30 November 2007

Implementation of the Documentation Requirements of Paragraphs 2(b) and 2(c) of the Cartagena Protocol: Experiences of the Global Industry Coalition

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,[1] 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.[2]

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.[3] At their second meeting, the Parties recognized the contribution of the GIC in developing these guidelines to implement the requirements

[1] See Decision BS-III/8.
[2] See UNEP/CBD/ICCP/3/10.
[3] See UNEP/CBD/BS/COP-MOP/1/15.

under Article 18.2(b) and (c) in accordance with the provisions of the Protocol as further elaborated by the COP/MOP-1 decision.[4] These guidelines are as follows:

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)[5] 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.[6] 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.[7]

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:[8] 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

[4] See UNEP/CBD/BS/COP-MOP/2/15.
[5] http://bch.cbd.int/.
[6] 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.
[7] Note that there are very few AIA decisions posted on the BCH.
[8] 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."

(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:

"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 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.

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.

Annex I
Examples of Existing Shipping Documentation

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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

*LMO – Living Modified Organism equivalent to Genetically Modified Organism

Any requirements for safe handling, storage, transport and use	____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. ____Not to be used for human consumption or animal feed, commercial sale or unauthorized transfers. See conditions of Permit No: 200603682 ____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

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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	• Only by the responsible person …….[4] 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	• Limited access to the responsible person …….[4] 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	• 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	• Only by the responsible person …….[4] 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

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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	• Only by the responsible person …….[4] 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	• Limited access to the responsible person …….[4] 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	• 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	• Only by the responsible person …….[4] 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

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[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

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EXAMPLE D

LETTERHEAD

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) *Escherichia coli* that contains the inserted *cry1Ab* gene from *Bacillus thuringiensis*. 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	*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.*
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