



Convention on Biological Diversity

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CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
SERVING AS THE MEETING OF THE PARTIES TO
THE CARTAGENA PROTOCOL ON BIOSAFETY

Fifth meeting

Nagoya, Japan, 11-15 October 2010

Item 10 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION: THE NEED FOR AND MODALITIES OF DEVELOPING STANDARDS (PARAGRAPH 3 OF ARTICLE 18)

Note by the Executive Secretary

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 finalize the list of questions in consultation with the Bureau. The Parties also requested the Executive Secretary to prepare a summary of the outcome of the conference, reflecting the full range of views expressed, for consideration at their fifth meeting.

* UNEP/CBD/BS/COP-MOP/5/1.

2. Accordingly, the Secretariat organized an on-line 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. A report of the on-line forum was prepared, reflecting the full range of views expressed, and is available as UNEP/CBD/BS/COP-MOP/5/INF/23. The present document is intended to provide background information on the on-line forum as well as summarize the main themes discussed during the forum. Section II describes how the forum was organized and structured as well as the modalities for participation. Section III contains a brief summary of the discussions in the forum while section IV enumerates the recommendations made during the forum. Section V presents some elements for a draft decision.

II. ORGANIZATION AND STRUCTURE OF THE ON-LINE FORUM AND PARTICIPATION THEREIN

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 on-line forum. The Secretariat received submissions of guiding questions from the European Union and the Global Industry Coalition by the deadline for submissions and also contributed three questions of its own. 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 on-line forum. The final set of guiding questions is listed in annex I below.

5. In addition to the guiding questions, a background document summarizing information on standards and standard-setting bodies relevant to the handling, transport, packaging and identification of LMOs was prepared for the on-line forum. An updated version of this document is available as document UNEP/CBD/BS/COP-MOP/5/INF/6.

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 four themes were: (i) existing standards and standard-setting bodies; (ii) possible gaps – general; (iii) possible gaps – objective of the Protocol, types of LMOs, segregation and traceability, thresholds; (iv) conclusions and recommendations. The other section 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.

7. 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 World Trade Organization (WTO). A list of the experts is provided in annex II below.

8. 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

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

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.

9. 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 participants registered for the forum. See Annex III for more statistical information on participation in the forum.

III. SUMMARY OF THE MAIN THEMES OF THE ON-LINE FORUM

10. As mentioned above, the full report of the on-line forum, including the synthesis of the views expressed, is available as document UNEP/CBD/BS/COP-MOP/5/INF/23. The summary below captures the main points discussed under the different themes. The discussions under the 'Ask an Expert' section of the forum have been included under the theme to which they most closely relate.

Theme 1. Existing standards and standard-setting bodies

11. Discussions under this theme covered a variety of issues including:

- (a) National implementation of regulations on the handling, transport, packaging and identification of LMOs;
- (b) The availability of standards developed by other international organizations;
- (c) Cooperation with other organizations developing standards related to the handling, transport, packaging and identification of LMOs;
- (d) Other existing standards including those on sampling and detection, standard form contracts for the shipment of grain, the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations (Model Regulations) and the nature of different standards (whether they are legally binding or not); and
- (e) Possible gaps including a number of interventions supporting the view that a standard should be developed under Article 18 of the Protocol as well as some concern about the possible development of a new standard.

12. A number of points from the "Ask an Expert" section of the forum were also relevant to this theme. Questions to and responses from the experts included consideration of:

- (a) The status in the WTO of standards adopted by multilateral environmental agreements;
- (b) The review process for the Harmonized Commodity Description and Coding Systems of the WCO;
- (c) Areas of overlap between the IPPC and the Biosafety Protocol;
- (d) The scope and nature of the IPPC mandate regarding genetically modified plants;
- (e) Areas for harmonization and potential areas of conflict between phytosanitary measures and biosafety at the national level;
- (f) The proposal for the IPPC to develop a standard on the international movement of grain;
- (g) Developments on the proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering in the Codex Committee on Food Labelling;

(h) Possible synergies and overlaps between the Biosafety Clearing-House and the database of the Food and Agriculture Organization of the United Nations (FAO) on recombinant DNA low-level presence plant material for food and/or feed safety assessment;

(i) Work at the OECD on a system of unique identifiers for transgenic micro-organisms and on low-level presence of transgenic seeds in bulk shipments of conventional seeds;

(j) Legal status of the Model Regulations including their incorporation into and implementation through the transport-related legal instruments of other bodies;

(k) Possible overlap between the Model Regulations and the Protocol; and

(l) Review and update of the Model Regulations and opportunities to include input on LMOs.

Theme 2. Possible gaps – general

13. Topics addressed under this theme included:

(a) The Trilateral Arrangement on “Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing” amongst the parties to the North American Free Trade Agreement (NAFTA), i.e. Canada, the United States and Mexico, as well as problems related to trade in LMOs in the NAFTA region;

(b) Trade between Parties and non-Parties;

(c) The need for the development of separate standards for LMOs; and

(d) Identification of possible gaps such as lack of information among the Parties on acceptable standards and an inadequate forum for coordinating acceptable standards.

14. Relevant discussions in the “Ask an Expert” section of the forum included:

(a) The protection of biodiversity in the IPPC context, whether IPPC sees a need for standards on the handling, transport, packaging and identification of LMOs and the role of the Commission on Phytosanitary Measures if such a need is identified;

(b) Possible gaps between the requirements in paragraph 2 of Article 18 of the Protocol and the Model Regulations;

(c) How the handling and identification requirements of the Protocol could be integrated into the Model Regulations where the latter already covers genetically modified organisms (GMOs); and

(d) Whether standards on the handling, packaging and transport of LMOs should be left to national measures.

Theme 3: Possible gaps – objective of the Protocol, types of LMOs, segregation and traceability, thresholds

15. Discussion under this theme focused on the distinction between adventitious presence and “may contain” language; and whether, if standards were developed for LMOs, they would also cover genetically modified organisms and products thereof.

Theme 4 – Conclusions and recommendations

16. There was extensive discussion under this theme. Points covered included:

- (a) The need for cooperation with other organizations working in the area of standards on the handling, transport, packaging and identification of LMOs;
- (b) Postings expressing the need for standards on LMOs and other postings opposed to the development of standards on LMOs or recommending the referral of any gaps identified to other standard-setting organizations;
- (c) Proposals for the formation of a working group to, *inter alia*, develop standards on the handling, transport, packaging and identification of LMOs;
- (d) Participation of the Secretariat of the Convention on Biological Diversity in meetings of other international organizations;
- (e) Capacity-building for the implementation of standards;
- (f) Supporting work on standards in other forums; and
- (g) The creation of a mechanism for information exchange, training and promotion of education and communications opportunities among institutions.

IV. SUMMARY OF RECOMMENDATIONS FROM PARTICIPANTS IN THE ON-LINE FORUM

17. Participants in the on-line forum made a number of recommendations under the different themes of the forum. Many of the recommendations touch on similar ideas:

(a) *Standards should be developed under the Protocol*

- (i) A special standard for the handling, transport and packaging of LMOs under paragraph 3 of Article 18 is needed. Parties and the Secretariat should provide guidance towards ensuring international harmonization;
- (ii) The gaps enumerated in themes 2 and 3 support the urgency of developing standards specific to the Protocol because the existing international standards do not meet all the needs of Parties to address all the provisions of the Protocol;
- (iii) It is necessary to elaborate comprehensive legally binding standards under the Protocol;
- (iv) Standards should be set by a group of international experts in different LMO-related fields as well as the Parties to the Biosafety Protocol;
- (v) Unified standards and guidelines under the Biosafety Protocol should be elaborated with regard to types of LMOs and their uses according to paragraph 2 of Article 18 (i.e. LMOs intended for direct use as food or feed, or for processing; LMOs for contained use and LMOs for intentional introduction into the environment.) The standards document should be agreed to by the Parties to the Protocol at a meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol and should be legally-binding;
- (vi) Developed country Parties should provide financial means to the Secretariat of the Convention on Biological Diversity for the process of developing new agreed-upon standards for shipments of LMOs through a biosafety framework for all Parties;
- (vii) A special standard under paragraph 3 of Article 18 could take the form of guidance on how to use the existing international regulations and standards and such a guideline should be prepared by stakeholders in and experts on the Protocol;

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

(b) Cooperation with other relevant organizations is needed, including by referral of gaps in standard and recommendations

- (ix) The Parties to the Protocol should identify safety needs and requirements and provide guidance for the Convention Secretariat to convey to the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods on which requirements should be integrated into the Model Regulations;
- (x) The Convention Secretariat could hold workshops, meetings and other forms of consultation with the relevant standard-setting organizations to prepare standards specifically on LMOs for the consideration of Parties to the Protocol;
- (xi) It is recommended that the Secretariat facilitate cooperation between the Parties and standard-setting bodies in order avoid overlap and duplication in the field of standards, databases and activities in biosafety;
- (xii) The Secretariat should establish formal contact with other organizations to support their work in building a comprehensive and non-redundant approach to standards for shipments of LMOs;
- (xiii) The Secretariat should continue its collaboration with IPPC, OIE, the United Nations Economic Commission for Europe, etc., and when gaps are identified by the Parties, these gaps should be directed to those organizations already addressing identification, handling, packaging and transport;
- (xiv) The development of standards on the shipment, handling and packaging of LMOs should be referred to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology;²
- (xv) It is recommended that the Secretariat establish contact with international organizations like the International Seed Testing Association, International Organization for Standardization (ISO), European Committee for Standardization (CEN), the Codex Alimentarius Commission, IPPC and FAO through meetings, workshops, missions, etc. to ensure harmonization of standards for LMO shipments;
- (xvi) The Secretariat should enter into a memorandum of understanding with ISO, CEN and the International Seed Testing Association in order to obtain observer status at their meetings, gain access to the standards and perhaps also be involved in the implementation of standards;
- (xvii) Participation of representatives from the Secretariat in the meetings of corresponding international organizations could not only extend cooperation but potentially enable access to information and data that is otherwise restricted;

² The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology completed its mandate in 2007 and no longer meets.

- (xviii) The IPPC and the Biosafety Protocol could cooperate on the development and use of specific terminology;
 - (xix) The creation of a special permanent working group responsible for cooperative relationships could become an instrument for cooperation and the creation of synergies among the international standard-setting organizations and the CBD Secretariat for coordinating activities such as the elaboration of databases, information exchange systems such as the BCH, the development of standards and ensuring the segregation and traceability of LMOs that are the subject of transboundary movements;
 - (xx) A working group should be established that would serve as a collaboration instrument among Parties, the Secretariat and international standard-setting bodies and should take into account the views of all actors. It would be expedient to use electronic means of information exchange such as the BCH;
 - (xxi) Cooperation and coordination of procedures with other international organizations and bodies is necessary to achieve unified regulation in this area and to avoid duplication of efforts. This is a very difficult and complex task that would require deep analysis and the involvement of experts, perhaps in the form of an *ad hoc* working group;
- (c) ***The question of standard setting should be left to action at the national level***
- (xxii) The issues of (a) whether, regarding standards or criteria for shipments of LMOs, it is better for each country to identify those standards that are in line with its situation or to set global standards agreed upon by all Parties; and (b) if each country has the right to develop its own standards, what standards may need to be consulted, should be taken into account at the next meeting of the Parties to the Protocol;
 - (xxiii) There is no need to pursue discussions regarding standards under paragraph 3 of Article 18 of the Protocol;
- (d) ***Capacity-building and exchange of information on standards are needed***
- (xxiv) The Secretariat should consider the possibility of coordinating a mechanism with other international institutions by which the training, information exchange and promotion of educational and communications opportunities could be a reality;
 - (xxv) Capacity-building programmes could be developed to provide assistance to the Secretariat and countries to harmonize their national standards and regulations in compliance with the international requirements;
 - (xxvi) Parties and the Secretariat should provide guidance and requirements of the Model Regulations to ensure international harmonization;
 - (xxvii) Detailed molecular information is needed in order to perform post-market monitoring of GM maize imports;
 - (xxviii) There should be regional exchanges of information among laboratories on the use of detection methods and standards;

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

V. ELEMENTS FOR A DRAFT DECISION

18. The Conference of the Parties serving as the meeting of the Parties may wish to consider all the views expressed in the on-line forum in adopting a decision on paragraph 3 of Article 18. It may also wish to consider the following proposals from the summary in sections III and IV above and the report of the on-line forum:

(a) Requesting or inviting, as appropriate, Parties, other Governments and relevant international organizations to:

- (i) Direct any gaps identified to those organizations already addressing transport, handling, packaging and identification for their consideration and appropriate action;
- (ii) Make available to the Biosafety Clearing-House information on methods for the detection and identification of living modified organisms;

(b) Requesting the Executive Secretary to:

- (i) Continue following developments in standards related to the handling, transport, packaging and identification of living modified organisms and to report to the Parties at their sixth meeting on any such developments. The report should include information on developments in standard-setting on the sampling and detection of living modified organisms;
- (ii) Organize, subject to the availability of funds, regional workshops for heads of laboratories for the detection of living modified organisms to exchange information and experience on the implementation of detection standards and methods;

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

(d) Inviting the International Plant Protection Convention to collaborate with the Secretariat of the Convention on Biological Diversity in the development of an explanatory document on the terminology of the Protocol in relation to the glossary of phytosanitary terms adopted by the Commission on Phytosanitary Measures; and/or

(e) Establishing an ad hoc technical expert group, that includes representatives from relevant international standard-setting organizations, to:

- (i) Collect information on standards that may apply to shipments of living modified organisms;
- (ii) Develop guidance on the use of existing international regulations and standards;

- (iii) Identify safety needs and requirements and provide recommendations to the Sub-Committee of Experts on the Transport of Dangerous Goods for inclusion in the United Nations Model Regulations on the Transport of Dangerous Goods;
- (iv) Elaborate standards, as appropriate, on the handling, transport, packaging and identification of living modified organisms under the Protocol; and/or
- (v) Facilitate cooperation with other relevant organizations.

*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?³
- What other international organizations are or may be involved in developing standards with regard to identification, handling, packaging and transport practices that are relevant to the different categories of LMOs addressed by the Cartagena Protocol on Biosafety?
- What types of LMOs could be shipped under the guidance or recommendations of the following organizations?
 - (a) United Nations Sub-Committee of Experts on the Transport of Dangerous Goods?
 - (b) International Maritime Organization?
 - (c) International Civil Aviation Organization?
 - (d) International Air Transport Association?
 - (e) International Plant Protection Convention (IPPC)?
 - (f) World Customs Organization (WCO)?
 - (g) Organization for Economic Cooperation and Development?
 - (h) Codex Alimentarius Commission?
 - (i) World Organization for Animal Health (OIE)?
- What are some examples of national governments or regional entities that have developed standards with regard to identification, handling, packaging and transport practices that are relevant to the different categories of LMOs addressed by the Protocol?
- How have different countries implemented the biosafety-related standards set by relevant organizations?

THEME 2. POSSIBLE GAPS – GENERAL

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

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

- Do existing standards contribute to achieving the objective of the Protocol?

³ See also the background document prepared by the Secretariat for the online conference (UNEP/CBD/BS/-ONLINECONF-HTPI/2).

* This question was developed by the Secretariat.

- 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.

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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 Kusakawa, 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

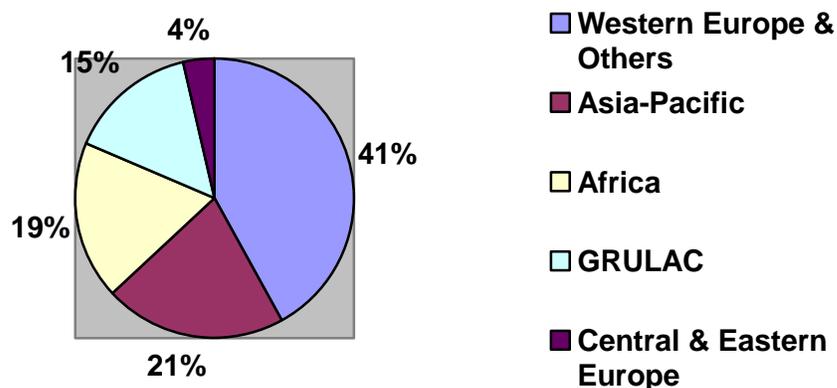


Figure 2. Sectoral breakdown of Forum participants

