UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/3/8/Add.1
3 January 2006

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITYY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Third meeting
Curitiba, Brazil, 13 -17 March 2006
Item 10 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Synthesis of information on experience gained with the use of documentation to fulfil the identification requirements of paragraphs 2(b) and 2(c) of Article 18

Note by the Executive Secretary

I. INTRODUCTION

1. The Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol considered, at its first meeting, several issues related to Article 18 and adopted decision BS-I/6, which *inter alia,* addressed documentation-related issues under paragraphs 2 (a), 2 (b) and 2 (c) of Article 18.

2. With respect to paragraphs 2 (b) and 2 (c) of Article 18, the Conference of the Parties serving as the meeting of the Parties to the Protocol, among other things, invited Parties, other Governments and relevant international organizations to submit to the Executive Secretary information regarding their experience, if any, in the implementation of the requirements specified in those paragraphs. The information was submitted to and considered by the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol at its second meeting.

3. The Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol also requested Parties and invited other Governments to submit information, in particular on experience gained with the use of documentation that the Conference of the Parties serving as the meeting of the Parties to the Protocol itself identified, in same decision (paragraph 2, decision BS-I/6 B), to fulfil the identification requirements of paragraphs 2 (b) and 2 (c) of Article 18. The Conference of the Parties

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serving as the meeting of the Parties to the Protocol requested submissions of such information with a view to future consideration of a stand-alone document. The Executive Secretary was requested to compile the information received and prepare a synthesis report presenting options for stand-alone documentation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its third meeting. The request was also recalled in decision BS-II/10 of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

4. Section II below, therefore, presents the synthesis of the information that the Executive Secretary has prepared on the basis of submissions that were received in accordance with the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Section III is intended to present options for stand-alone documentation on the basis of information included in the submissions. Finally, section IV suggests some elements of a draft decision for consideration by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

II. SYNTHESIS OF INFORMATION SUBMITTED ON EXPERIENCE GAINED WITH THE USE OF DOCUMENTATION ACCOMPANYING THE TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS DESTINED FOR CONTAINED USE AND FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT (PARAGRAPHS 2 (b) AND 2 (c) OF ARTICLE 18)

5. As of 20 September 2005, submissions had been received from Parties namely, the European Community and its member States and Norway, and from other Governments namely, Canada and United States of America. The Global Industry Coalition also made a submission. The full text of the submissions have been compiled and made available in an information document (UNEP/CBD/BS/COP-MOP/3/INF/2).

6. Most of the submitting parties recalled their previous submissions for the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in response to a similar but broader request, by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to provide information regarding experience in the implementation of the requirements of paragraphs 2 (b) and 2 (c) of Article 18. Two of the submissions are, in fact, the same as previous submissions that were compiled in an information document (UNEP/CBD/BS/COP-MOP/2/INF/4), with some adjustment to insert or emphasize information specific to experience in the use of documents accompanying the living modified organisms in question.

7. The submission on behalf of the European Community and its member States makes reference to several legal instruments that the European Union has put in place regarding genetically modified organisms that are also relevant to ensuring the implementation of the requirements under paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol.

8. The European Union submission also contains information, as an annex, regarding preliminary experience of one member State with the use of commercial invoice or other documents required or utilized by existing documentation systems to fulfil requirements under paragraphs 2 (b) and 2 (c) of Article 18 of the Protocol. Accordingly, the experience of the member State shows that there was a need for a specific document to fulfil the requirements under consideration. The submission argues that the inclusion of the requirements, as exactly as the Protocol specifies, in existing identification documents is fraught with difficulty as these existing documents depend on complex European Community or other international requirements that may hardly be adjustable to the needs of the Protocol. The submission added that the use of commercial invoice creates problems by channelling the information, in the

commercial chain, away from those authorities that are concerned with traceability or labelling of the organisms or products in question, as appropriate. It, however, suggests that the information required by the Protocol could be circulated in an annex to the commercial invoice provided the annex would be routed to the right authorities.

9. Sections 18 and 19 of Norway's new regulations of 2 September 2005 on labelling, transport, import and export of genetically modified organisms (GMOs) provide for identification requirements for GMOs destined for contained use and those for deliberate release into the environment. According to the regulations, the identification information is required to be provided on a label or in a document accompanying the GMOs in question. A standard format for transport documentation is also provided for use by applicants. It is indicated that the standard format does not include, for the time being, transport documents accompanying GMOs for intentional introduction into the environment in the form of marketing.

10. Norway's submission also makes reference to regulations relevant to the transport of dangerous goods. The regulations were issued in 2002 to implement the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and the international rules on transport of dangerous goods by railway (RID), which are also in accordance with the United Nations Model Regulations on the Transport of Dangerous Goods. The submission indicates that as a result of the low level of activities involving living modified organisms (LMOs) for contained use or for intentional introduction into the environment, and low level consumer demand for living modified organisms in general, the experience of Norway in the use of accompanying documentation is rather limited. The submission states Norway's support for a standard format of transport documents, preferably a stand-alone document, to fulfil the requirements of the Protocol under paragraphs 2 (b) and 2 (c) of Article 18. In that regard, the submission recalls the templates that Norway has presented to the relevant Protocol processes in its two earlier submissions dated 14 October 2003 and 23 August 2004.

11. Canada indicated that as a non-Party to the Protocol it has no regulations in place to implement its provisions, including those on documentation under paragraphs 2 (b) and 2 (c) of Article 18. It expressed the view that the consideration of a stand-alone document to fulfil identification requirements of paragraphs 2 (b) and 2 (c) of Article 18 should be separate from the consideration of such an issue in the context of paragraph 2 (a) of Article 18, where a decision on the detailed requirements of identification has not yet been taken by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

12. The United States expressed its belief that the documentation in common commercial practices for LMOs for contained use or intentional introduction into the environment is sufficient to ensure the safety of the environment and the protection of biodiversity. These practices, according to the submission, are well established, and recognized by both public and private sectors involved in the transboundary movement of the LMOs in question. The submission further pointed out that invoices that contain information concerning the cargo and handling procedures have functioned well and have not led to any reported adverse incidents.

13. The submission from the Global Industry Coalition (GIC) states that users and developers of biotechnology include the information required to identify shipments of LMOs for contained use and LMOs for intentional introduction into the environment on existing shipping documents such as commercial or proforma invoices and avoid unnecessary duplication of information. The submission indicates that commercial or proforma invoices have been used by the private and public sector to move biological material for many years and, therefore, are well recognized by customs officials. It argues that since the existing documents such as the invoices already contained most of the information required by paragraphs 2 (b) and 2 (c) of Article 18, the adjustments that are needed to comply with the Protocol is

minimal that could be done through the addition of only a small amount of text. A reference has been made regarding efforts done by the private sector in developing guidance for implementation of the documentation requirements that led to putting in place modifications that were necessary to be made on the existing documents since the entry into force of the Protocol.

14. The GIC submission points out that users and developers of biotechnology are in favour of using existing documentation to implement the requirements of paragraphs 2 (b) and 2 (c) of Article 18, and that they do not support the development of a stand-alone document as proposed by Norway and other proponents of a Protocol-specific transport document. GIC believes that the use of a stand-alone document would result in duplication of information that already exists on commercial and proforma invoices. In order to support its argument in this regard, the submission also contains, as an annex, a comparison of examples of existing documentation that includes the Protocol language under paragraphs 2 (b) and 2 (c) of Article 18, and the stand-alone document proposed by Norway.

15. The submission recommends to Parties to the Protocol to continue to accept shipments of LMOs for contained use and LMOs for intentional introduction into the environment that are accompanied by existing documentation as long as such documentation includes the additional requirements of paragraphs 2 (b) and 2 (c) of Article 18 as indicated in the guidance document developed by the GIC. This approach, according to the submission, avoids potential delays and allow for the continued transboundary movement of LMOs. The GIC, therefore, is of the view that there was no need for a stand-alone document and calls upon Parties to rather focus on clarifying national requirements of import of LMOs by posting clear information on the Biosafety Clearing-House.

III. OPTIONS FOR STAND-ALONE DOCUMENTATION

16. As mentioned in paragraph 1 above, decision BS-I/6 B, paragraph 2 of the first meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol includes a request to the Executive Secretary to prepare a synthesis report of the submissions presenting options for stand-alone documentation.

17. The Secretariat received a limited number of submissions. Out of the two submissions that expressed their preference to a stand-alone document to fulfil the identification requirements of paragraph 2 (a) and 2 (b) of Article 18 of the Protocol only one, namely, Norway, provided, by making reference to their earlier submissions, illustrative templates for a stand-alone document for use in the transboundary movement of LMOs for contained use and LMOs for intentional introduction into the environment. There are not, therefore, many options to present in response to the request by the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol.

18. However, the sample templates submitted by Norway and the model templates of invoices that the GIC included in its submission, are attached to this note as annexes 1a and 1b and 2a and 2b respectively, with a view to facilitating, to some extent, the consideration of a stand-alone document by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

IV. ELEMENTS FOR A DRAFT DECISION

19. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements in formulating and adopting a draft decision under this item:

(a) Consider the synthesis in section II above containing information on experience in the use of existing documentation;

(b) Determine whether the experience gained so far in the use of existing documents such as commercial invoices provides sufficient basis to take a decision on the need for a stand-alone document; or alternatively,

(c) Consider the templates annexed hereto with a view to determine whether existing commercial invoices or a stand-alone document would be a more convenient document to fulfil the requirements of identification of LMOs for contained use and LMOs for intentional introduction into the environment, and also appropriate to meet the objective behind these requirements; and

(d) Take into account the existing rules and practices of identification, packaging and transport under the United Nations Model Regulations on the Transport of Dangerous Goods in respect of some classes or types of LMOs that meet the criteria of dangerous goods or substances.

Annex 1a

SUBMISSION FROM NORWAY - EXAMPLE OF TEMPLATE FOR ARTICLE 18.2 (b) OF THE CARTAGENA PROTOCOL

Date:

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

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

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

If required by importing country:

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

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

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

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

Signature of exporter:_____ Date:___

Annex 1b

SUBMISSION FROM NORWAY - EXAMPLE OF TEMPLATE FOR ARTICLE 18.2 (c) OF THE CARTAGENA PROTOCOL

Date:

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

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

Unique identification number in BCH:

Description of the LMO:

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

Requirements by importing country:

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

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

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

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

Signature of exporter:_____ Date:_____

Annex 2a

SUBMISSION FROM THE GLOBAL INDUSTRY COALITION

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

Exporter: Address, Phone and Contact Person	
Recipient: Address, Phone and Contact Person	Name and address of consignee 1/
Permit/Notification No.	
Description of contents	"This Living Modified Organisms is for contained use" (may specify contents of shipment here, such as *Bacillus subtilis* containing the α-amylase gene from *G. stearothermophilus) .* Culture ID # if appropriate, general description of modification
Declared value	Sample for research purposes only – no commercial value
Number of pieces	
Net weight of shipment	
Gross weight of shipment	
Transporting company	
Airway bill number	
Any requirements for safe handling, storage, transport and use	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)
Shipper's name	
Shippers' signature	
Shipping date	

1/ Note that highlighted text indicates required language of Article 18.2 (b) and (c).

Annex 2b

SUBMISSION FROM THE GLOBAL INDUSTRY COALITION

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
100 0	80K bag Hybrid Maize, 2001Bt, Small Rounds this shipment contains living modified organisms (LMO) hybrid Maize seed with insect tolerance, UI=xxx88888 OECD Certified, Lot # 2001 – 1234 20 kgs per bag, Weight 20,000 kgs Shipped by Container Booking # 12234567, Sailing on: Zim Savannah v. Container # 9876543, Seal # 1813 Exporter declaration: the transboundary movement of this LMO is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter Treated Seed - Not to be used for human consumption or animal feed. There are no additional requirements for safe handling, storage, transport and use, if additional requirements exist, list them here) Additional information may be found on the BCH (or insert other information as appropriate)	$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.