



## Convention on Biological Diversity

Distr.  
GENERAL

UNEP/CBD/BS/COP-MOP/4/8  
4 February 2008

ORIGINAL: ENGLISH

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

Fourth meeting

Bonn, 12-16 May 2008

Item 10 of the provisional agenda\*

### **HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION: SYNTHESIS OF VIEWS AND INFORMATION ON THE NEED FOR AND MODALITIES OF DEVELOPING STANDARDS IN THE CONTEXT OF PARAGRAPH 3 OF ARTICLE 18**

*Note by the Executive Secretary*

#### **I. INTRODUCTION**

1. Article 18 provides for handling, transport, packaging and identification of living modified organisms that are subject to intentional transboundary movement. Paragraph 3 of the Article requires the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol to consider the need for and modalities of developing standards with regard to identification, handling, packaging, and transport practices. In doing so, the Conference of the Parties serving as the meeting of the Parties to the Protocol is required to undertake consultations with other relevant international bodies.

2. In this regard, at their second meeting, the Parties to the Protocol included a specific request to the Executive Secretary to establish cooperation with the World Customs Organization (WCO), the International Organization for Standardization (ISO), the United Nations Transport of Dangerous Goods Sub-Committee, the International Air Transport Association (IATA) and other relevant customs and transport organizations, with a view to developing a harmonized approach for the packaging and transport of living modified organisms in preparation for the consideration of paragraph 3 of Article 18 by the Parties at their third meeting (decision BS-II/6, para. (f)).

3. At their third meeting, the Parties to the Protocol invited Parties, other Governments and relevant international organizations to submit views and information on: (i) the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances to address concerns relating to living modified organisms that are subject to transboundary movements; and (ii) on gaps that may exist that may justify a need to develop new rules and standards, or to call upon relevant international bodies to modify or expand their existing rules and standards, as appropriate

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(decision BS-III/9, para. 1). The Executive Secretary was requested to compile the information received and prepare a synthesis report for consideration at the fourth meeting.

4. Furthermore, in paragraph 3 of decision BS-III/9, the Parties requested the Executive Secretary to continue collaborating with relevant international bodies and to gather information on existing rules and standards with a view to making the information available, including on the experiences of relevant international bodies in the establishment and implementation of rules and standards relevant to Article 18, at the fourth and fifth meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

5. Accordingly, section II of the present document contains a synthesis of the information received by the Executive Secretary, while section III provides information on measures taken by the Executive Secretary to forge or continue collaboration as well as obtain views as per decision BS-III/9 with some relevant international bodies. Section IV suggests some elements of a draft decision for consideration by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. An annex contains an overview of the work of some relevant international bodies.

## **II. SYNTHESIS OF VIEWS AND INFORMATION SUBMITTED ON THE ADEQUACY OF EXISTING RULES AND STANDARDS, AND ON GAPS**

6. As of 20 December 2007, submissions had been received from four Parties, namely China, Colombia, Mexico and South Africa, from two other Governments, namely, Canada and the United States of America, and from two international organizations, the Codex Alimentarius Commission and the Global Industry Coalition. The full text of all the submissions has been compiled and made available in the compilation of submission of views and information with respect to the need for and modalities of developing standards as specified in paragraph 3 of Article 18 (UNEP/CBD/BS/COP-MOP/4/INF/3).

7. A number of the submissions referred to countries' domestic requirements for the handling, transport, packaging and identification of living modified organisms. Some Parties made observations based on their experiences or their ongoing work in this area. One such observation was that the Party's existing national rules are sufficient to regulate identification, handling, packaging and transportation of some types of living modified organisms but analysis is ongoing as to whether new living modified organisms such as those for pharmaceutical use can be regulated under existing legal frameworks or whether these frameworks will require some adaptation.

8. Another Party explained that the permits it issues for living modified organisms that are subject to transboundary movement adequately prescribe the conditions/standards relating to the identification, handling, packaging and transport of consignments. With regard to gaps, and based on the Party's experience, it observed that permit conditions need to be clear to eliminate ambiguity, should be implementable on a practical level and should be reviewed on a regular basis to ensure that recent scientific developments and literature have been considered.

9. The submission from one Party noted that its existing national labelling regulation does not include a threshold value or qualitative analysis methods and standards. Furthermore, it was observed that it is difficult to deal with pollution from genetically modified organisms and their components that may occur due to accidents and technically inevitable factors. On this latter point, the submission stated that the Party's government authorities have undertaken to solve these issues.

10. Finally, one Party pointed to the Committee on Food Labelling of the Codex Alimentarius Commission (see paragraph 12 below) as being the appropriate international mechanism for a discussion on the labelling of food and food ingredients obtained through certain techniques of genetic modification

as, even though it has not made significant progress, the Committee allows the participation of the various stakeholders.

11. The two other Governments from whom submissions were received expressed the view that it is not necessary for the Conference of the Parties serving as the meeting of the Parties to the Protocol to develop new rules or standards. In support of this view, they cited a lack of information on any adverse impacts on biological diversity caused by inadequacies in the identification, handling, packaging or transport of living modified organisms as well as relevant work by other bodies in developing existing rules and standards. This work includes International Standards for Phytosanitary Measures under the International Plant Protection Convention and the United Nations Model Regulations on the Transport of Dangerous Goods. An overview of the work of these bodies can be found in the annex to this document.

12. The submission from the Codex Alimentarius Commission included an overview of its work on appropriate labelling provisions for genetically modified food through the Codex Committee on Food Labeling; methods of analysis and sampling for the detection of genetically modified foods through the Codex Committee on Methods of Analysis and Sampling; and more general work on traceability/product tracing through the Codex Committee on Import and Export Inspection and Certification Systems. An overview of the work of these bodies can be found in the annex to this document.

13. The submission from the Global Industry Coalition stated that most shipments of living modified organisms falling under paragraph 2 (c) of Article 18, i.e. shipments of living modified organisms intended for intentional introduction into the environment, are exempt from special standards for identification, packaging, handling and transport regulations. It was stated that such shipments are moved without any problems pursuant to national authorizations and in accordance with existing guidance on shipping documentation requirements agreed by Parties. Furthermore, shipments of living modified organisms under paragraph 2 (b) of Article 18, i.e. shipments of living modified organisms destined for contained use, are, when appropriate, covered by existing international transport regulations as well as the Protocol's shipping documentation requirements. The submission draws the conclusion that experience to date indicates that no gaps have been identified and so no further standards or requirements for these shipments need to be developed under paragraph 3 of Article 18 of the Protocol.

14. This submission suggested that the goal in 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 create further synergies and avoid duplication of efforts. The submission also included an overview of work on the identification, handling, packaging and transport of goods being undertaken by certain other international bodies of experts, namely the United Nations Model Regulations on the Transport of Dangerous Goods and the IATA Live Animals Regulations. An overview of the work of these bodies can be found in the annex to this document.

### **III. INFORMATION ON COLLABORATION**

15. As outlined above, in paragraph (f) of decision BS-II/6, the Parties to the Protocol requested the Executive Secretary to establish cooperation with a number of customs and transport organizations. A note by the Executive Secretary prepared for the third meeting of the Parties (UNEP/CBD/BS/COP-MOP/3/8/Add.2) included information on the Secretariat's consultations with international bodies. In decision BS-III/9, the Executive Secretary was further requested to continue collaborating with relevant international bodies and to gather information on existing rules and standards with a view to making this information available at the fourth and fifth meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Accordingly, this section of the document contains information on the Executive Secretary's activities regarding collaboration while the annex to this document contains information on existing rules and standards as well as the work of international bodies towards developing such rules and standards.

16. In October 2007, the Executive Secretary sent letters to a number of organizations inviting them to submit views and information on: (i) the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances to address concerns relating to living modified organisms that are subject to transboundary movement; and (ii) on gaps that may exist that may justify a need to develop new rules and standards, or to call upon relevant international bodies to modify or expand their existing rules and standards, as appropriate.

17. The organizations contacted were: the Codex Alimentarius Commission, the Secretariat of the International Plant Protection Convention, the United Nations Industrial Development Organization, the United Nations Economic Commission for Europe in its capacity as the Secretariat for the United Nations Transport of Dangerous Goods Sub-Committee, the World Customs Organization, the Organisation for Economic Co-operation and Development, and the International Air Transport Association. A response was received from the Codex Alimentarius Commission and the summary of the submission has been included in paragraph 12 above and the annex to this document.

18. It might also be noted that both the Secretariat of the Convention on Biological Diversity and the World Customs Organization are Partners in the Green Customs Initiative. The latter is a partnership of international organizations and secretariats that cooperates to enhance the capacity of customs and other relevant border enforcement personnel to deal with environmentally-sensitive items covered by the respective international agreements represented by the Partners. The Initiative provides, among other things, an opportunity for collaboration and exchange of information amongst the Partners. More information regarding this and other collaborative initiatives are available in the note by the Executive Secretary on cooperation with other organizations, conventions and initiatives (UNEP/CBD/BS/COP-MOP/4/6) prepared for the present meeting to assist in the deliberations under item 8 of the agenda.

#### IV. ELEMENTS OF A DRAFT DECISION

19. Based on the above information and that in the annex below, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish:

(a) To request Parties and encourage other Governments and international organizations to ensure that information related to rules and standards on the identification, handling, packaging and transport of living modified organisms are available via the Biosafety Clearing-House;

(b) To request Parties to support ongoing work on standards on identification, handling, packaging and transport practices taking place in other international organizations and, if any gaps are identified in the future, to refer them to the organizations that are already addressing those matters, e.g., the United Nations Committee of Experts on the Transport of Dangerous Goods and the IATA Live Animal Regulations;

(c) In light of related discussions regarding a possible subsidiary body or bodies to the Protocol (see Article 30 and the note by the Executive Secretary on potential mechanisms for the provision of scientific and technical advice (UNEP/CBD/BS/COP-MOP/4/12)), to defer discussions under paragraph 3 of Article 18 until a decision on subsidiary bodies has been taken. Then, if a decision to establish a subsidiary body is taken, the Parties may wish to request such a body to take up the issue of standards under paragraph 3 of Article 18, as appropriate;

(d) In addition or in the alternative, to consider requesting the Executive Secretary to organize an online conference to discuss the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices. The Parties to the Protocol may then wish to request that the outcomes of the online conference form the basis for a meeting of an ad hoc technical

experts group, which would make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting;

(e) To continue to gain experience in the implementation of the Protocol's provisions regarding handling, transport, packaging and identification, and to request the Executive Secretary to continue to collaborate with relevant international organizations in this regard.

*Annex***INFORMATION ON EXISTING RULES AND STANDARDS, INCLUDING ON THE EXPERIENCES OF RELEVANT INTERNATIONAL BODIES IN THE ESTABLISHMENT OF RULES AND STANDARDS RELEVANT TO ARTICLE 18 <sup>1/</sup>****A. *Codex Alimentarius Commission****Committee on Food Labelling*

The Committee on Food Labelling has been considering, since 1996, appropriate food labelling provisions for foods derived from biotechnology. This work aims at establishing “Definitions and Guidelines for the Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering”.

However, these draft texts are still under discussion due to lack of consensus. The most controversial point is whether or not mandatory labelling provisions should be established for the case where the production method is the sole difference between original products and genetically modified products.

The 35<sup>th</sup> Session of the Codex Committee on Food Labelling in May 2007 discussed the Draft Definitions and Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions and could not come to a consensus on how to proceed with the development of the text.

After some discussion, the Committee agreed to establish a physical working group, which would consider the approaches taken by Governments to the labelling of genetically modified/genetically engineered foods and the possible ways forward for the Committee to address this issue. It was agreed that the physical working group would take place in Ghana in early 2008. The Committee agreed to retain the texts at the current steps, for further consideration at the next session taking into account the outcome of the physical working group. The next meeting of the Committee on Food Labelling is scheduled to take place in Ottawa from 28 April to 2 May 2008.

*Committee on Methods of Analysis and Sampling*

The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing appropriate methods of detection and analysis for genetically modified foods since 2002. In view of the absence of precise provisions for genetically modified organisms in Codex and of difficulties with the practical application of methodology in this area, the CCMAS proposed to develop recommendations with respect to criteria for methods of analysis and for quality control measures that should be introduced in laboratories offering GM analysis (Guidelines for the Validations and Quality Control Requirements for the Analysis of Foods derived from Biotechnology).

The 28<sup>th</sup> Session of the Codex Committee on Methods of Analysis and Sampling, in March 2007, considered a new revised document on the criteria for the detection and identification of foods derived from biotechnology, including: (i) the information required for the validation of quantitative and qualitative methods; (ii) the characteristics that could be used to consider existing validated methods; (iii) issues related to measurement uncertainty and interpretation of the results; and (iv) proficiency testing. After some discussion, the Committee agreed that the electronic working group led by the delegations of

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<sup>1/</sup> The information below is intended to complement and update rather than repeat the information contained in section III of document UNEP/CBD/BS/COP-MOP/3/8/Add.2. It is based largely on the information contained in the submissions received pursuant to decision BS-III/9.

Germany and the United Kingdom would revise the current document and, in addition, would give consideration to the development of guidelines for governments and prepare a project document as a proposal for new work. The 29<sup>th</sup> Session of CCMAS is scheduled to be held in Budapest from 10 to 14 March 2008.

#### *Codex Committee on Food Import and Export Inspection and Certification Systems*

Following the adoption by the Codex Alimentarius Commission of the definition of “traceability/product tracing”, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its 13<sup>th</sup> Session in December 2004, started new work to develop the principles on traceability/product tracing in the context of food import and export inspection and certificate systems. The Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System were subsequently adopted by the 29<sup>th</sup> Session of the Commission in July 2006 and have been published in the Codex Alimentarius (CAC/GL 60-2006).

The CCFICS at its 16<sup>th</sup> Session on 26-30 November 2007 discussed the need for further guidance on traceability/product tracing by Codex and agreed to continue discussion on this matter at its next session, to address the present gaps in the implementation of traceability/products tracing, the key elements that would address these gaps, and the technical and economical feasibility of countries to implement traceability/product tracing. The 17<sup>th</sup> Session of CCFICS is scheduled to be held in Australia from 24 to 28 November 2008.

#### **B. *International Plant Protection Convention***

The International Plant Protection Convention (IPPC) develops standards and guidelines for the protection of plant health and is governed by the Commission on Phytosanitary Measures (CPM). The CPM adopts International Standards for Phytosanitary Measures (ISPMs). ISPM-11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*) provides guidance on pest risk analysis, including risk management, for organisms that can directly or indirectly cause harm to plants, in managed or unmanaged environments, and specifically includes potential effects on biodiversity (ISPM, annex 1). Pest risk analysis includes determination of risk management options for organisms determined to present plant pest risk (section 3 of ISPM-11), including on the need for handling or documentation measures to ensure the integrity of consignments. In addition, ISPM-3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) provides additional guidance relevant to the transport, handling and documentation of living organisms, including the need to ensure that the regulations of the importing country are complied with and to provide and assess documentation relevant to the export, shipment, import, or release of these organisms. In particular, for any organisms considered in these standards, including living modified organisms, the IPPC guidance recognizes the need for the National Plant Protection Organizations to carry out pest risk analysis on the organism, to determine if the organism provides a pest risk to the country of import, and if so, to determine risk management measures commensurate with the level of risk, so as not to create disguised barriers to trade.

#### **C. *World Organization for Animal Health (OIE)***

The World Organization for Animal Health develops standards aimed at preventing the introduction of infectious agents and diseases through international trade in animals. It also sets standards for vaccines, including those that are genetically engineered. OIE standards include the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code* both of which detail health measures to be used by veterinary authorities of importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.

**D. United Nations Sub-Committee of Experts on the Transport of Dangerous Goods**

The United Nations has issued recommendations in the form of the Model Regulations on the Transport of Dangerous Goods. The Model Regulations are general packing requirements, testing procedures for packages, marking or labelling and transport requirements for certain categories of substances. These Model Regulations are overseen by the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, and specifically, the Sub-Committee of Experts on the Transport of Dangerous Goods. The Committee of Experts recommendations are reviewed yearly and amended in response to developments in technologies, the advent of new substances and materials, the exigencies of modern transport systems and, above all, the requirements to ensure the safety of people, property and the environment.

The Model Regulations were created to facilitate direct integration of requirements into all model, national and international regulation thereby enhancing harmonization, facilitating regular updating of all legal instruments concerned, and resulting in resource savings for the Governments of the Member States, the United Nations, the specialized agencies and other international organizations. <sup>2/</sup> More information is available here: <http://www.unece.org/trans/danger/danger.htm>, including the full text of the Model Regulations.

Part 2 of the Model Regulations categorizes dangerous goods into classes such as explosives, gases or flammable liquids. The Model Regulations do not apply to living modified organisms that are authorized for use by the competent authorities of the Government of the countries of origin, transit and destination but the Model Regulations do apply to specific categories of living modified organisms. For example, those living modified organisms that meet the definition of an infectious substance under the Model Regulations are assigned to the appropriate category of infectious substance (Class 6) thereby becoming subject to all requirements under that category. Class 9 covers miscellaneous dangerous substances and articles. Genetically modified organisms (GMOs) and genetically modified microorganisms (GMMs) that are not infectious may be categorized as Class 9 dangerous goods provided they meet the definition below:

2.9.2.1 Class 9 includes, *inter alia*:

(...)

GMMs or GMOs which do not meet the definition of infectious substances (see 2.6.3) but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction. They shall be assigned to UN 3245.

GMMs or GMOs are not subject to these Regulations when authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination.

Parts 4 through 7 of the Model Regulations provide detailed instructions for the handling, transport, packaging and identification of dangerous goods.

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<sup>2/</sup> Recommendations on the Transport of Dangerous Goods, 15<sup>th</sup> revised edition, ST/SG/AC.10/1/Rev.15 (Vol. I).



***E. International Air Transport Association***

The 33<sup>rd</sup> edition of the Live Animals Regulations provides guidance on the packaging and documentation needed for the transport of live animals. <sup>3/</sup> The Live Animals Regulations have been developed by IATA in consultation with parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), OIE and government authorities that implement the Live Animals Regulations for animal transportation to ensure safety in transport and humane transportation of live animals. The Live Animals Regulations are applicable to IATA members and to airlines that are parties to the Multilateral Interline Traffic Agreement for Cargo. To the extent that any live animal would qualify as a living modified organism, the Live Animals Regulations would govern its international movement by air.

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<sup>3/</sup> See <http://www.iata.org/ps/publications/lar.htm>.