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Item 12 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18)

*Compilation of information submitted by Parties and other Governments and by organizations on experience gained with the use of documentation requirements under paragraphs 2 (b) and (c) of Article 18 of the Cartagena Protocol on Biosafety***

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SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS

AUSTRALIA

[17 DECEMBER 2004]
[SUBMISSION: ENGLISH]

Australia is not a party to the Protocol and therefore has not implemented these requirements as a party. However, implementation of these requirements by parties to the Protocol that also import Australian agricultural commodities mean that Australian agricultural exporters will need to comply with the requirements of the Protocol as transposed into the domestic law of these parties in order to maintain or gain new market access.

Australia notes that very few countries have implemented obligations under the Protocol, and in particular in relation to documentation requirements. Discussion of such issues as unique identification, co-mingling of living modified organisms (LMOs) with non-LMO shipments, and any possible relevance of Article 17 (Unintentional movements) are premature.

Australia is of the view that the Open-Ended Technical Experts Group (Open-Ended TEG) should take into account the extensive work already undertaken on this issue, as outlined in the chapeau of the decision BS-I/6 taken at the first meeting of the Parties (MOP-1).

In this context, Australia supports the recommendations of the most recent Meeting of Technical Experts on the Requirements of Paragraph 2(a) of Article 18 (March, 2002). Australia believes this document should form the basis for further work. However, this does not imply that such documentation is necessary to achieve the objectives of the Protocol.

Australia welcomes the reference in the Executive Secretary's information note to the June 2004 WTO Trade and Environment Committee to the trade implications of decisions taken at MOP1. In that note he wrote that *in order to avoid unnecessary burden to exporters*, MOP1 in decision BS-I/6 had decided to integrate identification requirements for LMOs for feed, food and processing (Article 18.2(a)) in commercial invoices or other relevant existing documentation (para 27, WT/CTE/W/235, emphasis added). Australia would like to encourage parties to the Protocol to take a similar approach in the implementation of documentation requirements for LMOs under the scope of Article 18.2(b) and 18.2(c).

It should be noted that the tonnage of international trade in LMOs under the scope of Article 18.2(b) and 18.2(c) is much more limited than the commodity trade under Article 18.2(a). In particular, trade that falls under Article 18.2(b) may represent a significant number of transboundary movements of a much broader range of LMOs than under Article 18.2(a), including non-plant LMOs.

It should also be recalled that:

- the documentation is not designed to be a tool for risk assessments. Such documentation is an inadequate basis for risk assessment.

- the documentation is not for a decision to allow importation, as this decision must take place before the first shipment as parties may carry out risk assessments prior to the first shipment in the case of LMOs under Article 18.2(c)

- the documentation is a tool to provide importers with information to comply with their own country's implementation of the protocol.

Australia considers parties to the Protocol can implement their obligations under Article 18.2(b) and 18.2(c) in such a way that:

- will be minimally disruptive to trade by taking account of, and being consistent with, other international obligations, including under WTO agreements
- will not be unduly burdensome or costly to implement or understand, from both the export and import perspective
- will allow required information to be incorporated into existing accompanying documentation
- do not go beyond meeting the requirements explicitly set out in the Protocol
- do not cast the Protocol as an arbitrary thresholds-setting instrument, and
- avoid duplication of on-going work within existing international organisations such as Codex Alimentarius, International Plant Protection Convention (IPPC), and the Office International des Epizooties (OIE) which develop standards on the basis of sound science.

Article 18.2(b)

In relation to documentation requirements under Article 18.2(b), the following information should be contained on existing documentation, which could include, *inter alia*, bills of lading, letters to the recipient:

- a statement to the effect that the LMOs are destined for contained use
- any requirements for the safe handling, storage, transport and use, and
- a contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned.

Any requirement beyond these would be neither simple nor practical to implement and would impose a significant additional burden on importers and exporters, many of whom in this case are researchers.

Article 18.2(c)

Prior to a transboundary movement of an LMO for intentional release into the environment, that movement should be consistent with the provisions of Article 7 (Application of the Advanced Informed Agreement Procedure). In particular, Parties should have carried out a risk assessment as specified in Annex III prior to importation. Having already received a notification, according to Article 8, containing the information specified in Annex I, the importer does not need that information duplicated on documentation accompanying the LMO shipment.

To meet the requirements of Article 18.2(c), the following information should be included on existing documentation, which could include, *inter alia*, a commercial invoice:

- a statement to the effect that the LMOs are intended for intentional introduction into the environment
- a statement to the effect that the material is an LMO and specify the identity and relevant novel or modified traits and/or characteristics
- any requirements for the safe handling, storage, transport and use
- a contact point for further information and, as appropriate, the name and address of the importer and exporter, and
- a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

EUROPEAN COMMUNITY AND ITS MEMBER STATES [6 JANUARY 2005]
[SUBMISSION: ENGLISH]

COPM0P/1 decision BS-I/6 on the handling, transport, packaging and identification of living modified organisms includes an invitation to "Parties, other Governments and relevant international organizations to make available to the Executive Secretary, not later than six months prior to the date of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information regarding their experience, if any, in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18" (document UNEP/CBD/BS/COP-MOP/1/15).

COPMOP/1 decision BS-I/6 made the information requirements for GMOs, destined for contained use or intended for intentional introduction into the environment operational. Furthermore, decision BS-I/6 included a number of additional information requirements that Parties are requested to ensure are contained in documentation accompanying GMOs.

With respect to the import of GMOs, the EU legislative framework on GMOs fulfils the documentation requirements, both for movements of GMOs between Member States and imports of GMOs into the EU. In particular, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Regulation (EC) No 1829/2003 on genetically modified food and feed and Directive 90/219/EEC on the contained use of genetically modified micro-organisms, as amended by Directive 98/81/EC, contain rules which are in line with the Protocol regarding imports of GMOs.

Regulation (EC) No 1946/2003 on Transboundary Movements of Genetically Modified Organisms implemented the specific requirements for exports of GMOs to third countries and includes the information requirements for GMOs destined for contained use or intended for intentional introduction into the environment laid down in Article 18.2(b) and (c) of the Biosafety Protocol. Below, the provisions of Article 12 of the Regulation are reproduced for identification and accompanying documentation of GMOs destined for contained use and deliberate release into the environment.

1. GMOs destined for contained use

Exporters of GMOs destined for contained use are required to “ensure that the following information is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO:

a) that it contains or consists of GMOs;
b) the unique identification code(s) assigned to those GMOs if such codes exist”

In addition, this information “shall be supplemented by a declaration by the exporter which shall specify:

a) any requirements for the safe handling, storage, transport and use of these GMOs;
b) the contact point for further information, including the name and address of the individual or institution to whom or which the GMOs are consigned."

2. GMOs destined for deliberate release into the environment

Exporters of GMOs destined for deliberate release into the environment are required to "ensure that the following information is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO:

a) that it contains or consists of GMOs;
b) the unique identification code(s) assigned to those GMOs if such codes exist."

In addition, this information "shall be supplemented by a declaration by the exporter which shall set out:

a) the identity and relevant traits and characteristics of the GMOs;
b) any requirements for the safe handling, storage, transport and use of these GMOs;
c) the contact point for further information and, as appropriate, the name and address of the importer and exporter;
d) a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter."

These requirements are to be without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Protocol.

The Annex to this submission contains a preliminary overview of the first experiences of EU Member States with the provisions of Article 18.2(b) and (c). It should be noted that this information is not exhaustive, nor reflecting an EU position.

Annex: Experiences related to the provisions of Article 18.2(b) and (c)

Italian National Experiences related to the provision of Article 18.2©

In spite of the fact that no authorisation is provided in Italy for the cultivation of genetically modified plants for agricultural purposes, several preliminary evidences indicated the occasional occurrence of LMOs in seed lots of traditional (i.e. non genetically modified) maize (Zea mais) and soybean (Glycine max) seeds.

For these reasons, the Italian Ministry for Agriculture (Ispettorato Centrale Repressione Prodi) has set a "Targeted Plan for controls on maize and soybean seeds. Research for possible GMOs" (Programma mirato di controllo sulle sementi di mais e di soia. Ricerca di eventuali OGM).

The Plan was fully run during the seasons 2002-2003 and 2003-2004, when samples of commercial seed lots were collected. The results of these activities are summarised in the table below.

	2002-2003	**2003-2004**
Samples collected	329	973
Samples with LMOs	28	30
Percentage of samples with LMOs	8.51%	3.08%

The results show that the control activity has clearly reduced the LMO presence in "traditional" seed lots. We conclude that this type of control is important to reduce the risk of accidental release of LMOs.

JAPAN

[20 DECEMBER 2004]
[SUBMISSION: ENGLISH]

I Under the Article 28 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, which enforced 19th Feb. '04, and the Article 37 of the Regulations related to the Enforcement of the Law, Government of Japan has prohibited exporters to export LMOs that are subject to the requirements of paragraph 2 (b) and 2 (c) of Article 18 to the Parties to the Cartagena Protocol on Biosafety without the indication stipulated in the Regulations.

In practice, exporters shall attach the following information along with the 12th or 14th form of the Regulations to the LMOs or their packaging, container or consignment invoice when exporters export LMOs to the Parties of the Protocol:

1 Exports as living modified organisms for use in importing Parties with containment measures (paragraph 2 (b) of Article 18 of the Cartagena Protocol on Biosafety)

1) Living modified organisms
2) Requirements for the safe handling, storage, transport and use
3) The contact point for further information (name, address, and contact details (tel, telex or fax number, contact person) of the exporter and importer).

2 Exports as living modified organisms that are not for use with containment measures and use for food, feed and processing (paragraph 2 (c) of Article 18 of the Cartagena Protocol on Biosafety)

1) Living modified organisms
2) The identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use
3) The contact point for further information (name, address, and contact details (tel, telex or fax number, contact person) of the exporter and importer).
4) Exporter's signature which certify that the movement is in conformity with the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

II Someone who violates the Article 28 of the Law and exported LMOs to the Parties of the Protocol without attaching necessary information or with false information shall be fined of no more than 500,000 yen.

III The Law and the Regulations in English are provided on the following website.
(http://www.bch.biodic.go.jp/english/law.html)

LITHUANIA

[14 DECEMBER 2004]
[SUBMISSION: ENGLISH]

Order on regulation on Contained Use of GMOs was adopted by the Minister of the Environment in August 2003, amended in April 2004. The overall objective of amended legal act: enable current and potential users to participate in the world GMOs research and development market, to ensure safe use of GMOs in contained use, thus protecting human health and environment from possible negative harmful effects posed by GMOs.

The amended Order has defined concrete procedures applicable for request and notification to issue consents for the contained use of GMOs, risk assessment procedures. Before requesting any

permission to use GMO, notifier is obligated to estimate and assess risk to determine the contained use class, containment and other precautionary measures.

The amended Order has identified general provisions according specific criteria to classify each contained use of GMOs into respective class (1,2,3 and 4), set up requirements for containment and other safety measures, provided clear definition on genetically modification cases, specifying detailed contents for description of notification for contianed use, identifying the elements and the extent of risk assessment for contained use.

According to established Order, Ministry of Environment controls and examines the containment and other applied safety measures, not less than once per 3 years (for safety class 1), not less than once per 2 years (for safety class 2), not less than once per 1 year (for safety class 3 and 4). The Ministry of Environment is responsible for implementation and enforcing the requirements of this Order.

There have been issued 4 standard consents for first class contained use of genetically modified micro-organism's in Lithuania. 2 consents have been issued to scientific institutions and 2 – to industrial companies.

SLOVENIA [4 JANUARY 2005]
[SUBMISSION: ENGLISH]

- *Invites* Parties, other Governments and relevant international organizations to make available to the Executive Secretary, not later than six months prior to the date of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, information regarding their experience, if any, in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18; 6 months prior to MOP-2 (i.e. 31 December 2004)
    - ***SI has no experiences yet on this point, since it has not yet taken any decisions on LMOs. In part of placing on the market SI is involved in the decision making procedure according to EU legislation.***
- *Encourages* the Organisation for Economic Co-operation and Development and other organizations involved in the development of unique identification systems for LMOs to initiate or enhance their activities towards the development of a harmonized system of unique identifiers for genetically modified micro-organisms and animals.
    - ***IN EU Commission regulation 65/2004 SI is covering this point.***

SWITZERLAND [23 DECEMBER 2004]
[SUBMISSION: FRENCH]

La nouvelle Ordonnance fédérale sur le mouvement transfrontière des organismes génétiquement modifiés (Ordonnance de Cartagena) entrera en vigueur le 1er janvier 2005. Cette ordonnance a comme objectif de mettre en œuvre au niveau national les dispositions du Protocole de Cartagena. Elle est basée sur les dispositions de la loi fédérale du 21 mars 2003 sur le génie génétique qui règle entre autre l'importation, l'exportation et le transit des organismes génétiquement modifiés.

L'article 4 de l'Ordonnance de Cartagena concerne spécifiquement la documentation d'accompagnement. Sur le plan substantiel, les informations requises dans la documentation accompagnant le mouvement transfrontière des organismes qui feront l'objet d'une dissémination dans l'environnement sont basée sur les dispositions du paragraphe 2 (c) de l'article 18 du Protocole. De même les informations requises dans la documentation accompagnant le mouvement transfrontière des organismes destinés à être utilisés en

milieu confiné sont basées sur les dispositions du paragraphe 2 (b) de l'article 18 du Protocole. La seule différence significative est la référence de l'ordonnance à l'identificateur unique au sens de l'annexe du Règlement (CE) n° 65/2004 de la Commission du 14 janvier 2004 instaurant un système pour l'élaboration et l'attribution d'identificateurs uniques pour les organismes génétiquement modifiés lorsque celui-ci existe. Dans un tel cas il n'est plus nécessaire de spécifier l'identité des organismes avec leurs traits et caractéristiques pertinents.

En plus, les modèles de documentation figurant à l'annexe de la décision BS-I/6 ont été mis à disposition des opérateurs en les invitant à faire part de leurs remarques et commentaires concernant leur utilisation. A ce jour ces modèles semblent donner entière satisfaction, en particulier en ce qui concerne le mouvement transfrontière des organismes génétiquement modifiés destinés à l'utilisation confinée.

Texte de l'ordonnance en français http://www.admin.ch/ch/f/as/2004/4801.pdf
Texte de l'ordonnance en anglais http://www.environnement-suisse.ch/imperia/md/content/stobobio/ch-bch/1.pdf

UNITED STATES OF AMERICA (USA) [31 DECEMBER 2004]
[SUBMISSION: ENGLISH]

Summary

Importing countries expect that agricultural products entering their country be accompanied by sufficient documentation to meet national laws and regulations to protect the environment and biodiversity and for Parties to the Protocol to meet the requirements under Article 18.2. While the discussions around Article 18.2(a) continue without a clear consensus (see U.S. submission on 18.2(a) at UNEP/CBD/BS/WS-CB-HTPI/1INF/1 – 5 October 2004), there are fewer issues and points of disagreement identified with respect to Articles 18.2(b) and 18.2(c), primarily because the documentation requirements specified by the Protocol have been and will continue to be met within common commercial practices. For many countries, these requirements will be described in domestic biosafety regulations promulgated for compliance with the Protocol. In situations where the importing country does not have domestic regulations in place, the importing country relies on the text of Article 18.2 and any guidance on implementation provided in decisions at the Meetings of the Parties.

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. In addition, current practices are consistent with the guidance on implementation of Articles 18.2(b) and 18.2(c) as elaborated in Decision BS –I/6 from COP/MOP-1. Additional information, beyond what is delineated in this decision document, is unnecessary.

Background

Recommendations on how Parties could best implement the documentation requirements under Article 18.2 (b) and (c) were forwarded to the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP-3) from two Technical Experts meetings held in June 2001 and in March 2002. Following discussions at ICCP-3, the recommendations were forwarded to the CBD Secretariat with little

change for consideration by the first Meeting of the Parties. Based on these recommendations, a summary of existing standards, practices, and rules on handling, transport, and packaging of LMOs, and on consideration of submissions by countries, Parties, and other stakeholders, the Secretariat prepared and Parties subsequently approved at COP/MOP-1 Decision BS –I/6 concerning all paragraphs in Article 18.2. This Decision, among other things, requests Parties to *"take measures to ensure the use of a commercial invoice or other documents required or utilized by existing documentation systems as documentation that should accompany LMOs for contained use and for intentional introduction into the environment…as appropriate, with a view to fulfill the identification requirements of these paragraphs."*

Additionally, Decision BS-I/6 requests Parties to take measures ensuring that documentation accompanying LMOs for contained and/or intentional introduction into the environment have the following information and declaration:

(a) LMOs for contained use (**Article 18.2(b)**):

i. Clear identification as "living modified organisms" including common and scientific names of the organisms and as "destined for contained use";
ii. The name and address of the consignee, and exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;
iii. Any requirements for the safe handling, storage, transport and use of the living modified organisms under applicable existing international instruments, such as the United Nations Recommendations on the Transport of Dangerous Goods, the International Plant Protection Convention, and the Organization Internationale des Epizooties, domestic regulatory frameworks or under any agreements entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
iv. Where appropriate, further information should include the commercial names of the living modified organisms, if available, new or modified traits and characteristics such as event(s) of transformation, risk class, specification of use, as well as any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House;

(b) LMOs for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol (**Article 18.2(c)**):

i. Clear identification as "living modified organisms" and a brief description of the organisms, including common and scientific name, relevant traits and genetic modification, including transgenic traits and characteristics such as event(s) of transformation or, where available and applicable, a reference to a system of unique identification;
ii. Any requirements for the safe handling, storage, transport and use of the living modified organisms as provided under applicable existing international requirements, domestic regulatory frameworks, or under any agreement entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
iii. The name and address of the exporter and importer;
iv. The details of the contact point for further information, including an individual or organization in possession of relevant information in case of emergency;
v. A declaration that the movement of the living modified organisms is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter; and,

vi. Where appropriate, further information should include the commercial name, risk class, and import approval for the first transboundary movement of living modified organisms.

U.S. Experiences

It is important that domestic requirements put in place by importing countries are clear, practical, and do not burden exporters with unnecessary requirements that do not further the goals of the Protocol with respect to protection of biodiversity.

Documentation of LMO Seeds and LMOs for Research Purposes Precede the Biosafety Protocol: 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 employ invoices that contain pertinent information concerning the cargo and handling procedures, have functioned well and have not led to any reported adverse incidents. When seed or preparative material is shipped by or to public and private institutions, it typically is accompanied by information that complies with national regulations and laws that govern the safe handling of LMOs destined for contained use and for intentional introduction into the environment.

The requirements in Decision BS –I/6 pertaining to Article 18.2(b) and Article 18.2(c) are met under current standard practices. Based on the extensive experience of the export and import communities, the potential for any negative impact on biodiversity from existing practices appears minimal. 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 and Education About Protocol Obligations at the National-Level: 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. For many years, university and private sector scientists have used commercial carriers to ship LMO materials accompanied by an invoice that includes relevant identification, handling, contact, and other pertinent information.

However, communication between newly formed national authorities and the well-established existing import/export community could be improved. In some instances, we have found that the university or entity interested in importing LMO materials for intentional release or contained use is unclear on any potential impact the Biosafety Protocol has (or may have) on existing national laws or regulations governing these practices**.** In these cases newly-formed governmental bodies charged with implementing the requirements in Articles 18.2(b) and (c) have not effectively communicated to the importers (public and private) any changes to the laws and regulations governing the import or export of LMO materials that may occur as a result of implementation of the Biosafety Protocol. These instances serve as a reminder of the importance of education of and communication with stakeholders, including Parties, Non-Parties, importers, and exporters of any potential changes in obligations due to the Biosafety Protocol. It will be of benefit to all stakeholders for these communications mechanisms to be robust and operational.

Information and Input to the Biosafety Clearing-House. 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 111 Parties have not yet met their obligations to provide such information to the Biosafety Clearing-House.

While the Biosafety Clearing-House is "fully operational," the paucity of information actually available limits its utility. Although both Parties and Non-Parties have posted 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).

The insufficiency of information available on the Clearing-House has led to a number of difficulties for importers and exporters. There have been instances where exporting entities are unclear as to whether the appropriate clearance from importing Parties has been obtained for certain LMOs. Also, exporting entities and exporting country competent authorities can often be unaware that approval for commercial use or a permit number for experimental use in the importing country may be insufficient for clearance. Potential delays, misunderstandings, and problems could be avoided if the Biosafety Clearing-House clearly indicated each country's requirements for import of LMOs for contained use and intentional release into the environment.

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC) [21 DECEMBER 2004]
[SUBMISSION: ENGLISH]

Implementation of the Documentation Requirements of Paragraphs 2(b) and 2(c) of the Cartagena Protocol: Experiences of the Users and Developers of Biotechnology

I. Guidance Language

On 11 September 2003, the Cartagena Protocol on Biosafety (the "Protocol") entered into force - the first legally binding international agreement governing the movement of living modified organisms (LMOs) 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 of its provisions. In addition, 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. As such, entities in countries that have not ratified the Protocol but that export LMOs to Parties are encouraged to comply with the Protocol's provisions implemented in the importing country. Thus, entry into force ultimately impacts both Party and non-Party countries that export LMOs to countries that are Parties to the Protocol that have national implementing legislation.1

Although the Protocol officially entered into force in September 2003, a decision on the documentation requirements for Article 18.2(b) and (c) indicating specific implementation and compliance requirements was not finalized. Therefore, at the time of entry into force of the Protocol, the users and developers of biotechnology suggested guidelines that were based on the recommendations made at the third meeting of the Intergovernmental Committee for the Cartagena Protocol2 for entities shipping LMOs (including research material) from or to Parties in order to meet the requirements outlined in the Protocol. These documentation recommendations were discussed again at the Conference of the Parties serving as the first meeting of the Parties to the Protocol, and the Global Industry Coalition revised its guidelines to reflect the Parties' decision at this meeting regarding the documentation requirements for Article 18.2(b) and (c)3. These guidelines are as follows:

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

(a) With respect to LMO seeds, 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 first shipment may be required. The technology developer will typically perform this procedure and the importing country should post its decisions on the Biosafety Clearing House (BCH). Since the BCH is still under development, complete information may not be available on the website.4 To date, countries that have completed risk assessments and approved local

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

2 See UNEP/CBD/ICCP/3/10.

3 See UNEP/CBD/BS/COP-MOP/1/15.

4 Note that there have been no AIA decisions posted on the BCH to date.

production of an LMO consider that approval equivalent to an AIA, but may or may not have posted this decision on the BCH. In the absence of information about a particular LMO on the BCH, licensees of a commercial or research and development transgenic plant trait may need to clarify with the technology provider and/or importing authority that a risk assessment and clearance to ship to a country has been previously approved. In the future, this clearance and risk assessment information should be available on the Biosafety Clearing-House: http://bch.biodiv.org/decisions/decisionsunderaia.aspx.

(b) For contained use under Article 18.2(b),[5] an AIA is not required by the Protocol, 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.

In order to meet the documentation requirements of the Protocol, users and developers of biotechnology suggest that the private sector include the following information on existing shipping documentation for shipments of LMOs for contained use (Article 18.2(b)) and LMOs for intentional release into the environment (Article 18.2(c)):

(a) 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 private sector 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" (may specify common and scientific name of the organism 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; 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 (such as the International Plant Protection Convention or the UN Model Regulations on the Transport of Dangerous Goods) 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.

(b) 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 invoices):

i. The following statement outlining the shipment contents:
"This shipment contains living modified organisms";

[5] 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."

ii. A brief description of the LMO, including category, common and scientific name, relevant traits and/or characteristics, and a reference to a system of unique identification, where available;

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 (such as the requirements under the OECD Seed Schemes) 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 (designate which is to be used 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 Paragraphs 2(b) and 2(c) of Article 18 can be included on existing documentation in a clear and transparent manner. Note that the language suggested here is in addition to existing national regulations or requirements and the language may already be a part of existing shipping documentation.

II. Experience to Date

In preparation for the Workshop on capacity-building and exchange of experiences as related to the implementation of paragraph 2 of Article 18 of the Biosafety Protocol that was held in November 2004, the Global Industry Coalition surveyed its members to determine their experiences with shipments under Article 18.2(b) and (c).

With respect to Article 18.2(b), the informal survey showed that such shipments comprise the entire range of organisms and microorganisms, including viruses, bacteria, fungi, parasites, insects and plants. The majority of shipments are for research and development purposes, mainly for the testing and treatment of disease. In any event, shipments of products under Article 18.2(b) classified as dangerous goods are already regulated appropriately by the *UN Model Regulations on the Transport of Dangerous Goods*, even in the absence of any Protocol-specific documentation requirements.

The majority of shipments that fall under Article 18.2(c) are for commercial purposes, crop or seed production. In these cases, the LMO has completed approval in the importing country for commercial use. A smaller number are for research and development purposes, and are planted to assess the suitability of the crop variety for local use or to develop data in order to complete regulatory requirements for commercialization. Requirements for safe handling for the LMO research material are typically specified in national regulations.

The survey showed that the guidance language provided by the Global Industry Coalition and based on the decision by the Parties was working satisfactorily in identifying shipments of LMOs under Article 18.2(b) and (c), in conjunction with other country-specific information. 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 recognize this simple, step-wise process for Article 18 documentation requirements added to existing shipping documentation.

III. Ongoing Concerns

Over one hundred countries have ratified the Protocol to date, thus obligating themselves to comply with its provisions, either directly or through Protocol-consistent national legislation. Non-Parties (and their technology providers or users) do not have direct obligations to comply with the Protocol itself, but may post information to the BCH. Although the Protocol has officially entered into force, many countries have not yet met their obligations to provide specific information on the BCH – a website database designed to provide information on national regulatory requirements, facilitate information exchange and assist those who intend to ship LMOs for release into the environment and material destined for food, feed and for processing to a Party to the Protocol.

Entities shipping LMOs are expected to comply with provisions of the Protocol in countries that have ratified it, but the extent of this obligation is not clear. In some cases, Parties' existing national legislation, regulations or other requirements may fulfill the obligations outlined in the Protocol, so it may not be necessary to modify import processes for LMOs.

A continuing concern of the users and developers of biotechnology is the difficulty Parties are facing in meeting their obligations to implement the Protocol with regard to shipments of LMOs for intentional release and LMOs for food, food and for processing due to the lack of information being provided by other Parties to the BCH. While the BCH is fully operational, the lack of information available limits its utility. As stated above, Parties have specific obligations regarding provision of information and shipment of LMOs for intentional introduction and for direct use for food, feed or for processing. Few Parties, however, have posted the necessary information on the BCH that outlines how they intend to implement these provisions of the Protocol, or have otherwise clarified the applicable processes for such imports. This was also a key finding of the Secretariat of the Convention on Biological Diversity's survey on the BCH undertaken in August and September 2004.

Some countries, both Parties and non-Parties, have posted information regarding approvals for domestic use or import approvals, but only a small number of countries have specifically indicated that their existing domestic regulations, including shipping regulations, apply to imports. In addition, there have been instances where exporting entities are unclear as to whether the appropriate clearance from importing Parties has been obtained for certain LMOs. Other examples indicate a lack of understanding by exporting entities and exporting country competent authorities that approval for commercial use or a permit number for experimental use in the importing country means that no additional clearance is needed. Potential trade delays would be avoided if Parties specified the shipping documentation requirements for their country and clarified that approval for cultivation and use meets clearance to ship requirements. In addition, clear indication in the BCH by each country (whether a Party or not) on its requirements for import for contained use and intentional release into the environment would prevent delays.

IV. Conclusions

The users and developers of biotechnology recommend that Parties:

- indicate when their current import rules apply;
- continue to accept shipments of LMOs with existing documentation that includes the additional requirements of Article 18.2(b) and (c) as indicated in the guidance document developed by the Global Industry Coalition that is based on the decision by the Parties;
- indicate that an existing approval for an LMO in the importing country means that no further approval to ship the LMO is required;

- indicate that a permit number for experimental use or field trial in the importing country means that no additional clearance or AIA is required; and
- take immediate actions to post clarifying information to reduce any additional confusion and delays in shipments of LMOs that may otherwise occur.

Annex I

Examples of Existing Documentation Including Required Article 18.2(b) and (c) Language

The following is an example of a standard pro forma invoice. Added to this standard invoice is a model template of basic text that the private sector recommends is used to address the requirements of Article 18.2(b) for many microorganisms not considered infectious substances and samples of seeds intended for contained use. The proposed template for the Article 18.2(b) requirements is highlighted within the text box of this example.

COMPANY OR INSTITUTION LETTERHEAD

PRO FORMA INVOICE

AWB # _____

Exporter:

Company Name: _____
Company Address: _____
Phone:_____

Date: _____
Our reference: _____(Shipping reference # or Culture ID # (for microorganisms))
Forwarded by: (Carrier or transporter) _____
Payment: No Payment required

_____ Box(s) containing _____ vials

Box

Net weight:_____ kilograms
Gross weight:_____
Dimensions: __ x __ x __ cm
For Contained Use Only

NO COMMERCIAL VALUE AND IS FOR EXPERIMENTAL PURPOSES ONLY

MODEL TEMPLATE LANGUAGE:

Requirements under the Cartagena Protocol on Biosafety:

- "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)*
- Name and address of consignee
- Additional requirements for safe handling, storage, transport and use, if any, or indicate that no additional requirements exist: (insert information here or refer to attached documents, as appropriate)

/…

The following is an example of a standard commercial invoice used in seed shipments. Added to this standard invoice is a model template of basic text that could be used to address the requirements of Article 18.2(c) for LMOs intended for intentional introduction into the environment. The proposed template for Article 18.2(c) requirements is highlighted within the text box in this example.

Selling Company Inc. **Invoice No.** **1001**
Company Address
City, State ZIP Code
Phone Number Fax Number

INVOICE

Customer/Importer:
Name: International Buying Company Inc.
Address:
City: State: ZIP:
Phone:

Date:
Order No.:
Rep:
FOB: Iowa, USA

Qty	Description	Unit Price	TOTAL
	-"This shipment contains Living Modified Organisms." - Brief description of the LMO (such as " hybrid maize seed with insect tolerance") -Requirements for safe handling, storage, transport and use, if any, or indicate that no additional requirements exist (insert reference to AIA requirements, or other information as appropriate) -Name, address and telephone number of exporter, importer and contact point - "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."	$150.00 US	$150,000.00 US

Payment Details		
	Subtotal	$150,000.00 US
	Shipping & Handling	$0.00
Payment Transferred electronically to ING Bank, Account #123-4567 Payment due against documents on arrival of vessel.	Taxes	
Ing Bank, Acct # 123-4567 Date:	**TOTAL**	$150,000.00 US

FIS Cereal Trading Rules, Dispute Settlement and other fine print warranties.

WORLD TRADE ORGANIZATION (WTO) [14 DECEMBER 2004]
[SUBMISSION: ENGLISH]

1. Most labelling requirements, nutrition claims and concerns, quality and packaging regulations are generally not considered to be SPS measures and normally fall under the auspices of the TBT Agreement. Some packaging and labelling requirements, if directly related to the safety of food or to the protection against pests or diseases, are subject to the SPS Agreement. The determination of which Agreement applies is occasionally complicated when a single measure has been implemented to satisfy multiple policy objectives.

2. Within the SPS Agreement, Annex C provides details about Members' obligations under the Agreement regarding control, inspection, and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs. In recent a Committee meeting Members have drawn attention to the increasing number of requests for inspection visits and the resource intensive nature of these visits.
