UNEP

CBD

Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/5/INF/23
13 August 2010

ENGLISH ONLY

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
SERVING AS THE MEETING OF THE PARTIES
TO THE CARTAGENA PROTOCOL ON
BIOSAFETY
Fifth meeting
Nagoya, Japan, 11-15 October 2010

SUMMARY OF THE OUTCOME OF THE ONLINE FORUM ON STANDARDS FOR SHIPMENTS OF LIVING MODIFIED ORGANISMS (PARAGRAPH 3 OF ARTICLE 18)

I. INTRODUCTION

1. In its decision BS-IV/10, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to organize an online conference to: (i) identify the relevant standards with regard to handling, transport, packaging and identification of living modified organisms (LMOs); (ii) identify where gaps exist; and (iii) suggest possible modalities to fill the gaps (paragraph 3 of Article 18). 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.

2. 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]

3. The present document is intended to provide background information on the Online Forum as well as summarize the outcome of the Forum. Section II describes how the Forum was organized and structured as well as the modalities for participation. Section III contains the summary of the outcome of the Forum.

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

II. ORGANIZATION AND STRUCTURE OF AND PARTICIPATION IN THE ONLINE FORUM

4. Following the request of the fourth meeting of the Parties, the Secretariat sent a notification to Parties, other Governments and relevant international organizations on 11 September 2008 to solicit guiding questions for the Online Forum. The Secretariat received submissions of guiding questions from the European Union and the Global Industry Coalition by the deadline for submissions. The Secretariat also put forward three questions that it thought would facilitate the discussions of the Forum. The questions were grouped into four themes and submitted to the Bureau. The Bureau approved the questions and also gave the Secretariat the flexibility to amend the guiding questions as necessary. Accordingly, the Secretariat added some guiding questions received from Colombia after the deadline, finalized the guiding questions and made them available for the Online Forum. The final set of guiding questions is listed in Annex I to this document.

5. 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 (document UNEP/CBD/BS/ONLINECONF-HTPI/1/2). An addendum included additional information on the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations.

6. 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 accepted the invitation of the Secretariat and 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). A list of the experts is provided in Annex II to this document.

7. The website for the Online Forum was launched on 20 March 2009 and registration was opened on 14 April 2009. Individuals needed to register for the Forum in order to be able to post messages in the Forum. Registration was open to everyone. Information posted on the Forum website could be read by everyone regardless of whether they had registered for the Forum or not.

8. The Forum was initially scheduled to run from 18 to 29 May 2009. An increase in the number of postings over the last week of the Forum as well as requests for more time to participate led to the Forum being extended by one week to 5 June 2009. Eighty-one people registered for the Forum. See Annex III for more statistical information on participation in the Forum.

III. SUMMARY OF THE OUTCOME OF THE ONLINE FORUM

9. 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

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

considered to have been made in their personal capacity unless they stated that their interventions represented the views of their Government or organization.

Theme 1. Existing standards and standard-setting bodies

10. Ten different discussion threads were created under this theme.

11. 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, 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.

12. One intervention commented that the background document that had been prepared for the Forum by the Secretariat (document UNEP/CBD/BS/ONLINECONF-HTPI/1/2) did not cover the biotechnology-related standards of the International Organization for Standardization (ISO) or those of other regional or national organizations (such as the European Committee for Standardization (CEN)). The intervention 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 intervenor requested a reply if she had misstated any points about the standards or standards bodies.

13. The Secretariat responded by commenting 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 agreed that there are a number of standards in the area of sampling and detection that have been developed by ISO and CEN as well as other organizations. She noted, however, 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.

14. A participant responded by suggesting 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. He

inquired as to what sort of mandate the Secretariat would need to obtain in order to pursue such an MOU. The representative of the Secretariat responded by referring to decision BS-II/6 which requests the Executive Secretary to cooperate with a number of other organizations. She noted that this provides the Secretariat with the mandate to enter into MOUs with other organizations. She noted that participation in the meetings of other organizations would require agreement from the Parties to provide sufficient funds in the Protocol's budget to cover the associated costs.

15. 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.

16. 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 but 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.

17. 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 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.

18. The initiator of the discussion thread inquired whether the secretariat of the Rotterdam Rules should be included in the Online Forum. He referred to another intervention where he inquired as to why

[3]/ Section IX of the background document for the Online Forum (document UNEP/CBD/BS/ONLINECONF-HTPI/1/2) includes a discussion of the Rotterdam Rules as well as the Hague-Visby rules they are intended to replace.

the WTO and Interpol as well as the secretariats of certain other multilateral environmental agreements were excluded from the list of organizations in one of the guiding questions for the theme. He stated that the inclusion of the secretariat for the Rotterdam Rules will ensure that the implementation of the Rules will take the provisions of the Protocol into consideration.

19. Another discussion thread raised a question about the London Corn Trade Association 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.

20. 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.

21. The initiator of the discussion thread responded by asking what the major concerns of the previous intervenor were and asked that the previous intervenor list those concerns in the Online Forum so that all the participants could clearly understand the issues better.

22. 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.

23. 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.

24. 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 to give 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.

25. 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.

26. 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 [4]/ 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.

27. 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, UNEP/CBD/BS/ONLINECONF-HTPI/1/2. [5]/

28. 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 if each country has the right

[4]/ See section V.A of document UNEP/CBD/BS/ONLINECONF-HTPI/1/2 for more details on the classification system of the UNTDGs.

[5]/ See paragraphs 78 to 84 of the document.

to develop its own standards, what are the standards that may need to be consulted. He felt that these issues should be taken into account at the next meeting of the Parties to the Protocol.

29. One participant posted his responses to the guiding questions and also suggested a number of new topics. He 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 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? Lack of capacity for the implementation of the identification and monitoring of LMOs.

30. 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. Ms. Gretchen Stanton from the Secretariat of the World Trade Organization was asked the following question: "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 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.

31. Ms. Stanton continued by describing how, in the GMO dispute case, [6]/ 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.

32. 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.

33. One participant indicated that there have been concerns about standards that could create barriers to free trade. He suggested that some critics of the Biosafety Protocol use this as an argument against the Protocol. He asked Ms. Stanton two questions in this context: (a) what are the criteria for having standards that are not considered to be technical barriers to trade; and (b) 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?

34. 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.

35. 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

[6]/ EC–Approval and Marketing of Biotech Products, dispute DS291.

TBT Agreement gives greater importance to the process and procedures used for the development of standards.

36. A representative of the CBD Secretariat posed a question to Mr. Alexey Shcheglov, the expert representing the World Customs Organization. The question was whether the secretariat of a multilateral environmental agreement can request an amendment to the Harmonized System [7]/ or whether proposals for amendments must 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.

37. Another participant asked Ms. Christina Devorshak, the expert representing the International Plant Protection Convention Secretariat, about 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.

38. A participant asked Ms. Devorshak about the scope and nature of IPPC's mandate regarding genetically modified plants. He asked about the potential areas of harmonisation with the ongoing processes of developing and implementing national biosafety frameworks in relation to obligations in the Biosafety Protocol. Finally, he inquired about potential areas of conflict in the mandates of national plant protection organizations and the national competent authorities for biosafety if responsibilities are assigned to different institutions within a country.

39. 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

[7]/ See section VII of document UNEP/CBD/BS/ONLINECONF-HTPI/1/2 for a description of the Harmonized System.

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 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.

40. 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.

41. One participant pointed to the IPPC Standard Setting Work Programme as adopted at the third session of the Commission on Phytosanitary Measures (CPM) which indicates that the IPPC intends to develop an ISPM on the International Movement of Grain. She inquired as to the intended scope and objective of this ISPM and how it would relate to other standards and industry practices in this area.

42. 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.

43. 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.

44. Mr. Masashi Kusukawa was available online as an expert on behalf of the Codex Alimentarius Commission. A representative of the CBD Secretariat asked him whether there had been 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.

45. 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.

46. A participant referred to section 3 of the annex to "Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food" which 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). He asked Mr. Kusukawa for his view on 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). He also asked Mr. Kusukawa's opinion on possible synergies and overlaps between the two.

47. Mr. Kusukawa began by explaining that the FAO-managed database [8]/ 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.

48. 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.

49. 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.

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[8]/ The database can be accessed here: http://www.ipfsaph.org/servlet/CDSServlet?status=ND1jdGh0dHB3d3dmYW9vcmdhb3NpcGZzYXBoaXNzdWVrZXl3b3Jkc2Jpb3RlY2hub2xvZ3lmb29kc2FmZXR5cmlza2Fzc2Vzc21lbnQmNj1lbiYzMz0qJjM3PWtvcw~~.

50. One participant inquired of Mr. Peter Kearns from the OECD whether the OECD has guidelines or standards that are specific to genetically modified seeds. She also referred to the "OECD Schemes for the Varietal Certification or Control of Seeds Moving in International Trade" and stated that it does not make mention of GM seeds or seeds produced through techniques of modern biotechnology. She asked whether this means that the OECD's policy does not see the need for different treatment/standards for seeds that are genetically modified.

51. 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.

52. A representative of the CBD Secretariat pointed to the background document prepared for the Forum, which stated 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. She asked how far the work has progressed and whether the intention is for the unique identifiers for transgenic micro-organisms to take a similar form as the unique identifiers for genetically modified plants.

53. Mr. Kearns replied that 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 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.

54. A participant noted that the background document prepared for the Forum stated 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. She asked for an update on the status of the project and for more information on its scope and purpose. In another thread, the same participant noted that 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. She asked whether the OECD would be interested in setting up a project or training for the latter situation.

55. 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.

56. 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.

57. Mr. Olivier Kervella from the Dangerous Goods and Special Cargoes Section of the Transport Division of the United Nations Economic Commission for Europe was available online as an expert on the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations. In response to a question, he stated that he was not aware of any statistics on the quantity of GMOs and genetically modified micro-organisms (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.

58. 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.

59. 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 UN Economic Commission for Europe 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 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.

60. A participant asked whether the scope of class 9 of the Model Regulations can be considered as overlapping with the Protocol and whether the Model Regulations would therefore be the right place to have the discussion on standards that may be required for shipments of LMOs. He also asked how the overlap between the Model Regulations and the Protocol can be avoided.

61. 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

62. There were three discussion threads created under this theme.

63. 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 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.

64. 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.

65. 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.

66. 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.

67. 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. The Arrangement had the objective of "articulating an understanding among Canada, Mexico and the

United States of America 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." [9]/ 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.

68. 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. [10]/

69. 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.

70. 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 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 (see paragraph 63, above.)

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[9]/ 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.

[10]/ 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.

71. 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 paragraph 100, below.

72. Under the 'Ask an Expert' section of the Forum, a participant asked the following questions of the representative of the IPPC Secretariat: "Are standards for identification/documentation, packaging handling and transport of living modified organisms necessary, in IPPC's views? 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?"

73. 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.

74. 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.

75. Another participant posed three questions to Mr. Kervella from the 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?

76. 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.

77. 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.

78. 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'. [11] 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 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.

[11]/ See pp. 12-13 of document UNEP/CBD/BS/ONLINECONF-HTPI/1/2/Add.1.

79. 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.

80. 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

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

82. 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.

83. 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.

84. 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.

85. 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.

86. 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

87. There were thirteen discussion threads created under theme 4.

88. 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.

89. 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.

90. 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.

91. 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 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.

92. 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 paragraph 99, below.) She felt that this would allow the Parties to the Protocol to leverage the work going on by qualified experts in other international fora and avoid the duplication of resources and efforts.

93. 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.

94. 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.

95. 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.

96. 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.

97. 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.

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

99. 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.

100. 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 ideas he listed were that:

- 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 need to be addressed;
- the challenges for certified reference materials also 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.

101. 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.

102. 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.

103. 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.

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? 12/
- 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?

12/ See also the background document prepared by the Secretariat for the online conference, document UNEP/CBD/BS/ONLINECONF-HTPI/2.

* This question was developed by the Secretariat.

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 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 these 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

EXPERTS PARTICIPATING IN THE 'ASK AN EXPERT' SECTION OF THE ONLINE FORUM

Ms. Christina Devorshak, Agricultural Officer, Secretariat of the International Plant Protection Convention

Mr. Peter Kearns, Principal Administrator, Organisation for Economic Co-operation and Development

Mr. Olivier Kervella, Chief, Dangerous Goods and Special Cargoes Section, Transport Division, United Nations Economic Commission for Europe

Mr. Masashi Kusukawa, Food Standards Officer, Secretariat for the Codex Alimentarius Commission

Prof. Paul-Pierre Pastoret, Head, Publications Department, World Organisation for Animal Health (OIE)

Mr. Alexey Shcheglov, Senior Technical Officer, Tariff and Trade Affairs Directorate, World Customs Organization

Ms. Gretchen Stanton, Senior Counsellor, Agriculture and Commodities Division, World Trade Organization

Annex III

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

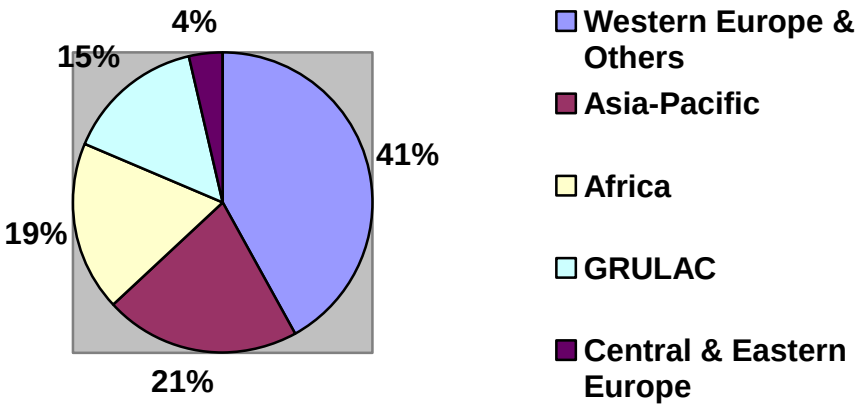
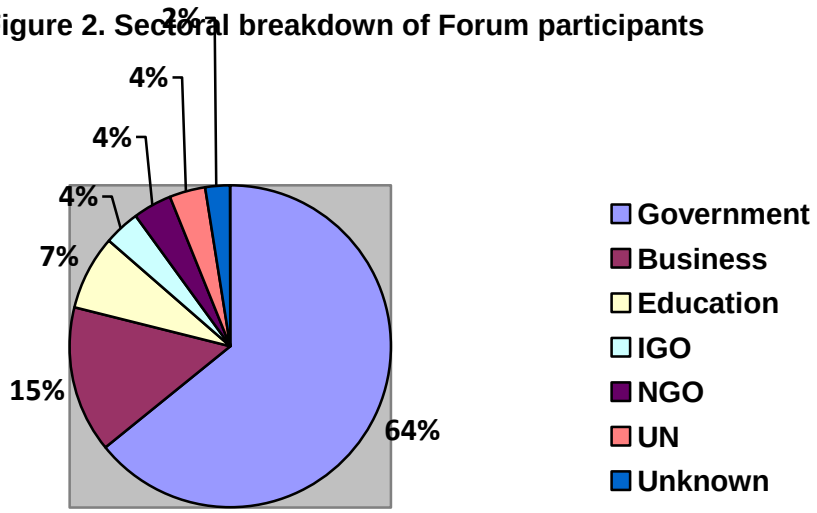


Figure 2. Sectoral breakdown of Forum participants



Annex IV

LIST OF ACRONYMS

BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CEN	European Committee for Standardization
CPM	Commission on Phytosanitary Measures
FAO	Food and Agriculture Organization
GE	Genetically engineered
GM	Genetically modified
GMOs	Genetically modified organisms
GMMOs	Genetically modified micro-organisms
IGTC	International Grain Trade Coalition
IPPC	International Plant Protection Convention
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*
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
SPS Agreement	*Agreement on the Application of Sanitary and Phytosanitary Measures*
TBT Agreement	*Agreement on Technical Barriers to Trade*
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
