



Cartagena Protocol on Biosafety: Identification & Documentation of Shipments of Living Modified Organisms

Kathryn Garforth, Legal Officer
Secretariat of the Convention on Biological
Diversity

Introduction & Context

- Requirements for the handling, transport, packaging & identification of living modified organisms (LMOs) are set out in Art. 18 of the Protocol
- Art. 18 was one of the most difficult parts during the negotiation of the Protocol
 - Some countries were opposed to any labelling or identification requirements. They argued that it would be onerous for exporters and that it would hamper trade in commodities
 - Others wanted flexibility to be able to know what is coming into their country and trace LMOs once they entered their territory & so wanted all LMOs in all shipments to be identified.

Introduction & Context

- Compromise: Identification using shipping documentation
- Art. 18 sets out basic documentation requirements. These have been elaborated by subsequent COP-MOP decisions:
 - Decision BS-I/6 includes more details on documentation requirements for LMOs for contained use & LMOs for intentional introduction into the environment
 - Decision BS-III/10 includes detailed documentation requirements for LMOs intended for direct use as food or feed, or for processing

Introduction

- A country importing LMOs may wish to ensure that it has approved the LMOs contained in a shipment for their intended use in order to fulfill the objective of the Protocol
- To do this:
 1. The documentation that accompanies a shipment that contains LMOs must identify the shipment as such;
 2. The sampling of shipments and the detection of any LMOs contained therein can be used to verify documentation; and
 3. The documentation and detection of LMOs in a shipment can be used to check whether the national competent authority has approved the LMOs for their intended use in the country.

Introduction

- 3 main types of transboundary movements of LMOs under the Protocol:
 - Intentional transboundary movements
 - Unintentional transboundary movements
 - Illegal transboundary movements

Intentional transboundary movements

- Protocol has different requirements for information to be contained in documentation that is to accompany shipments of:
 - LMOs intended for direct use as food or feed, or for processing (LMOs-FFP)
 - LMOs intended for contained use
 - LMOs intended for intentional introduction into the environment and other LMOs within the scope of the Protocol

Intentional transboundary movements

Shipments of LMOs-FFP should be accompanied by documentation that clearly states:

- Where identity of the LMOs is known, that the shipment contains LMOs-FFP
- Where identity of the LMOs is not known, that the shipment “may contain” one or more LMOs-FFP
- That the LMOs are not intended for intentional introduction into the environment
- Common, scientific &, where available, commercial names of the LMOs
- Transformation event code or, where available, the LMOs’ unique identifiers
- The website of the Biosafety Clearing-House (BCH) for further information

Intentional transboundary movements

Shipments of LMOs for contained use must be accompanied by documentation that:

- Clearly identifies content as LMOs including common & scientific names of organisms and as “destined for contained use”
- Provides the name & address of the consignee, and exporter or importer, including contact details necessary to reach them as fast as possible in case of emergency
- Specifies any requirements for the safe handling, storage, transport and use of the LMOs. In the event that there is no requirement, indicate that there is no specific requirement
- Provides further information, where appropriate, such as the commercial name of the LMOs, new or modified traits, transformation events, risk class, specification of use, and any unique identification as a key to accessing information in the Biosafety Clearing-House

Intentional transboundary movements

Shipments of LMOs intended for intentional introduction into environment must be accompanied by documentation that:

- Clearly identifies content as LMOs and briefly describes the organisms, including:
 - Common & scientific names
 - Relevant traits and genetic modification, including transgenic traits and characteristics such as transformation event(s) or reference to system of unique identification
- Gives any requirements for safe handling, storage, transport and use. In the event that there is no requirement, indicates that there is no specific requirement
- Contains the name & address of exporter & importer
- Provides a contact point for further information, including an individual or organization in possession of relevant information in case of emergency
- Includes a declaration that movement of the LMOs is in conformity with the Protocol's requirements
- Provides further information, where appropriate, e.g. commercial name, risk class & import approval for first transboundary movement of the LMO

Intentional transboundary movements

Where to find information on LMOs in shipping documentation?

- COP-MOP has not adopted a stand-alone document to accompany shipments of LMOs
- Instead, the information that is to accompany shipments of LMOs will be included in existing types of shipping documentation, e.g. invoices, bills of lading, way bills, etc.
- COP-MOP has adopted templates for how the required information for shipments of LMOs for contained use and LMOs for intentional introduction into the environment can be integrated into existing documentation

Template for integrating information requirements into existing documentation: shipments of LMOs for contained use

COMPANY OR INSTITUTION LETTERHEAD				
Invoice				
		EXPORTER	CONSIGNEE	Date CONTACT POINT Exporter <input checked="" type="checkbox"/> Consignee <input type="checkbox"/> Other <input type="checkbox"/>
COMPANY OR INSTITUTION		XXXX	YYYY	
CONTACT PERSON				
STREET				
CITY, POSTAL CODE				
COUNTRY				
PHONE, FAX				
EMAIL				
Shipping details		Shipper reference number		Shipper contact details

Item	Amount	Weight/Volume	Description	Value
1	bag	50 g	Living modified organisms: Destined for contained use Papaya Research material seeds, PRSV (Papaya Ring Spot Virus) resistant	none

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	Should only be used in registered facilities
--	--

Template for integrating information requirements into existing documentation: shipments of LMOs for intentional introduction into the environment

COMPANY OR INSTITUTION LETTERHEAD				
Invoice				
		EXPORTER	IMPORTER	Date CONTACT POINT Exporter <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Other <input type="checkbox"/>
COMPANY OR INSTITUTION		XXXX	YYYY	
CONTACT PERSON				
STREET				
CITY, POSTAL CODE				
COUNTRY				
PHONE, FAX				
EMAIL				
Shipping details		Shipper reference number		Shipper contact details

Item	Amount	Weight/Volume	Description	Value
4	Bags	1 Kg	Living modified organism: Rice, resistance against <i>Xanthomonas campestris</i> pv. <i>Orizae</i> , RI323, 327, 432 & 726 Permit RICE3434-02 for experimental release Research material	none

ANY REQUIREMENTS FOR SAFE HANDLING, STORAGE, TRANSPORT AND USE	• See permit RICE3434-02
--	--------------------------

I declare that this transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter _____ Date _____

Intentional transboundary movements

Unique identifiers

- Documentation requirements for the 3 categories of LMOs mention unique identifiers
- To date, only one unique identification system exists: OECD Unique Identifiers for Transgenic Plants
- OECD Unique Identifier is a simple alphanumeric code that is given to each living modified plant that is approved for commercial use
- Developers of transgenic plants are the ones to assign the unique identifier

Intentional transboundary movements

Unique identifiers, cont.

- 9-digit code composed of 3 elements separated by dashes
 - 2 or 3 alphanumeric digits to designate the applicant;
 - 5 or 6 alphanumeric digits to designate the transformation event; and
 - 1 numerical digit for verification

Example: MON-00810-6

Monsanto's YieldGard Maize

- Can use unique identifier to search BCH

Intentional transboundary movements

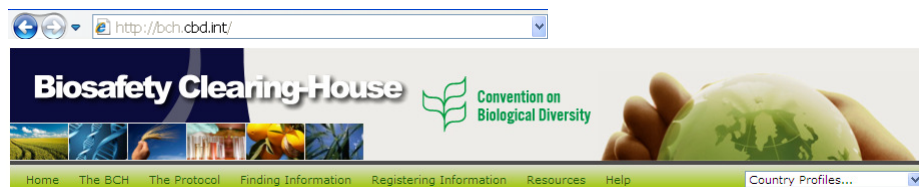
Biosafety Clearing-House – What is it?

- BCH is an information exchange mechanism to support implementation of Protocol
- Its creation was mandated by the Biosafety Protocol and Parties are required to share certain types of information through the BCH
 - E.g.: relevant national laws, regulations and guidelines; decisions on LMOs

Intentional transboundary movements

Biosafety Clearing-House – What is it?

- BCH has been developed as a website
- It is free and available to everyone
- BCH can be accessed at <http://bch.cbd.int>



العربية | 中文 | english | español | français | русский

Sign Up for an Account | Sign In

Biosafety Clearing-House

Convention on Biological Diversity

Home The BCH The Protocol **Finding Information** Registering Information Resources Help Country Profiles...

Finding Information

- National Contacts
- Laws and Regulations
- Country's Decisions and other Communications
- LMOs, Genes or Organisms
- Roster of Experts
- Capacity-Building
- Biosafety Information Resource Centre (BIRC)
- Scientific Bibliographic Database
- Organizations

Compiled Information

- National Contacts
- LMO Registry
- Organism Registry
- Gene Registry

Go to record ID

Search for LMOs, Genes or Organisms

On this page you can search: (i) The **LMO-Unique Identifiers Registry (LMO-Ulds)**, which provides summary information on all living modified organisms registered in the BCH including transformation events, genetic modifications, and the unique identification code (if available) for each record. Links to all decisions that refer to these organisms are provided at the bottom of each LMO record accessible through the registry; (ii) The **Gene Registry**, which provides summary information on gene inserts and characteristics of the genetic modifications of LMOs; and (iii) The **Organism Registry**, which provides summary information on parental, recipient or donor organisms related to the LMOs registered in the BCH.

Choose fields as needed to narrow search results. If no category is selected to narrow the search for a particular field, a default value of "all" will be used.

Registries

Type of living modified organism

Unique Identifier

Type of gene

Type of organism

Date of record

Keyword search

Home The BCH The Protocol Finding Information Registering Information Resources Help Country Profiles...

Finding Information

- National Contacts
- Laws and Regulations
- Country's Decisions and other Communications
- LMOs, Genes or Organisms
- Roster of Experts
- Capacity-Building
- Organizations
- The BCH Virtual Library
- Advanced Search --

Compiled Information

- National Contacts
- LMO Registry
- Organism Registry
- Gene Registry

Go to record ID

Modified Organism

MON-00810-6 - YieldGard™ maize

LMO Information **Decisions on the LMO** Risk Assessments

Country	Domestic Use			Import			Environmental Release	Other
	Food	Feed	Processing	Food	Feed	Processing		
Argentina								
Austria								
Australia								
Brazil								
Canada								
Switzerland								
China								
Colombia						39602 49280 49281		
European Union						7877.7892.7897.100388		
Indonesia								

Intentional transboundary movements

Sampling & Detection

- The Protocol does not set specific requirements for methods for the sampling of shipments and detection of LMOs
- Work on how to sample shipments and detect whether they contain LMOs and if so, what kinds of LMOs, is largely taking place outside the Protocol.

Unintentional transboundary movements

- Could include:
 - Gene flows through natural processes
 - Accidental contamination, during transit, for instance

Illegal transboundary movements

- The Protocol defines an illegal transboundary movement of an LMO to be a transboundary movement that is carried out in contravention of domestic measures to implement the Protocol (Art. 25).
- Customs officers will need to be familiar with their national biosafety laws in order to know what constitutes an illegal transboundary movement

Conclusion & Review

- Protocol specifically recognizes 3 types of transboundary movements of LMOs:
 - Intentional, unintentional and illegal
- Protocol groups LMOs into 3 categories:
 - LMOs-FFP, LMOs for contained use and LMOs for intentional introduction into the environment
- Requirements for information to be included in documentation accompanying intentional transboundary movements of each type of LMO are set out in:
 - Art. 18 of Protocol, decision BS-I/6 and decision BS-III/10
- Information to accompany shipments of LMOs likely to be incorporated into other shipping documents
- Unique identifiers for LMO plants can help access information on BCH