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HANDBOOK FOR CUSTOM AND QUARANTINE OFFICIALS

Genetically Modified Seeds and Regulations

Prepared under

gef UNEP

Phase-II Capacity Building Project on Biosafety

Ministry of Environment
Forests and Climate Change

Ministry of Environment
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Government of India

In association with

BCIL
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2019

Handbook for Custom and Quarantine Officials
Transboundary Movement of Living Modified Organisms (LMOs)

Prepared by
Ministry of Environment, Forest and Climate Change (MoEFCC) and
Biotech Consortium India Limited, New Delhi
under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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Introduction

India is a Party to the Cartagena Protocol on Biosafety (CPB), an international agreement under the Convention on Biological Diversity (CBD). The CPB focusses on transboundary movement of living modified organisms (LMOs) resulting from modern biotechnology, also commonly referred to as genetically modified organisms (GMOs) or genetically engineered (GE) organisms.

Modern biotechnology involving genetic engineering has made remarkable advances in medicine, agriculture and other fields. These include new medical treatments and vaccines, improved agricultural crops and foods, industrial products etc. The CPB has been developed in recognition that while biotechnology holds great promise for improving human well being, advances in biotechnology must be developed and used with adequate safety measures for the environment and human health. The CPB is an environmental treaty so it uses the term 'living modified organisms (LMOs)' as these are the organisms that may enter the environment and have impacts on biodiversity. It does not address products derived from LMOs such as recombinant drugs and GM foods where the organisms have been processed and are no longer living.

Countries have put in place regulatory systems for biosafety evaluation of LMOs prior to permitting their use. India has a systematic and structured regulatory system in place for regulation of GMOs and products thereof since 1989. The “Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells” (referred to as Rules, 1989) have been notified under the Environment (Protection) Act, 1986. There are various committees scrutinizing the applications and monitoring the data generation process at central, state and institutional level. Genetic Engineering Appraisal Committee (GEAC) functioning in the Ministry of Environment, Forest and Climate Change (MoEFCC) is the apex committee that authorizes activities involving LMOs/GMOs. MoEFCC is also the competent authority and nodal ministry for implementation of CPB in India.

Customs officials and quarantine officers (referred to as border control officials) contribute to implementation of the CPB and national biosafety regulations by inspecting shipments and relevant

[1]The term "living modified organism (LMO)" refers to any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology.

documents to verify their validity and accuracy and enforcing regulations related to the import and export of LMOs.

MoEFCC being the nodal ministry for biosafety regulation of LMOs has implemented the Phase II Capacity Building Project on Biosafety with support from Global Environment Facility (GEF) through the United Nations Environment Program (UNEP), aimed to strengthen the biosafety management in India. 'Enhancing Public Awareness' is one of the key thrust areas of the project and is essential for better understanding of biosafety regulatory framework. Accordingly, several knowledge products have been developed as part of the project. Significant efforts have been made to ensure outreach through multiple tools viz. workshops, printed material, short film etc.

In continuing with the same, MoEFCC in association with Biotech Consortium India Ltd. (BCIL), the project coordination unit has prepared booklet for specific categories of stakeholders focusing on their information requirements. This handbook has been prepared as part of UNEP/GEF supported Phase II Capacity Building Project on Biosafety implemented by MoEFCC for providing relevant information about the transboundary movement of LMOs and role of customs officials. It has the following five sections:

1 LMOs: Applications and status
2 Regulations of LMOs in India
3 Relevant provisions of CPB
4 Role of customs and quarantine officials
5 Detection of LMOs

Section-1 | LMOs: Applications and Status

In general, an LMO is made by taking a gene (a piece of DNA) from one organism and inserting it into the DNA of another organism. Scientists search for genes that correspond to desired characteristics. By inserting these genes into other organisms, scientists can create organisms that display the traits coded for by the gene.

Using modern biotechnology to make LMOs is based on the chemical composition of DNA, which is the same in all organisms. DNA is found in the nucleus of the cells of all living creatures. DNA contains the instructions for making proteins which, in turn, carry out various functions.

DNA and Gene

- Deoxyribonucleic acid, more commonly known as DNA, is a complex molecule that contains all of the information necessary to build and maintain an organism. All living organisms have DNA within their cells.
- A gene is a sequence of DNA that contains information that determines a particular characteristic/trait.
- Genes are units of inheritance that are passed from one generation to the next
- All organisms have varying number of genes. For instance, the human has an estimated 60-100,000 genes, most plants have about 20,000, a nematode has about 18,000 and a single celled Escherichia coli bacterium just about 4,000.
- The genetic differences among different species as well as organisms within a species lie in difference in number and sequence of these genes in the DNA/genome.

As the genetic code is universal i.e. the DNA of all organism is made up of the same building blocks and is encoded in exactly the same way, the copying and transfer of genes from one organisms to another can be done in the laboratory. Hence it is possible to transfer a copy of DNA sequence (or gene) that codes for a particular characteristics into the cell of a different organism. Once the gene is incorporated into the genome of recipient, the resulting organism is considered to be GMO or LMO and the new characteristic coded by that gene is inherited by subsequent generations.

As with any new emerging technologies, safety concerns have been expressed for LMOs produced with the use of modern biotechnology techniques. These apprehensions arise because LMOs may contain genes that have crossed the species barriers as compared to classical selection techniques. There is no evidence that any unique hazards exist in the development of LMOs, because of novel combination of genes. However, specific gene organism combination may be harmful by virtue of novel combination of traits they possess and therefore the concerns associated with the use of LMOs differ greatly depending on the particular gene-organism combination. A case by case approach is adopted for assessment of

safety concerns. Potential risks from the use of LMOs broadly fall under two categories i.e. risks to human and animal health and risks to environment. Risks to human health may include introducing of any toxins, allergens or other anti-nutrient factors. Risks to environment may include effects on non-target organisms, invasiveness or weediness, resistance development in target organisms or movement of a transgene outside the LMO.

In view of the above, safety of LMOs is evaluated in a comprehensive process that involves several steps. Systematic safety assessment methodologies have been developed at national and international level that give conclusion on whether or not the LMO is as safe as its conventional counterpart. LMOs are permitted to be grown and used only after they have passed safety assessment and are not likely to pose risks for human health and environment.

Genetic engineering is more precise and the outcomes more certain, resulting in faster production of organisms with desired traits. Hence the technology has found applications in several areas such as healthcare, agriculture, process industry and environment for the production of GMOs/LMOs:

a. Healthcare: The healthcare applications of LMOs and their products are playing an increasing role in conventional drug discovery as well as opening up new possibilities to prevent, treat and cure many incurable diseases using novel methods of treatment and diagnosis. LMOs have been extensively used for production of therapeutics, vaccines and monoclonal antibiotics. Most common examples of products from use of LMOs include human insulin, hepatitis B vaccine, and interferons.

b Agriculture: The plants are being subject to genetic modification for multiple traits including production of transgenic plants with increased resistance to pest and disease, higher crop yield and nutritional content and increased resistance to abiotic stresses such as draught, salt etc. Most common agricultural crops being cultivated and traded have genes inserted to make them resistant to certain insects or tolerant to different herbicides, as explained below:

- Insect resistant plants like the Bt cotton described before, have an introduced gene that causes the plant itself to produce insecticides that will kill pests that try to eat the plant. Farmers that grow insect resistant plants don't need to spray as much insecticide to kill the pests that attack their plants.
- Herbicide tolerant plants have an introduced gene that allows them to withstand being sprayed with a herbicide that would normally kill the plant. Farmers that grow herbicide tolerant plants can spray their fields with herbicides, killing the weeds but leaving the desired crops.

Example of a LMO: Bt cotton

The *cry* gene (also called Bt gene) in the soil bacteria *Bacillus thuringiensis* (Bt) is known to produced insecticidal protiens that are harmful to specific target insects. The insecticidal protiens (crystal protiens) produced by *cry* gene bind to specific receptors on the mid gut of the specific target insects. The *cry* gene from the Bt soil bacteria has been inserted into the DNA of cotton. The Bt Cotton containing the *cry* gene kills the target insects that try to feed on the plant. Due to the highly specific mode of action of the crystal protiens, no harm is caused to humans, animals, fish, birds and beneficial insects.

Bt cotton, has been approved for use in a number of countries. India is the fifth largest producer in the world after USA, Brazil, Argentina and Canada.

The application of modern biotechnology in agriculture was started in the 90s. From 1994 to 2017, a total of 67 countries have issued regulatory approvals to GM crops for consumption either as food and/or feed as well as for environmental release. While 24 countries planted GM crops, an additional 43 countries have granted regulatory approval for GM crops for import as food and feed use. As per the recent reports, 16 GE plants have been cultivated in 24 countries in 2017 on approximately 190 million hectares. The four major crops are maize, soybeans, cotton and canola (rapeseed).

In India, Bt cotton is the only GM crop approved for commercial cultivation in India. The total area under Bt cotton has been increased substantially since it was introduced in 2002. As of now, Bt cotton is cultivated in more than 90% of the area under cotton cultivation in India. Several public and private sector institutions are involved in research and development of GM crops in India. These include brinjal, cabbage, mustard, potato, rice, chickpea, pigeonpea etc.

c. Process industry: Useful products and materials through development of improved microorganisms with increased enzymes, bioplastics etc are being developed for specific consumer needs and provide eco-friendly alternatives to chemical processes.

d. Environment: Bioremediation programmes involving the use of microorganisms are currently in progress to clean up contaminated air, tracks of land, lakes and waterways. GMOs help in improving the efficacy of these processes so that their basic biological processes are more efficient and can degrade more complex chemicals and higher volumes of waste materials.

Section-2 | Regulation of LMOs in India

The use of LMOs in India is governed by the **"Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989"** (Rules 1989) notified under the Environment (Protection) Act, 1986 (EPA, 1986). Rules, 1989 essentially cover entire spectrum of activities involving GMOs and products thereof including the sale, storage, exportation, importation, production, manufacturing, packaging etc.

The Rules, 1989 are implemented by the MoEFCC, the Department of Biotechnology (DBT) of Ministry of Science & Technology and State Governments through six competent authorities viz. (i) Recombinant DNA Advisory Committee (RDAC), (ii) Institutional Biosafety Committee (IBSCs), (iii) Review Committee on Genetic Manipulation (RCGM), (iv) Genetic Engineering Appraisal Committee (GEAC), (v) State Biotechnology Coordination committee (SBCC) and (vi) District Level Committee (DLC). While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function, SBCC and DLC are for monitoring purpses (Figure 1).

1. Recombinant DNA Advisory Committee (RDAC)	→	Advisory
2. Institutional Biosafety Committee (IBSCs) 3. Review Committee on Genetic Manipulation (RCGM) 4. Genetic Engineering Appraisal Committee (GEAC)	→	Approval
5. State Biotechnology Coordination committee (SBCC) 6. District Level Committee (DLC)	→	Monitoring

Fig 1: Competent authorities notified under Rules, 1989

Guidelines for biosafety evaluation for each step of development process viz. contained use, confined field trials, food safety assessment and environment safety assessment have been prepared by regulatory authorities and are listed in Box 1.

In India, no person can import, export, transport, manufacture, store, process, use or sell any GMOs, substances or cells except with the approval of GEAC. RCGM is authorised to permit imports only for research purpose. Deliberate or unintentional release of GMOs is not be allowed. Production in which GMOs are generated or used cannot be commenced except with the approval of GEAC.

Box 1: Biosafety Guidelines in India

Contained Use

- Recombinant DNA Safety Guidelines, 1990 (Updated, 2017)
- Revised Guidelines for Research in Transgenic Plants, 1998

Confined Field Trials

- Guidelines for Conduct of Confined Field Trials (CFTs) of Regulated GE Plants, 2008
- Standard Operating Procedures (SOPs) for CFTs of Regulated GE Plants, 2008
- Guidelines for Monitoring of CFTs of Regulated GE Plants, 2008

Food Safety Assessment

- Guidelines for the Safety Assessment of Foods Derived from GE Plants, 2008 (Updated in 2012)
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008

Environmental Safety Assessment

- Guidelines for Environmental Risk Assessment (ERA) of GE Plants, 2016
- Risk Analysis Framework, 2016
- ERA of GE Plants: A Guide for Stakeholders, 2016

Others

- Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999
- Guidelines and Handbook for Institutional Biosafety Committees (IBSCs), 2011
- Guidelines on Similar biologics: Regulatory requirements for Marketing Authorization in India, 2012 (updated in 2016)

All approvals are for limited period as per Rules, 1989. GEAC has powers to revoke approvals in case of any new information on harmful effects of GMOs, any damage to the environment that could not be envisaged when approval was given or non-compliance of any conditions stipulated by GEAC. Details of applicable rules, guidelines and decisions of GEAC can be accessed at http://www.geacindia.gov.in/

In addition to the Rules, 1989, provisions in other acts, rules and policies are also applicable to GMOs/ LMOs. Relevant details concerning import/export of LMOs are as under:

I. **Plant Quarantine Order, 2003** covers regulation of import of germplasm/ GMOs/transgenic plant material for research purpose (Figure 2). The Indian Council of Agricultural Research, National Bureau of Plant Genetic Resources (ICAR-NBPGR) has been designated as the Competent authority to issue

the import permits[2] for import of seeds for research purposes after getting permission under Rules, 1989 and to receive import material from customs authorities for quarantine inspection. A phytosanitary certificate issued from exporting country is needed during the imports of transgenic material.

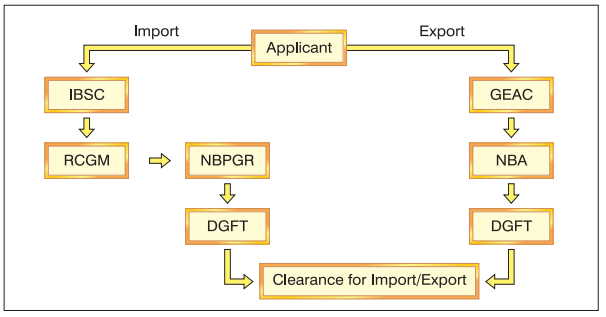


Fig. 2: Procedure for Import/Export of GE Planting Material for Research Purpose.

ii. **Food Safety and Standards Act, 2006,** regulates manufacture, storage, distribution, sale and import of food which includes GM food.

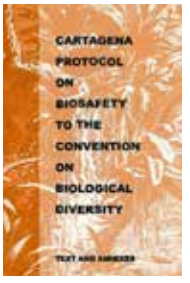
iii. **DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy (2006-09)** -At time of imports of a consignment, declaration stating that it contains genetically modified material is needed or importer is liable to penal action under the Foreign Trade (Development and Regulation) Act of 1992. Pursuant to these acts, rules, policies and guidelines, the mandate of various ministries/ departments are summarised in table 1.

Table 1: Mandate of Ministries/Departments

Ministry of Environment, Forest and Climate Change	• Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of GMOs / LMOs. • Nodal agency for implementing Rules, 1989 and the Cartagena Protocol on Biosafety
Department of Biotechnology (Ministry of Science & Technology)	• Nodal department for promoting biotechnology programs • Provides scientific support in implementation of biosafety regulations
Ministry of Agriculture & Farmer Welfare	• Policies aimed at agriculture growth. • Indian Council of Agricultural Research (ICAR) responsible for monitoring agronomic benefits of GM technology. • Monitoring post-release performance of GM crops.
Ministry of Health and Family Welfare	• Policies aimed at protecting and monitoring human health. • Food Safety and Standards Authority of India responsible for regulating GE foods.
Ministry of Commerce and Industries	• Enhance trade with other countries through export/ import policies. • Nodal agency for implementing DGFT notification on GMOs
Central Board of Excise and Customs, Department of Revenue, Ministry of Finance	• Enforcement of regulation pertaining to transboundary movement of GMOs/ LMOs at point of entry

[2] Import Permit: An official document authorizing importation of a consignment in accordance with specified phytosanitary requirements. It is issued by National Bureau of Plant Genetic Resources, New Delhi. In case of GMOs, issue of Import Permit also requires previous authorization by RCGM/GEAC

Section-3 | Relevant Provisions of CPB



The Cartagena Protocol on Biosafety (CPB) is a supplementary agreement to the Convention on Biological Diversity (CBD) that was adopted on 29 January, 2000 and entered into force on 11 September, 2003. 171 countries have ratified or acceded to the CPB, as on March 2019. India is a Party to the CPB having ratified the Protocol on January 23, 2003. MoEFCC is the nodal ministry in India.

The CPB applies to transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. LMOs covered under the CPB are categorized as under

- LMOs for intentional introduction into the environment (seedlings, trees, animals for breeding, live fish, bacteria or other microorganisms)
- LMOs intended for direct use as food or feed, or for processing (FFP) (e.g. agricultural commodities- corn, canola, cotton)
- LMOs for contained use (e.g. bacteria for laboratory scientific experiment)

Exemptions under CPB

- LMOs that are pharmaceutical for humans if they are covered by other international agreements or arrangements
- Products derived from LMOs such as processed food (e.g. soybean oil, corn flour)

The CPB promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of LMOs, with specific focus on regulating the transboundary movement of LMOs. The Protocol aims to ensure the safety of LMOs and not to prohibit their trade.

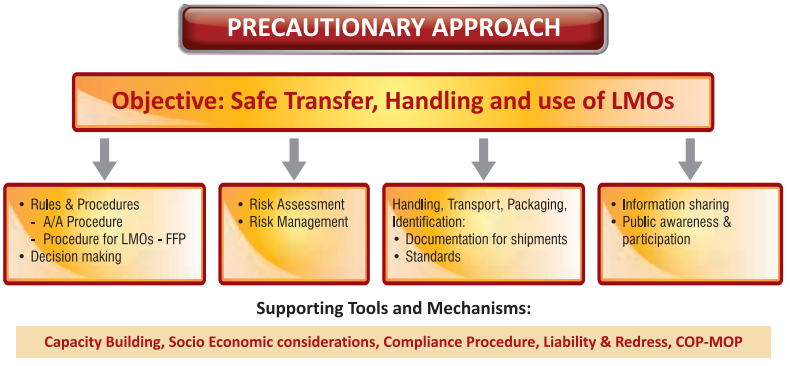


Fig 3: Key Elements of the Protocol

There are 40 Articles in the CPB, which could be categorized into key elements and supporting tools and mechanisms. The four key elements include Procedures for transboundary movement of LMOs, Risk Assessment and Risk Management, Handling, Transport, Packaging & Identification and Information Sharing (Figure 3).

There are three main types of transboundary movements of LMOs under the Protocol i.e. intentional, unintentional and illegal.

i **Intentional:** The focus of CPB is much on LMOs that may have impacts on biodiversity and the environment i.e. LMOs for intentional release. The decision-making procedures have been defined separately for two categories i.e. LMOs for intentional release and LMOs for FFP (Table 2). LMOs that are for intentional introduction into the environment need extensive environmental risk assessment than from LMOs that are not intended to be introduced into the environment. A great deal of trade involves organisms that are intended to be used in the importing country as food for humans or feed for animals or to be processed into other products (FFP). The organisms that are being shipped, however, are still living and can propagate and if these organisms are not used as they were intended for FFT and instead are somehow introduced into the environment of the importing country, they may grow and spread and potentially have impacts on the environment.

   The CPB does not include a decision-making procedure for LMOs for contained use but it does include rules for their handling, transport, packaging and identification.

ii **Unintentional:** Unintentional transboundary movements could include gene flow through natural processes or accidental contamination e.g. during transit. In the event of a release which leads to, or may lead to, an unintentional transboundary movement of an LMO that is likely to have adverse effects on biodiversity, Parties are required to notify the BCH, and potentially affected States. Parties under whose jurisdiction such releases occur are also required to consult potentially affected States to determine appropriate responses, including emergency measures.

   Customs officers can do little to prevent gene flow but they can help to prevent accidental contamination by ensuring that shipments of LMOs are handled accordingly to the information provided in the accompanying documentation. In case of a spill or any unintentional transboundary movement is detected, the customs should report the same to the competent national authority i.e GEAC.

iii **Illegal:** The CPB defines an illegal transboundary movement of an LMO as a transboundary movement that is carried out in contravention of domestic measures to implement the Protocol. Parties are required to adopt domestic measures to prevent and if appropriate, penalize transboundary movement of LMOs

that occur in contravention of its domestic measures to implement the Protocol. Such movements are deemed as illegal transboundary movements. In the case of such illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the LMO in question by repatriation or destruction, as appropriate. Each Party is required to make available information concerning cases of illegal transboundary movement to BCH.

Customs officers need to be familiar with their national biosafety rules in order to know what constitutes an illegal transboundary movement. Regarding the transboundary movements between Parties and non-Parties, it has been indicated in CPB that it must be carried out in a manner i.e. consistent with the objective of the CPB. The Parties can enter into bilateral, regional and multilateral agreements and arrangements with non Parties regarding transboundary movements of LMOs.

Table 2: Procedure for Transboundary Movement of LMOs: Key Components

<table>
<tr><th>Advance Informed Agreement for LMOs for Intentional Release</th><th>Procedures for LMOs for Food, Feed or Processing (FFP)</th></tr>
<tr><td>Notification by the Party of export or the exporter</td><td>A Party must inform other Parties through the BCH, within 15 days, of its decision regarding domestic use of LMOs that maybe subject to transboundary movement</td></tr>
<tr><td>Acknowledgement of receipt of notification by the Party of import within 90 days</td><td>Decisions by an importing country on whether or not to import these LMOs-FFP are taken under its domestic regulatory framework that is consistent with the objective of the Protocol</td></tr>
<tr><td>Party of import must communicate its decision on whether or not to import the LMO within 270 days of receipt of notification</td><td rowspan="2">In absence of domestic regulatory framework, importing Country may declare through the BCH that its decisions on the first import of LMOs-FFP will be taken in accordance with risk assessment as set out in the Protocol and timeframe for decision making</td></tr>
<tr><td>Parties are required to ensure that their decisions are based on a risk assessment of the LMO, which must be carried out in a scientifically sound and transparent manner</td></tr>
<tr><td colspan="2">While the AIA procedures is bilateral based on direct communication between Parties, the procedure for LMOs-FFP is essentially a multilateral information exchange mechanism centred on the BCH</td></tr>
</table>

Requirements for the Handling, Transport, Packaging and Identification of LMOs

The Protocol requires that LMOs be handled, packaged and transported under conditions of safety. It also sets identification and documentation requirements. Documentation requirements for the three categories of LMOs are as indicated in Table 3.

Table 3: Documentation requirements for Transboundary movement of LMOs

LMOs-FFP Article 18 (2a)	LMOs for contained use Article 18 (2b)	LMOs for intentional introduction into environment Article 18 (2c)
• Clearly identify that the shipment contains specific LMOs-FFP, where the identity is known • Where identity of the LMOs is not known, it is to be stated that the shipment (may contain) one or more LMOs-FFP • To indicate 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 identifier • Interned address of the BCH for further information.	• To clearly identify content as LMOs including common scientific names of organisms and as "destined for contained use" • Provide 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 • Specify 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 BCH	• To clearly identify 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

The information that is to accompany shipments of LMOs and identify them can be included in existing types of shipping documentation such as the invoice, bill of lading, way bill, etc. There is no specific requirement of a stand alone document to accompany shipments of LMOs.

Templates are available to demonstrate 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.

Examples from the grain trade industry are available as to how information on LMOs for direct use as food, feed or processing is included in invoices accompanying their shipment (Figures 4, 5 & 6, Sourced from https://scbd.unssc.org/)

All categories of LMO's require reference to a unique identifier code as indicated in Box 2.

Fig 4: Example of identification requirements for LMOs for introduction into the environment

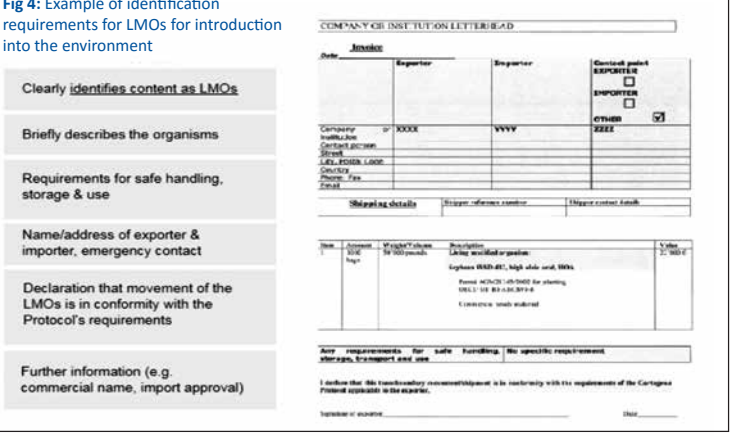


Fig 5: Example of identification requirements for LMOs for contained use

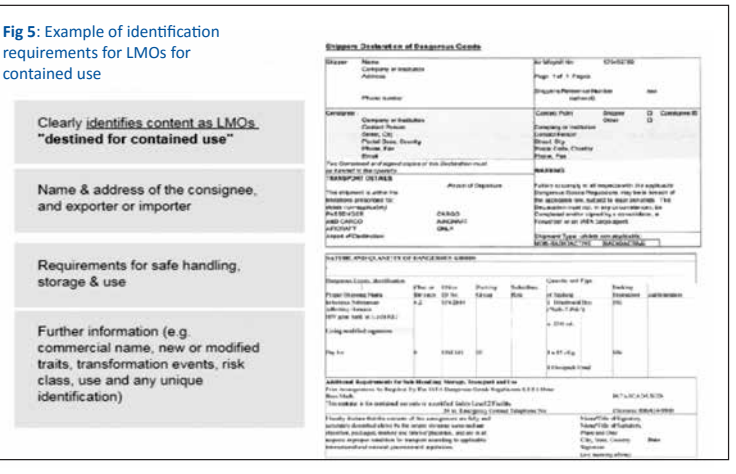


Fig 6: Example of how a shipping invoice can be used to indicate that a shipment 'contains LMOs for direct use as food, feed or processing and can include the unique identifier codes in order to identify the LMOs in the shipment

Box 2: LMO Unique Identifiers

- Documentation requirements for all categories of LMOs require reference to a unique identifier code. To date, only one unique identification system exists: OECD Unique Identifiers for Transgenic Plants
- OECD Unique Identifier is a simple alpha numeric 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
- 9- digit code composed of 3 elements separated by dashes
  - 2 or 3 alpha numeric digits to designate the applicant;
  - 5 or 6 alpha numeric digits to design at the transformation event; and
  - 1 numerical digit for verification Example: MON-00810-6M on santo's YieldGardMaize
- Unique identifier codes can be used to search BCH for information about specific LMOs

LMO Quick-link

LMO Quick-links are a tool developed to assist in the identification of LMOs in documentation accompanying their transboundary movement They are also intended to facilitate the work of customs officers by providing clear identification of living modified organisms and easy access to the BCH where customs officers can view the decision of their country on the import of the organism, as appropriate.

LMO Quick-links are small image files, which can be easily copied and pasted in documentation accompanying LMOs for the purpose of providing information on a specific living modified organism. LMO Quick-links identify a LMO through the organism's unique identifier (for plants), trade name and a link to the BCH where more information on the LMO is available.

Biosafety Clearing-House

Biosafety Clearing-House (BCH), set up as per provision of CPB, wherein Parties to the Protocol are required to share certain types of information and decisions via the BCH. It is a repository of up-to-date information on LMOs and biosafety including information about the national laws, regulations, guidelines, competent national authorities and final decisions taken by countries that is Party

In addition, the Governments that are not Parties to the CPB are also encouraged to contribute information to the BCH. It can be accessed at http://bch.cbd.int/

To facilitate easier understanding about results of queries involving decisions on LMOs, different icons have been used in the BCH as indicated in Table 4. In addition to the core information above, the BCH also provides general information on the CPB and links to resources for the implementation of the CPB.

Icon	Approval of LMO for
	Intentional introduction into the environment
	Direct use as food
	Direct use as feed
	Processing
	Confined Use
	Pharmaceuticals
	Transit

Table 4: Icons used for conveying information about decisions

Customs officials who need information about contact information of national authorities and national decision on whether or not the import of a specific LMOs is allowed can procure this information from the BCH as it is readily available.

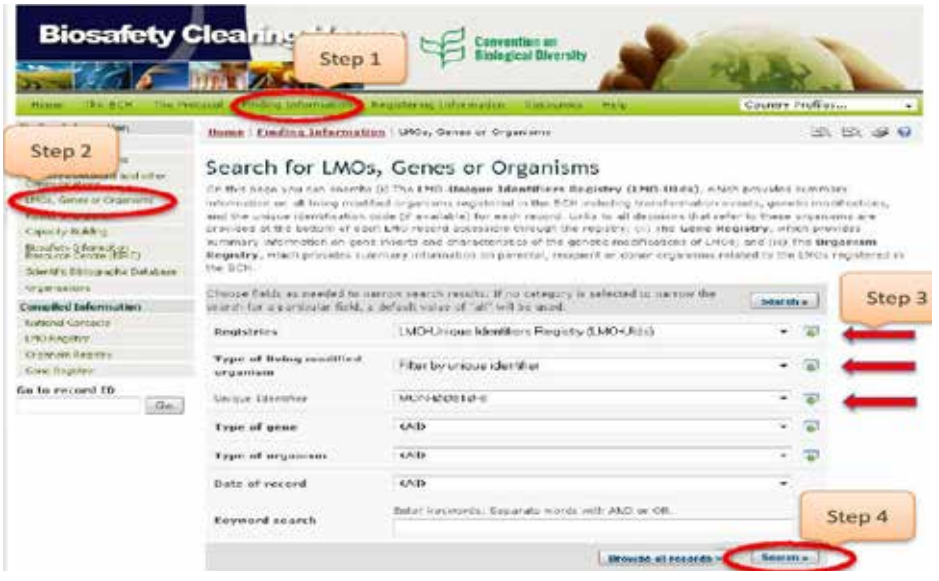
Other databases which can be accessed for information on LMOs include OECD BioTrack Online Website (http://www2.oecd.org/biotech/); FAO GM Foods Platform (http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/) and a website containing information about Indian biosafety regulations has been established by MoEFCC. The website http://geacindia.gov.in provides information about decisions taken by the GEAC, the apex regulatory committee in India.

How to use the BCH – An Example

For example finding information to verify that the LMOs for import have received the necessary approvals through BCH, you need to follow the indicated steps:

1. From the 'Finding information' section of the BCH, choose to search the 'LMOs, Genes or Organisms' database.
2. In the first drop-down menu for 'Registries', choose the 'LMO-Unique Identifiers Registry (LMO-UIds)'.
3. Under 'type of living modified organism', choose to filter by unique identifier. A new drop-down menu will appear in which you will find a list of all the unique identifiers that have been made available to the BCH. Select the unique identifier you are looking for and click 'search'.
4. Clicking on the record will bring you to a page providing detailed information on the LMO

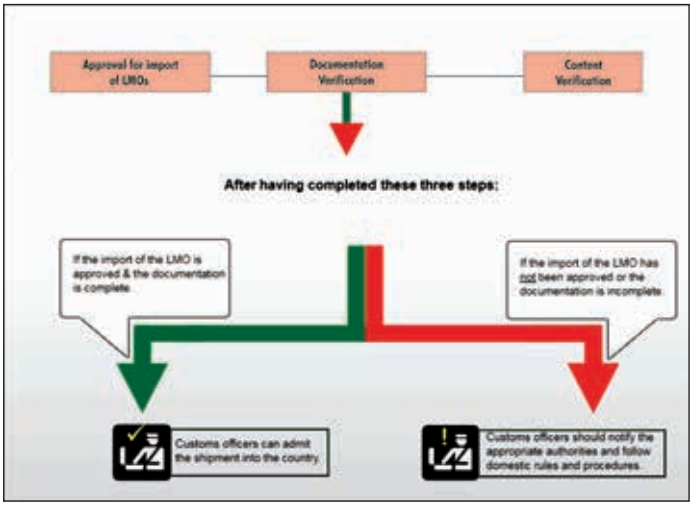
Figure below shows an example of searching for MON-00810-6, the unique identifier for Monsanto's YieldGard maize.



Section-4 | Role of Customs and Quarantine Officials

Customs officials have to verify the shipments of LMOs before permitting their entry in India. Once a shipment arrives at a port of entry, they are expected to verify the following:

- **Approvals for import of LMOs:** It is important to ensure that the LMOs contained in a shipment are approved for their intended use in India. Customs officers can use the Biosafety Clearing House (http://bch.cbd.int/) or websites of national regulatory authorities for information regarding approved use of different LMOs. The decisions by GEAC in India can be seen at http://geacindia.gov.in.
- **Documentation:** The information required in the documentation will vary depending on the intended use of the shipment, i.e. whether it contains LMOs for intentional introduction into the environment, for contained use, or for use as food, feed or processing. Customs officers should compare the information received in the documentation accompanying a shipment of LMOs with the information requirements for specific categories.
- **Contents of the shipment:** Specific cases may require verifying that the contents of the shipment correspond to the information in the documentation. This would require collecting a sample from the shipment and testing it to see what LMOs are detected. Sampling and detection are necessary because it is not possible to visually distinguish LMOs from their conventional counterparts. Sampling and detection may go beyond the work of customs officers and require input from other border control personnel such as health officials or phytosanitary inspectors, in view of the technicalities involved (Box 3).



On the basis of these three steps, customs officers can determine whether or not a shipment containing LMOs can be allowed to enter in the country.

Box 3: Sampling and Detection of LMOs

- ***Objective of Sampling:*** Sampling is a complex process. The objective of sampling is to provide a representative sample as the basis for analysis while minimizing error. Sampling is a crucial first step in any analytical process and, if not done correctly, can be a major source of error in the analysis of LMOs.
- ***Sampling Approaches:*** Approaches to sampling vary depending on the type of material being sampled and the way it is packaged. Some standardized approaches have been developed for sampling shipments of seeds but there is not a unified approach to sampling bulk shipments of grain. Different countries decide on the sampling procedure they wish to follow.
- ***Detecting LMOs:*** Once a sample has been collected, it must be tested to determine what LMOs, if any, it contains. Two basic approaches to testing for LMOs include:
  - Methods that test for the protein produced by the gene that has been inserted into the DNA of the LMO; and
  - Methods that test for the introduced gene itself

It is important to follow the requirements for the handling, storage, transport and use of the LMOs indicated in the shipping documentation of LMOs to prevent accidental contamination due to a spill while a shipment is in transit. However in case a spill occurs or an unintentional transboundary movement is detected, the national competent authority under the CPB viz., MoEFCC should be informed.

Similarly, the illegal transboundary movement of LMOs also need to be informed to the national competent authority under the CPB viz., MoEFCC. Familiarity of customs and border control officials with the national and international biosafety regulations to detect an illegal transboundary movement of an LMO is important.

So far, India has not permitted import of LMOs on a commercial scale. Transboundary movement of LMOs has been permitted only for research. Continuous efforts are made for capacity building of custom officials by organizing series of workshop in association with Central Board of Excise and Customs (CBEC), National Academy of Customs, Indirect Taxes and Narcotics formerly (NACEN) and NBPGR, invited lectures for IRS probationers and preparing booklets for information. More than 16 workshops has been organized under Phase II Capacity Building Project on Biosafety by NBPGR. Capacity building activities for customs officials are also organized at the international level. The CPB is one of the partners in the Green Customs Initiative, a partnership to enhance the capacity of customs and other relevant border control officers to monitor and facilitate the legal trade and to detect and prevent illegal trade in environmentally sensitive commodities covered by trade related conventions and multi-lateral environmental agreements. An e-learning course on Handling, Transport, Packaging, and Identification of LMOs, specifically for customs officials can be accessed at https://scbd.unssc.org/.

Section-5 | Detection of LMOs

The objective of this section is to introduce the methods used to detect whether or not LMOs are present in a shipment, to identify which LMOs are present and to calculate the quantity of LMOs in a shipment. In many instances, this work will not be done by frontline customs officers but may be performed by customs laboratories or other health or phytosanitary inspectors.

Reasons for testing of LMOs in a shipment include screening for the presence of LMOs, testing for specific LMOs and quantification of LMOs. For countries that have not approved the import of any LMOs, the detection of any LMO content in a shipment would mean that shipment is not allowed. Testing for specific LMOs is done to verily that the LMOs declared in the documentation accompanying a shipment are actually in the shipment.

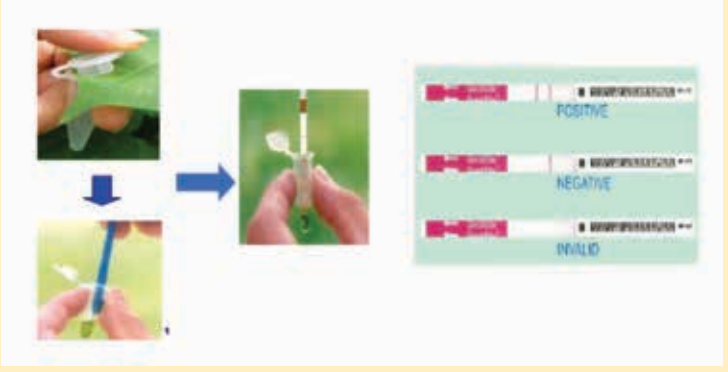
Another objective of detection is to test for LMOs that have not been declared as being in the shipment. This is important if a country has authorized some LMOs for import but not others and wants to make sure that non-authorized LMOs do not enter the country. Testing for LMOs is also used to calculate the quantity of LMOs in a shipment. Some countries have laws that require the labelling of foods derived from LMOs. Typically, these laws set a threshold for LMO content, e.g. 0.9%, 5%. If the LMO content exceeds this level, then it must be labelled. In order to implement these laws, it is necessary to test for the amount of LMO contained in the ingredients.

Methods for detecting LMOs: As indicated in Section 1 of this booklet, a LMO is created by inserting a gene from one organism into the DNA of another organism and this new gene usually leads the organism to produce a protein that gives the organism a desired characteristics. In view of the above, there are two basic approaches to test the LMOs. These include protein based methods for testing for the proteins produced by the gene that has been inserted into the LMO and DNA based testing for the introduced gene itself.

- **Protein based methods:** These methods can be used for screening (yes/no) and quantification of expressed protein in a LMO using strip test and ELISA based test respectively.
    i) Strip tests are simplest of all the detection methods. Strip test kits produced by different companies, include specially coated paper strips that are designed to detect specific proteins produced by different LMOs.

Methodology for Strip Test

Typically, a small sample is first ground into a powder. A liquid extraction buffer, included in the kit is added to a tube along with the powder. The tube is then shaken to allow the maximum amount of protein to be released into the buffer. A small amount of this mixture (referred to as extract) is transferred into vial. The coated paper strip is then placed in the vial. The result monitored as the colour of the strip changes indicating whether or not it is a LMO. Unskilled personnel in the field can easily carry out strip based tests.



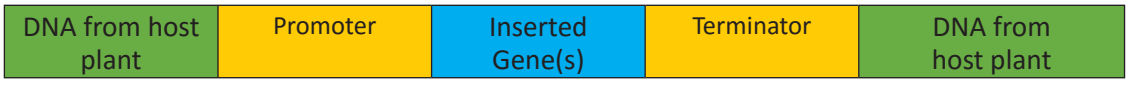
ii) ELISA based test: This test uses antibody (polyclonal or monoclonal) raised against a specific protein encoded by transgene. These antibodies are colour coated to enable them to be easily detected and quantified. The kits for ELISA test are also produced by companies that specialize in LMO testing. ELISA kits include plastic plates with number of wells, which are pre-treated so that the protein of interest in the sample will stick to the well.

Methodology for ELISA test

For the ELISA test, an extract is prepared by grinding the sample into a powder and adding an extraction buffer (similar to the process with strip tests). The extract is then added to the wells in a plate. If the extract contains the protein of interest then this protein will stick to the bottom and sides of the well.

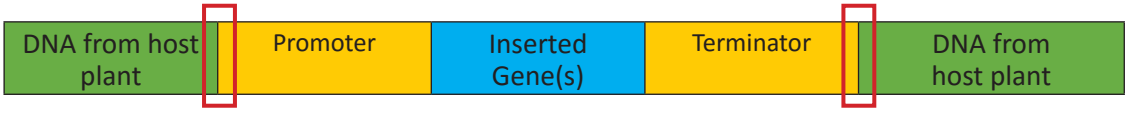
Whether the protein has stuck to the well is not visible to the human eye so additional steps are needed to determine the results of the test. A reagent (a chemical used for analysis and reactions, also provided in the kit) is then added to the wells and it attaches to the protein of interest that is stuck to the well. Finally, the results of the test are visualized with a colour development step. In this step, another chemical is added to the wells, which causes a reaction that changes the colour of the contents in the well. The darker the colour, the higher the concentration of the protein of interest. The Intensity of color is measure using an "ELISA Reader".

2. **DNA based testing:** The DNA that is introduced into an organisms to create a GM crop consists of several components and is known as a gene construct. Components of a gene construct are generally as follows:



DNA-based testing involves testing for any of the components of a gene construct.Some of the components e.g. promoters are widely used in development of different GM crops. In such cases detection of a promoter sequence helps in knowing presence of LMO in a sample, but does not allow for specific identification of LMO.

A more specific test for detecting and identifying a particular LMO is to test for the combination of the host organism's DNA and either the promoter or the terminator from the gene construct. This is called 'Event-Specific detection'. Event-specific detection allows identification of the specific LMO in a sample.



DNA based testing involves multiplying/amplifying a specific DNA through polymerase chain reaction (PCR) technique. Specific gene/transgene/elements associated with the transgene can be amplified using a PCR machine. The amplified DNA is then visualized using the gel electrophoresis technique.

DNA methods are highly sensitive and can test for multiple LMOs simultaneously. However, these requires highly skilled personnel, laboratory infrastructure and are more expensive. For both the protein and DNA based detection methods there are several general considerations that include sampling, food matrix effects on protein/DNA extraction, reference materials, method validation, harmonization of standards and access to information database.

No specific requirements on the method for sampling of shipments and detection of LMOs are specified under the CPB and countries that are Party need to follow their national rules and procedures.

In India, several public and private sector organizations have capabilities for detection of LMOs. There are also companies supplying various types of test kits. Four laboratories, strengthened under Phase II

Capacity Building Project on Biosafety have been designated as National Referral Laboratories to detect the presence or absence of LMOs/GMOs under the Seeds Act, 1966.

The laboratories strengthened for detection of LMOs /GMOs include:

1. DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Department of Agriculture, Government of Andhra Pradesh, Guntur, Andhra Pradesh
2. ICAR-National Bureau of Plant Genetic Resources (NBPGR), New Delhi
3. Export Inspection Agency (EIA), Kochi Laboratory, Kochi, Kerala
4. Punjab Biotechnology Incubator (PBTI) Mohali, Punjab

More information about detection of GM crops can be seen at http://gmolabs.nbpgr.ernet.in:9090/ maintained by ICAR-NBPGR.

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(कृषि, सहकारिता एवं किसान कल्याण विभाग)

अधिसूचना

नई दिल्ली, 15 नवम्बर, 2017

का.आ. 3604(अ).—केंद्रीय सरकार बीज नियम, 1968 के नियम 5 के खंड (च) के साथ पठित बीज अधिनियम, 1966 (1966 का 54) की धारा 4 की उप-धारा (1) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, संपूर्ण भारत के लिए इसके प्रकाशन की तारीख से उक्त अधिनियम के अधीन जीवित परिवर्तित जीवों और आनुवंशिक रूप से परिवर्तित जीवों की उपस्थिति या अनुपस्थिति की जांच का पता लगाने हेतु निम्नलिखित प्रयोगशालाओं को राष्ट्रीय सशक्तीकरण प्रयोगशाला घोषित करती है, अर्थात्—

(i) डीएनए फिंगर प्रिंटिंग और ट्रांसजेनिक फसल निगरानी प्रयोगशाला (डीएफटीसीएमएल), गुंटूर (आंध्र प्रदेश);

(ii) आईसीएआर-राष्ट्रीय पौध आनुवांशिक संसाधन ब्यूरो (एनबीपीजीआर), पूसा परिसर, नई दिल्ली;

(iii) निर्यात निरीक्षण एजेंसी (ईआईए), कोच्ची प्रयोगशाला (केरल);

(iv) पंजाब बैव प्रौद्योगिकी इनक्यूबेटर (पीबीटीआई), मोहाली (पंजाब)।

[फा. सं. 13-127/2017-बीज-IV]

बी. राजेन्द्र, संयुक्त सचिव

2 THE GAZETTE OF INDIA EXTRAORDINARY [PART II—SEC. 3(ii)]

MINISTRY OF AGRICULTURE AND FARMERS WELFARE

(Department of Agriculture, Cooperation and Farmers Welfare)

NOTIFICATION

New Delhi, the 15th November, 2017

S.O. 3604(E).—In exercise of the powers conferred by sub-section (1) of Section 4 of the Seeds Act, 1966 (54 of 1966), read with clause (c) of Rule 5 of the Seeds Rules, 1968, the Central Government hereby declares the following laboratories as the National Referral Laboratories to detect the presence or absence of Living Modified Organisms and Genetically Modified Organisms under the said Act with effect from the date of publication, for the whole of India, namely:—

(i) DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Guntur (Andhra Pradesh);

(ii) ICAR-National Bureau of Plant Genetic Resources (NBPGR), Pusa Campus, New Delhi;

(iii) Export Inspection Agency (EIA), Kochi Laboratory (Kerala);

(iv) Punjab Biotechnology Incubator (PBTI), Mohali (Punjab).

[F. No. 13-127/2017-SD.-IV]

NOTES

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