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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
FIRST MEETING OF THE PARTIES TO THE
CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
Kuala Lumpur, 23-27 February 2004
Agenda item 6.4 of the provisional agenda *

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18)

Compilation of views and relevant information on Article 18 of the Cartagena Protocol on Biosafety

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SUBMISSIONS FROM GOVERNMENTS

AUSTRALIA

[22 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Australia submitted these views on documentation requirements in 2001. The following comments are resubmitted as they contain additions based on further consideration of issues.

The Protocol is intended to assist countries to safeguard their biodiversity when making decisions on the import of living modified organisms (LMOs). It facilitates the provision of information by which countries can:

- initiate scientifically-sound and transparent case-by-case assessments about whether the import of an LMO (or group of LMOs) would pose any risks to their biodiversity; and

- initiate consideration of appropriate risk management action if necessary (based on those assessments).

Australia notes that such assessment processes should conform to standards that are propagated by relevant international standards-setting agencies, such as the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the International Plant Protection Commission.

It is important to recognize that the key source of such information under the Protocol will be the Biosafety Clearing-House (BCH). It is not intended that shipping documentation substitute for, or duplicate, the detailed information provided through the Biosafety Clearing-House. There appeared to be some confusion about this during the intergovernmental discussions.

For the functionality and credibility of the Protocol, it is essential that information under Article 18(2)(a) be:

- **Clear and simple.** This would facilitate appropriate science-based decisions and avoid creating misunderstandings with importing parties. It would also avoid impediments to commerce through costly and overly-complex information requirements. Information not needed to assist countries to make decisions under the Protocol's regime, such as quality considerations, should not be required under Article 18(2)(a).

- **Timely.** In line with the timeline agreed by participants at Montreal, Australia recalls the necessity of resolving the details of the information requirements in the first sentence by the time of entry into force of the Protocol. This suggests a step-wise approach, with those elements on which a decision is required no later than two years after the date of entry into force being left for subsequent consideration.

Specific Elements of Article 18(2)(a)

First sentence

- *Nature of the information* - Australia suggests that a standard statement be agreed to the effect that:

This shipment may contain living modified organisms for direct use as food or feed, or for processing. This shipment is not intended for intentional introduction into the environment.

On the basis of the specific commodity involved and the country of origin of the shipment being known, importing countries could use the Biosafety Clearing-House database to review the information on potential LMOs that may be involved.

- *Presentation of the information* – Australia suggests that, in line with the approach to Article 18(2)(b) and (c), such a statement could be provided on accompanying documentation provided by the originator and/or required by existing international documentation systems.

- *Contact point* – Australia suggests that, in the first instance, the contact point be identified as a representative of the originating party, who would readily have basic information associated with details of the consignment. Should additional information, such as the nature and safe handling of the LMOs, be sought by importers, they should draw on the Biosafety Clearing-House database.

Second sentence

Australia suggests that, in line with the text of the Protocol and the lack of agreement on the requirements of the first sentence, consideration should not be given to the detailed requirements referred to in the second sentence at this time. An opportunity to draw on the experience of Parties with implementation of the requirements of the first sentence of Article 18(2)(a) would be an important input to these subsequent considerations.

Progress

Australia notes that the outcomes of the second Experts Meeting held from 18 to 20 March 2002 formed a basis for discussion at the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP 3). Australia agrees that these outcomes and the record of discussions at ICCP 3 be provided in full to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to form the basis for discussion.

Submission of the Government of Australia

Views on Article 18.2(a)
Invitation to examine unique identification systems with a view to considering their applicability to the requirements of identification of LMOs and their linkage to the Biosafety Clearing-House (paragraph 4(b), recommendation 3/6)

The Protocol text states that "[…] Parties to this Protocol shall take a decision on the detailed requirements [..], including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol".

Australia suggests that, in line with the text of the Protocol and the lack of agreement on the requirements of the first sentence, consideration should not be given to the detailed requirements referred to in this sentence at this time. An opportunity to draw on the experience of Parties with implementation of the requirements of the first sentence of Article 18.2(a) would be an important input to these subsequent considerations. Therefore, although the sentence enables unique identifiers to be considered, the case for their necessity is yet to be made.

CANADA [14 OCTOBER 2003]
[SUBMISSION: ENGLISH]

Clarification of how the documentation provisions of the Cartagena Protocol on Biosafety will be implemented is essential for both Parties and non-Parties. Canada believes strongly that the success of

the Protocol in meeting its objective will depend upon consistent implementation by Parties of provisions which are clear, predictable and not subject to numerous interpretations. It is also Canada's view that all decisions from the meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety should be by consensus (the lack of any formal objection). In this regard, Canada looks forward to the seventh meeting of the Conference of the Parties providing greater clarity, predictability and consistency on the application of consensus

It is Canada's view that at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, priority should be given to implementing the first sentence of Article 18.2(a) in a practical and predictable manner; particularly as the need for additional documentation requirements will be dependent on the experience gained from implementing the first sentence. Therefore, Canada would look to a decision at the second meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety as to whether or not additional requirements are necessary and may be practically implemented, based on the experience Parties have gained.

Recommendations of the Technical Expert Group

Canada supports the agreed recommendations of the Technical Expert Group on the implementation of Article 18.2(a). However, Canada has the following views regarding how Article 18.2(a) is to be implemented.

Implementation of the first sentence

Currently, intentional transboundary movements of products intended for direct use as food or feed, or for processing (FFP), whether they are LMOs or not, are accompanied by some documentation. The information required under Article 18.2(a) should be included in the existing exporter-generated documentation that accompanies transboundary movements of LMO FFPs. In the interest of efficiency and to follow current trade practices, Canada would recommend that the commercial invoice be used for the purpose of documentation requirements under the Biosafety Protocol.

Canada recommends that the last exporter and the first importer should be identified as the contact points for additional information.

Canada supports the recommendation that the documentation should state:
CARTAGENA PROTOCOL ON BIOSAFETY PROVISION: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment.

It is Canada's view that the scope of the Protocol extends only to the intentional transboundary movement of LMOs. This intent is made clear, for example, through specific references in the Protocol's definitions of "import" and "export" as well as in the first paragraph of Article 18 to "intentional transboundary movements". Hence, Article 18.2(a) documentation requirements apply only to *intentional transboundary movements of LMOs* intended for direct use as food or feed, or for processing.

It is Canada's view that documentation requirements should not apply to shipments for which the exporting country does not have in commerce any LMO of that species.

Canada supports the recommendation of the Technical Expert Group that adventitious material is excluded from the scope of Article 18 (documentation) and that adventitious material therefore does not trigger the Article 18.2(a) provisions. Consistent with this recommendation, adventitious material does not fall, in Canada's view, under the scope of Article 17.

Canada believes that additional clarity in a decision on implementation of the first sentence of Article 18.2(a) is necessary for both importers and exporters, in particular clarity on the conditions for application of the "may contain language" provision does not affect a Party of import's decision on the import of LMOs destined for food or feed, or for processing under its domestic regulatory framework or according to a risk assessment, pursuant to Article 11 of the Protocol.

Transit, although not an identified topic on the agenda of the meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, relates directly to the implementation of Article 18. Canada is of the view that documentation requirements under Article 18 do not arise for transit Parties. Parties need a clear and common understanding of what constitutes "transit". To this end, Canada would propose the following definition: LMO shipments shall be deemed to be in transit across the territory of a party when the passage across such territory, with or without transhipment, warehousing, breaking of bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the Party across whose territory the LMO shipment passes. Canada would like to secure MOP concurrence on this, or some other, definition.

Implementation of the second sentence

It is Canada's view that the need for, and nature of, a decision from the meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, under the second sentence will depend on experience gained through the implementation of the first sentence.

EUROPEAN UNION [21 OCTOBER 2003]
[SUBMISSION: ENGLISH]

Introduction

In the present document, the EU expresses its views on the content of Article 18.2(a), the unique identifiers and on other relevant issues to be considered in the context of Article 18.

A brief description of recent developments in the EU legislative framework (relevant in the context of discussion on Article 18) is annexed to this document.

Article 18.2(a)

As regards the implementation of Article 18.2(a), the EU wishes first to recall its previous submission made in January 2002, which contains a detailed analysis of the implementation of that provision.

The EU foresees a workable implementation of the identification provisions in Article 18.2(a) of the Protocol and in that respect welcomes the useful suggestions on how to take the issue forward contained in the recommendations from the Technical Expert Group meeting annexed to recommendation 3/6 of ICCP 3, and the Chair's summary also annexed to that recommendation, which contains numerous suggestions for moving forward.

The EU also welcomes the fact that the recommendations of the TEG meeting, annexed to the ICCP3 recommendation, recognize the need to address thresholds for adventitious/unintentional presence, as well as the need for clarification/elaboration on the application of the language in paragraph 2(a) of Article 18, specifically the "may contain" phrase, where the identity of the specific LMO(s) in a transboundary movement is known and verified. These two issues, as well as the issue of identification of LMOs, are also addressed in paragraphs (k), (l) and (n) of the Chair's summary.

Unique identification system

The EU welcomes the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants developed by the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology and now widely used within the OECD LMOs product database, as well as for recent LMOs submissions to the EU regulatory approval process.

As such a system can only be operational if it is globally harmonized, the EU supports the adoption of the same unique identification system within its own regulatory framework, as well as within the context of the Protocol, and specifically supports the development of a register for unique identification codes to be placed under the Biosafety Clearing-House.

The EU also welcomes the establishment of further international work, possibly under the OECD Working Group, to examine the issue of unique identification systems for microorganisms and animals, not yet addressed. If such a system is not available before the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety, the EU is of the opinion that the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety should take a decision that includes wording that will ensure the best possible coverage of microorganisms and animals, or at least operative paragraphs to ensure swift development of a complete system.

Other elements on Article 18

The EU would like to see the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety address the issues of the implementation of the requirements of Article 18.1, and the relationship with other international organizations in order to ensure that existing international documentation systems contribute to the achievement of the objectives of the Protocol.

The EU also considers that it would be useful for the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety to adopt, under Article 18.3, recommendations on the appropriate implementation of Article 18.2 and, where appropriate, guidance on the implementation of Article 18.1.

The EU is ready further to discuss the proposals for the implementation of Article 18.2 (a), (b), and (c), through templates for stand-alone documents or the incorporation of the required information in existing documents, as annexed to the recommendation from ICCP 3, as well as those submitted by Norway. The EU is of the view that a decision on this issue should be possible at the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety, in order to ensure appropriate and timely implementation of Article 18.2.

Annex

Recent developments in the EU legislative framework

The European Union has recently adopted three legal acts which are all relevant to the implementation and operation of the Cartagena Protocol on Biosafety:

- *Regulation on Genetically Modified Food and Feed*
- *Regulation concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms and amending Directive 2001/18/EC*
- *Regulation on Transboundary Movements of Genetically Modified Organisms.*

Regarding the implementation of Article 18.2 of the Protocol, the EU considers that, in order to provide adequate information to importers of LMOs in third countries, it is appropriate to impose similar requirements on the operators exporting LMOs from the EU and on those using LMOs within the EU.

The three Regulations should enter into force in November 2003. The Community will then have in place an exhaustive set of requirements concerning the identification of LMOs, for any use foreseen in Article 18.2 of the Protocol.

The provisions on identification of LMOs as set out in the Regulations on Transboundary Movements and on Traceability and Labelling of GMOs are without prejudice to other specific requirements imposed by Community legislation and international identification requirements to be developed in accordance with Article 18 of the Protocol.

EU rules address, *inter alia*, the issues of adventitious presence of LMOs (Article 12.2, Article 24.2 and Article 47 of the EU Regulation on Genetically Modified Food and Feed, and Article 4, section C, of the EU Regulation on Traceability and Labelling of GMOs) and the issue of identification of LMOs in mixtures (Article 12.1 last subparagraph of the EU Regulation on Transboundary Movements of GMOs, and Article 4.3 of the EU Regulation on Traceability and Labelling of GMOs).

Moreover, the EU internal standards are subject to review on the same (two-year) time scale as the determination of detailed requirements under the Protocol for the purposes of Article 18.2(a). This review will take account of the detailed requirements eventually agreed by Parties to the Protocol on identification of LMOs.

NORWAY

[15 OCTOBER 2003]
[SUBMISSION: ENGLISH]

Submission from Norway - Example of template for Article 18.2 (a) of the Cartagena Protocol

Date:

Transport documentation of LMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (a) – LMOs intended for direct use as food, feed or processing only

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Unique identification number in BCH:

Description of the LMO(s), including specification of their identity:

Ordinary name of the LMO(s) (including variety and transformation event for all LMOs in the shipment if relevant)	
Taxonomic name	
Gene modification (characteristics, including inserted or changed traits and genes)	

Requirements by importing country:

Reference to import approval	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement.

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	**Amount**	**Weight / Volume**	**Value**

I declare that the information above and this shipment of LMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:_____

Submission from Norway - Example of template for Article 18.2 (b) of the Cartagena Protocol

Date:

Transport documentation of LMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (b) – LMOs destined for contained use only

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Ordinary name of the LMO	
Taxonomic name	
Unique identification number, if existing	
Reference to BCH, if relevant	
Risk categorization, if relevant	
Type of intended use: Commercial Research Other	

If required by importing country:

Reference to import approval	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement.

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

I declare that the information above and this shipment of LMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:___

Submission from Norway - Example of template for Article 18.2 (c) of the Cartagena Protocol

Date:

Transport documentation of LMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (c) – LMOs destined for intentional introduction into the environment

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Unique identification number in BCH:

Description of the LMO:

Ordinary name of the LMO (including variety and transformation event if relevant)	
Taxonomic name	
Risk categorization, if relevant	
Gene modification (characteristics, including inserted or changed traits and genes)	
Type of intended use: Commercial Research Other	

Requirements by importing country:

Reference to import approval (e.g. in accordance with AIA)	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

I declare that the information above and this shipment of LMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:_____

PARAGUAY

[22 SEPTEMBER 2003]
[SUBMISSION: SPANISH]

Borrador de documento a ser presentado a la Secretaría del Convenio para el 22 de septiembre de 2003, para la preparación de la reunión de la Conferencia de las Partes en el Protocolo de Cartagena sobre Seguridad de la Biotecnología.

Elementos considerados del Informe del Comité Intergubernamental para el Protocolo de Cartagena sobre Seguridad de la Biotecnología documento UNEP/CBD/ICCP/3/10 :

Ítem 3/6 Manipulación, transporte, envasado e identificación (Artículo 18), página 90

1. En este ítem se manifiesta en el párrafo 1. La clara obligatoriedad de que los OVM que serán transportados deberán tener identificación y los requisitos para la manipulación, almacenamiento, transporte y uso seguros. El Punto de Contacto para una ulterior información, nombre y señas de la persona e institución a la que se envían los OVM Artículo 18 inciso b.
2. (a)(b) Que se proporcione información para satisfacer los requisitos de documentación en virtud del Artículo 18 2(c) "Organismo vivo modificado" (OVM), especificando la identidad y los rasgos y/o características pertinentes especificados en el Protocolo:

(i) Una breve descripción de los organismos, categoría, nombre, rasgos pertinentes, incluidos rasgos transgénicos y características tales como sucesos de transformación.

2.(c) Cualesquiera de los requisitos para la manipulación, almacenamiento, transporte y uso seguros parágrafos (i) (ii) (iii) (iv) (v).
2. (d) Punto de Contacto para obtener información adicional.
2. (e) Nombre y señas del exportador e importador
2. (f) Una declaración de que el movimiento transfronterizo se ajusta a los requisitos del Protocolo de Cartagena aplicables al exportador.

En este sentido la Secretaría del Ambiente se encuentra gestionando los mecanismos para el cumplimiento del Artículo 18

Anexo I, página 94

Artículo 18, párrafo 2 a)

Del Tema 3, página 98, párrafo 22 (g)(h)(i) (j) (k) (l) son elementos fundamentales para la identificación en el movimiento transfronterizo, transporte, almacenaje de los OVM y por lo tanto habrían de incluirse en la factura comercial.

Párrafo 25 (b) En la cadena de transborde de carga a granel será importante la responsabilidad de cada país por donde pasa la descripción de la carga que abandona sus fronteras. En este caso las aduanas juegan un papel importante.

Punto de contacto: página 101

32. (g) (l) Será conveniente que sean el exportador y la autoridad competente que autoriza dicho movimiento.

(o) Es muy importante considerar que en los países en desarrollo no siempre se tiene la facilidad de acceso al BCH.

Página 102: Identificación de OVM destinados a uso directo como alimento humano o animal o para su procesamiento.

35. (m) Los OVM deben ser identificados para asegurarse de que se están cumpliendo las normas aprobadas por el país de importación.

(u) Es necesario aplicar el enfoque de precaución.

(v) Es necesario identificar los OVM, incluida una referencia al suceso de transformación y a un identificador exclusivo si se dispusiera del mismo.

(aa) Los costos asociados al tener que retirar productos de la circulación después de que haya entrado al país.

Página 104, párrafo 39 (a) (i) (K) (l) (n) (p) (v)(x) (z) luego (gg) relacionado estrechamente con (l)

En las referencias a los OVM-AHAP deberá incluirse también una referencia al suceso de transformación, variedad del OVM, información sobre el origen del OVM y el donante.

No existe en la actualidad ningún modo apropiado para detectar la presencia de OVM de manera fortuita / indeliberada en un envío a granel.

Es necesario que la información aclare el contenido desde el exportador para aquellos que la utilizarán.

Por lo que el punto de contacto debe ser el exportador y una autoridad competente del país que lo envía para proporcionar información.

Debe señalarse que los OVM-AHAP están destinados a uso directo como alimento humano o animal o para procesamiento.

Es necesario el vínculo con el BCH en las notificaciones.

Es necesario impulsar la confianza de los consumidores; en esto los productores de OVM son los que deben dar mayor énfasis en divulgar esa confianza y que están acordes con los procedimientos del Protocolo de Cartagena Sobre Seguridad de la Biotecnología.

Será necesario establecer umbrales para estos productos. En esto ayudaría la experiencia de los países que lo establecieron y transmitir sus experiencias locales.

Página107 : presencia fortuita / indeliberada de los OVM en envíos ajenos a OVM

Párrafo 45 (b): este punto habría que considerarse en la legislación nacional.

(c) Los umbrales deberán estar enlazados con la expresión “pueden llegar a contener” y vinculado al BCH

Página108, párrafo 45

(h) Debería esperarse que los exportadores no infrinjan los objetivos del Protocolo de Cartagena sobre Seguridad de la Biotecnología.

(i) Si el exportador no fuera responsable jurídicamente de la presencia de OVM en un envío declarado e identificado, entonces debería ser responsable la Parte en el Protocolo a través de la autoridad competente que otorgó el permiso.

(k) El objetivo de la expresión “puede llegar a contener” era el de destacar que los OVM serán probablemente parte de cualquier envío a granel.

(m) La expresión “libre de OVM” era inapropiada.

(s) El problema era en realidad una cuestión del equilibrio al que debería llegarse entre el exportador y el importador, especialmente con los países en desarrollo.

(t) Aunque haya distintos niveles de riesgo, ha de establecerse una línea de base; y esto puede lograrse en un marco regulatorio nacional.

(aa) Debería realizarse un muestreo para verificar si se cumplen las leyes nacionales.

(bb) Deberían adoptarse medidas de precaución para aislar los OVM de otros artículos ajenos a OVM.

(dd) Los umbrales solamente deberían aplicarse cuando haya una inclusión deliberada de OVM en un envío.

(ee) El objetivo del Protocolo es proteger a la diversidad biológica.

(ff) (gg) Debería instarse a las industrias en mejorar sus prácticas, no debería estar ciega respecto a los efectos de sus prácticas.

(hh) Es importante proteger la diversidad biológica y los exportadores deberán comunicar datos normalizados sobre cualesquiera OVM detectados en un envío.

Párrafo 48 (h), La mayoría de los países desarrollados tienen una tolerancia cero respecto a OVM no aprobados.

(i) La tolerancia cero era la única aceptable para el medio ambiente.

(o) Los OVM-AHAP presentan diversos niveles de riesgo y estos riesgos aumentan cuando está implicada la polinización cruzada.

(p) En espera del desarrollo de normas de muestreo científico y de técnicas de detección era necesario convenir niveles de tolerancia.

Cuestiones que puedan afectar a la capacidad técnica de las Partes en cuanto a aplicar el Artículo 18, párrafo 2 a)

Párrafo 51 (b) Era necesario elaborar un identificador exclusivo conectado con el Centro de Intercambio de Información (BCH).

(c) Era necesario obtener el asesoramiento de la industria acerca del muestreo de los OVM fortuitos.

(d) Era necesario obtener el asesoramiento de los gobiernos y de la industria

(e) La expresión “puede llegar a contener ” implicaba umbrales.

(g) Aunque la industria debería elaborar métodos científicos de muestreo e identificación, han de divulgarse los rasgos de transformación asociados a los OVM que sean objeto de movimiento transfronterizo.

Anexo, página 112, Recomendaciones de la reunión de expertos técnicos sobre los requisitos del Artículo 18, párrafo 2 a)

1. Respecto a las modalidades de aplicación de los requisitos para la documentación que acompaña a los movimientos transfronterizos de OVM destinados a uso directo como alimento humano o animal o para su procesamiento y reconociendo las recomendaciones de los expertos se considera que:

a) a través de los marcos nacionales con reglamentos y directrices claros se debe acompañar la documentación en los envíos de OVM para uso directo como alimento humano o animal o para procesamiento.

Estamos de acuerdo con los párrafos (a) (b) (c) (d) (e) (f).

2. Estamos de acuerdo con los párrafos (b) (c) La necesidad y el desarrollo de un sistema de identificación armonizado y exclusivo aplicable a los OVM en virtud del Artículo 18.2 a), como medio para proporcionar acceso directo a la información pertinente así como la necesidad de desarrollar una metodología normalizada, de precio razonable, accesible e internacionalmente aceptada para el muestreo, detección e identificación de los OVM destinados a uso directo como alimento humano o animal o para su procesamiento.

SWITZERLAND [26 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Article 18.2(a)

On the issue related to Article18.2(a), we would like to refer to our position expressed in document UNEP/CBD/ICCP/3/INF/5.

Unique identification systems

A unique identification system for LMOs based on a transformation event is essential for the efficient functioning of the decisions database of the Biosafety Clearing-House. This is especially critical for the tracking of decisions under Article 11.1 of the Cartagena Protocol.

So far, the only available system is the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants. All commercialized transgenic crops now have a unique identifier developed according to this guidance (OECD's unique identifier). Indeed, the OECD unique identifier is required under our national system for any application for commercial release of transgenic plants including for use as food, feed or for processing. Therefore, Switzerland fully supports the use in relevant Biosafety Clearing-House databases of the OECD unique identifier as the internationally-recognized identification code for transgenic plants approved for commercialization.

The use of the OECD unique identifier requires the establishment of a central database on living modified plants (LMP) that would contain all detailed information specific to the LMPs such as paragraphs (c) (d), (f), (g), (h) and (k) of Annex II to the Protocol. The database on national decision under Article 11.1 will then focus on letters (a), (b), (i) and (j) of Annex II to the Protocol.

Switzerland also supports the development of unique identification systems for other groups of LMOs such as microorganisms or animals. Those systems should be kept short, simple and user friendly and should be built up on experience gained with the OECD's unique identifier for plants.

UNITED STATES OF AMERICA [25 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Paraphrased, the first sentence of Article 18.2(a) of the Cartagena Protocol on Biosafety (CPB) requires documentation accompanying shipments of living modified organisms (LMOs) intended for use as food, feed, or processing (FFP) to identify that they “may contain” LMOs and are not intended to be introduced into the environment.

The United States supports the following set of “key elements” and considers that, when exporters and importers trade commodities with documentation in this way, they will have fulfilled both the objectives and the requirements of Article 18.2(a) of the CPB. We recommend that Parties adopt

these "key elements" for practical implementation of Article 18.2(a) in a predictable and transparent manner using existing documentation.

As the second sentence of Article 18.2(a) calls for the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to take a decision on any detailed requirements within two years of entry into force, such decision can be informed by the practical experience gained in the interim by applying these elements.

Key elements of Article 18.2(a) Implementation

- The "may contain" language, when required, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry.
- The "may contain" language, when required, should state:

  "Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing that are not intended for intentional introduction into the environment.
- The last exporter before the transboundary movement and the first importer after the transboundary movement named on the invoice are the contact points for further information.
- Applicability:

  (a) The "may contain" documentation is required for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is deregulated in or sold from the country of export, except:

  (i) Shipments for which the exporting country does not have in commerce any LMO of that species; or

  (ii) When the exporter and importer have contractually defined a "non-LMO shipment", provided that such a shipment achieves a minimum of 95 per cent non-LMO content and that such definition does not conflict with regulations of the importing country.

  (b) Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation.

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC) [22 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

On 11 September 2003, the Cartagena Protocol on Biosafety (Protocol) entered into force - the first legally-binding international agreement governing the movement of living modified organisms across national borders. Following entry into force, those countries that ratified the Protocol became Parties to the Protocol and are required to comply with and implement all its provisions. However, countries that are Parties to the Protocol are not the only countries that are affected by its requirements. Article 24 of the Protocol states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objectives of the Protocol - in other words, countries that have not ratified the Protocol but that export LMOs to Parties must also comply with the Protocol's provisions implemented in the importing country. Thus, entry into force will ultimately impact both Party and non-Party countries

that export LMOs to countries that are Parties to the Protocol that have national implementing legislation.1/

One aspect of entry into force of the Protocol deals with the information required on shipping documentation for LMO imports to Parties as outlined in Article 18.2(b) and (c). Article 18 outlines requirements for the safe handling, packaging and transport of LMOs covered within the scope of the Protocol. Paragraphs 2(b) and (c) specify the documentation requirements for LMOs destined for contained use and those intended for intentional introduction into the environment, respectively. The Intergovernmental Committee for the Cartagena Protocol (ICCP) - the Committee mandated to undertake the preparations necessary for the first meeting of the Parties to the Protocol - reviewed these two paragraphs and the recommendations of the Second Meeting of Technical Experts on Article 18.2(b) and (c) 2/ during its third meeting in April 2002. As a result of these discussions, the ICCP made specific recommendations on implementation of Article 18.2(b) and (c) for submission to the first meeting of the Parties serving as the meeting of the Parties to the Protocol .3/

Following entry into force, the decision-making body of all the member countries of the Protocol will convene at the first meeting of the Parties serving as the meeting of the Parties to the Protocol on Biosafety to address topics related to the operation and implementation of the Protocol, including Article 18.2(b) and (c); however, this meeting does not take place until February 2004. Therefore, on 11 September and until that time, delineation of what is required in order to meet the requirements of Article 18.2(b) and (c) was not finalized nor implemented by the Parties. As such, the private sector set forth certain guidelines to ensure consistency with the intent of the Protocol before further decisions on interpretation are made. The guidelines were based on the ICCP 3 recommendations,4/ and the private sector recommends that they be accepted at the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol as a workable system for all involved in transporting LMOs across national boundaries.

(a) LMOs destined for contained use (Article 18.2(b)):5/

In order to meet the documentation requirements of Article 18.2(b) of the Protocol, the private sector suggests that the following information be included in *existing shipping documentation* (such as commercial invoices);

(i) The following statement outlining the shipment contents:

"This shipment contains living modified organisms for contained use" (may specify contents of shipment here, such as "*Bacillus subtilis* containing the α-amylase gene from *B. stearothermophilus*");

(ii) The name and address of the exporter, importer or consignee, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;

(iii) A brief description of any requirements for the safe handling, storage, transport and use of the LMO when safe handling requirements under other international agreements (such as the International Plant Protection Convention, or in the case of movement of

1/ Many countries, whether Parties or non-Parties, have existing national regulatory requirements for shipping LMOs with which exporters must currently comply.

2/ UNEP/CBD/ICCP/3/7/Add.2.

3/ UNEP/CBD/ICCP/3/10, pp. 76-78.

4/ Ibid.

5/ Article 18.2(b) of the Protocol covers LMOs destined for contained use and provides that, "[l]iving modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned."

genetically-modified microorganisms, the United Nations Recommendations on the Transport of Dangerous Goods) have not already been met. In the event that there is no requirement, indicate that there is no specific requirement; and

(iv) The name and address of the consignee.

(b) LMOs for intentional introduction into the environment (Article 18.2(c)):6/

In order to meet the documentation requirements of Article 18.2(c) of the Protocol, the private sector suggests that the following information be included in *existing shipping documentation* (such as commercial invoices);

(v) The following statement outlining the shipment contents:

"This shipment contains living modified organisms";

(vi) A brief description of the LMO, including category, name, relevant traits and/or characteristics;

(vii) A brief description of any requirements for the safe handling, storage, transport and use of the LMO as provided under applicable existing international requirements (such as the requirements under the OECD Seed Schemes), under the domestic regulatory framework, under the advanced informed agreement procedure, or under any agreement by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;

(viii) The name and address of the exporter and importer, including contact details necessary to reach them as fast as possible in case of emergency (designate which is to be used as the contact point for further information); and

(ix) The following declaration:

"The exporter declares that the transboundary movement of this LMO is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter."

Use of a system of identification

The ICCP 3 recommendations for Article 18.2(c) include a reference to a system of identification in the details accompanying the Protocol requirement that the shipping documents specify the "identity and relevant traits and/or characteristics" of the LMO being shipped.7/ One such system of identification listed is the reference to a harmonized code such as a unique identifier. This particular recommendation is bracketed text and was not agreed to by the participants at ICCP 3.

The language of the Protocol does not require the use of a unique identifier on the shipping documentation, nor are unique identifiers available or appropriate for all transgenic material that may be subject to the Protocol. For instance, many of the shipments will be for limited research use and the specific identification of the material will be contained in the advanced informed agreement or permit for

6/ Article 18.2(c) of the Protocol addresses shipments of LMOs for intentional introduction into the environment and states that, "[l]iving modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter."

7/ UNEP/CBD/ICCP/3/10, pp. 77, paragraph 2(b)(ii).

research. Thus, Parties would already have the detailed scientific, transformation event-specific information for the LMO being shipped.

While the private sector suggests that the use of a unique identifier should not be a mandatory requirement under Article 18.2(c) of the Protocol, in some cases such an identifier may allow Parties to access the most precise description of an LMO. As such, the private sector has supported the development of the OECD unique identifier 8/ for transgenic plants which have been approved for commercial application and looks forward to discussing how this system may be appropriate for use in some instances with regard to the Protocol.

INTERNATIONAL GRAIN TRADE COALITION (IGTC) [22 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Background

The Cartagena Protocol on Biosafety will have a profound effect on the international trade in grains, oilseeds, pulses and special crops. As of 11 September 2003, the transboundary movement of most living modified organisms (LMOs) to or from countries that are Parties to the Protocol must be accompanied by appropriate documentation.

The Protocol impacts both Parties and non-Parties. Article 24 of the Protocol states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objectives of the Protocol – in other words, countries that have not ratified the Protocol but that export LMOs to Parties must also comply with the Protocol's provisions implemented in the importing country. Thus, entry into force will ultimately impact both Party and non-Party countries that export LMOs to countries that are Parties to the Protocol that have national implementing legislation.

Article 18 requires the safe handling, packaging and transport of LMOs covered within the scope of the Protocol. In addition, paragraph 2(a) describes the requirements for the transboundary movement of LMOs for food, feed, or for processing.

The text in Article 18 is of a general nature and unfortunately many documentation issues remain unresolved after three meetings of technical experts and three meetings of the Intergovernmental Committee on the Cartagena Protocol. These issues have been deferred for resolution to the the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to be held in Malaysia in February 2004. As a result, when the Protocol entered into force on 11 September 2003 some confusion on documentation requirements existed.

Industry's objective is to implement the Protocol to protect the world's biodiversity while maintaining the benefits of the current low-cost global handling and transportation system.

The International Grain Trade Coalition (IGTC) was formed in 2001 in recognition of the fact that the Protocol could have a profound impact on maintaining a low-cost bulk handling system to ensure an inexpensive food supply for world consumers. Today, the IGTC has 17 members representing more than 1,000 organizations in more than 80 countries.

The IGTC represents importers, exporters and food, feed and industrial processors. On documentation issues, the IGTC has concentrated on Article 18.2(a).

8/ See OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants available at http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)7.

Article 18.2(a)

With the Protocol coming into force on 11 September, the IGTC is urging an early resolution of the outstanding issues associated with Article 18.2(a) in order to avoid unnecessary disruptions in commodity trade. The transboundary movement of these commodities is staggering. For food, feed and processing alone, the volume of international trade each year amounts to about 200 million tonnes of cereals, 30 million tonnes of rice, more than 70 million tonnes of oilseeds and more than 7 million tonnes of pulses.

The IGTC encourages major exporters to use Article 24 of the Protocol to bring greater clarity to documentation requirements for grain destined for food, feed and processing. Article 24 enables Parties to enter into arrangements with non-Parties on the transboundary movement of LMOs provided that the arrangements are consistent with the Protocol. Major exporters have met on two occasions in Argentina to seek agreement on how best to clarify documentation requirements under Article 18.2(a) to avoid trade disruptions.

Article 18.2(a) states that each Party (government) shall take measures to require that documentation accompanying:

> "Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;"

The IGTC recommends that Article 18.2(a) be clarified by naming the commercial invoice as the document to be used to carry the "may contain" language, when required. If all exporters use the same document, then custom officers do not have to search through all shipping documents to see whether or not the cargo is an LMO shipment. The IGTC suggests that the "may contain" language, when required, should be as agreed upon at the Montreal Expert Committee meeting:

> *"Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."*

The last exporter prior to transboundary movement and the first importer after transboundary movement named on the invoice should be the contact points for further information. And finally, it is also important that the unintentional presence of LMOs in a non-LMO shipment is not a trigger for the "may contain" documentation.

There also is need to clarify when the documentation should be used. The IGTC recommends that the "may contain" documentation for transboundary movements of commodities intended for food or feed or for processing be provided for an LMO of that commodity species covered under the scope of the Protocol that is authorized in or sold from a country of export, except for those shipments for which:

(i) The exporting country does not have in commerce any LMO of that species; or

(ii) The exporter and importer have contractually defined a "non-LMO shipment;" provided, that such shipment achieves a minimum of 95 per cent non-LMO content, and that such definition does not conflict with regulations of the importing country.

Exporters are currently in discussions with major importers to seek agreements to clarify Article 18.2(a) to ensure trade is not disrupted when the Protocol comes into force. The IGTC believes that such agreements between importers and exporters should also facilitate resolution of outstanding Article

18.2(a) issues at the first meeting of the Parties serving as the Parties to the Cartagena Protocol on Biosafety.

International Grain Trade Coalition Members and Contact Points

The Grain and Feed Trade Association (GAFTA): GAFTA is the only worldwide trade association representing the interests of members who trade in grains, feeding stuffs, pulses and rice internationally, with over 800 members in 80 countries. Contact point: Pamela Kirby Johnson, Director General, GAFTA House, 6 Chapel Place, Rivington Street, London, EC2A 3SH, United Kingdom, Tel: 44 20 7814 9666, Fax: 44 20 7814 8383 E-mail: PamelaKirbyJohnson@gafta.com

The North American Export Grain Association (NAEGA): NAEGA is comprised of grain and oilseed exporters and interested parties whose purpose is to promote and sustain the development of commercial export grain and oilseed trade from the United States. NAEGA members include 35 private and publicly- owned companies and cooperatives domiciled in the United States and Canada. Contact point: Gary C. Martin, President and CEO, North American Export Grain Association, Incorporated, Suite 1003, 1250 Eye Street NW, Washington, D.C. 20005, Tel: 202 682 4030, Fax: 202 682 4033, E-mail: gcmartin@naega.org

COCERAL: COCERAL is the representation of the European trade in cereals, feedstuffs, oilseeds, olive oil, vegetable oil and agrosupply. It comprises the trade organizations in 15 EU member States, which for their part represent collectors, distributors, exporters, importers and storekeepers of the above-mentioned commodities. Furthermore COCERAL has associated members in Hungary, Poland and Switzerland. Contact point: Klaus Schumacher, Vice Chairman, or Chantal Fauth, Secretary General, COCERAL, 18 Square de Meeus, B 1050 Brussels, Belgium, Tel 02 502 08 08, Fax 02 502 60 30, E-mail: secretariat@coceral.com

Canada Grains Council (CGC): CGC has a membership of about 30 organizations involved in Canada's grains, oilseeds, pulses and special crops industry including producers, handlers, transporters, processors, exporters, banks and provincial and federal governments and their agencies. Contact point: Dale Adolphe, Chairman Biosafety Committee, or Patty Rosher, Member, Biosafety Committee or Dennis Stephens, Consultant, Canada Grains Council, 1215-220 Portage Avenue, Winnipeg, MB, R3C 0A5, Canada Tel 204 925 2133, Fax 204 925 2132, E-mail: dstephens@canadagrainscouncil.ca

AWB Limited (Australian Wheat Board): AWB Limited is Australia's major national grain marketing organization and is one of the world's largest wheat management and marketing companies. It is involved in the management and marketing of wheat (for which it is the nation's exclusive bulk exporter) as well as other grains including barley, sorghum, oilseeds and pulses. Contact point: Darryl Hockey; Ceres House, 528 Lonsdale Street, Melbourne 3000,Victoria, Australia Tel 61 3 9209 2555; mobile 61 407 920 911; E-mail jmolan@awb.com.au

National Grain and Feed Association (NGFA): NGFA consists of 1,000 grain, feed, processing and grain related companies that operate about 5,000 facilities that store, handle, merchandise, mill, process and export more than two-thirds of all US grains and oilseeds. About 70% of NGFA member firms are small businesses — country elevators and feed mills. Also affiliated with NGFA are 36 state and regional grain and feed associations. Contact point: Mr. Tom O'Connor, Director of Technical Services, National Grain and Feed Association, Suite 1003, 1250 Eye Street NW, Washington, D.C. 20005. E-mail toconnor@ngfa.org

Soybean Processors Association of India (SOPA): SOPA is an all-India-based association having a membership of 600 members representing processing industries, exporters, buyers, brokers, surveyors, analysts as well as farmers. The Association members are actively involved in trading soybean meal for food and feed purposes. Contact point: Mr. D. R. Kalra, Executive Director, Soybean Processors Association of India, Scheme No. 53, Bear Malviya Nagar, A. B. Road, Indore 452 008, India, E-mail sopain@bom4.vsnl.net.in

ANIAME: ANIAME is the Association of Oilseed (including soya, canola and sunseeds) Processors in Mexico. Contact point: Lic Amadeo Ibarra, Director General, ANIAME, Praga 39 Piso 3, Col. Juarez, C. P. 06600, Mexico, D.F., Mexico, E-mail aibarra@aniame.com

Hungarian Grain and Feed Association: the Hungarian Grain and Feed Association represents 80 –90% of the companies involved in Hungary's milling, grain-export, soymeal-import and feed milling industry. Contact point: Mr. George Makay, General Secretary, Hungarian Grain and Feed Trade Association, Alkotmany U.16.11.9, H-1054 Budapest, Hungary, E-mail gabonaszov@mail.datanet.hu

The Solvent Extractors' Association of India: The Solvent Extractors' Association of India was formed in 1963 to help and foster the development and growth of India's solvent extraction industry. At present the Association has about 900 members including about 550 solvent extraction plants having a combined oilcake/oilseed processing capacity of about 30 million tonnes. Contact point: Mr. B.V. Mehta, Executive Director, 142 Jolly Maker Chambers No 2, 14th Floor, 225, Nariman Point, Mumbai-400 021 India, E-mail solvent@vsnl.com

National Corn Growers Association (NCGA): NCGA is a coalition of 27 affiliated state organizations and represents the interests of 350,000 corn producers in the United States. Contact point: Mr. Fred Yoder, President, National Corn Growers Association, E-mail seedman@netwalk.com or Hayden Milberg, e-mail: milberg@ncga.

APPAMEX: the Mexican Association of Providers of Agricultural Products represents organizations involved in the trade of imported and exported agricultural commodities in Mexico. Contact point: Ricardo Calderon, Director, Durango 245 Desp. 203, Col. Roma, 06700 Mexico D.F, E-mail appamex@attglobal.net

US Wheat Associates: US Wheat Associates is the market development arm of the United States wheat industry. Contact point: Nelson Denlinger, US Wheat Associates, Suite 801, 1620 I Street, N.W., Washington, D.C. 20006-4005, E-mail: ndenlinger@uswheat.org

Centro de Exportadores de Cereales (Chamber of Grain Exporters of the Argentine Republic: the Chamber was formed in 1944 and includes the 12 largest grain exporters, marketing approximately 30 million tonnes per year. Contact point: Ciro Echesortu, President, or Gabriel Gilges, General Manager, or Alberto Rodriguez, Bouchard 454 7th floor, C1106ABF, Buenos Aires, Argentina, phone 54 11 4311 1697, fax: 54 11 4311 7767, E-mail: Cerex@datamarkets.com.ar

Wheat Export Trade Education Committee: WETEC is responsible for carrying out activities that advance and help formulate the trade policies of the United States wheat industry. Contact point: Barbara Spangler, Executive Director, 415 Second Street, N.E., Suite 300, Washington, D.C. 20002. Tel 202-547-2004, Fax 202-546-2638, E-mail: Spangler@USWheat.org.

US Grains Council: The US Grains Council builds global markets and serves international customers for United States grains through a unique partnership of United States producers, agribusiness and the public sector. Contact point: David McGuire, Director of Trade Relations and Global Strategies, 1400 K Street NW, Suite 1200 Washington, DC 20005, phone: (202) 789-0789, fax: (202) 326-0660, E-mail: dmcguire@grains.org; Website: http://www.grains.org

Russian Grain Union: Contact point: Arkady Zlochevsky, President: 107139, Moscow, Orlikov Per, 1/11, Office 576, 821: tel: (095) 207-8256, 207-8285, 207-8345, 207-5279, tel/fax: (095) 207-8379, 207-5344; E-mail: rgumsk@dol.ru

INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC SECRETARIAT) [24 SEPTEMBER 2003] [SUBMISSION: ENGLISH]

PEST RISK ANALYSIS FOR LIVING MODIFIED ORGANISMS

The purpose of the International Plant Protection Convention (IPPC) is to secure "common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control". Its application is much wider than the protection of cultivated plants. The IPPC extends to the protection of natural flora and plant products. It includes both direct and indirect damage by pests. The provisions extend to cover conveyances, containers, storage places, soil and other objects or material capable of harbouring and spreading pests. The IPPC is recognized under the Agreement on Sanitary and Phytosanitary Measures as the relevant international organization for the development of standards on phytosanitary measures. There are over 120 contracting parties to the IPPC. The Secretariat to the Convention is provided by the Food and Agriculture Organization of the United Nations, Rome.

The IPPC develops and approves standards on phytosanitary measures through the Interim Commission on Phytosanitary Measures (ICPM). There are currently 19 IPPC standards covering a range of relevant topics including basic principles, risk analysis, risk management, surveillance, pest eradication, certification systems, biological control agents and area freedoms. The ICPM is acting as the meeting of parties to the Convention in advance of the coming into force of amendments and the formation of the Commission on Phytosanitary Measures.

Phytosanitary risks that may be associated with living modified organisms (LMOs) are within the scope of the IPPC and should be considered using pest risk analysis (PRA) to facilitate decisions regarding pest risk management.

The IPPC has organized a series of workshops and consultations resulting in the production of a draft supplement on the risk analysis of LMOs to be included in the *International Standard for Phytosanitary Measures No.11 – Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks.* These workshops involved representatives from the Cartagena Protocol on Biosafety and others with specific expertise in LMOs.

The purpose of this supplement is to assist National Plant Protection Organizations (NPPOs) assess the pest risks of LMOs and develop appropriate risk management measures. This text provides guidance on the criteria for evaluating potential risks to plants and plant health posed by living modified organisms (LMOs). It does not alter the scope of the standard but is intended to clarify issues related to the pest risk analysis of LMOs.

The 120-day formal country consultation period on the draft supplement closes on 24 October 2003. Comments will be considered by the Standards Committee and, if appropriate, the amended supplement sent to the ICPM for formal adoption in March/April 2004.

The draft supplement on LMOs and other information about the IPPC can be accessed via the website (www.ippc.int).

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE) [26 SEPTEMBER 2003] [SUBMISSION: ENGLISH]

The World Organisation for Animal Health (OIE) is an intergovernmental organization created by the International Agreement of 25 January 1924, signed by 28 countries. In May 2003, the OIE comprised 164 member countries.

The OIE's missions are as follows:

1. Transparency in animal disease status worldwide

Each member country is committed to report to the OIE on its health status regarding significant animal diseases and diseases transmissible to humans. The OIE then disseminates the information to all member countries to enable them take appropriate action to protect themselves. Dissemination is via the OIE Website, e-mail and various OIE periodicals.

2. Collection, analysis and dissemination of veterinary information

Using its network of internationally-recognized scientists, the OIE collects, analyzes and publishes the latest scientific information on significant animal diseases, including those transmissible to humans, especially regarding their prevention and control.

3. Strengthening of international coordination and cooperation in the control of animal diseases

The OIE provides technical expertise to member countries requesting assistance with animal disease control and eradication operations, particularly developing countries. It does this in coordination with other international organizations responsible for supporting and funding the eradication of animal diseases.

4. Promotion of the safety of world trade in animals and animal products

The OIE develops standards for use by member countries to protect themselves against disease incursions during trade in animals and animal products, while avoiding unjustified sanitary barriers. These standards are developed by experts from member countries and from the OIE's network of 156 Collaborating Centres and Reference Laboratories. The World Trade Organization recognizes OIE standards as international references in the fields of animal diseases and zoonoses.

In addition, at the request of Member Countries, the OIE has taken on two new mandates - animal welfare and animal production food safety.

OIE's international standards

The above missions highlight the OIE's international responsibilities with regard to the agents (and their vectors) of significant animal diseases and zoonoses.

In a similar fashion to the emphasis the Convention on Biological Diversity has placed on the greater likelihood of incursions of invasive species due to rapidly accelerating human trade and modern forms of transport, the OIE is faced with addressing the increased spread of recognized pathogenic agents and their vectors, and of emerging pathogens, resulting from similar factors. A significant difference in our mandates is that, while the Convention on Biological Diversity confines its activities in this regard to “alien invasive species” i.e. species occurring outside their normal distributions, the OIE does not distinguish pathogenic agents on the basis of their origins. OIE Standards are developed and member countries' reporting obligations are based on the importance of a pathogenic agent to international trade in animals and animal products, and on its potential impact on public health.

The OIE does not include in its standards an assessment of the impact a live animal (excluding pathogenic agents) itself may have on the environment of an importing country. Save for several pest species (such as screwworm) which are subject to compulsory reporting, the OIE's primary concern is that the imported commodity (animal or animal product) does not introduce into the importing country a significant pathogenic agent and its vector. Such an approach reflects the primarily animal health orientation of the OIE.

The OIE has decided to do away with the current A and B lists of diseases and to have a single list of diseases for reporting purposes and on which to base its international standards. In deciding the criteria for listing diseases, the OIE is now placing less emphasis on the economic impact of disease incursions (in recognition of the variety of economic and public health effects incursions of the same

disease may have), especially between developing and developed countries. The new criteria focus on the likelihood and rapidity of international spread, and on zoonotic potential. This may allow a greater emphasis on the impact incursions may have outside agricultural industries.

The work of the OIE's Working Group on Wildlife Diseases, which advises the OIE on diseases of wild animals (whether in the wild or in captivity) and reports annually on disease occurrences, is part of this broader approach.

Both our organizations place emphasis on strong competent authorities adopting national strategies for an effective response to preventing and addressing incursions. The OIE also emphasizes the use of risk analysis to assess the risks and to develop effective management strategies, without putting in place unnecessary trade barriers.

Genetically-modified organisms

Given the role of the OIE in setting international standards for veterinary drugs, especially diagnostic tests and vaccines, and recognizing the importance of the current use of genetically-modified organisms for the generation of diagnostic reagents and immunological preparations when safer and more effective, I would urge the Convention to consult the OIE in developing recommendations on GMOs related to these products.

I believe that our two organizations should seek to work more closely to address our many common objectives.

WWF INTERNATIONAL [30 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Operation of Article 18.2(a) now that the Protocol has entered into force

WWF notes that the "may contain" provision of Article 18.2(a) is now operational following the entry into force of the Protocol, and that therefore Parties should now implement this, and taking into account Article 24, should require similar "may contain" statements and identification for shipments made by non-Parties to Parties. WWF suggests that the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopt an appropriate statement to confirm and emphasise this.

Integral treatment of Articles 18.2 (a), (b) and (c)

WWF suggests that to ensure a consistent approach and to avoid duplication, it is important for the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol to consider all parts of Article 18.2 in an integrated manner and that Article 18.2(a) should not be treated differently from Articles 18.2(b) and (c).

Article 18.2(a) of the Protocol states that each Party shall take a decision on detailed requirements concerning LMO-FFPs no later than two years after the date of entry into force of the Protocol. Taking this into account, WWF recommends that first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopt requirements for LMO-FFPs in relation to Article 18.2(a), at the same time dealing with Articles 18.2(b) and (c).

Identification

In relation to LMO-FFPs, WWF's view is that it would <u>not</u> be appropriate to set a minimum threshold for LMO content, below which Article 18.2(a) would not apply; and that all shipments that may

contain LMO-FFPs should be subject to the identification requirements of the Protocol, with no exemptions**.**

Information about LMOs known to be present or which may be present within shipments of LMO-FFPs is important and should be provided so as to allow importing countries to verify whether such LMOs have been approved and posted on the Biosafety Clearing-House, and also whether they comply with the requirements of their domestic regulatory frameworks. Such information should therefore be specified in accompanying documentation.

WWF also notes the need for a standardized and thorough system of identification for all LMOs, including LMO-FFPs, and suggests that first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety should decide to move ahead with adoption of a system of unique identification in relation to LMO-FFPs, and that consideration be given by the meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to extending unique identification to cover all LMOs subject to transboundary movements. Application of this system to all LMOs would assist measures to ensure traceability of LMOs.

Traceability

WWF suggests that the meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety agree on measures to ensure the traceability of all LMOs, including LMO-FFPs, so as to enable LMOs to be traced back to the original exporter, for example, through audit trails as part of product stewardship; and to require originators and exporters of LMOs to notify the Biosafety Clearing-House of ways to distinguish each LMO from non-LMOs through identifying features and diagnostic tests.

Capacity-building for implementation of all parts of Article 18(2)

WWF also notes that effective implementation of all parts of Article 18(2) is an essential component in relation to biosafety, and recommends that first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety consider the need for capacity-building in this area, and for the Protocol's financial mechanism to provide appropriate financial resources to developing countries for this.
