

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

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



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

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Intentional transboundary movements



e.g. seeds,
live fish



e.g. agricultural
commodities:
maize, canola
(rapeseed),
cotton, rice,
soybean



e.g. bacteria for
laboratory

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Intentional transboundary movements



Different requirements under the Protocol for handling, transport, packaging and identification (Art.18 and related COP-MOP decisions)

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Intentional transboundary movements:

Documentation requirements



- **Clearly identifies content as LMOs and briefly describes the organisms**
- Any requirements for safe handling, storage, transport & use
- Name/address of exporter & importer
- Emergency contact point
- Declaration that movement of the LMOs is in conformity with the Protocol's requirements
- Further information, where appropriate (e.g. commercial name, risk class & import approval for the LMO)

Intentional transboundary movements:

Documentation requirements



- “**contains LMOs-FFP**” (if identity known) or
- “**may contain one or more LMO-FFP**” (if identity not known)
- The LMOs are not intended for intentional introduction into environment
- Common, scientific & commercial names of the LMOs
- Transformation event code
- BCH website for further information

Intentional transboundary movements:

Documentation requirements



- **Clearly identifies content as LMOs and “destined for contained use”**
- Name & address of the consignee, and exporter or importer
- Any requirements for the safe handling, storage, transport and use
- Further information, where appropriate (commercial name of the LMOs, new or modified traits, transformation events, risk class, use, and any unique identification)

Intentional transboundary movements



Where to find information on LMOs in shipping documentation?

- The Parties have 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



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Example 1 (intentional introduction into env):

Clearly identifies content as LMOs

Briefly describes the organisms

Requirements for safe handling, storage, transport & use

Name/address of exporter & importer, emergency contact

Declaration that movement of the LMOs is in conformity with the Protocol's requirements

Further information (e.g. commercial name, import approval)

COMPANY OR INSTITUTION LETTERHEAD

Invoice

Date	Exporter	Importer	Contact point EXPORTER <input type="checkbox"/> IMPORTER <input type="checkbox"/> OTHER <input checked="" type="checkbox"/>
Company Institution	or XXXX	YYYY	ZZZZ
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	1000 bags	50'000 pounds	<p>Living modified organism:</p> <p>Soybean WSD 432, high oleic acid, HOA</p> <p>Permit: AGM21345C002 for planting</p> <p>OECD UE: BF-ABC891-8</p> <p>Commercial seeds material</p>	22'000 €

Any requirements for safe handling, storage, transport and use

No specific requirement

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

Example 2 (contained use):

Clearly identifies content as LMOs “**destined for contained use**”

Name & address of the consignee, and exporter or importer

Requirements for safe handling, storage, transport and use

Further information
(e.g. commercial name, new or modified traits, transformation events, risk class, use, and any unique identification)

Shippers Declaration of Dangerous Goods

Shipper: Name Company or Institution Address Phone number		Air Waybill No: 123456789 Page 1 of 1 Pages Shipper's Reference Number (optional) sso	
Consignee: Company or Institution Contact Person Street, City Postal Code, Country Phone, Fax Email		Contact Point Shipper <input type="checkbox"/> Consignee <input checked="" type="checkbox"/> Other <input type="checkbox"/> Company or Institution Contact Person Street, City Postal Code, Country Phone, Fax	
Two Completed and signed copies of this Declaration must be handed to the operator		WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be Completed and/or signed by a consolidator, a Forwarder or an IATA cargo agent	
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (delete non-applicable) PASSENGER AND CARGO AIRCRAFT AIRCRAFT ONLY Airport of Destination:		Airport of Departure: CARGO AIRCRAFT ONLY Shipment Type: (delete non-applicable) NON-RADIOACTIVE RADIOACTIVE	
NATURE AND QUANTITY OF DANGEROUS GOODS			
Dangerous Goods Identification Proper Shipping Name Infectious Substances Affecting Humans EBV gene bank in E. coli K12 Living modified organisms Dry Ice		Quantity and Type Class or Division UN ID No. Packing Group Subsidiary Risk of Packing Packing Instruction Authorization	
6.2 UN 2814 I III		1 Fiberboard Box ("Safe-T-Pak") x 25.0 mL 1 x 12.4Kg 1 Overpack Used 602 904	
Additional Requirements for Safe Handling, Storage, Transport and Use Prior Arrangements As Required By The IATA Dangerous Goods Regulations 1.3.3.1 Have Been Made This material is for contained use only in a certified Safety Level 2 Facility 24 hr. Emergency Contact Telephone No.			
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.		IATA/ICAO USED Chemtrec 800/424-9300 Name/Title of Signatory Name/Title of Signatory Place and Date City, State, Country Date Signature (see warning above)	

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

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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

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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>



Biosafety Clearing-House

[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

 [Home](#) | [Finding Information](#) | LMOs, Genes or Organisms

Search for LMOs, Genes or Organisms

On this page you can search: (i) The **LMO-Unique Identifiers Registry (LMO-UIs)**, 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

LMO-Unique Identifiers Registry (LMO-UIs)



Type of living modified organism

Filter by unique identifier



Unique Identifier

MON-00810-6



Type of gene

<All>



Type of organism

<All>



Date of record

<All>

Keyword search

Enter keywords. Separate words with AND or OR.

Finding Information

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

Compiled Information

National Contacts
LMO Registry
Organism Registry
Gene Registry

Go to record ID

Home Finding Information Record details Decisions



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								
Australia								
Austria								
Brazil								
Canada								
China								
Colombia	39602,49280,49281,102230,102237,102239,102240,102244,102254							
European Union	7877,7892,7897,100388,101792							
Indonesia								
Japan								
Mexico								
New Zealand								
Philippines								
Republic of Korea								
South Africa								
Switzerland								
United States of America								

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.

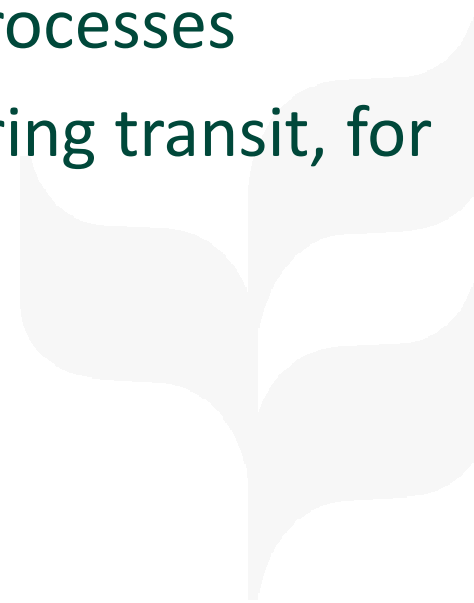
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Unintentional transboundary movements



Could include:

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



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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

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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



Thank you

**Secretariat of the
Convention on Biological Diversity**
World Trade Centre
413 St. Jacques Street, suite 800
Montreal, Quebec, Canada H2Y 1N9
Tel. 1 (514) 288 2220
secretariat@cbd.int
www.cbd.int



<http://bch.cbd.int/protocol>



secretariat@cbd.int



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