



# Convention on Biological Diversity

Distr.  
GENERAL

UNEP/CBD/BS/COP-MOP/4/INF/3  
4 April 2008

ENGLISH AND SPANISH ONLY

## 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 (ARTICLE 18.3)**

*Compilation of views submitted by Parties, other Governments and relevant international organizations on 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 (paragraph 3 of Article 18) and on gaps that may exist that may justify a need to develop new rules and standards<sup>1/</sup>*

### **CONTENTS**

SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS.....	2
CANADA .....	2
CHINA .....	3
COLOMBIA .....	4
MEXICO.....	4
SOUTH AFRICA.....	7
UNITED STATES OF AMERICA (USA).....	8
SUBMISSIONS FROM ORGANIZATIONS.....	9
CODEX ALIMENTARIUS COMMISSION.....	9
GLOBAL INDUSTRY COALITION (GIC) .....	11

\* UNEP/CBD/BS/COP-MOP/4/1.

<sup>1/</sup> The submissions are reproduced in the form and the language in which they were received by the Secretariat.

/...

In order to minimize the environmental impacts of the Secretariat's processes, and to contribute to the Secretary-General's initiative for a C-Neutral UN, this document is printed in limited numbers. Delegates are kindly requested to bring their copies to meetings and not to request additional copies.

## SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS

CANADA

[18 DECEMBER 2007]  
[SUBMISSION: ENGLISH]

[...]

### **View on the adequacy of existing rules and standards for identification, handling packaging and transport relating to LMOs subject to transboundary movement under Article 18.3.**

The Protocol identifies three classes of LMOs by use:

- food feed or for processing.
- contained use;
- intentional release into the environment; and

Canada believes that with respect to possible negative effects on biodiversity, these use-classes have significantly different risk potential.

LMOs for food, feed or processing may, depending on national requirements, have undergone a risk assessment prior to transportation and are usually approved by the country of import.

LMOs for contained use usually have limited information associated with the application/notification for approval because they are used in more restricted setting. Certain LMOs for contained use may be exempted from risk assessment requirements whereas others will have an associated risk assessment. Any requirement for appropriate packaging and documentation for such uses will be covered by the relevant regulations.

LMOs for intentional release in the environment will have undergone a stringent risk assessment and should have associated risk management practices and requirements attached, if necessary.

Under the requirements of the Protocol, the country of import has the right to identify conditions of handling, packaging, identification and transport, taking into account the relevant international rules and standards.

Canada is of the view that the current rules and standards for the handling, packaging, identification and transport are adequate, and the further development of new rules and standards is not necessary at this time. One example of an appropriate international rule/standard is the UNECE guidelines on the transport of dangerous goods. These guidelines have a role to play because they address standards for packaging and identification of material that might be deemed hazardous, in particular materials that are intended for use as human pharmaceuticals, veterinary use, or for research. In Canada's view this guidance coupled with the requirements under the Protocol fully address the needs for handling, packaging and identification and that there is no need for additional rules and standards for LMOs.

CHINA

[11 DECEMBER 2007]  
[SUBMISSION:  
ENGLISH/CHINESE]

[...]

**Paragraph 3, Article 18: The COP-MOP invites 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 living modified organisms that are subject to transboundary movement, and (ii) on gaps that may exist that 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 appropriated (decision BS-III/9, paragraph 1)**

The existing regulation for identification, handling, packaging and transport of goods and substances to address concerns relating to living modified organisms that are subject to transboundary movement in China is the “Regulations on Labeling of Agricultural LMOs”. This regulation obliges three kinds of products listed below to be labeled:

- (1) Genetically modified animals, plants (including plant seeds, breeding livestock and poultry, and aquatic fry and seeds) and microorganisms shall be directly labeled as “genetically modified x x”;
- (2) This provision also applies to the products derived from such GMOs and plant seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary medicine and biologics, fertilizers and additives containing such GMOs or products derived from them.
- (3) The product directly processed from the agricultural GMOs shall be labeled as “genetically modified x x product (finished product)” or “processed with genetically modified x x as raw material.” With regard to products that are made from GMOs or products containing GMO ingredients but are found to contain no genetically modified ingredients or show no traces of such ingredients when they are finally sold, the following label shall be used: “This product is made from genetically modified X X but no longer contains genetically modified ingredients” or “The raw material of this product contain genetically modified X X, but the product itself no longer contains genetically modified ingredients.”

The existing labeling regulation of China does not include threshold value, and qualitative analysis methods and standards as well. It is hard to deal with the pollution from GMOs and its components due to accidents and technical inevitable factors. Since related government authorities have launched on solve these issues, China suggests the Secretariat collect and offer the standards and regulations to those parties and countries lack of sufficient capacity on detection.

[...]

**COLOMBIA**[4 DECEMBER 2007]  
[SUBMISSION: SPANISH]

[...]

**(i) La idoneidad de las reglas existentes y de las normas para la identificación, manejo, empaque y transporte de bienes y sustancias y (ii) las discrepancias que puedan existir y que justifiquen la necesidad de desarrollar nuevas reglas y normas, o para hacer llamado a los organismos internacionales a fin de modificar o ampliar las reglas y normas ya establecidas.**

A la fecha en Colombia el rotulado de alimentos se encuentra reglamentado en la Resolución 5109 de 2005, en la cual se establecen los requisitos de rotulado o etiquetado que deben cumplir los alimentos envasados y materias primas de alimentos para consumo humano, estos requisitos son los que a la fecha debe cumplir cualquier alimento independientemente que contenga o no OVM, esta norma no establece ningún requisito adicional de identificación por el hecho de tratarse de un alimento que contenga OVM.

Por otra parte, cursan en el Congreso de República dos (2) proyectos de Ley que pretenden establecer el rotulado obligatorio para los alimentos derivados de plantas genéticamente modificadas, los cuales desde el punto de vista técnico y científico presentan inconsistencias, además de no ser coherentes con las normas nacionales existentes (Ley 740 de 2002, Decreto 3075 de 1997, Decreto 4525 de 2005).

Por su parte el Comité del Codees sobre el Etiquetado de Alimentos (CCFL) desde el año 1996 viene trabajando en el Proyecto de Directrices para el Etiquetado de Alimentos e Ingredientes Alimentarios Obtenidos por Ciertas Técnicas de Modificación Genética/Ingeniería Genética, el cual pese a no presentar avances significativos, consideramos constituye el mecanismo internacional que permite realizar una discusión sobre el tema con la participación de los diferentes actores involucrados.

**MEXICO**[3 DECEMBER 2007]  
[SUBMISSION: SPANISH]**De conformidad con la decisión BS III/9 numeral 3, que dice a la letra:**

*Invita* a las Partes, otros Gobiernos y organizaciones internacionales pertinentes a presentar, a más tardar seis meses antes de la cuarta reunión de la Conferencia de las Partes que actúa como reunión de las Partes en el Protocolo, opiniones e información sobre (i) la suficiencia de los reglamentos y normas vigentes para la identificación, manipulación, envasado y transporte de mercancías y sustancias para responder a las inquietudes relacionadas con los organismos vivos modificados que sean objeto de un movimiento transfronterizo, e (ii) las lagunas que pudieran existir y que pudieran justificar la necesidad de elaborar nuevos reglamentos y normas, o hacer un llamamiento a los órganos internacionales pertinentes para que modifiquen o amplíen sus reglamentos y normas vigentes, si fuera apropiado;

El Gobierno de México informa lo siguiente.

**Antecedentes**

El 18 de marzo de 2005 se publicó en el Diario Oficial de la Federación, la Ley de Bioseguridad de Organismos genéticamente Modificados (LBOGM), el objetivo de esta Ley es regular las actividades de

/...

utilización confinada, liberación experimental, liberación en programa piloto, liberación comercial, comercialización, importación y exportación de organismos genéticamente modificados (organismos vivos modificados OVMs), con el fin de prevenir, evitar o reducir los posibles riesgos que estas actividades pudieran ocasionar a la salud humana o al medio ambiente y a la diversidad biológica o a la sanidad animal, vegetal y acuícola.

### **Materia de la Ley**

Es materia de esta Ley la bioseguridad de todos los OVMs obtenidos o producidos a través de la aplicación de las técnicas de la biotecnología moderna a que se refiere el presente ordenamiento, que se utilicen con fines agrícolas, pecuarios, acuícolas, forestales, industriales, comerciales, de biorremediación y cualquier otro, con las excepciones que establece esta Ley

### **Actividades que regula la LBOGM**

Las actividades con OVMs que la LBOGM regula son las siguientes:

- *Utilización confinada:* que es cualquier actividad por la que se modifique el material genético de un organismo o por la que éste, así modificado, se cultive, almacene, emplee, procese, transporte, comercialice, destruya o elimine, siempre que en la realización de tales actividades se utilicen barreras físicas o una combinación de éstas con barreras químicas o biológicas, con el fin de limitar de manera efectiva su contacto con la población y con el medio ambiente. Para los efectos de esta Ley el área de las instalaciones o el ámbito de la utilización confinada no forma parte del medio ambiente.

La utilización confinada de OVMs puede ser con fines de enseñanza, de investigación científica y tecnológica, industriales o comerciales.

- *Liberación experimental:* Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, siempre que hayan sido adoptadas medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente, exclusivamente para fines experimentales, en los términos y condiciones que contenga el permiso respectivo.
- *Liberación en programa piloto:* Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, con o sin medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas biológicas, para limitar su contacto con la población y el medio ambiente, que constituye la etapa previa a la liberación comercial de dicho organismo, dentro de las zonas autorizadas y en los términos y condiciones contenidos en el permiso respectivo.
- *Liberación comercial:* Es la introducción, intencional y permitida en el medio ambiente, de un organismo o combinación de organismos genéticamente modificados, sin que hayan sido adoptadas medidas de contención, tales como barreras físicas o una combinación de éstas con barreras químicas o biológicas, para limitar su contacto con la población y el medio ambiente, que se realiza con fines comerciales, de producción, de biorremediación, industriales y cualesquiera otros distintos de la liberación experimental y de la liberación en programa piloto, en los términos y condiciones que contenga el permiso respectivo.

### **Autoridades competentes y trámite administrativo utilización confinada**

La utilización confinada de OVMs requiere de la presentación de aviso que es la comunicación que deben presentar en formatos oficiales los sujetos a la Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT) o a la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA), según corresponda.

La utilización confinada de OVMs y la importación de dichos organismos para esa actividad, podrá realizarse a partir del momento en que la comisión interna de bioseguridad o el importador, según se trate, presente el aviso respectivo a la Secretaría correspondiente.

### **Autoridades competentes y trámite administrativo para la liberación intencional al medio ambiente en sus tres modalidades (experimental, piloto y comercial)**

En principio, toda liberación, experimental, piloto y comercial, así como su importación para esa actividad debe cumplir con el requisito de la solicitud y obtención del permiso que le corresponde emitir a la SEMARNAT o la SAGARPA, dependiendo del tipo de OVM del que se trate, así como del propósito final de dicho uso.

Será requisito para obtener el permiso de liberación al ambiente, que el solicitante cuente con la autorización del OVM que expida la SSA de conformidad con esta Ley, cuando dicho organismo tenga finalidades de salud pública o se destine a la biorremediación.

### **Autorizaciones**

Los OVMs que se destinen a su uso o consumo humano o al procesamiento de alimentos para consumo humano, que se destinen para finalidades de salud pública o biorremediación para poder realizar su comercialización e importación para su comercialización, requerirán autorización por parte de la Secretaría de Salud (SSA).

### **Exportación**

Los interesados en exportar OVMs que se destinen a su liberación al ambiente en otros países, notificarán por sí, conforme se determine en las disposiciones reglamentarias que deriven de la LBOGMs, su intención de exportar dichos organismos, a las autoridades competentes del país respectivo.

Dicha notificación sólo se realizará en los casos en que los tratados y acuerdos internacionales en los que los Estados Unidos Mexicanos sean parte, establezcan ese requisito para efectuar la exportación al país de que se trate. La información que el interesado adjunte a la notificación a que se refiere este artículo, deberá ser exacta, fidedigna y ajustada a lo que establezcan dichos tratados y acuerdos internacionales.

### **Identificación**

Los requisitos de información que deberá contener la documentación que acompañe a los OVMs que se importen conforme a la LBOGMs, se establecerán en normas oficiales mexicanas que deriven del presente ordenamiento, considerando en su expedición la finalidad a la que se destinen dichos organismos y lo que se establezca en tratados internacionales de los que los Estados Unidos Mexicanos sean parte. Actualmente se están desarrollando los criterios que contendrán las Normas.

## Transporte

El transporte de OVMs o de productos que los contengan, así como el tránsito de dichos organismos y productos por el territorio nacional, cuando tengan como destino otro país, se regirán por las normas oficiales mexicanas que expidan de manera conjunta las Secretarías competentes, con la participación de la Secretaría de Comunicaciones y Transportes.

**(i) la suficiencia de los reglamentos y normas vigentes para la identificación, manipulación, envasado y transporte de mercancías y sustancias para responder a las inquietudes relacionadas con los organismos vivos modificados que sean objeto de un movimiento transfronterizo,**

Conforme a lo anterior podemos decir que la LBOGMs representa un instrumento legal general, obligatorio y amplio que permite regular diversas actividades con OVMs dentro de las cuales se incluye la identificación, manipulación, envasado y transporte de mercancías y sustancias provenientes de OVMs. En el país se están desarrollando los reglamentos y normas que derivarán de esta Ley y que permiten detallar los requisitos para el desarrollo de estas y otras actividades con OVMs.

**(ii) las lagunas que pudieran existir y que pudieran justificar la necesidad de elaborar nuevos reglamentos y normas.**

En los análisis internos que se han llevado a cabo en México se considera que con los reglamentos y las normas que se deriven de la LBOGMs será suficiente para reglamentar las actividades de identificación, manipulación, envasado y transporte de mercancías y sustancias de manera congruente con otras legislaciones nacionales como es la Ley General de Salud; entre otras actividades. Se está en proceso de analizar si nuevos OVMs como son los que tienen usos farmacéuticos, pueden regularse conforme al marco legal vigente o bien si se requiere alguna adecuación al mismo.

## SOUTH AFRICA

[13 DECEMBER 2007]  
[SUBMISSION: ENGLISH]

[...]

Paragraph 3, Article 18.

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 LMO's that are subject to transboundary movement.

In SA permits issued for LMO's that are subject to transboundary movement adequately prescribe conditions / standards relating to the identification, handling, packaging, and transport of consignments.

- ii) The 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.

In SA our experience with the permit system has indicated that permit conditions need to be clear in order 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.

[...]

UNITED STATES OF AMERICA (USA)

[30 NOVEMBER 2007]  
[SUBMISSION: ENGLISH]

***Paragraph 3, Article 18:* The COP-MOP invites 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 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 (decision BS-III/9, paragraph 1).**

Since the Protocol came into force, Parties have continued to develop their national regulatory systems in order to meet their domestic needs and comply with their international obligations. Further, international bodies, such as the International Plant Protection Convention (IPPC) and the U.N. have also addressed the need for rules regarding the identification, handling, packaging, and transport of LMOs. These efforts are consistent with the objectives of the Protocol, and we are unaware of any adverse impacts to biodiversity caused by inadequacies in identification, handling, packaging or transport of LMOs.

Therefore, the United States does not believe the MOP needs to develop new or additional standards. We continue to support Parties as they develop their own national policies to address their needs with regard to identification, handling, packaging and transport of LMOs. The Biosafety Clearing House currently lists 96 separate entries related to national laws, regulations or guidelines dealing with identification, handling, packaging and transport of LMOs which represents the contributions more than 50 countries. Together, the national experience of these countries combined with the international work detailed below, provides evidence that there is not a need for the development of additional rules and standards.

#### **Relevant Work of Other Bodies:**

**IPPC:** The International Plant Protection Convention develops standards and guidelines for the protection of plant health, governed by the Committee on Phytosanitary Measures (CPM). The CPM adopts International Standards for Phytosanitary Measures (ISPM). 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-11, 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 LMOs, the IPPC guidance recognizes the need for the National Plant Protection Organization to carry out a 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.

**UN Recommendations on Transport of Dangerous Goods:** The UN has issued recommendations in the form of the Model Regulations on the Transport of Dangerous Goods. 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 Labeling of Chemicals, and specifically, the Sub-Committee of Experts on the Transport of Dangerous Goods. The recommendations can be found here: (<http://www.unece.org/trans/danger/danger.htm>). Genetically Modified Organisms (GMO) and Genetically Modified Microorganisms (GMMOs) 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:

GMMOs 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.

GMMOs 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.

## SUBMISSIONS FROM ORGANIZATIONS

### CODEX ALIMENTARIUS COMMISSION

[30 NOVEMBER 2007]  
[SUBMISSION: ENGLISH]

[...]

Apart from the above work by the Codex Task Force, the Codex Alimentarius Commission has been undertaking on: 1) appropriate labelling provisions to genetically modified food through the Codex Committee on Food Labelling (CCFL); 2) methods of analysis and sampling for the detection of genetically modified foods through the Codex Committee on Methods of Analysis and Sampling (CCMAS); and 3) more general work on traceability/product tracing through the Codex Committee on Import and Export Inspection and Certification Systems (CCFICS).

#### **Committee on Food Labelling (CCFL)**

The Committee on Food Labelling (CCFL) 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 difference between original products and genetically modified products is solely the production method.

/...

The 35th 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 labelling of GM/GE 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.

#### **Committee on Methods of Analysis and Sampling (CCMAS)**

The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing appropriate methods of detection and analysis for the GM foods since 2002. In view of the absence of precise provisions for GMOs 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 28th 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 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.

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

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 13th 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 29th Session of the Commission in July 2006 and have been published in the Codex Alimentarius (CAC/GL 60-2006).

The CCFICS at its 16th 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.

[...]

**GLOBAL INDUSTRY COALITION (GIC)**

[30 NOVEMBER 2007]  
[SUBMISSION: ENGLISH]

*In response to the request by the Parties in Decision BS-III/9 for views and information on 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 (LMOs) and the existing gaps that may justify a need to develop new rules and standards, please find below the views of the Global Industry Coalition (GIC) on this issue.*

**Experience to date indicates that existing Protocol guidance on documentation for shipments under Article 18.2(b) and (c) are working well and that shipments are moving globally without problems. For some categories of LMOs that require special identification, handling, packaging or transport, other international bodies already provide such requirements. Therefore, and in order to create synergies and avoid duplication of efforts, the GIC recommends that Parties focus on information-sharing with these other relevant international bodies rather than developing any new rules or standards under Article 18.3 of the Protocol.**

**I. Existing Guidance on Shipping Documentation Provided by the Parties is Adequate for the Majority of LMO Shipments**

**A. Article 18.2(b)**

With respect to Article 18.2(b), such shipments comprise the entire range of organisms and microorganisms, including viruses, bacteria, fungi, parasites, insects, other animals and plants. The majority of shipments are for research and development purposes, mainly for the testing and treatment of disease, and are shipped in accordance with national regulations and pursuant to authorizations or permits as required. A survey conducted by the GIC and the International Seed Federation (ISF) indicates that shipments to and from Parties and non-Parties under Article 18.2(b) using the existing guidance provided by the Parties are working well, and no problems or concerns have been reported to date.<sup>2/</sup>

**B. Article 18.2(c)**

The majority of shipments that fall under Article 18.2(c) are for commercial purposes, crop or seed production. In these cases, the LMO has completed approval for commercial release into the environment in the exporting and importing country. A smaller number of shipments are for research and development purposes, and are planted to assess the suitability of the crop variety for local use or to develop data in order to complete regulatory requirements for commercialization. These shipments move pursuant to regulatory approvals in accordance with a positive Advanced Informed Agreement under the Protocol or authorizations under national regulations. Any special requirements for safe handling of the LMO research material are typically specified in environmental release authorizations. Again, the GIC and ISF survey results indicate that such shipments under Article 18.2(c) are occurring globally without problems.

**II. Adequacy of Existing Rules and Standards for Identification, Handling, Packaging and Transport of Goods and Substances**

---

<sup>2/</sup> See the GIC submission to the Secretariat of the Convention on Biological Diversity in response to a request for information on Article 18.2(b) and (c) implementation, dated 30 November 2007.

The vast majority of shipments of LMOs falling under Article 18.2(c) are exempt from special standards for identification, packaging, handling and transport regulations. They are moved pursuant to national authorizations and in accordance with existing guidance on shipping documentation requirements agreed by Parties without any problems.

Shipments of LMOs under Article 18.2(b) comprise a wide range of goods that, when appropriate, are covered by existing international transport regulations as well as Protocol shipping documentation. Experience to date indicates that no gaps have been identified; therefore, no further standards or requirements for these shipments need be developed under Article 18.3.

### **III. International Bodies of Experts on the Identification, Handling, Packaging and Transport of Goods**

#### **a. UN Committee of Experts on the Transport of Dangerous Goods and the UN Model Regulations**

The United Nations Economic and Social Council's Committee of Experts developed the "Model Regulations on the Transport of Dangerous Goods" (UN Model Regulations) which are general packing requirements, testing procedures for packages, marking or labeling and transport requirements for certain categories of substances. 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 UN Model Regulations were created to facilitate direct integration of requirements into all model, national and international regulation and 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>3/</sup>

While not applicable to LMOs that are authorized for use by the competent authorities of the government of the countries of origin, transit and destination (i.e., the vast majority of shipments under Article 18.2(c)), these regulations apply to specific categories of LMOs, for example, those that meet the definition of an infectious substance under the UN Model Regulations. Those that do are assigned to the appropriate category of infectious substance, thereby becoming subject to all requirements under that category.

Given this existing set of requirements and body of expertise, any further development or refinement of rules and standards for identification, handling, packaging and transport of LMOs subject to these recommendations and the UN Model Regulations should be referred to the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods.

#### **b. International Air Transport Association Live Animals Regulations (LAR)**

---

<sup>3/</sup> Recommendations on the Transport of Dangerous Goods, 15<sup>th</sup> revised edition, ST/SG/AC.10/1/Rev.15 (Vol.I)

The 33rd edition of the LAR provides guidance on packaging and documentation needed for the transport of live animals. <sup>4</sup>The LAR has been developed by the International Air Transport Association (IATA) in consultation with Parties to the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES), the World Organisation for Animal Health (OIE) and government authorities that implement the LAR for animal transportation to ensure safety in transport and humane transportation of live animals. The LAR is 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 an LMO, the LAR would govern its international movement by air.

#### IV. Conclusions

- The Secretariat should continue collaborating with relevant international bodies to ensure that information on existing rules and standards governing special categories of LMOs are available to the Parties via the Biosafety Clearing-House.
- Parties should also support the ongoing work on this issue taking place in other international organizations. Accordingly, if any gaps are identified in the future, they should be referred to the organizations that are already addressing those matters, e.g. the UN Committee of Expert on the Transport of Dangerous Goods and the IATA Live Animal Regulations.
- The goal in further discussions by the Parties under Article 18.3 should be to ensure awareness of existing requirements under other international agreements and organizations and to further create synergies and avoid duplication of efforts.

-----

---

<sup>4</sup>/

[Http://www.iata.org/ps/publications/lar.htm](http://www.iata.org/ps/publications/lar.htm).