosafety Protocol, the dispute settlement panel could choose to take it into consideration in interpreting the SPS Agreement but was not required to do so.

She expressed the view that what is probably most important is to ensure that the standards and recommendations developed by Codex, IPPC and OIE do not contradict the work being done under the Protocol and, if possible, should complement this work. She felt that this already seems to be the case especially in terms of the close liaison between the IPPC and the CBD on living modified plant species. She stated that this collaborative relationship could be strengthened if WTO Members would agree to grant the CBD Secretariat observer status to the SPS Committee, which unfortunately has not yet been the case.

QUESTION: there have been concerns about standards that could create barriers to free trade. Some critics of the Biosafety Protocol use this as an argument against the Protocol. What are the criteria for having standards that are not considered to be technical barriers to trade; and is it the procedure/process used to develop and adopt standards that matters or is it the content of the standards that caused issues related to technical barriers to trade?

Ms. Stanton indicated that the reply varies slightly depending on whether the technical standards fall within the scope of the SPS Agreement or the *Agreement on Technical Barriers to Trade* (TBT Agreement). She explained that the SPS Agreement applies if the objective of the technical regulation is to protect human health from food safety risks or from animal-carried diseases, or to protect plant or animal health from pests and diseases, or to protect the territory of a country from other damage caused by pests. She noted that the SPS Agreement requires that any measure imposed by a Government for one of these objectives that may affect international trade must be based on scientific evidence of a potential health risk. She elaborated that Governments can either base their requirements on the health standards developed by the Codex Alimentarius Commission, the IPPC or the OIE or else on an appropriate risk assessment. She added that the requirements cannot be more than what is necessary to protect health although she noted that it is possible to impose temporary trade restrictions in situations where there is insufficient scientific evidence to undertake a risk assessment. She concluded that, for SPS requirements, the process of determining the technical requirement is important but the scientific justification for the requirement is most important. A measure that is scientifically justified would normally be considered an acceptable restriction of international trade.

She explained that the TBT Agreement covers technical requirements and voluntary standards that fall outside the scope of the SPS Agreement. She indicated that these may include such things as measures taken to protect human health from risks other than food safety and zoonotic risks (e.g. pharmaceuticals, human-spread diseases, medical devices), measures to protect the environment that are not within the scope of SPS, or measures to ensure the quality of foodstuffs. She noted that because TBT requirements may be imposed to meet different legitimate objectives (e.g. informing consumers), they are not required to necessarily have a scientific justification. She added that, although Governments are strongly encouraged to base their national requirements on relevant internationally-adopted standards, the TBT Agreement does not identify which international standards may be considered relevant. Rather, the TBT Agreement gives greater importance to the process and procedures used for the development of standards.

7 EC–Approval and Marketing of Biotech Products, dispute DS291.

QUESTION from the CBD Secretariat to Mr. Alexey Shcheglov, World Customs Organization: can the secretariat of a multilateral environmental agreement request an amendment to the Harmonized System[8] or must proposals for amendments come from national authorities?

Mr. Shcheglov responded that it has become a well-established practice for the WCO to receive proposals to amend the Harmonized System from international organizations or secretariats of multilateral agreements. He explained that such proposals are examined on the same footing as those submitted by WCO Members, i.e. national customs administrations. Mr. Shcheglov noted that the WCO Harmonized System Review Sub-Committee, under the general guidance of the Harmonized System Committee, is responsible for reviews of the Harmonized System. Representatives of intergovernmental or other international organisations can attend the Sub-Committee meetings subject to invitation by the WCO Secretary General. He added that proposals concerning amendments of the Harmonized System are normally submitted directly to the Harmonized System Review Sub-Committee.

QUESTION to Ms. Christina Devorshak, International Plant Protection Convention Secretariat: what are the areas of overlap in functions and responsibilities between the IPPC and the Biosafety Protocol?

Ms. Devorshak responded by pointing to the objectives of the two agreements. She noted that the objective of the Protocol is "… to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity…" while the purpose of the IPPC is "securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control". She described how, in the case of the IPPC, pests are any organism that may be injurious to plants—the latter including both wild and cultivated flora. She explained that to the extent that an LMO may have the potential to be injurious to plant health, it may be considered a 'pest' in IPPC terms. She added that, to the extent that the IPPC plays a role in protecting wild flora, it contributes to protecting biodiversity and this can be understood as the overlaps in objective and scope of the two agreements. She expressed the view that the area where there is perhaps the most overlap and the greatest potential for synergy between the two agreements is in the application of risk analysis.

> another possible area for harmonization between the IPPC and the Biosafety Protocol is the development and use of specific terminology

QUESTION: What is the scope and nature of IPPC's mandate regarding genetically modified plants or crops? What are the potential areas of harmonisation with the ongoing processes in Developing and Implementing National Biosafety Frameworks in relation to obligations to the Cartagena Protocol on Biosafety? What are the potential areas of conflict in mandate between the national plant protection organizations and the National Competent Authorities for Biosafety if different institutions are mandated in the country (in most cases between Ministries of Agriculture and Environment)?

In response, Ms. Devorshak explained that if a genetically modified plant has the potential to be a 'pest' in IPPC terms (i.e. has a negative impact on plant health), it would fall within the scope of the IPPC and therefore could be subject to phytosanitary measures. She elaborated that the guidance provided in international standards for phytosanitary measures (ISPMs) would apply to assessing and managing risks associated with the GMO if it has the potential to be harmful to plant health. She suggested that, in addition to methodologies for conducting risk analysis, another possible area for harmonization between the IPPC and the Biosafety Protocol is the development and use of specific terminology. She described how the IPPC has developed a glossary of phytosanitary terms that are used in ISPMs and by countries in their national legislation. The Convention and the Protocol also have specific terminology. She found that there are many overlapping terms used by the different agreements but the terms have different meanings and applications depending

8 See part B below for a description of the Harmonized System.

on the organization or text being referred to. She used the example of the term 'introduction' which in the IPPC has one meaning ("the entry of a pest resulting in its establishment") but means something else in the context of the CBD and the Protocol. She noted that if a national plant protection organization is using specific terms in the IPPC context and another regulatory agency is using similar terms but in the context of the CBD or the Protocol, this could lead to contradictory or inconsistent regulatory frameworks.

In response to the final part of the question, Ms. Devorshak felt that, although the potential for conflict exists, it is up to countries to coordinate their national agencies to ensure that they are consistent in their approaches to regulating various types of organisms and to ensure that the country is meeting its obligations under all the different agreements to which it is a party. She suggested that, at the national level, agencies responsible for implementing the agreements should find ways to coordinate their work and that countries may wish to consider coordinating expertise and resources to ensure a more consistent approach to their regulations.

QUESTION: the IPPC Standard Setting Work Programme as adopted at the third session of the Commission on Phytosanitary Measures (CPM) indicates that the IPPC intends to develop an ISPM on the International Movement of Grain. What is the intended scope and objective of this ISPM and how would it relate to other standards and industry practices in this area?

Ms. Devorshak explained that the third meeting of the CPM discussed two issues: the need for an ISPM on the international movement of grain and, as a separate issue, the need for an open-ended workshop on the international movement of grain. On the first point, she stated that a specification for an ISPM on the international movement of grain has not yet been drafted and so it is difficult to say what will or will not be addressed in the standard. She did note, however, that any standard drafted to address phytosanitary risks associated with the international movement of grain would apply to quarantine pests as defined in the IPPC. She concluded that as the IPPC considers that guidance on assessing phytosanitary risks of LMOs/GMOs as quarantine pests is provided in ISPMs No. 2 (Framework for pest risk analysis) and No. 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms), any new ISPM would be consistent with the requirements of these two ISPMs.

She highlighted that the CPM also agreed that an open-ended workshop, pending the availability of external resources, would be a useful forum for discussing phytosanitary issues related to the international movement of grain.

QUESTION from the CBD Secretariat to Mr. Masashi Kusukawa, Codex Alimentarius Commission: were there any developments on the 'Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/ Genetic Engineering' at the meeting of the Codex Committee on Food Labelling that had been held at the beginning of May 2009?

Mr. Kusukawa replied that not much progress was made on the proposed draft Recommendations. He described how the Committee started with discussions on whether or not to continue the work and considered suspending the discussion for three years by which point countries might have obtained more experience in the labelling of genetically modified/ genetically engineered (GM/GE) foods and found a common ground for negotiation. He noted that the Committee did in the end agree to continue work on this topic based on the support of many delegations. He described how, as a result of the discussions, the proposed draft Recommendations along with a number of new proposals have been circulated to members and observers for comments and further discussion at the next session of the Committee.

QUESTION: section 3 of the annex to "Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food" indicates that the maintenance of a publicly accessible central database on living modified organisms (including information related to identification and detection) is also within the mandate of the Food and Agriculture Organization (FAO). What is the current status of the implementation of the information requirements of the Cartagena Protocol (in the

form of the BCH) and the Annex (the FAO database)? What is your view on possible synergies and overlaps between the two?

Mr. Kusukawa began by explaining that the FAO-managed database[9] is not a reproduction of the BCH, rather it is an online tool allowing easy access to information relevant to the purposes of the Food Safety Assessment Annex. He noted that the Food Safety Assessment Annex provides the recommended approach to the food safety assessment when food derived from a recombinant-DNA plant not having been authorized in the importing country is found at a low level in the imported food because it has been authorized for food use in the exporting country.

Mr. Kusukawa went on to describe some of the background to the database and how it is managed. He noted that the need for an information exchange system was repeatedly stressed throughout the consideration of the Annex as it was felt that a database providing information on recombinant-DNA plants authorized for food use and, in particular, a summary of the risk assessment and contact details for further information, would improve the preparedness of importing countries, bearing in mind that a food safety assessment in a situation of low-level presence needs to be completed very quickly in order to avoid a prolonged import restriction of the commodity concerned. He outlined the information provided by the FAO database on recombinant-DNA plants that have been authorized for use as food in various countries which includes a summary of the application; a summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline; and where to obtain detection method protocols and appropriate reference material suitable for low-level situations.

Mr. Kusukawa noted that the types of data to be stored in the database are mostly covered in the BCH and he explained that the developer of the FAO database was mindful of the existing resources in the BCH as well as in the OECD BioTrack Product Database and tried not to duplicate work. He described how the FAO database is updated regularly by an automated process, extracting data from several online resources including the BCH and the OECD BioTrack Product Database and only selecting data for recombinant-DNA plants authorized for use as food. He noted that the database does not currently contain the records of authorizations for which no risk assessment information is available as knowing the fact that a certain recombinant-DNA plant is authorized in a country without the rationale for the decision would not be helpful for users. Mr. Kusukawa explained that the database also allows countries to enter relevant data manually if the information has not been captured through the automated process.

QUESTION to Mr. Peter Kearns, OECD: does the OECD have guidelines or standards that are specific to genetically modified seeds? The "OECD Schemes for the Varietal Certification or Control of Seeds Moving in International Trade" do not make mention of GM seeds or seeds produced through techniques of modern biotechnology. Does this mean that the OECD's policy does not see the need for different treatment/standards for seeds that are genetically modified?

In response, Mr. Kearns indicated that there has been much discussion on the issue of whether to make reference to GM seeds in the Seed Schemes and that some delegations believe that the Schemes is not the appropriate mechanism to address the issue.

QUESTION from the CBD Secretariat: the background document prepared for the Forum states that the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology is undertaking work on a system of unique identifiers for transgenic micro-organisms. How far has this work progressed? Is the intention for the unique identifiers for transgenic micro-organisms to take a similar form as the unique identifiers for genetically modified plants?

Mr. Kearns replied that the OECD has been working on a system of unique identifiers for transgenic micro-organisms for quite a while and that it had proved quite challenging due, in part, to the highly diverse nature of micro-organisms. He pointed to

9 The database can be accessed here: http://www.ipfsaph.org/servlet/CDSServlet?status=ND1jdGh0dHB3d3dmYW9vcmdhb3NpcGZzYXBoaXNzdWVrZXl3b3Jkc2Jpb3RlY2hub2xvZ3lmb-29kc2FmZXR5cmlza2Fzc2Vzc21lbnQmNj1lbiYzMz0qJjM3PWtvcw--.

the paucity of examples of the use of such organisms except in contained use settings (when the OECD focus is on transgenic organisms that might be used in the environment). He explained that the sub-group working on the issue is focusing on bacteria and has been exploring other existing systems that might form a basis for a bacterial unique identifier, such as those in culture collections. He added that it does not look like a unique identifier for bacteria will be the same as the one for transgenic plants.

QUESTION: the background document prepared for the Forum states that the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology is considering undertaking a project on the low-level presence of transgenic seeds in bulk shipments of conventional seeds. Can you update the status of the project and provide more information on its scope and purpose? The OECD includes countries with varied legislation on GMOs—European countries with mandatory labelling and identification requirements which usually result in the detection of low levels of GMOs on the one hand, and the countries of the North American Free Trade Agreement (NAFTA) on the other where labelling is not necessarily enforced and high concentrations of different LMOs are often found in shipments. Would the OECD would be interested in setting up a project or training for the latter situation?

On the first point, Mr. Kearns stated that it was a bit early to be clear on the scope for the project on low-level presence. He explained that there are many differing opinions on the issue and the Working Group continues to consider what it might best undertake, if anything, on the topic. He added that any project that is developed will be firmly within the terms of reference of the Working Group, i.e. it will focus on risk/safety assessment. He noted that the details were to be further clarified at a meeting of the Working Group to be held in October 2009 and he suspected that the first steps in the project would focus on information exchange amongst delegations.

Mr. Kearns felt that the second point was closely linked to the first. He noted that all NAFTA members participate in the OECD Working Group and he was sure that the Working Group would appreciate information on experiences with low-level presence from all delegations. He did not think the OECD was well-placed to consider training.

QUESTION to Mr. Olivier Kervella, Dangerous Goods and Special Cargoes Section of the Transport Division of the UNECE regarding the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations: Are there any statistics available on the quantity of GMOs and genetically modified micro-organisms (GMMOs) that are transported according to the Model Recommendations?

He responded that he was not aware of any statistics on the quantity of GMOs and GMMOs that are transported according to the Model Regulations. He explained that all GMOs and GMMOs that are infectious are carried in accordance with the Model Regulations when they are carried internationally but those which are not infectious or toxic are not subject to the Model Regulations if they are authorized for use in the countries concerned by the transport.

Another intervenor in this thread suggested the consideration of differentiated approaches to the conditions of transport, handling, packaging and identification for LMOs depending on their intended use—direct use as food or feed, or for processing; contained use; or intentional introduction into the environment. She felt that it would be a good opportunity for the Parties to the Protocol to identify safety needs and requirements and to provide guidance for the CBD Secretariat to convey to the Sub-Committee on which requirements should be integrated into the Model Regulations. She requested clarification as to whether the Model Regulations are a legally binding document. She supposed that it would be necessary to elaborate specific regulations on the segregation and traceability of LMOs so as to ensure safe transboundary movements.

Mr. Kervella replied that the Model Regulations are not legally binding *per se* as is suggested by their name. He explained that the UN Economic and Social Council recommends to all Governments and international organizations concerned to take the Model Regulations into account when elaborating national transport regulations. He noted that as a result many

countries in the world fully or partially implement the Model Regulations through their national legislation but more importantly in the context of international transport, all organizations or bodies of the UN system that are involved in regulating different modes of transport, i.e. the International Maritime Organization, the International Civil Aviation Organization and the UNECE are committed to implementing these Model Regulations through their own legal instruments. He explained that, in practice, for international maritime or air transport and for international inland transport in the UNECE region, the UN Model Regulations are of mandatory application although there can be some deviations in specific cases justified by the safety needs of a particular mode of transport such as air transport where the packing requirements are more stringent. He highlighted one difficulty faced by the UN Sub-Committee of Experts on the Transport of Dangerous Goods which is the lack of expertise for defining exactly what kind and level of danger are presented by LMOs during transport. He stated that the UN Sub-Committee may rely on the expertise of other organizations for advice on specific substances to help it define the appropriate transport conditions in a manner that is coherent with the system all carriers are used to as this integration is important for proper compliance with the rules by carriers.

QUESTION: can the scope of class 9 of the Model Regulations be considered as overlapping with the Protocol and would the Model Regulations therefore be the right place to have the discussion on standards that may be required for shipments of LMOs? How can the overlap between the Model Regulations and the Protocol be avoided?

Mr. Kervella responded that he does not think there is any overlap. He noted that Article 18 of the Protocol specifies that each Party shall take necessary measures to require that LMOs that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. He explained that the UN Model Regulations contain relevant rules in this respect and these rules are made mandatory through certain legally binding instruments. He elaborated that the rules in the UN Model Regulations are not static, they are updated as necessary every two years, and all relevant international organizations may participate in the debates to ensure that their concerns are taken into account. Any input from the CBD Secretariat as regards LMOs would be duly considered and taken into account if the current rules were not deemed adequate. He concluded that what is important is that those involved in transport operations, in particular the carriers, can easily find the rules they have to comply with in a document that contains consistent regulations.

THEME 2: POSSIBLE GAPS—GENERAL

There were three discussion threads created under this theme.

In one discussion thread, a participant posted his response to the first guiding question for the theme. The question asked about possible gaps in the standards relating to the handling, transport, packaging and identification of LMOs. The participant noted the following possible gaps:

- support and relying on international standard-setting bodies;
- lack of information among the Parties on acceptable standards;
- inadequate forum for coordinating acceptable standards;
- non-involvement of the local communities in detection and monitoring;
- accreditation of laboratories;
- information dissemination; and
- conflicts in the rules of international standard-setting organisations.

He also suggested three possible additional topics of discussion:

- certification and accreditation of laboratories involved in the sampling and detection of LMOs;
- who verifies or validates the standards; and
- what are the envisaged standards for sampling DNA, DNA extraction and protein analysis.

Under another discussion thread, one participant wrote that she believed there is still a great gap in standardization for the shipment and handling of LMOs. She stated that there are many different

regulations that have been prepared by relevant organizations and that cover LMOs or GMOs and this may subsequently cause some confusion as none of them pointed directly to genetically modified organisms. She suggested that a working group under Article 18 could act as a coordinator for existing or future standards. She felt that this working group should work exclusively on standards for the shipment, handling and packaging of LMOs, including collecting the guidelines, acts or standards that can be applied in the shipment of LMOs. An alternative suggestion would be to transfer the task to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

even if a standard for the labelling of genetically modified foods is adopted by the Codex Committee on Food Labelling, the gap regarding standards for the handling and shipment of GMOs or LMOs that are not packaged as food will remain

The participant noted that the current guidelines that have been prepared by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology are helpful in assessing the safety of foods derived from modern biotechnology but there is no obligation for the packaging or labelling of GMOs that are transported. She added that even if a standard for the labelling of genetically modified foods is adopted by the Codex Committee on Food Labelling, the gap regarding standards for the handling and shipment of GMOs or LMOs that are not packaged as food will remain.

Another discussion thread focused on the 2003 North American Trilateral Arrangement and on why it is important to fill gaps. The first intervention in the thread described the Trilateral Arrangement as being an agreement among the three NAFTA partners, namely Canada, the United States and Mexico, with the objective of articulating an understanding among the three countries "with respect to the documentation requirements of the Cartagena Protocol on Biosafety pertaining to living modified organisms intended for direct use as food or feed, or for processing. Specifically to clarify documentation requirements such that they fulfill the objectives of the Protocol without unnecessarily disrupting commodity trade."[10] The intervention described the Arrangement as having been made under Article 24 of the Protocol and as having entered into force on 29 October 2003 for a period of two years.

The intervenor also stated that the Arrangement was one-of-a-kind, constituting a relevant effort between two non-Parties to the Protocol and Mexico, a Party. She described how commodity trade in this region is very large including a large trade in GM maize for food, feed and processing. The intervention explained that, due to challenges in the interpretation of the Mexican Biosafety Law after its entry into force (May 2005), only a few companies still utilize the phrase "may contain LMOs" in their invoices.[11]

The intervenor described how special attention was paid to the issue of information exchange during the trilateral meetings for the implementation of the Arrangement. She commented that information exchange would have led to a closer relationship with Mexico as a Party to the Protocol, a megadiverse country as well as a centre of origin and diversity of maize that needs detailed molecular information in order to perform post-market monitoring of GM maize imports. She felt that a transparent procedure must exist between Parties and non-Parties where the provisions of the Biosafety Protocol are honoured but this understanding still remains to be fulfilled in the North American region.

In another post, the intervenor listed a number of problems that she identified in the NAFTA region:

- Lack of official information exchange with regional partners: laboratories are left alone in their efforts to implement detection methodologies. She expressed the desire for the BCH to include space for the exchange of information

10 The Arrangement clarified how the three countries would apply Article 18.2(a) of the Protocol which obliges Parties to take measures to require that documentation accompanying LMOs-FFP clearly identifies that they "may contain" LMOs. The Arrangement provided, among other things, that the "may contain" language should appear on the commercial invoice as provided by the exporter.

11 The current status of the Arrangement is unclear. The participant noted in her intervention that the Arrangement was not renewed after its initial two-year period. Information submitted by Mexico in the context of paragraph 2(a) of Article 18 indicates, however, that the Arrangement was extended indefinitely (see para. 15 of document UNEP/CBD/BS/COP-MOP/5/8). The Secretariat was unable to locate information in the BCH on a possible extension.

on such things as target sequences for developing detection methods for new commercial events and movements of harvested GMOs that might be exported.
- Disparities in regulations, e.g. the US does not require safety evaluations of stacked transformation events whereas such assessments are required in Mexico. She stated that the resulting complications for the detection and monitoring of stacked events are evident.
- Considering that many methodologies and systems for monitoring are European, some harmonization with US labs and developers would be interesting. She felt that the published methodologies for detection posted on the internet by the developers are very useful but there are still a number of gaps such as free exchange of validated reference materials; lack of harmonized detection methods; and accreditation of laboratories.
- Lack of information/educational campaigns for teaching the public and consumers.

She felt that all of the above would be useful for improving understanding and decision-making respecting LMOs. She also agreed with the list of gaps posted to the Forum by another participant as summarized at the beginning of this section.

Another participant responded that the information on the Trilateral Arrangement confirms the need to develop separate standards and not simply use existing standards. This participant felt that the gaps enumerated in this theme and theme 3 support the urgency of developing standards specific to the Protocol because the existing international standards do not meet all the needs of Parties to address all the provisions of the Protocol. He felt that this was the purpose of paragraph 3 of Article 18 even though there was no time during the negotiations of the Protocol to ascertain the need for standards and to specify the modality for completing the negotiation process. He proposed a number of ideas to be used as the basis for conclusions and recommendations (see the list on page 23, below.)

A number of questions from the 'Ask an Expert' section of the Forum were relevant here.

QUESTION to Ms. Devorshak, IPPC Secretariat: Are standards for identification/documentation, packaging handling and transport of living modified organisms necessary, in IPPC's view? If so, what is the most appropriate and suitable modality to develop these standards? Can IPPC undertake this responsibility with respect to environmental protection and the conservation and sustainable use of biodiversity?

Ms. Devorshak began by explaining three points. She noted that the IPPC and its contracting parties can be understood as playing an important role in protecting biodiversity to the extent that protecting plant health (which is the purpose of the IPPC) is part of environmental protection and the conservation of biodiversity. Secondly, she described how the IPPC is primarily concerned with measures to protect plants from the introduction and spread of regulated pests (quarantine pests and regulated non-quarantine pests). IPPC defines a quarantine pest as "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled". She explained that this means that a country may put in place measures aimed at preventing the entry of new species that pose a threat to their plant life or health and noted that, as the IPPC considers 'economic importance' to include environmental damage, it takes environmental and biosafety concerns into account in the development of new ISPMs.

She elaborated that the IPPC considers that in cases where LMOs pose a phytosanitary risk, they would fit the definition of a 'pest' or 'quarantine pest' and would be subject to pest risk analysis and could be regulated as pests. In response to the question posed by the participant, Ms. Devorshak expressed the view that specific standards for identification/documentation, packaging, handling and transport for LMOs are probably not necessary as there are already ISPMs that provide specific guidance on these matters in relation to pests. She stated that where LMOs fit the criteria of 'pests' and have the potential to pose a phytosanitary risk, then such ISPMs (current and future) are applicable. She concluded by considering the issue of additional guidance in the form of standards. She noted that the IPPC works closely with international partners such as the CBD as well as with countries to identify what new standards need to be developed. She suggested that if countries

agree that additional guidance on identification/documentation, packaging, handling and transport is necessary, the issue can be addressed by the CPM and added to the work programme if agreed by the IPPC members.

QUESTION to Mr. Kervella, UNECE:

(a) What possible gaps do you see between the requirements of identification of LMOs under paragraph 2 of Article 18 of the Protocol and the recommendations in the relevant sections of the Model Regulations?

(b) What possible modalities exist that allow integration of the full range of requirements of the Biosafety Protocol with respect to the identification and handling of LMOs into the Model Regulations for GMOs that are already covered by the latter?

(c) Should the setting of standards with regard to handling, packaging and transport of LMOs be left to national measures altogether?

Mr. Kervella responded to the first question by noting that the Model Regulations only contain requirements that are intended to ensure safety during transport. He explained that if the use of GMOs or GMMOs is authorized for whatever purpose by countries concerned by the international transport, then the GMOs and GMMOs are not subject to transport regulations. In this case, he felt that the requirements of paragraph 2 of Article 18 of the Protocol are not covered by the UN Model Regulations. He stated that they could be but, for the time being, the experts of the UN Sub-Committee are not convinced that LMOs that are authorized for use require specific safety transport measures. He added that if Parties to the Protocol consider that specific safety transport requirements are needed, e.g. for emergency response, they should provide guidance to the Sub-Committee regarding the type of measures to be taken and the risk during transport. He suggested that if it is just a question of entering information in the transport document and the labelling or marking of packages, this should not be too difficult but it would require some inputs by countries interested in using the Model Regulations for meeting the requirements of paragraph 2 of Article 18.

He also noted that when GMOs/GMMOs possess other hazards (infectiousness or toxicity), they are only subject to the requirements for toxic or infectious substances but they are not required to be identified as GMOs or GMMOs. Mr. Kervella stated that feedback from the CBD Secretariat would be welcomed as regards the suitability for meeting the requirements of the Protocol of the forthcoming 16th revised edition of the Model Regulations if they had to apply, for example, to GMOs/GMMOs authorized for use.

He subsequently added information on revised requirements in the UNTDGs that will be reflected in international transport legal instruments from 1 January 2011. According to Mr. Kervella, under these revisions, documentation will no longer be required under transport regulations for GMOs/GMMOs packed in accordance with packing instruction P904, i.e. bearing a diamond-shaped mark with the indication 'UN 3245'.[12] Mr. Kervella felt that it was not clear in paragraph 2 of Article 18 whether the word 'accompanying' means that the documentation referred to in the paragraph would have to physically accompany the goods during transport or whether it could be transmitted by other means to the different actors involved (e.g. carriers, freight forwarders, customs authorities, etc.) He explained that the documentation required under the UN Model Regulations is mainly intended to provide information to certain specific entities: (a) the carrier to warn about the danger presented during transport so that it can comply with the appropriate safety regulations; (b) emergency services if immediate emergency action has to be taken in case of accidental release; and (c) control authorities if the danger is such that spot checks during transport to verify compliance with the safety requirements are deemed necessary. He felt that it would be useful to know the type and level of danger presented during the transport of living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP), LMOs for intentional introduction into the environment and LMOs for contained use to determine whether the information normally required to be entered in the transport document for transport of dangerous goods is also needed for LMOs. He concluded that if the documentation prescribed under Article 18 is not related to safety during transport

12 See pp. 12-13 of document UNEP/CBD/BS/ONLINE CONF-HTPI/1/2/Add.1.

but is mainly intended for the control of transboundary movement, then the Model Regulations and related instruments are not necessarily the best tools for implementing paragraph 2 of the Article.

In response to the second question, Mr. Kervella believed that it would be up to Parties to the Protocol to define what kind of transport conditions they would like to require for the carriage of LMOs. He stated that it would then be possible for the CBD Secretariat to ask the UN Sub-Committee to consider how to integrate these requirements into the Model Regulations in a manner that is consistent with requirements applicable to the carriage of dangerous goods.

Regarding the third question, Mr. Kervella explained that the purpose of the UN Model Regulations is to ensure safety during transport and at the same time to facilitate trade through harmonization of national and international regulations. He commented that it is clear that if standards are not the same in all countries, international transport becomes impossible as it is not practical to change packaging, labels, information in the transport document, etc., in the course of an international journey. He thus believes that international harmonization is necessary and leaving each country to develop its own national standards would render international transport impossible.

THEME 3: POSSIBLE GAPS—OBJECTIVE OF THE PROTOCOL, TYPES OF LMOS, SEGREGATION AND TRACEABILITY, THRESHOLDS

There were four discussion threads under this theme including a welcome message posted by the Secretariat.

Under one thread, a participant explored the distinction between adventitious presence and the language of 'may contain'. He stated that thresholds for 'may contain' language and adventitious presence appear to be similar concepts in that both allow for the possibility of a shipment containing LMOs but, in fact, they are different from each other. He explained that thresholds for adventitious presence are used where efforts have been made to segregate LMOs from non-LMOs whereas 'may contain' is applied to a shipment that contains products where there was no special effort to separate non-LMOs from LMOs at the harvest stage. He concluded that a shipment identified as 'may contain' is usually regarded as containing products of which over 90% are LMOs as opposed to one with an adventitious presence threshold which is accepted as not containing LMOs. He was of the opinion that a threshold for adventitious presence is not compatible with the use of 'may contain' language in a shipment.

Another participant responded by asking whether the specific gap or challenge for a Party to the Protocol is about how to implement the various standards that it may be obligated to follow. The intervention pointed to the case of India, which is looking to become a member of the OECD and will then need to comply with OECD standards in addition to its own national standards. The intervenor stated that the gap in India is in handling, identification and verification mechanisms and the country still needs to build its capacity in segregation and traceability, particularly at ports since bulk shipments arrive by sea. For other Parties such as Nepal, bulk imports would mostly arrive by road. He felt that Nepal would face the same gap should it decide to pass regulations for the labelling of imported GM food and feed but it may not be feasible for the country to do so.

Another participant started a discussion thread to address a question to the Secretariat. She described a limitation of the Protocol as being that it just covers living modified organisms whereas most genetically modified food and feed may not contain LMOs as such but have been produced from them. She wondered whether developing standards related to paragraph 3 of Article 18 is also just for the identification, handling, packaging and transport of LMOs rather than GMOs and how this problem can be solved.

The Secretariat responded by agreeing that the Protocol does not cover products derived from living modified organisms and that this exclusion was a result of a deliberate decision by the negotiators of the Protocol. The representative of the Secretariat stated that generally, products are outside the scope of the Protocol. However, relevant information regarding products is required to be made available to the BCH along with summaries of risk assessment or environmental reviews of living modified organisms. Such

information, required under paragraph 3(c) of Article 20 of the Protocol, is to be made available where appropriate. The paragraph also describes 'products thereof' as "processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology". The representative of the Secretariat explained that this means the information that should be made available, where appropriate, to the BCH, is only regarding products which fit this description.

In response to the question of how the problem could be solved, the representative of the Secretariat did not foresee the Protocol to be a possible venue to reopen this issue. The domestic sphere is always available for each country to take action that it believes to be more protective of biological diversity, taking also into account risks to human health. It is up to national governments to set regulatory requirements such as for the labelling of products derived from genetically modified organisms. He concluded that a Party that decides to take domestic measures must make sure that such measures are consistent with that Party's other obligations under international law.

THEME 4: CONCLUSIONS AND RECOMMENDATIONS

There were thirteen discussion threads created under theme 4. In one thread, an intervenor suggested that developed country Parties should provide financial means to the CBD Secretariat for the process of developing new agreed-upon standards for shipments of LMOs through a biosafety framework for all Parties. He stated that this would be useful for international cooperation and safe trade.

Another participant noted the usefulness of the discussions in the Forum and the complexity of the problem. She stated that cooperation and coordination of procedures with other international organizations and bodies is necessary to achieve unified regulation in this area and to avoid duplication of efforts. She noted that this is a very difficult and complex task that would require deep analysis and the involvement of experts, perhaps in the form of an *ad hoc* working group. The participant was of the view that the participation of representatives from the Secretariat in the meetings of corresponding international organizations could not only extend cooperation but potentially enable access to information and data that is otherwise restricted. Finally, she felt that even if international regulations were created, they would need to be completed by regulations at the national or regional level especially if these regulations are not mandatory or legally binding as experience to date with other conventions has shown.

One participant commented that, in regard to justifications for the administrative and technical expenses that would be involved in developing new standards, the development of internationally-agreed standards for shipments of LMOs would increase international trade and open the way for all countries to handle these products with confidence, secure in the knowledge that a legal framework is in place setting rules to protect human and animal health as well as the environment.

In response, another intervention highlighted the importance of the work of various organizations that have been involved in the elaboration of different standards concerning handling, transport, packaging, labelling and identification, namely the Codex Alimentarius Commission, IPPC, OECD, OIE, UNECE and FAO. The intervenor felt that it seems necessary to elaborate unified standards and guidelines under the Biosafety Protocol with regard to types of LMOs and their uses according to paragraph 2 of Article 18 (i.e. LMOs-FFP, LMOs for contained use and LMOs for intentional introduction into the environment.) She felt that the standards document should be agreed to by the Parties to the Protocol at a meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol and should be legally-binding. She noted that this would serve as a good basis for the development of national standards for transport, packaging, labelling and identification. She considered that the practical experience of the above-listed organizations would need to be taken into consideration. The intervenor proposed a working group be established that would serve as a collaboration instrument among Parties, the Secretariat and international standard-setting bodies and should take into account the views of all actors. She noted that it would be expedient to

use electronic means of information exchange such as the BCH. She recommended that the Secretariat facilitate cooperation between the Parties and standard-setting bodies in order avoid overlap and duplication in the field of standards, databases and activities in biosafety. She concluded that it would be good to develop capacity-building programmes to provide assistance to the Secretariat and countries to harmonize their national standards and regulations in compliance with the international requirements.

the goal of further discussions by the Parties under paragraph 3 of Article 18 should be to ensure awareness of existing requirements under other international agreements and organizations and to further create synergies and avoid duplication of efforts

In another discussion thread, a participant commented that the points raised during the Forum demonstrate that there are already a large number of international bodies of experts currently undertaking work on rules and standards with respect to the identification, handling, packaging and transport of goods, including LMOs. She noted that having experts from these other organizations participate in the Forum was very useful as it enabled participants to learn about the potential for collaboration among international organizations on this issue. In light of the existing work plan of the Parties to the Protocol and the limited budget for any new activities, she supported the suggestion that the Secretariat should establish formal contact with other organizations to support their work in building a comprehensive and non-redundant approach to standards for shipments of LMOs (see below.) She felt that this would allow the Parties to the Protocol to leverage the ongoing work by qualified experts in other international fora and avoid the duplication of resources and efforts.

The participant further suggested that the Secretariat continue its collaboration with IPPC, OIE, UNECE, etc. and when appropriate gaps are identified by the Parties, these gaps should be directed to those organizations already addressing identification, handling, packaging and transport. She felt that the goal of further discussions by the Parties under paragraph 3 of Article 18 should be to ensure awareness of existing requirements under other international agreements and organizations and to further create synergies and avoid duplication of efforts. She concluded that any further development or refinement of rules and standards for identification, handling, packaging and transport of LMOs could be referred to the organizations already addressing those matters.

Another participant responded to the above post by agreeing that establishing coordination with other relevant international organizations is important and necessary. He pointed to another post in the Forum where he had suggested additional organizations and UN treaty secretariats that should also be included in the coordination efforts. He then added the World Health Organization (WHO) and its Food Safety Department as another organization to cooperate with. The intervention suggested a number of things developing country Parties can do themselves: at the World Health Assembly, proposing a specific biosafety work programme for the WHO to undertake; using the Codex Trust Fund to enable their participation at Codex Alimentarius meetings; and persuading their national experts to volunteer for the various expert group meetings for which the WHO does not always have adequate experts, particularly from developing countries.

The response went on to pose a number of questions. He asked whether it was not clear from the discussions in the Forum that there are significant gaps and who would fill these gaps if not the Parties to the Protocol and the CBD Secretariat. He asked whether the mandates of other international organizations are not restricted to the scope of their own work, their treaty obligations and their member/Party needs that are not exactly the same as the provisions of the Protocol. He noted that not all countries can become members of some organizations such as the UNECE or the OECD and noted the challenges of Parties trading with non-Parties as is being experienced by Mexico. Finally, he asked whether there is not a limit to what one international organization can request another to do.

In one discussion thread, a participant noted that countries that are centres of origin and who work with open systems of seeds where seed exchange is

customary, have a large responsibility to protect and sustain biodiversity. She pointed to the example of Mexico which is the centre of origin for maize, a crop that is also subject to extensive manipulation. She felt that the responsibilities for countries of origin and diversification under the Protocol in terms of monitoring and controlling the dispersal of transgenes via LMOs-FFP become very complicated. The participant suggested that the help of the Secretariat in promoting closer communication between the actors involved in the trade of LMOs intended for direct use as food or feed, or for processing is crucial. She proposed that the Secretariat consider the possibility of coordinating a mechanism with other international institutions by which the training, information exchange and promotion of educational and communications opportunities could be a reality.

The participant also felt that the different views expressed during the Online Forum need to be reconciled with one another. She stated that efforts should not be spared to help countries that are centres of origin and diversity and countries in need of better monitoring systems. She concluded by stating that everyone should avoid duplication by joining forces in a level arena and let the Secretariat coordinate efforts/modalities for cooperation with other international organizations.

In a response, another participant pointed to coordination with Genøk on capacity-building needs as being useful.

Participants in different discussion threads made recommendations for further steps that could be undertaken in this area. One noted that the work done by various standard-setting bodies is laudable and could inform the elaboration of standards in the context of the Biosafety Protocol. He suggested that the CBD Secretariat could hold workshops, meetings and other forms of consultation with the relevant standard-setting organizations to prepare standards specifically on LMOs for the consideration of Parties to the Protocol. Another participant recommended that the Secretariat establish contact with international organizations like the International Seed Testing Association, ISO, CEN, the Codex Alimentarius Commission, IPPC and FAO through meetings, workshops, missions, etc. to ensure harmonization of standards for LMO shipments.

In another discussion thread, a participant pointed to the ideas from a 2004 conference that he felt clearly specified the details to consider as conclusions and recommendations for this Forum. In a separate post, the participant listed a number of ideas from the conference that could be used for the development of conclusions and recommendations:

- the need for standardized methods to test for agricultural biotechnology products is multi-faceted;
- standardization initiatives need to be coordinated;
- testing methods need to be publicly available;
- the challenges of standardization of methods and certified reference materials need to be addressed;
- detection methods need to be consistent and valid;
- different testing thresholds for unapproved and approved events;
- large sample sizes are important and required;
- testing needs to cover the entire supply chain;
- there are a number of capacity building needs in the fields of science, regional cooperation and law; and
- South-South cooperation needs to be strengthened through the creation of an interface organisation.

Mr. Dennis Stephens and Mr. Gary Martin posted a joint response on behalf of the International Grain Trade Coalition (IGTC). They noted that the issue of standards is also of great interest to the IGTC—a coalition of 22 trade organizations involving more than 8,000 companies operating in more than 80 countries involved in the production, handling, transport, export, import and processing of grains, oilseeds, pulses, special crops and their derived products. They commented that IGTC focuses on grain destined for food, feed or processing. They noted that trade in LMOs is not a new phenomenon, that these commodities have been deemed safe by governments for use as food or feed, or for processing and that they are not intended for intentional introduction into the environment.

They explained that IGTC members are not involved in performing risk assessments; instead, they accept the decisions of governments. They remarked that it is exporting and importing governments that approve LMOs for use as food or feed, or for processing and it is the grain industry's challenge to produce and move these approved products from

areas of surplus to areas of deficit in the most cost efficient manner possible.

Mr. Stephens and Mr. Martin noted that the IGTC is concerned that the development of a new international standard for products produced through modern biotechnology would create further complexity in the handling, transport and documentation of LMO commodities for food, feed or processing. They described how this increase in complexity would increase costs and inhibit trade and the utilization of crop biotechnology. They expressed the view that this would be dramatically negative to the sustainable provision of food, energy and economic security at a time when economies are already challenged by increasingly scarce land and water resources and a rapidly expanding global population.

IV. Summary of recommendations

The working document on paragraph 3 of Article 18 that was prepared for COP-MOP 5 included a summary of the recommendations from participants in the Online Forum. Many of the recommendations touched on similar themes:

(A) STANDARDS SHOULD BE DEVELOPED UNDER THE PROTOCOL

(i) A special standard for the handling, transport and packaging of LMOs under paragraph 3 of Article 18 is needed. Parties and the Secretariat should provide guidance towards ensuring international harmonization;

(ii) The gaps enumerated in themes 2 and 3 support the urgency of developing standards specific to the Protocol because the existing international standards do not meet all the needs of Parties to address all the provisions of the Protocol;

(iii) It is necessary to elaborate comprehensive legally binding standards under the Protocol;

(iv) Standards should be set by a group of international experts in different LMO-related fields as well as the Parties to the Biosafety Protocol;

(v) Unified standards and guidelines under the Biosafety Protocol should be elaborated with regard to types of LMOs and their uses according to paragraph 2 of Article 18 (i.e. LMOs intended for direct use as food or feed, or for processing; LMOs for contained use and LMOs for intentional introduction into the environment.) The standards document should be agreed to by the Parties to the Protocol at a meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol and should be legally-binding;

(vi) Developed country Parties should provide financial means to the Secretariat of the Convention on Biological Diversity for the process of developing new agreed-upon standards for shipments of LMOs through a biosafety framework for all Parties;

(vii) A special standard under paragraph 3 of Article 18 could take the form of guidance on how to use the existing international regulations and standards and such a guideline should be prepared by stakeholders in and experts on the Protocol;

(viii) A working group under Article 18 could act as a coordinator for existing or future standards. The working group should work exclusively on standards for the shipment, handling and packaging of LMOs, including collecting the guidelines, acts or standards that can be applied in the shipment of LMOs;

(B) COOPERATION WITH OTHER RELEVANT ORGANIZATIONS IS NEEDED, INCLUDING BY REFERRAL OF GAPS IN STANDARDS AND RECOMMENDATIONS

(ix) The Parties to the Protocol should identify safety needs and requirements and provide guidance for the Convention Secretariat to convey to the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods on which requirements should be integrated into the Model Regulations;

(x) The Convention Secretariat could hold workshops, meetings and other forms of consultation with the relevant standard-setting organizations to prepare standards specifically on LMOs for the consideration of Parties to the Protocol;

(xi) It is recommended that the Secretariat facilitate cooperation between the Parties and standard-setting bodies in order avoid overlap and duplication in the field of standards, databases and activities in biosafety;

(xii) The Secretariat should establish formal contact with other organizations to support their work in building a comprehensive and non-redundant approach to standards for shipments of LMOs;

(xiii) The Secretariat should continue its collaboration with IPPC, OIE, the United Nations Economic Commission for Europe, etc., and when gaps are identified by the Parties, these gaps should be directed to those organizations already addressing identification, handling, packaging and transport;

(xiv) The development of standards on the shipment, handling and packaging of LMOs should be referred to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology;[13]

(xv) It is recommended that the Secretariat establish contact with international organizations like the International Seed Testing Association, ISO, CEN, the Codex Alimentarius Commission, IPPC and FAO through meetings, workshops, missions, etc. to ensure harmonization of standards for LMO shipments;

(xvi) The Secretariat should enter into a memorandum of understanding with ISO, CEN and the International Seed Testing Association in order to obtain observer status at their meetings, gain access to the standards and perhaps also be involved in the implementation of standards;

(xvii) Participation of representatives from the Secretariat in the meetings of corresponding international organizations could not only extend cooperation but potentially enable access to information and data that is otherwise restricted;

(xviii) The IPPC and the Biosafety Protocol could cooperate on the development and use of specific terminology;

(xix) The creation of a special permanent working group responsible for cooperative relationships could become an instrument for cooperation and the creation of synergies among the international standard-setting organizations and the CBD Secretariat for coordinating activities such as the elaboration of databases, information exchange systems such as the BCH, the development of standards and ensuring the segregation and traceability of LMOs that are the subject of transboundary movements;

(xx) A working group should be established that would serve as a collaboration instrument among Parties, the Secretariat and international standard-setting bodies and should take into account the views of all actors. It would be expedient to use electronic means of information exchange such as the BCH;

(xxi) Cooperation and coordination of procedures with other international organizations and bodies is necessary to achieve unified regulation in this area and to avoid duplication of efforts. This is a very difficult and complex task that would require deep analysis and the involvement of experts, perhaps in the form of an *ad hoc* working group;

(C) THE QUESTION OF STANDARD SETTING SHOULD BE LEFT TO ACTION AT THE NATIONAL LEVEL

(xxii) The issues of (a) whether, regarding standards or criteria for shipments of LMOs, it is better for each country to identify those standards that are in line with its situation or to set global standards agreed upon by all Parties; and (b) if each country has the right to develop its own standards, what standards may need to be consulted, should be taken into account at the next meeting of the Parties to the Protocol;

(xxiii) There is no need to pursue discussions regarding standards under paragraph 3 of Article 18 of the Protocol;

13 The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology completed its mandate in 2007 and no longer meets.

(D) CAPACITY-BUILDING AND EXCHANGE OF INFORMATION ON STANDARDS ARE NEEDED

(xxiv) The Secretariat should consider the possibility of coordinating a mechanism with other international institutions by which the training, information exchange and promotion of educational and communications opportunities could be a reality;

(xxv) Capacity-building programmes could be developed to provide assistance to the Secretariat and countries to harmonize their national standards and regulations in compliance with the international requirements;

(xxvi) Parties and the Secretariat should provide guidance and requirements of the Model Regulations to ensure international harmonization;

(xxvii) Detailed molecular information is needed in order to perform post-market monitoring of GM maize imports;

(xxviii) There should be regional exchanges of information among laboratories on the use of detection methods and standards;

(xxix) The Biosafety Clearing-House should include a dedicated site for the exchange of information on issues such as target sequences for developing detection methods for new commercial events and movements of harvested GMOs that might be exported.

V. Decision BS-V/9

As a result of the discussions during the Online Forum and deliberations during COP-MOP 5, the Parties adopted decision BS-V/9.

BS-V/9. HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS: PARAGRAPH 3 OF ARTICLE 18

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling paragraph 3 of Article 18 of the Protocol on the consideration of the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for transboundary movements of living modified organisms,

Recalling also its decision BS-IV/10,

Welcoming the outcomes from the Online Forum on Standards for Shipments of Living Modified Organisms,

1. *Requests* the Executive Secretary to:

(a) Continue following developments in standards related to the handling, transport, packaging and identification of living modified organisms and to report to the Parties at their sixth meeting on any such developments. The report should include information on developments in standard-setting on the sampling and detection of living modified organisms;

(b) Disseminate the results of the Online Forum on Standards for Shipments of Living Modified Organisms, including information about potential gaps in international standards, to relevant organizations;

(c) Organize regional workshops for: (i) heads of laboratories involved in the detection of living modified organisms to exchange information and experience on the implementation of relevant standards and methods; and (ii) customs officers requiring capacity in the sampling and detection of living modified organisms further to paragraph 10 of decision BS-III/10 and paragraph 3 of decision BS IV/9;

(d) Commission a study to analyse information on existing standards, methods and guidance relevant to the handling, transport, packaging and identification of living modified organisms and to make the study available for consideration by the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. This study should address in particular:

(i) Possible gaps in existing standards, guidance and methods;

(ii) Ways to facilitate cooperation with relevant organisations;

(iii) Guidance on the use of existing international regulations and standards;

(iv) The possible need for the elaboration of standards for handling, transport, packaging and identification of living modified organisms;

2. *Invites* standard-setting bodies to form an electronic communications group with the Secretariat of the Convention on Biological Diversity to exchange information on activities relevant to the handling, transport, packaging and identification of living modified organisms being undertaken in each forum;

3. *Invites* the International Plant Protection Convention to collaborate with the Secretariat of the Convention on Biological Diversity in the development of an explanatory document on the terminology of the Protocol in relation to the glossary of phytosanitary terms adopted by the Commission on Phytosanitary Measures;

4. *Requests* Parties and encourages other Governments and relevant organizations, as appropriate, to make available to the Biosafety Clearing-House information on:

(a) Standards relevant to the handling, transport, packaging and identification of living modified organisms;

(b) Existing guidance on the use of relevant international standards;

(c) Methods for the detection and identification of living modified organisms;

5. *Invites* Parties to nominate national and international reference laboratories with the view to establishing, through the Biosafety-Clearing House, an electronic network of laboratories to facilitate the identification of living modified organisms as well as the sharing of information and experiences.

Summary of standards and standard-setting bodies relevant to the handling, transport, packaging and identification of living modified organisms

I. Introduction

In decision BS-III/9, the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to gather information on existing rules and standards relevant to Article 18 and to make the information available at the fourth and fifth meetings of the COP-MOP. A background document compiling information on relevant standards and standard-setting processes was also prepared to aid the deliberations in the online forum. The information below is an updated version of the document prepared for COP-MOP 5 (document UNEP/CBD/BS/COP-MOP/5/INF/6).

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 and to report to the Parties at their sixth meeting on any such developments. The information below will thus be updated as necessary for COP-MOP 6.

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

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.

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)).

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

- the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology;
- the Codex Committee on Food Labelling;
- the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding;
- the Codex Committee on General Principles;
- the Codex Committee on Food Import and Export Inspection and Certification Systems; and
- the Codex Committee on Methods of Analysis and Sampling.

A. CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

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";[14] (ii) "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants";[15] and (iii) "Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms"[16].

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.[17] 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.

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."[18]

At its twenty-seventh session, held in Geneva from 28 June to 3 July 2004, the Codex Alimentarius Commission agreed to establish a new *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology with the understanding that the Task Force's final report should be sub-

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

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

16 CAC/GL 46-2003.

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

18 "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.

mitted 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";[19] (ii) an annex on "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits";[20] 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"[21]. 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

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

The 62nd and 63rd sessions (held in 2009) of the Executive Committee of the Commission discussed progress on the definitions and Proposed Draft Recommendations and noted the 2011 deadline that the Codex Committee on Food Labelling had set for the completion of the work. If the Committee does not meet the deadline, the Executive Committee has agreed to recommend corrective action.

At the 38th session of the Codex Committee on Food Labelling (held in May 2010), the Committee agreed to circulate revised proposals on the definitions and the Proposed Draft Recommendations at step 6 for comments and consideration by the next session. The Committee also accepted an offer from the European Union "to host a facilitated work session in Brussels in the three working languages that would be chaired by Ghana and facilitated by the chair of CCFL with the goal of exploring the objectives of different delegations and reconcil[ing] them in one text if possible."[22]

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). According to the project document, the work would cover such things as the origin of the stock of aquaculture animals, husbandry practices and breeding, feed and the separation of organic and non-organic production. The project document proposes that the work begin in 2010 with a view to adoption by the Commission within four years. The work was approved by the 33rd session of the Codex Alimentarius Commission (2010).

C. CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANIMAL FEEDING

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"[23]. The Code provides guidance for developing a feed safety system for food producing animals.

19 CAC/GL 68-2008.

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

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

22 "Report of the Thirty-Eighth Session of the Codex Committee on Food Labelling", UN Doc. ALINORM 10/33/22 (May 2010) at para. 159.

23 CAC/RCP 54-2004.

The Code focuses on consumer health issues in line with the Codex mandate, but it does also include animal health and environmental considerations.

An earlier draft of the Code had allowed for competent authorities to decide that feed and feed ingredients "consisting, containing or produced from GMOs" should be labeled.[24] 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."[25]

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).

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 enables the correct feed to be sent to the right animal group."

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."

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.

At its 33rd session, the Codex Alimentarius Commission again established an *Ad Hoc* Intergovernmental Task Force on Animal Feeding. The extent to which the work to be undertaken by this Task Force may relate to living modified organisms is currently unclear.

> "Traceability/product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution."

D. CODEX COMMITTEE ON GENERAL PRINCIPLES

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

24 "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.
25 CAC/RCP 54-2004 at footnote 5.

distribution." The definition was then forwarded to the Codex Alimentarius Commission at its twenty-seventh session, held in 2004, where it was adopted and included in the Procedural Manual.

E. CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Following the adoption by the Codex Alimentarius Commission of the definition of "traceability/product tracing", the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its thirteenth session, in December 2004, started new work to develop the principles on traceability/product tracing in the context of food import and export inspection and certificate systems. The "Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System"[26] were subsequently adopted at the twenty-ninth session of the Commission, in July 2006.

> there was insufficient information to clearly identify gaps and needs in relation to the implementation of traceability/product tracing

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 intersessionally 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 Committee 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.

F. CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

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.

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

Also at its twenty-ninth session, CCMAS agreed to circulate at Step 3 the Proposed Draft Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology as they stood at that point.

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 Committee also agreed to change the structure and outline of the draft guidelines. It returned the text to Step 2 and established an electronic working group to revise the proposed draft guidelines. The revised text was to be circulated for comments at Step 3 and consideration at the next session of CCMAS.

26 CAC/GL 60-2006.

A report from the electronic working group was presented during the 31st session of CCMAS held in March 2010. The Committee noted the unusually large number of participants in the development of the guidelines which it felt indicated the importance and relevance of the document. The proposed draft guidelines were discussed and revised and the Committee agreed to forward them to the 33rd session of the Codex Alimentarius Commission for adoption at Step 5/8.

The 33rd session of the Codex Alimentarius Commission was held in July 2010 and 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".[27] 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.

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.

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.

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

A. INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

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

ISPM No. 12: Guidelines for phytosanitary certificates (2001)

ISPM No. 12 elaborates principles and guidelines for preparing and issuing phytosanitary certificates following the model certificates contained in the Annex to the IPPC. The ISPM states that phytosanitary certificates "should include only information related to phytosanitary matters. They should not

27 CAC/GL 74-2010.

include statements that requirements have been met and should not include references to animal or human health matters, pesticide residues or radioactivity, or commercial information such as letters of credit" (section 2). The ISPM does allow for attaching a note to the phytosanitary certificate to associate the certificate with the symbol or code of other relevant documents 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 of the product in the consignment should be specified in the phytosanitary certificate as different phytosanitary requirements may apply to different end uses (e.g. consumption versus propagation.)

> phytosanitary certificates "should include only information related to phytosanitary matters. They should not include statements that requirements have been met and should not include references to animal or human health matters, pesticide residues or radioactivity, or commercial information such as letters of credit"

ISPM No. 7: Export certification systems (1997)

This ISPM describes the components of a national system for the issuance of phytosanitary certificates. It provides that each national plant protection organization should maintain guidance documents, procedures and work instructions covering every aspect of the certification system including sampling, inspection and verification procedures and consignment identification, traceability and security (section 4.3). Section 4.5 of the standard states that "[c]onsignments and their certification should be traceable as appropriate through all stages of production, handling and transport to the point of export."

ISPMs 7 and 12 were jointly revised beginning in 2006 in order to reduce duplication between the two standards and provide more clarity. The revised ISPMs were presented to CPM-6 in March 2011 for adoption. The structure and content of the proposed revised ISPM 7 are very similar to the 1997 version and the changes do not appear to be relevant here. The proposed revised ISPM 12 has quite a few changes compared to the 2001 version, including additional information on the types and forms of phytosanitary certification. The proposed revised ISPM 12 also contains guidance regarding the use of electronic phytosanitary certificates—known as Phyto eCert—and indicates that an appendix on electronic certification is under development.

Phyto eCert is defined at the IPPC as "the authenticated and secure electronic transmission of phytosanitary certification data, including the certifying statement, from the National Plant Protection Organization (NPPO) of the exporting country to the NPPO of the importing country."[28] As discussed at CPM-5 and in the Phyto eCert work programme adopted by the meeting, this would involve developing the standard (both the technical/programming and business aspects) by which Phyto eCert would function. The IPPC is planning a Working Group meeting on Phyto eCert to be held in April 2011. The Phyto eCert concept was first developed by the North American Plant Protection Organization with the involvement of other interested countries. See the section on UN/CEFACT, below, for more information on standards related to the electronic and internet-based exchange of trade information.

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)

This ISPM provides additional guidance relevant to the transport, handling and documentation of living

28 "Report of the Fifth Session of the Commission on Phytosanitary Measures", UN Doc. CPM-5 (2010)/REPORT (March 2010) at appendix 18.

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)

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)

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.

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).

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)

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).

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.

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

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. According to the IPPC Standard Setting Work Programme adopted during CPM-5 (held in March 2010), the standard is pending the results of an open-ended workshop (discussed below) and is to be drafted by an expert working group.

> The tasks for the workshop on the international movement of grain include … considering and discussing the relevance of other specific issues such as deviation from intended use

CPM-4 agreed that an open-ended workshop on the international movement of grain should be convened. The Government of Canada has undertaken to organize the workshop, which is tentatively planned for September 2011. Terms of reference for the workshop were drafted and reviewed by the IPPC Standards Committee in May 2009, were approved by the CPM Bureau in June 2009 and were noted by CPM-5. The terms of reference specify that the workshop "should 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."[29] The tasks for the workshop include:

- considering the relevance of existing ISPMs and clarifying whether further specific harmonized guidance for the international movement of grain is considered necessary to minimize the risk of introduction of quarantine pests;
- considering and discussing the relevance of other specific issues such as deviation from intended use;
- exploring the need and feasibility of harmonized recommendations for phytosanitary requirements for some types of grain moved internationally; and
- where possible, developing common conclusions.

Other standards that are proposed in the IPPC Standard Setting Work Programme from CPM-5 that could be of relevance to the handling, transport, packaging and identification of LMOs include:

- plants for planting;
- international movement of forest tree seeds;
- import of plant breeding material;
- minimizing pest movement by sea containers and conveyances;

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

- minimizing pest movement by air containers and aircrafts;
- guidelines for the movement of used machinery and equipment; and
- international movement of seed.

The IPPC has drafted a specification for the standard on minimizing pest movement by sea containers and conveyances in international trade. An expert working group will be convened to draft the standard. The Secretariat of the Convention on Biological Diversity has been invited to nominate an expert to participate in relevant parts of the meetings of the expert working group. Discussions are currently taking place electronically and a meeting of experts is tentatively scheduled to take place in New Zealand at the end of 2011.

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.[30]

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.

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.

> 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 IPPC has also prepared a draft specification for the development of an ISPM on the international movement of seed. According to the draft specification, 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 may be applied at seed harvest, seed extraction, during post-harvest seed processing, and on arrival, testing and inspection. … 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."

The draft 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";

30 International Plant Protection Convention, "Minimizing pest movement by sea containers and conveyances in international trade", Specification n. 51 for ISPM (no date).

- 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.

The draft specification has been sent for member comments.

C. REGIONAL PHYTOSANITARY ORGANIZATIONS: THE NORTH AMERICAN PLANT PROTECTION ORGANIZATION

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

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).

The risk management measures in module 2 on confined release into the environment specify information requirements related to handling, disposal, record keeping and other considerations. These requirements should include adequate identification, packaging and segregation measures to prevent seed mixing, spillage and dispersal into the environment during transit; and the devitalization of surplus seed or seeds and any viable transgenic plant material remaining at the confined field site. Transgenic material harvested from the confined field site can only 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).

The Biotechnology Panel of NAPPO is currently considering whether to revise RSPM No. 14.

IV. World Organisation 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*, the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Aquatic Animals*. The standards are aimed at preventing the introduction of infectious agents and diseases through international trade in animals.

In similar fashion to the Codex Alimentarius Commission and the IPPC, 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.[31]

> 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 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*).

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

As mentioned, the Terrestrial Animal Health Standards Commission is responsible for the Terrestrial Code. In recent years, the Terrestrial Animal Health Standards Commission carried out an extensive re-organization of the Terrestrial Code which was reflected in the 2008 version. The Terrestrial Code has been divided into two volumes: volume one contains recommendations that apply to a wide range of species, production sectors or diseases ('horizontal standards') while volume two contains recommendations on specific diseases ('vertical standards').

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

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

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

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

The Working Group on Animal Production Food Safety was established in 2002 "with a view to strengthening the OIE's activities in the food safety area and further developing collaboration with the

31 "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.

Codex Alimentarius Commission."[32] The Working Group established an *ad hoc* Group on Identification and Traceability of Live Animals that has been meeting since June 2005. The *ad hoc* Group developed "General principles on the identification and traceability of live animals" that were adopted at the 74th General Session of OIE's International Committee held in May 2006 and are now chapter 4.1 of the Terrestrial Code. It also developed standards on the "Design and implementation of identification systems to achieve animal traceability" which were adopted at the 76th General Session in May 2008 and are now chapter 4.2 of the Terrestrial Code.

As its title suggests, the provisions in chapter 4.1 provide general principles on the identification and traceability of live animals.[33] 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.

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).

At its January 2008 meeting, the *ad hoc* Group on Identification and Traceability of Live Animals concluded that it had accomplished the mandate it had been given. The *ad hoc* Group did recognize, though, "that additional guidelines may need to be developed to address some specificities relevant to the issue of biotechnology derived animals."[34]

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.

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

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.

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

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

33 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/.

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

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.

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.[35]

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).

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

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

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.

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.

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.

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.

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.

An *ad hoc* Group on Laboratory Animal Welfare and an *ad hoc* Group on the Use of Animals in Research and Education drafted a chapter on the "Use of Animals in Research and Education" which was adopted at the 78th General Session of the OIE held in May 2010. 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).

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).

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).

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).

At its ninth meeting, the Working Group on Animal Welfare noted that there is no work currently underway in relation to animals produced using biotechnology. The Group agreed to keep a watching brief on this issue.

> 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.

B. BIOLOGICAL STANDARDS COMMISSION

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.

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.

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.

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.

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.[36]

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 16th revised edition.

The Model Regulations were created to facilitate direct integration of requirements into all modal,

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

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.[37] The Model Regulations are amended every two years as necessary to take into account technological developments as well as the advent of new substances and materials, the exigencies of modern transport systems and, above all, the requirements to ensure the safety of people, property and the environment.

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).

> 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.

A. CLASSIFICATION SYSTEM OF THE MODEL REGULATIONS

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.

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").

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. 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."[38] 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.

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.

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

37 *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations*, 16th revised edition, UN Doc. ST/SG/AC.10/1/Rev.15 (Vol. I) at iii.

38 *Ibid.* at para. 2.6.3.2.2.1.

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.[39] 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

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.

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.

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 micro-organisms 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.

There are also a number of regional inland transport agreements that follow the Model Regulations. In Europe, these include:

- the *European Agreement concerning the International Carriage of Dangerous Goods by Road* (ADR);
- the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)[40]; and
- the *European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways* (ADN).

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

39 Note that for ADR, RID and ADN (see the full titles and descriptions 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.

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

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.

The Universal Postal Union (UPU) largely follows the ICAO Technical Instructions and the IATA Dangerous Goods 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).

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.

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).

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.

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

- 2 or 3 alphanumeric digits to designate the applicant;
- 5 or 6 alphanumeric digits to designate the transformation event; and

- 1 numerical digit for verification (this is intended to reduce errors by ensuring the integrity of the alphanumeric code.)

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

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).

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.

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

The Harmonized System is a structured nomenclature comprising a series of 4-digit headings, most of which are further subdivided into 5- and 6-digit subheadings. For the purposes of tariff classification, the Harmonized System also provides a legal and logical structure within which a total of 1,221 headings are grouped in 96 Chapters, the latter being themselves arranged in 21 Sections. Each heading of the HS is identified by a 4-digit code, the first two digits of which indicate the Chapter wherein the heading appears, while the latter two digits indicate the position of the heading in the Chapter. The HS Nomenclature 2007 Edition comprises a total of 5,051 separate groups of goods identified by a 6-digit code. 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".

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).

Living modified organisms are not provided for separately in the HS Nomenclature 2007 Edition, nor did they form part of the fourth general review of the HS which was completed in March 2009 (see hereafter). Some countries do, though, use the HS codes for identifying and tracking shipments of LMOs. See box 2 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.

BOX 2

In September 2005, the Mexican Ministry of the Economy, the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food Supply, the Mexican National Service for Agri-Food Health, Safety and Quality, and the Customs Administration under the Ministry of Finance adopted a "Pilot programme dealing with the documentation accompanying imports of yellow maize intended for direct use as food or feed, or for processing". The objective of the pilot programme was to enable the identification of imports of yellow maize which may contain LMOs and make it possible to track them from their entry into the country to their final destination to ensure the maize did not enter the environment.

One step in the pilot programme involved the importer receiving the shipping documents for admission of the yellow maize to Mexico from the point of shipment. These documents were to include the invoice with the customs code 100595003, which consists of the six-digit HS code for 'maize–other' plus a national code forming a specific code for yellow maize. As yellow maize is primarily used for animal feed in Mexico, the customs code implicitly indicates that the imported product is not seeds for sowing.

The pilot programme was revised in 2009 but it continues to use customs codes to help identify imports of yellow maize that may contain LMOs.

For more details, see the relevant document prepared for COP-MOP 5: "Handling, transport, packaging and identification of living modified organisms: Synthesis of information on experience gained with the implementation of requirements related to paragraph 2 (a) of Article 18", UNEP/CBD/BS/COP-MOP/5/8, http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-08-en.pdf.

The original submission from Mexico can be found in: "Handling, transport, packaging and identification: Compilation of submissions on experience gained with the implementation of requirements related to paragraph 2 (a) of Article 18", UNEP/CBD/BS/COP-MOP/5/INF/5, http://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-05-en.pdf.

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.

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

VIII. United Nations Centre for Trade Facilitation and Electronic Business

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 harmonisation of processes, procedures and information flows, and so contribute to the growth of global commerce. UN/CEFACT is part of the UNECE.

In 1973, UN/CEFACT adopted Recommendation No. 1, "United Nations Layout Key for Trade Documents". The Layout Key is also a joint standard with the International Organization for Standardization (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).

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.

> 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.

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 import, export, and transit-related regulatory requirements. If information is electronic, then individual data elements should only be submitted once."[41]

The Recommendations and Guidelines focus largely on the form a single window might take, steps in establishing a single window and background infor-

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

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

mation 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.

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 is exchanged as part of international trade.[42] 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.

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[43] 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.

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.

42 Version 10A of the Core Component Library is available from the UN/CEFACT website: http://www.unece.org/cefact/codesfortrade/unccl/CCL10A.xls.

43 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.

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.

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*.[44] 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".

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.[45]

The Hague-Visby Rules address, amongst other things, the responsibilities of carriers of goods and to the extent that such responsibilities are relevant to the handling, transport, packaging and identification of LMOs, the Hague-Visby Rules are relevant here. It should be noted, however, that the definition of "goods" in the Hague-Visby Rules excludes live animals (Art. I(c)).

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

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)).

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)).

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.

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

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

45 As of 24 March 2011, there was one ratification and 23 signatures to the Convention. The Convention requires 20 ratifications, acceptances, approvals or accessions in order to enter into force (Article 94(1)).

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.

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.[46] Article 36 sets out the contract particulars that must be included in the transport document. These particulars include a description of the goods, the leading marks necessary for identification of the goods and a statement of the "apparent order and condition of the goods" at the time the carrier receives them (Art. 36(2)(a)). Paragraph 4 of the Article elaborates on the latter phrase, stating that it means the order and condition of the goods based on:

(a) A reasonable external inspection of the goods as packaged at the time the shipper delivers them to the carrier or a performing party; and
(b) Any additional inspection that the carrier or a performing party actually performs before issuing the transport document or electronic transport record.

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.

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

X. Standard Form Contracts for Shipments of Grain

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.

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.

In the case of NAEGA number 2,[47] 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."[48] 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 character-

47 "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.
48 *Ibid*. at section 6.

istics 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).

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

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.

There are a large number of other standard form contracts besides the GAFTA and NAEGA contracts described above. GAFTA maintains over 70 other 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.

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 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.

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%."[50] 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.

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%."[51] 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

49 *Ibid*. at section 7.

50 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.

51 *Ibid*. at p. 2.

presence of approved events of 0.9%."[52] Finally, the third declaration would apply in situations where the company supplying the commodity has a quality assurance program in place to verify the variety or varieties of the grain in question. This declaration reads: "This commodity has been received into and stored in facilities run by a company which operates under an independently audited QA program. This commodity is of known varieties that are not known to contain any approved genetically modified material in excess of the allowed adventitious presence of approved events of 0.9%."[53]

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

XI. Private standards

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

A. INTERNATIONAL SEED FEDERATION

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"[54] which are intended to clarify and standardize contractual relations between buyers and sellers.

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.

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).

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 changes (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)).

> Article 39 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.

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.

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

52 *Ibid.*
53 *Ibid.*
54 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/Trade%20Rules_2009.pdf.

intended for intentional introduction into the environment (Art. 18.2(b) and (c)).[55]

B. NON-GMO PROJECT

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'.

A few key points of the standard may be noted.[56] 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).

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).

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).

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

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55 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.

56 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.

Annex I

THEME 1: EXISTING STANDARDS AND STANDARD-SETTING BODIES

- What relevant standards with regard to handling, transport, packaging and identification of living modified organisms already exist?
- What other international organizations are or may be involved in developing standards with regard to identification, handling, packaging and transport practices that are relevant to the different categories of LMOs addressed by the Cartagena Protocol on Biosafety?
- What types of LMOs could be shipped under the guidance or recommendations of the following organizations?
  (a) United Nations Sub-Committee of Experts on the Transport of Dangerous Goods?
  (b) International Maritime Organization?
  (c) International Civil Aviation Organization?
  (d) International Air Transport Association?
  (e) International Plant Protection Convention (IPPC)?
  (f) World Customs Organization (WCO)?
  (g) Organization for Economic Cooperation and Development?
  (h) Codex Alimentarius Commission?
  (i) World Organization for Animal Health (OIE)?
- What are some examples of national governments or regional entities that have developed standards with regard to identification, handling, packaging and transport practices that are relevant to the different categories of LMOs addressed by the Protocol?
- How have different countries implemented the biosafety-related standards set by relevant organizations?

THEME 2: POSSIBLE GAPS—GENERAL

- What types of gaps may exist in the current set of standards that relate to the handling, transport, packaging and identification of LMOs? For example, are there gaps in the scope of the subject matter that is covered by existing standards? Or are there gaps in the capacity to implement existing standards? Please provide and discuss concrete examples where possible.*
- Where do the Protocol's rules regarding the handling, transport, packaging and identification of living modified organisms end and the measures of other international organizations regarding the handling, transport, packaging and identification of food derived from genetically modified organisms begin?

THEME 3: POSSIBLE GAPS—OBJECTIVE OF THE PROTOCOL, TYPES OF LIVING MODIFIED ORGANISMS, SEGREGATION AND TRACEABILITY, THRESHOLDS

- Do existing standards contribute to achieving the objective of the Protocol?
- Are all types of LMOs covered by the Protocol addressed by relevant existing standards?
- How can the segregation and traceability of LMOs that are subject to transboundary movement be ensured? Seeing as many LMO shipments are authorized for several uses, how can we determine which portions of the shipment are for human consumption, animal consumption or planting?
- Does the phrase "may contain" in paragraph 2(a) of Article 18 of the Protocol make it necessary to

* This question was developed by the Secretariat.

establish a threshold for the presence of LMOs in a shipment? According to which criteria would such a threshold be established? How will the issues concerning increased costs and increased trade barriers be handled?

THEME 4: CONCLUSIONS AND RECOMMENDATIONS

- If there are identified gaps, what modalities are available to fill those gaps? Which organizations may be appropriate to address these gaps?
- Should the consideration of standard-setting in the context of the Protocol be limited to the requirement for the identification of LMOs? If so, do the requirements in paragraph 2 of Article 18 and the relevant decisions of the governing body of the Protocol not already constitute such standards?*
- Is the development of new standards a justifiable administrative and technical expense?
- How can the Parties leverage the work ongoing in other international fora to take advantage of the expertise present in these fora and to avoid duplication of resources and efforts?
- A number of standard-setting organizations (e.g. IPPC, WCO, OIE) have expressed a need or a willingness to cooperate with the Protocol on issues of mutual relevance. Similarly, the Parties to the Protocol have requested the Executive Secretary to cooperate with these organizations. How might this be translated into practice?*
- How can the Executive Secretary further establish cooperative relationships with the relevant international bodies working in the areas of developing standards with regard to identification, handling, packaging and transport practices in order to ensure that any relevant concerns and/or gaps identified by the Parties are appropriately addressed?

* This question was developed by the Secretariat.

* This question was developed by the Secretariat.

Annex II

Statistical information on participation in the online forum	
Registered participants	81
Duration	3 weeks
Posts	104
26 of 81 participants posted in the Forum	32%

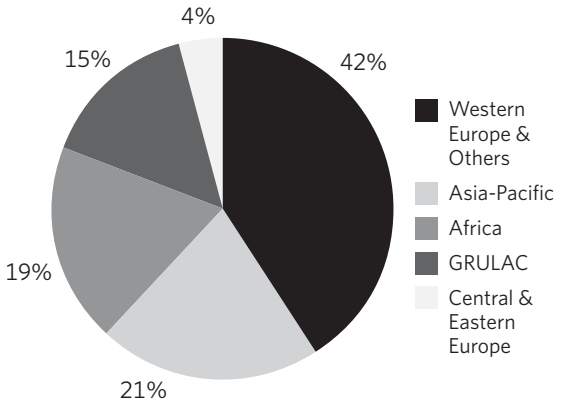


FIGURE 1: Regional breakdown of Forum participants

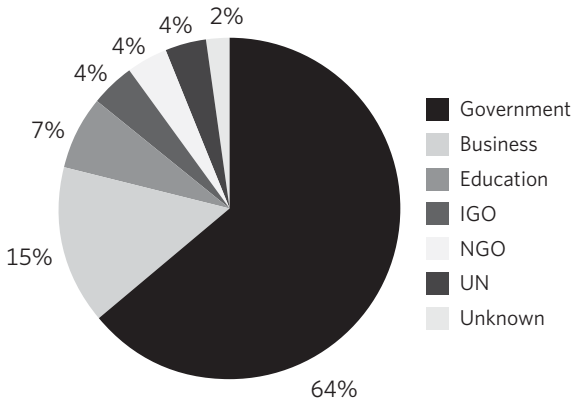


FIGURE 2: Sectoral breakdown of Forum participants

Annex III

List of Acronyms	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CEN	European Committee for Standardization
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP-MOP	Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
CPM	Commission on Phytosanitary Measures
FAO	Food and Agriculture Organization of the United Nations
GAFTA	Grain and Feed Trade Association
GE	Genetically engineered
GISPA	Grain Inspection, Packers and Stockyards Administration
GM	Genetically modified
GMOs	Genetically modified organisms
GMMOs	Genetically modified micro-organisms
GTA	Grain Trade Australia
HS	Harmonized Commodity Description and Coding System
IATA	International Air Transport Association
IBC	Intermediate bulk container
ICAO	International Civil Aviation Organization
IGTC	International Grain Trade Coalition
IMO	International Maritime Organization
IPPC	International Plant Protection Convention
ISF	International Seed Federation
ISO	International Organization for Standardization
ISPMs	International Phytosanitary Measures
LMOs	Living modified organisms
LMOs-FFP	Living modified organisms intended for direct use as food or feed, or for processing
MOU	Memorandum of understanding

NAEGA	North American Export Grain Association
NAFTA	North American Free Trade Agreement
NAPPO	North American Plant Protection Organization
NPPO	National plant protection organization
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RSPMs	Regional Standards for Phytosanitary Measures
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
UN/CEFACT	United Nations Centre for Trade Facilitation and Electronic Business
UNCITRAL	United Nations Commission on International Trade Law
UNECE	United Nations Economic Commission for Europe
UNTDGs	United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations
WCO	World Customs Organization
WHO	World Health Organization
WTO	World Trade Organization