



Convention on Biological Diversity

Distr. GENERAL

UNEP/CBD/BS/COP-MOP/4/INF/10/Add.1 3 April 2008

ORIGINAL: ENGLISH/SPANISH

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*

ASSESSMENT AND REVIEW (ARTICLE 35)

Compilation of submissions of information on experience gained with the use of documents to identify transboundary movements of living modified organisms destined for contained use and those intended for intentional introduction into the environment (paragraphs 2(b) and 2(c), Article 18)**

CONTENTS

SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS..... 2 ARMENIA..... 2 CANADA 2 CHINA 3 COLOMBIA 3 LITHUANIA..... 4 NORWAY 4 SOUTH AFRICA..... 5 UNITED STATES OF AMERICA (USA)..... 6 SUBMISSIONS FROM ORGANIZATIONS..... 8 GLOBAL INDUSTRY COALITION (GIC) 8 PUBLIC RESEARCH AND REGULATION INITIATIVE 12

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

** 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

ARMENIA

[28 DECEMBER 2007]
[SUBMISSION: ENGLISH]

In Armenia it was developed draft law on “LMOs”, which will soon be presented to public audience and then to the National Assembly of RA by the Government for its endorsement. The law regulates all the functions of LMOs. Thus, I would like to mention during 2007 in Armenia no LMO was imported.

As to article 18 paragraph a, b and c we approved by-law, that the LMOs that are subject to transboundary movement, be handled, packaged and transported according to international rules and standards, as well as requirements of article 18.

[...]

Living 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; and living 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.

CANADA

[18 DECEMBER 2007]
[SUBMISSION: ENGLISH]

[...]

Information on Canada’s experience with the use of commercial invoices or other documents under Article 18.2(b) and (c).

It is Canada’s experience that, most countries have either not implemented such documentation requirements, or have only recently implemented them. It is difficult therefore to provide views or relate experience on the use of these documents at this time because there has been little practical application of the documentation requirements. Canadian regulatory requirements for LMOs vary according to product and end use and are implemented in accordance with Canada’s domestic regulatory framework.

Canada would welcome a further opportunity to provide feedback on the implementation of Article 18(2), and suggests that Parties and Non-Parties be given another chance to comment on Article 18(2) at COP/MOP-5.

[...]

CHINA

[11 DECEMBER 2007]

[SUBMISSION:
ENGLISH/CHINESE]

[...]

Paragraphs 2 (b) and 2 (c), Article 18, Living modified organisms for contained use and Living modified organisms for intentional introduction into the environment: The COP-MOP requests Parties and invites other Governments and relevant international organizations to submit to the Executive Secretary further information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements (decision BSIII/8, paragraph 1);

In the process of safety management on transboundary movement of LMOs, China has followed all relevant standards and technical specifications by ISO and CAC. The Regulations on Risk Management of Agricultural LMOs, the Regulations on Labeling of Agricultural LMOs, the Measures for Inspection and Quarantine of Import and Export LMOs have all served to regulate the transportation, packing and labeling of LMOs.

[...]

COLOMBIA

[4 DECEMBER 2007]

[SUBMISSION: SPANISH]

Información sobre la experiencia adquirida con el uso facturas comerciales u otros documentos requeridos o utilizados por sistemas de documentación ya establecidos o de conformidad con los requisitos nacionales.

La verificación de las facturas comerciales cuando es del caso y de los documentos propois del proceso de importación de un alimento o materia prima para la industria de elimento el país, es verificada por los funcionarios del INVIMA en las oficinas ubicadas en los puntos de primera barrera (aeropuertos, puerto y pasos fronterizos), tras lo cual se realiza la inspección sanitaria respectiva con base en la cual se expide el certificado de inspección para la nacionalización.

Respecto a los OVM de uso en alimentación humana o procesamiento (artículo 11 del Protocolo de Cartagena), a la fecha en los puntos de primera barrera no se realiza verificación de la factura comercial en relación con OVM. No obstante, el Comité Técnico Nacional de Bioseguridad de OVM de uso en salud y alimentación humana exclusivamente (CTNSalud), como parte de las recomendaciones hechas para autorizar un OVM para consumo humano ha incluido el requerimiento de que el importador debe dar cumplimiento con lo establecido en el artículo 18.2 (a), del PC acogido mediante la Ley 740 de 2005, en el cual se establece que en la documentación que acompaña el cargamento debe identificar claramente que “puede contener OVM” y que no está destinado a ser introducido intencionalmente en el medio ambiente.

Con el fin de poder hacer seguimiento a estas recomendaciones, una vez sean acogidas por acto administrativo del Ministerio de la Protección Social, el INVIMA se encuentra trabajando en el procedimiento a seguir por sus funcionarios en los puntos de primera barrera.

[...]

/...

LITHUANIA

[28 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

1. Lithuania implementing Article 18. Handling, Transport, Packaging and Identification of Cartagena Protocol on Biosafety in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health have a requirement for exporters - importers to inform the Competent Authority in transport documentation of LMOs.
2. Lithuania has not any experience gained with the use of a commercial or other documents required or utilized by existing documentation system.

NORWAY

[12 DECEMBER 2007]
[SUBMISSION: ENGLISH]

[...]

Decision BS-III/8 - Documentation

Paragraph 1 of Decision BS-III/8 of the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested Parties and invited Governments to submit further information on experience gained with the use of existing documents accompanying transboundary movements of living modified organisms for contained use and those for intentional introduction into the environment (paragraphs 2(b) and 2(c) of Article 18), with a view to future consideration of a stand-alone document.

The labeling requirements set out in Norwegian legislation for living modified organisms (LMOs) destined for contained use and LMOs intended for intentional introduction into the environment are in conformity with paragraphs 2(b) and (c) of Article 18 and Decision BS-II/10. They are described in Norway's First Regular National Report on the Implementation of the Cartagena Protocol on Biosafety 1/.

There are currently no field trials in Norway. Only a very limited number of transport and import occasions for contained use and intentional introduction into the environment other than marketing have been reported. The only LMO authorized for marketing (and thus for intentional introduction into the environment) in Norway are one tobacco and three different kinds of carnations. Norwegian consumers have a restrictive attitude towards LMOs, and consequently there is no consumer demand for LMO in Norway.

Activities involving transport, import and export of LMO for contained use or intentional introduction, and our experience with the use of documentation accompanying LMOs destined for contained use or intended for intentional introduction into the environment, are therefore limited.

Given the low level of activity and lack of consumer demand within this field in Norway, and the ongoing discussions under the Cartagena Protocol on transport documentation, Norway has for the time being chosen not to establish a standard format for transport documents accompanying LMO for intentional introduction into the environment in the form of marketing.

1/ <http://www.cbd.int/biosafety/parties/reports.shtml?report=NR-CPB-01>

Norway's position on the identification and documentation requirements pursuant to paragraph 2 of Article 18 has consistently been that they should be as detailed, clear and informative as possible and be conveyed in a manner that is easy to find and understand, both in relation to the content of the information and the way it is presented, in order to allow importing countries to verify that the imported LMOs are those that they agree to import. We recall our previous submissions of 14 October 2003 and 20 August 2004 and 14 September 2005, the two first submissions containing templates for stand-alone documents to accompany LMOs that are destined for contained use or intended for intentional introduction into the environment.

Norway is still of the opinion that a standard format for transport documents, preferably a stand-alone document, should be established by the Parties to the Protocol to fulfill the requirements mentioned above. A standard format would also make the fulfilment of the information requirements of the Protocol easier for traders in LMO. We therefore enclose revised templates for such documents adapted to the information requirements set out in Decision BS-I/6 B. 2/ The template could also be used as a harmonized documentation format if that would be the preferred option of the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

[...]

SOUTH AFRICA

[13 DECEMBER 2007]

[SUBMISSION: ENGLISH]

[...]

Paragraphs 2b & c, Article 18, LMO's for contained use and LMO's for intentional introduction into the environment: Information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements.

South Africa makes use of existing documentation in the form of a permit to limit the burden of additional bureaucracy that could negatively impact on trade. Permits are issued in terms of national legislation (GMO Act) and accompany LMO consignments for contained use and intentional introduction into the environment. All requirements pertaining to the safe handling, transport, packaging and identification of LMO's have been incorporated into existing permits in the form of permit conditions.

[...]

2/ See Annex I to this document

UNITED STATES OF AMERICA (USA)

[30 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

The COPMOP requests Parties and invites other Governments and relevant international organizations to submit to the Executive Secretary further information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements (decision BSIII/8, paragraph 1)

Summary

Decision BS-I/6 on documentation accompanying transboundary movements of LMOs intended for contained use or for intentional introduction into the environment is currently consistent with the guidance on implementation of Articles 18.2(b) and 18.2(c).. Additional information, beyond what is delineated in this decision document, is unnecessary. Use of the commercial invoice has been easy to implement and the consideration of a stand-alone document should be set aside. Although a number of Parties and Non-Parties have posted information regarding approvals for domestic use or importation, more Parties need to post information on the Biosafety Clearing-House concerning how they intend to implement Article 18.2(b) and 18.2(c).

There is a history in both the public and private sectors concerning transboundary movement of LMO materials for contained use and intentional introduction into the environment that precedes the Biosafety Protocol. These transactions have been and will continue to be governed by national laws and regulations. Common commercial practices have evolved for shipping these organisms, including establishment of the information included on the shipping documentation. The United States believes that the documentation in common commercial practice for shipment of LMOs for contained use or intentional introduction is sufficient to ensure the safety of the environment and protection of biodiversity.

Background

Decision BS – I/6 on documentation accompanying transboundary movements of LMOs intended for contained use or for intentional introduction into the environment is currently consistent with the guidance on implementation of Articles 18.2(b) and 18.2(c).. Additional information, beyond what is delineated in this decision document, is unnecessary. Use of the commercial invoice has been easy to implement and the consideration of a stand-alone document should be set aside.

It is important that the domestic requirements that are put in place by importing countries are clear, practical, and do not unduly burden exporters with requirements that do not further the goals of the Protocol with respect to protection of biodiversity. There are well-established commercial practices that are recognized by those in the public and private sectors involved in the transboundary movement of LMOs destined for contained use and for intentional introduction into the environment. These time-tested procedures, which use invoices that contain pertinent information concerning the cargo and handling procedures, have functioned well and have not led to any reported adverse incidents.

Based on the extensive experience of the export and import communities, no potential for adverse impact on biodiversity from existing practices has been observed. Additional requirements under these articles have the potential to create needless burden and would likely compromise existing well-functioning procedures, which already comply with the relevant requirements of Article 18.2(b) and 18.2(c).

Communication channels between the import and export community are well established and generally operate smoothly. Both importers and exporters know and understand the requirements for transboundary movement of LMOs destined for contained use and for intentional introduction into the environment. However, communication between newly formed national authorities and the well-established existing import/export community could be improved. It will be of benefit to all stakeholders for these communications mechanisms to be robust and operational.

Communication between national authorities and entities shipping LMO materials would be greatly facilitated by taking full advantage of the Biosafety Clearing-House to post national laws, regulations, and guidelines regarding requirements for LMOs destined for release into the environment or contained use. Since the Protocol entered into force, many of the 142 Parties have not yet met their obligations to provide such information to the Biosafety Clearing-House.

The utility of the Biosafety Clearing-House is limited by the lack of information actually available on it. Although both Parties and Non-Parties have posted a limited amount of information regarding approvals for domestic use or importation, few Parties have posted information on the Clearing-House concerning how they intend to implement Article 18.2(b) and 18.2(c).

SUBMISSIONS FROM ORGANIZATIONS**GLOBAL INDUSTRY COALITION (GIC)**[30 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

Further to the request by the Parties to Cartagena Protocol on Biosafety (Protocol), other Governments and relevant international organizations to submit to the Executive Secretary further information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements with a view to future consideration of a stand-alone document, ^{3/} please find below the views of the Global Industry Coalition (GIC) in response to this request.

Based on the results of a survey conducted by the GIC and the International Seed Federation (ISF), shipments to and from Parties and non-Parties under Article 18.2(b) and (c) using the existing guidance provided by the Parties are working well, and no incidents or concerns have been reported to date. It is therefore the GIC's recommendation that Parties continue to accept shipments of living modified organisms (LMOs) for contained use and intentional introduction into the environment that are accompanied by documentation in conformity with existing guidance from the Parties. Current efforts should focus on clarifying national requirements for import by posting clear information on the Biosafety Clearing House, rather than on development of new systems or stand-alone documentation for these shipments.

I. GUIDANCE LANGUAGE

When the Protocol entered into force on 11 September 2003, thus requiring those countries that ratified it to comply with and implement all of its provisions, a final decision on the documentation requirements for Article 18.2(b) and (c) indicating specific implementation and compliance requirements had not yet been taken. In order to continue to serve the Parties in a productive manner and in keeping with their commitment to abide by the provisions of the Protocol, the GIC members developed guidelines based on the recommendations made at the third meeting of the Intergovernmental Committee for the Cartagena Protocol for entities shipping LMOs destined for contained use and intended for intentional introduction into the environment to or from Parties in order to meet the requirements outlined in the Protocol. ^{4/}

The Parties again discussed the implementation of Article 18.2(b) and (c) at the first meeting of the Parties to the Protocol, and the GIC revised its guidelines to reflect the Parties' decision at this meeting. ^{5/} At their second meeting, the Parties recognized the contribution of the GIC in developing these guidelines to implement the requirements under Article 18.2(b) and (c) in accordance with the provisions of the Protocol as further elaborated by the COP/MOP-1 decision. ^{6/} These guidelines are as follows:

^{3/} See Decision BS-III/8.
^{4/} See UNEP/CBD/ICCP/3/10.
^{5/} See UNEP/CBD/BS/COP-MOP/1/15.
^{6/} See UNEP/CBD/BS/COP-MOP/2/15.

1. Determine whether there is necessary clearance for the shipment of the LMO.

(a) LMOs for intentional introduction into the environment: If the LMO is for cultivation (deliberate release into the environment) either as a commercial product or as research and development material, an Advanced Informed Agreement (AIA) prior to the very first shipment of that particular LMO to the importing country may be required. The technology developer will typically follow this procedure and the importing country should post its decisions on the Biosafety Clearing House (BCH) ^{7/} as stipulated by Article 20.2(d) of the Protocol. Alternatively, countries can complete a risk assessment and issue an approval of an LMO for local commercial cultivation under their domestic regulatory system in lieu of requiring an AIA. ^{8/} Parties must also post these decisions on the BCH. Since the BCH is still under development, complete information may not be available on the website. ^{9/}

In the absence of information about a particular LMO on the BCH, licensees of a commercial or experimental transgenic plant trait may need to clarify with the importing country authority that a risk assessment and clearance to ship to that country has been previously approved. The Parties are working toward ensuring that this clearance and risk assessment information is available on the BCH to facilitate compliance.

(b) LMOs for contained use: ^{10/} Under Article 18.2(b), an AIA is not required by the Protocol for LMOs for contained use, but existing national regulations may require an approval or permit number for shipping or experimental use.

2. Ensure the appropriate information is included on the shipping documentation specific to a shipment of LMOs for contained use or for intentional introduction into the environment.

(a) Type of document: In order to meet the documentation requirements of the Protocol and avoid unnecessary duplication of information, GIC members include the following information on existing shipping documentation (such as commercial or proforma invoices) for shipments of LMOs for contained use (Article 18.2(b)) and LMOs for intentional release into the environment (Article 18.2(c)).

(b) Information content: LMOs destined for contained use (Article 18.2(b))

In order to meet the documentation requirements of Article 18.2(b) of the Protocol, the GIC suggests that the following information be included on existing shipping documentation (such as pro forma invoices);

(i) The following statement outlining the shipment contents:

^{7/} <http://bch.cbd.int/>.

^{8/} See Article 14.4 which allows Parties to make a determination that its domestic regulations apply with respect to specific imports and requires those Parties to post decisions taken under these domestic regulations on the BCH.

^{9/} Note that there are very few AIA decisions posted on the BCH.

^{10/} Article 3 of the Protocol defines “contained use” as meaning “any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.”

“This shipment contains living modified organisms for contained use.” It may specify common and scientific name of the organism, such as “*Bacillus subtilis* containing the α -amylase gene from *G. stearothermophilus* (formerly *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; and
 - (iii) A brief description of any requirements for the safe handling, storage, transport and use of the LMO. Note that safe handling requirements may be covered under other international agreements and are not specific to the LMO status of the shipment. In the event that there is no requirement, indicate that there is no specific requirement.
- (c) Information content: LMOs for intentional introduction into the environment (Article 18.2(c))

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 on existing shipping documentation (such as commercial or proforma invoices):

- (i) The following statement outlining the shipment contents:

“This shipment contains living modified organisms”;
- (ii) A reference to a system of unique identification, where available for commercial products, otherwise a brief description of the LMO, including category, common and scientific name, relevant traits and/or characteristics;
- (iii) A brief description of any requirements for the safe handling, storage, transport and use of the LMO as provided under applicable existing international requirements under domestic regulatory frameworks, 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;
- (iv) The name and address of the exporter and importer, including contact details necessary to reach them as fast as possible in case of emergency (may designate one of them as the contact point for further information); and
- (v) 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.”

Examples are provided in Annex I ^{11/} that demonstrate how the language required by Article 18.2(b) and (c) can be included on existing documentation in a clear and transparent manner. Note that the language suggested here may need to be supplemented by additions required by existing national regulations or requirements.

^{11/} See Annex II to this document.

II. TYPE OF DOCUMENTATION

Commercial or proforma invoices have been used by the private and public sector to move biological material for many years. These documents are well recognized by customs officials and already contained most of the information required by Article 18.2(b) and (c) before the Protocol was even ratified. For example, compliance with the Protocol for shipments of LMOs intended for intentional release into the environment requires the addition of only a small amount of text, namely “any requirements for safe handling, storage, transport and use” and the declaration that the transboundary movement of the LMO is in conformity with the Cartagena Protocol on Biosafety applicable to the exporter.

Due to the efforts of the GIC in developing guidance implementation language, these modifications have been in place since the entry into force of the Protocol. The development of a stand-alone document for use under the Protocol would only result in the duplication of information that already exists on the commercial or proforma invoices. For this reason, GIC supports the use of existing documentation in implementing the requirements of Article 18.2(b) and (c) of the Protocol and believes that experience to date clearly demonstrates that development of a stand-alone document is not warranted.

III. EXPERIENCE TO DATE

To substantiate GIC’s belief that documentation used to date is adequate to meet the requirements of Article 18.2 (b) and (c) and in preparation for the discussions by the Parties on Article 18.2(b) and (c) at their fourth meeting, the GIC again surveyed its members to determine their experiences with shipments under these provisions. In addition, the GIC consulted the ISF on this issue, and the ISF conducted its own member survey. The data from these surveys is summarized as follows.

GIC and ISF members are currently shipping LMOs that fall under Article 18.2(b) and (c) to/from the following 39 countries: Argentina, Australia, Belgium, Brazil, Burkina Faso, Canada, Chile, China, Colombia, Costa Rica, Denmark, Finland, France, Germany, Greece, Guatemala, Honduras, Hungary, India, Indonesia, Israel, Italy, Japan, Mexico, the Netherlands, New Zealand, Pakistan, Panama, the Philippines, Puerto Rico, Republic of Korea, Romania, South Africa, Spain, Thailand, Turkey, Venezuela, United Kingdom, the United States and Uruguay. Most of these countries are Parties to the Protocol (32 out of 39), and none have reported any concerns with the use of the GIC’s guidance language on existing documentation. No problems have occurred to date and all GIC and ISF members report that shipments of LMOs that fall under Article 18.2(b) and (c) are taking place regularly and without incident.

The survey clearly demonstrates that the guidance language provided by the GIC and based on the decision by the Parties is working well in identifying shipments of LMOs under Article 18.2(b) and (c), in conjunction with other country-specific information when needed. In order for such shipments to continue to move across boundaries in a practical and problem-free manner, it is suggested that countries continue to apply this simple but effective implementation of Article 18 documentation requirements by adding the required language to existing shipping documentation.

IV. CONCLUSIONS

- Surveys undertaken by the GIC and ISF indicate that the detailed guidance on implementing documentation and identification requirements for LMO shipments destined for contained use or

for intentional introduction into the environment using existing commercial and other standard shipping forms (e.g. invoices or bills of lading) does not require further attention at this time.

- The decisions taken by the Parties at their first meeting that provided guidance on how the Article 18.2(b) and (c) requirements could be met using existing documentation systems are effective and are working well. The GIC members have been using this guidance and applying it on existing documentation to ensure that shipments are in compliance with the Protocol. Shipments are taking place to a large number of Parties and non-Parties using this guidance, and no incidents or concerns have been reported.
- To avoid disruption of shipments of LMOs, the GIC recommends that Parties:
 - Continue to accept shipments of LMOs with existing commercial or other standard documentation that includes the additional requirements of Article 18.2(b) and (c) in conformity with the guidance provided by the Parties at their first meeting;
 - Indicate on the BCH when their current import rules apply (for AIA procedures);
 - Post information on how to obtain an AIA on the BCH;
 - Clarify on the BCH that an existing approval for experimental release or commercial use of an LMO in the importing country means that no additional clearance or AIA is required; and
 - Engage in outreach and education efforts, particularly with customs officials, to ensure awareness of and compliance with Protocol documentation and identification requirements by public research institutes, universities, local companies and others less involved with the Protocol.

PUBLIC RESEARCH AND REGULATION INITIATIVE

[30 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

Article 18 Paragraphs 2(b) and 2 (c) deal with Living modified organisms for contained use and Living modified organisms for intentional introduction into the environment. The MOP invites information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements (decision BSIII/ 8, paragraph 1).

Research in modern biotechnology typically involves sending research material between research labs in countries and between countries for further development and testing in contained facilities and field trials. Researchers thereby routinely, with great care and using their scientific knowledge and experience take care of handling, transport, packaging and identification of all kinds of organisms, including LMOs.

The appropriate way for packaging, handling and labeling often has to take into account requirements resulting different regulations and guidelines, such as internal biosafety procedures, regulations for pathogens, transport regulations, phytosanitary regulations etc. In addition, transport, packaging,

handling and labeling of organisms have to be done in a manner that the involved organisms are carefully protected from outside influences and contaminations.

PRRI believes that the existing documentation systems in combination with the additional guidance provided by the MOP at its first meeting are sufficient and that there is at this stage no need to develop further documentation requirements.

Annex I

Example of template for transport documentation in accordance with Article 18.2 (b) of the Cartagena Protocol submitted by Norway

Transport documentation in accordance with Article 18 2 (b) of the Cartagena Protocol on Biosafety

**LIVING MODIFIED ORGANISM(s) (LMO)
DESTINED FOR CONTAINED USE ONLY**

Contact Point

	EXPORTER	IMPORTER	CONSIGNEE
<i>Company or institution</i>			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Description of the LMO(s)

Common, scientific and commercial ^{12/} names of the LMO(s):	
Transformation event(s)	
Unique identification (if available)	
Risk class	
Type of intended use: (Commercial, Research or Other)	

^{12/} If available

Any requirements for safe handling, storage, transport and use

<ul style="list-style-type: none"> • As provided under applicable international instruments; • As provided under domestic regulatory frameworks; • As agreed to by the importer and exporter; or • No specific requirements: 	<ul style="list-style-type: none"> • • • •
--	--

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: _____

**Example of template for transport documentation in accordance with Article 18.2 (c) of the
Cartagena Protocol submitted by Norway**

<p>Transport documentation in accordance with Article 18 2 (c) of the Cartagena Protocol on Biosafety</p>
--

**LIVING MODIFIED ORGANISM(s) (LMO)
FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT**

	EXPORTER	IMPORTER	CONTACT POINT
<i>Company or institution</i>			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Description of the LMO(s)

Common and scientific names of the LMO(s):	
Transformation event(s):	
Unique identification (if available):	

Any requirements for safe handling, storage, transport and use

<ul style="list-style-type: none"> • As provided under applicable international requirements; • As provided under domestic regulatory frameworks; • As agreed to by the importer and exporter; or • No specific requirements; 	<ul style="list-style-type: none"> • • • •
---	--

Further information ^{13/}

Commercial name:	
Risk class:	
Import approval:	

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: _____

**Annex II
Examples of Existing Shipping Documentation submitted by the Global Industry Coalition**

EXAMPLE A

COMPANY NAME

PROFORMA INVOICE/PACKING LIST/MATERIAL TRANSFER FORM

Date:	
Invoice No.	
Contract No. or Shipment Letter	

PURPOSE: This shipment contains: __Living Modified Organisms (LMO) for Contained use
 __Living Modified Organisms (LMO) for Field release for experimental purposes
 __Non-commercial samples of Conventional and/or GM (LMO) SEED of approved events

Sending Party: Contact name: Address: Tel:		Receiving Party: Contact name: Address: Tel:	
--	--	--	--

Country of Origin	Country of Destination	Declared Value

HTS # 1205.00.0090

No. of pieces	Net weight	Gross weight	Transport Co.	Airway Bill No.	Flight No.	Flight Date	Arrival Airport

Package ID Label	Seedlot Number	If GM: OECD unique identifier or Event Code No.	Quantity			Material Description: (scientific and common name, traits or characteristics, material name and type, vector name, unique identifier – as applicable)	Permit No. at Importing Country	LMO* (Y/N)
			No. Units	Weight/Unit	Gross Weight			

Please sign form and return to sender

Material Transfer Form – Packing List

1 of 2

--	--	--	--	--	--	--	--	--

*LMO – Living Modified Organism equivalent to Genetically Modified Organism

Any requirements for safe handling, storage, transport and use	<input type="checkbox"/> To be used for testing under containment. Not to be used for intentional release into the environment, human consumption or animal feed, commercial sale or unauthorized transfers. <input type="checkbox"/> Not to be used for human consumption or animal feed, commercial sale or unauthorized transfers. See conditions of Permit No: 200603682 <input type="checkbox"/> To be used only under the conditions of authorization. Not to be used for human consumption or animal feed, or unauthorized transfers.
---	--

I declare that the above information is correct and that this shipment is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter.

Prepared by:

Name: _____

Signature: _____

Date: _____

International Traffice

Confirmation of receipt – Please sign and return to Sending Party

I hereby declare that I have received in good condition and accepted the above described materials.

Received by:

Name: _____

Signature: _____

Date: _____

IMPORTANT NOTICE: BY SIGNING THIS PROFORMA INVOICE/MATERIAL TRANSFER FORM AND ACCEPTING TRANSFER OF THE MATERIAL TRANSFERRED HEREUNDER, YOU AGREE TO BE BOUND BY THE TERMS AND CONDITIONS OF THE MATERIAL TRANSFER AGREEMENT – SEED, DATED, AND/OR THE MATERIAL TRANSFER AGREEMENT – BIOLOGICAL MATERIAL, DATED, AS APPLICABLE.

Please sign form and return to sender

EXAMPLE B**SHEET 1**

Information sheet accompanying the transboundary movement of the <<LMO 1/>> towards <<the recipient country 2/>> for contained use

1 – Identification – Labelling

Name of LMO:

OECD's unique identifier if existing:3/

2 – Safety rules to apply

Handling	<ul style="list-style-type: none"> • Only by the responsible person<u>4/</u> and his delegates. • Apply the rules in force in the importing country for this contained use. • Conserve and maintain the identification of the LMO product on all the used containers. • In case of accidental dissemination, recover all the plant material, put it in an appropriate container in order to stop this accidental dissemination and to identify it. In any case inform the shipper so that he will define the next step to do according to the rules in force of the importing country
Storage	<ul style="list-style-type: none"> • Limited access to the responsible person<u>4/</u> and to his delegates. • Clear identification of the LMO product on the used containers. • Storage assuring the protection of the LMO product and its non dissemination.
Transport and transit storage	<ul style="list-style-type: none"> • Packaging assuring the protection of the product and its non dissemination (for example: double packaging in sewn polypropylene bag put in a box with a sheet under and on it indicating the address of the person to contact in case of incident). • In case of accidental breaking of the packaging in the importing country, take back all the plant material, put it in an appropriate container to stop the accidental dissemination and identify it. In any case, inform the shipper so that he will define the next step to do according to the rules in force of the importing country.
Use	<ul style="list-style-type: none"> • Only by the responsible person<u>4/</u> and his delegates. • Conserve and maintain the identification of the LMO product on all the used containers. • Apply the rules of contained use and the prescriptions of the importing country, or, failing that, respect the good practice rules and methods linked to the use of this type of product and the know-how of the Profession or the requests of the exporting shipper. • Discard according to the prescriptions defined by the importing country, or, failing that, by incineration through adapted containers assuring the non dissemination. • Not allowed food or feed.

3 – Contact for additional information

Name and address of the shipper :

4 – Name and address of the recipient and his company

.....

1/ Name of the LMO: example Maize TC 1507

2/ Name of the recipient country: example the Netherlands

3/ Available information in the table <<choice of the information sheet>> : example DAS-01507-1.

4/ Complete with the name of the responsible person where the LMO is sent

EXAMPLE C

SHEET 1

Information sheet accompanying the transboundary movement of the <<LMO 1/>> towards <<the recipient country 2/>> having a dissemination authorization for experimental introduction into the environment (equivalent to part B in Europe)

1 – Identification – Labelling

Name of the LMO:
 OECD's unique identifier if existing:3/
 Relevant traits and characteristics of the LMO:3/

2 – Safety rules to apply

Handling	<ul style="list-style-type: none"> • Only by the responsible person<u>4</u>/ and his delegates. • Apply the rules in force in the importing country relative to this authorization. • Conserve and maintain the identification of the LMO product on all the used containers. • In case of accidental dissemination, follow the defined rules in the authorization of the dissemination delivered by the importing country, and/or recover all the plant material, put it in an appropriate container in order to stop this accidental dissemination and to identify it. In any case contact the shipper so that he will define the next step to do according to the rules in force of the importing country
Storage	<ul style="list-style-type: none"> • Limited access to the responsible person<u>4</u>/ and to his delegates. • Clear identification of the LMO product on the used containers. • Storage assuring the protection of the LMO product and its non dissemination.
Transport and transit storage	<ul style="list-style-type: none"> • Packaging assuring the protection of the product and its non dissemination (for example: double packaging in sewn polypropylene bag put in a box with a sheet under and on it indicating the address of the person to contact in case of incident). • In case of accidental breaking of the packaging in the importing country, take back all the plant material, put it in an appropriate container to stop the accidental dissemination and identify it. In any case, inform the shipper so that he will define the next step to do according to the rules in force of the importing country.
Use	<ul style="list-style-type: none"> • Only by the responsible person<u>4</u>/ and his delegates. • Conserve and maintain the identification of the LMO product on all the used containers. • Apply the rules regarding isolation, cultivation, post harvest monitoring and all other prescriptions defined by the dissemination authorization delivered by the imported country. • Discard according to the prescriptions defined by the importing country, or, failing that, destroy the LMO by incineration through adapted containers assuring the non dissemination. • Cannot be marketed. • Not allowed for food or feed, unless mentioned in the dissemination authorization.

3 – Contact for additional information

Name and address of the shipper :

4 – Name and address of the importer and exporter:

5 – Declaration that the transboundary movement is in conformity with the requirements of the Cartagena Protocol applicable to the exporter

EXAMPLE D

LETTERHEAD

-
- 1/ Name of the LMO: example Maize TC 1507.
2/ Name of the recipient country: example Argentina.
3/ Available information in the table <<choice of the information sheet>>.
4/ Complete with the name of the responsible person where the LMO is sent

PROFORMA INVOICE – CUSTOMS DECLARATION

Invoice No.

Contract No.

Shipper: Address, Phone and Contact Person	
Recipient: Address, Phone and Contact Person	
Country of origin	
Country of destination	
Permit/Notification No.	
Description of contents	Living Modified Organism (LMO) <i>Escherichia coli</i> that contains the inserted <i>cryIAb</i> gene from <i>Bacillus thuringiensis</i> . This preparation does not contain animal derived additives such as serum, albumin, etc. This organism is to be used under contained use only.
Declared value	Laboratory sample for research purposes only – no commercial value
Number of pieces	1 box
Net weight of shipment	xx kg
Gross weight of shipment	xx kg
Transporting company	Federal Express
Airway bill number	xxx
Flight number	N/A
Flight date	N/A
Airport of arrival	N/A
Any requirements for safe handling, storage, transport and use	<i>This LMO is for contained use only and not for intentional release into the environment or for use of human consumption and/or animal feed.</i>
Shipper's name	
Shippers' signature	
Shipping date	

I hereby declare that I have received in good condition and accepted the above described materials

Received by:

Name: _____ **Signature:** _____ **Date:** _____

Please sign form and return to Sender