

Procedure of Import and Export of GM Plant and Planting Material



Phase II: Capacity Building Project on Biosafety



Ministry of Environment,
Forest and Climate Change
Government of India



In association with





Procedure of Import and Export of GM Plants & Planting Material



Introduction

Import of plants or planting material is defined as an act of bringing into the country any kind of seed, plant or other planting material from a place outside India either by sea, land, air or across any customs frontiers. Similarly, export of plants or planting material is the act of taking out of the country any kind of seed, plant or other planting material outside India either by sea, land, air or across any customs frontiers.

The import and export of genetically modified organisms (GMOs)/ living modified organisms (LMOs) (hereinafter referred to as GMOs) and their products is regulated under the Environment Protection Act (1986), The Destructive Insects and Pests Act, 1949, and the Foreign Trade (Development & Regulation) Act, 1992 No. 22 of 1992. Under these Acts import and export of GMOs will be allowed only with the approval of Genetic Engineering Approval (now Appraisal) Committee. [Box 1, 2, 3]



Box 1 : The Environment Protection Act (1986)

The Act empowers the Central Government to establish authorities charged with the mandate of preventing environmental pollution in all its forms and to tackle specific environmental problems that are particular to different parts of the country.

Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells (1989)

- No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.
- Use of pathogenic microorganism or any genetically engineered organisms or cell for the purpose of research shall only be allowed in laboratories or inside laboratory areas notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.
- The Genetic Engineering Approval Committee shall give directions to the occupier to determine or take measures concerning the discharge of micro-organisms/genetically engineered organisms or cells mentioned in the schedule from the laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.
- Any person operating or using genetically engineered organisms/ microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for licence in prescribed proforma.
- Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of Genetic Engineering Approval Committee.

http://www.moef.nic.in/sites/default/files/eprotect_act_1986.pdf
<http://envfor.nic.in/legis/hsm/hsm3.html>

Box 2 : The Foreign Trade (Development & Regulation) Act, 1992 No.22 of 1992

Notification No.2 (RE-2006)/2004-2006

It is an Act to provide for the development and regulation of foreign trade by facilitating imports into, and augmenting exports from India and for matters connected therewith or Incidental thereto.

Section 18 of the Rules under this Act deals with the Import of Genetically Modified Food, Feed, Genetically Modified Organism (GMOs) and Living Modified Organisms (LMOs) subject to the following conditions:

- The import of GMOs/LMOs for the purpose of (i) R&D; (ii) Food; (iii) Feed; (iv) Processing in Bulk and (v) For Environment release will be governed by the provisions of the Environment Protection Act, 1986 and Rules 1989.
- The import of any Food, Feed, raw or processed or any ingredient of food, food additives or any food product that contains GM material and is being used either for Industrial production, Environmental release, or field application will be allowed only with the approval of the Genetic Engineering Approval Committee (GEAC).
- Institutes/Companies who wish to import Genetically Modified material for R&D purposes will submit their proposal to the Review Committee for Genetic Modification (RCGM) under the Department of Biotechnology. In case the Companies/Institutes use these Genetically Modified material for commercial purposes, approval of GEAC is also required.
- At the time of import all consignments containing products which have been subjected to Genetic Modification will carry a declaration stating that the product is Genetically Modified. In case a consignment does not carry such a declaration and is later found to contain Genetically Modified material, the importer is liable to penal action under the Foreign Trade (Development and Regulation) Act, 1992.

<http://dgft.gov.in/exim/2000/not/not06/not0206.html>



Box 3 : The Destructive Insects and Pests Act, 1914

Enacted to make provision for preventing the introduction into India of any insect, fungus or other pest, which is or may be destructive to crops.

Plant Quarantine (Regulation of import into India) Order, 2003

Permits required for import of Germplasm, Transgenic or Genetically Modified

Organisms

- No consignment of germplasm/transgenics/Genetically Modified Organisms (GMOs) shall be imported into India for research/ experimental purpose without valid permit issued by the Director, National Bureau of Plant Genetic Resources, New Delhi-110012.
- Every application for import of plant germplasm/ transgenics/ genetically modified organisms for research/experimental purpose by the public/private organizations will be made to the Director, National Bureau of Plant Genetic Resources, New Delhi in form PQ 08 and the permit shall be issued in form PQ 09 in triplicate and a red/ green tag in PQ 10 for germplasm and a red/white tag in PQ 11 for transgenic/Genetically Modified Organisms. Such permits for import of transgenic/Genetically Modified Organisms shall be issued subject to the approval of Review Committee on Genetic Manipulation (RCGM) setup by Department of Biotechnology.
- No imported consignments of plant germplasm/ transgenics/ genetically modified pests shall be opened at the point of entry and it shall be forwarded to the Director, National Bureau of Plant Genetic Resources, New Delhi.

http://plantquarantineindia.nic.in/PQISPub/docfiles/dip_act.htm

http://dbtbiosafety.nic.in/act/Plant%20Quarantine%20_order_2003.pdf

Import

Procedure

- Import of GM plants and planting material has so far remained confined to that meant for research or experimentation.
- The Plant Quarantine Order (2003) under the Destructive Insects and Pests Act, 1914 prohibits or restricts the import of some plants species or plants from some countries, irrespective of GMO or non-GMO.

List of plants/planting materials and countries from where import is prohibited
<http://plantquarantineindia.nic.in/PQISPub/pdf/files/pqorder2015.pdf>

- This order also regulates the import of GM plants for the purpose of research or experimentation. Such an import requires a permit to be issued by the Director, National Bureau of Plant Genetic Resources, New Delhi (NBPGR) of the Indian Council of Agricultural Research. The permit is issued subject to the issue of Import Clearance by the Review Committee on Genetic Manipulation (RCGM) of the Department of Biotechnology, Government of India (DBT).
- Importer who wishes to import a GM plant or planting material for research or experimental purposes must have in place, (i) Institute Biosafety Committee (IBSC), and (ii) post-entry quarantine facility certified by DBT.

Application for registration of an Institutional Biosafety Committee (IBSC)
http://dbtbiosafety.nic.in/Files/CD_IBSC/Files/Files/A1.pdf

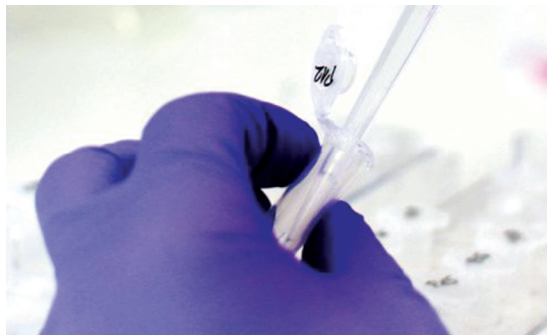
Application for certificate of approval of post-entry quarantine facility
<http://plantquarantineindia.nic.in/PQISPub/docfiles/PQForm-18.htm>



- The importer submits the proposal for import to RCGM through the IBSC.

Proforma for submitting application to IBSC/RCGM for permission to import/exchange of GMOs/LMOs and products thereof for research and development purposes
<http://dbtbiosafety.nic.in/forms/ibsc-import.htm>

- RCGM assesses the import application and examines the desirability of import from biosafety point of view. When satisfied, RCGM issues Permit letter valid for one year.
- Importer applies to NBPGR along with RCGM Permit letter for issue of Import Permit.



Application Proforma (PQ 08) for permit to import seed/planting material/Transgenics/GMOs (for research purpose)
<http://www.nbpgr.ernet.in/Downloads/cid/Downloadfile.aspx?EntryId=5494>

- NBPGR assesses the application also taking note of RCGM Permit letter and requirements laid out comprising the type of permit and instructions for use, conditions of issuance, and handling and packaging instructions. NBPGR issues the Import Permit sending copies to the importer and the exporter along with instructions for other documentation needed for import (Phytosanitary Certificate, Supplier Declaration that the GM material does not contain any embryogenesis deactivator gene sequence).



- The exporter sends the consignment addressed to Director, NBPGR enclosing a copy of the Import Permit along with the documents as above. The port of entry is Delhi airport only.
- Since the material is meant for research purposes, only a small quantity of seed/planting material sufficient enough to establish the plant is considered optimum and permitted for import. The quantity is specified by DBT in its Permit letter
- At the airport customs, the consignment without opening is examined for the required documentation.
- NBPGR verifies the contents and the accompanying documents (Import permit, Phytosanitary Certificate, Supplier Declaration that the GM material does not contain any embryogenesis deactivator gene sequence).
- At NBPGR, the material is tested for the absence of diseases, pests and other undesirable material and also for absence of embryogenesis deactivator gene sequence. The material is also tested for the presence of the declared transgene.
- The material is released to the importer under the condition that it would be grown in the post-entry quarantine facility certified by DBT and under prescribed supervision.
- The importer informs NBPGR within one month of sowing. NBPGR carries out field examination and required laboratory tests for absence of quarantine pests and diseases.
- The material is released for experimentation if free of quarantine pests and diseases. Otherwise, it is destroyed in presence of Plant Quarantine Officer.



Export

Introduction

Besides being regulated under the EPA Act, 1986 and the Foreign Trade (Development & Regulation) Act, 1992, export of GM plants and planting material would also attract the provisions of Biological Diversity Act, 2002, the latter related to access and use of biological resources. [Box 4]

Box 4 : Biological Diversity Act 2002

- No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for biosurvey and bioutilization.
- (2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub section (1) are the following, namely: (a) a person who is not a citizen of India; (b) a citizen of India, who is a non resident as defined in clause (30) of section 2 of the Income tax Act, 1961; (c) a body corporate, association or organization-
- (i) not incorporated or registered in India; or
 - (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.
- The above provisions shall not apply to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects (a) conform to the policy guidelines issued by the Central Government in this behalf; (b) be approved by the Central Government.

<http://nbaindia.org/content/25/19/1/act.html>

Procedure

- Under the EPA Act 1986 and Rules 1989, Section 7 deals with approval and prohibitions whereby no person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms of genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.
- The following persons/organizations are required to take prior approval of National Biodiversity Authority (NBA) for export of biological resources:
 - ◆ A person who is not a citizen of India
 - ◆ A citizen of India who is a non-resident
 - ◆ A body corporate, association or organization not registered in India/ or incorporated or registered in India under any law for the time being in force which has any non-India participation in its share capital or management.
- On approval by NBA, the material is sent to NBPGR for quarantine inspection and issuance of Phytosanitary Certificate.
- For material under bilateral agreements/collaborative projects the request for export is addressed to the Director, NBPGR. The requests are to be accompanied by copy of work plan/MoU, list of material along with importing country's permit, details of the material, signed copy of the Material Transfer Agreement.



Material Transfer Agreement :
(<http://www.nbpr.ernet.in/Downloads/cid/Downloadfile.aspx?EntryId=5495>)

- The Plant Genetic Resources Export Facilitation Committee of NBPGR examines the request and gives its recommendation to the Department of Agricultural Research and Education, Government of India (DARE).
- On receipt of approval from DARE, the exporter is informed and the material submitted to NBPGR for quarantine inspection and issuance of Phytosanitary Certificate.
- NBPGR issues Phytosanitary Certificate and verifies the phytosanitary conditions laid out in the Import Permit of the importing country. The material with Import Permit, Phytosanitary Certificate and Foreign Supply Order is dispatched to the importing country by NBPGR.
- The party of import communicates the decision to the notifier and the Biosafety Clearing House approving import with or without conditions.
- Under the The “Advance Informed Agreement” (AIA) procedure of the Cartagena Protocol which applies to the first intentional transboundary movement of GMOs for intentional introduction into the environment, the exporter/Govt. of India needs to notify the competent national authority of the party of import by providing a detailed, written description of the GMO in advance of the first shipment. [Box 5]



Box 5 : Advance Informed Agreement

The “Advance Informed Agreement” (AIA) procedure applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import.

It includes four components:

- Notification by the Party of export or the exporter to the competent national authority of the party of import by providing a detailed, written description of the LMO in advance of the first shipment
- Acknowledgment of receipt of notification by the Party of import within 90 days
- Decision procedure within 270 days to import, prohibit, ask for further information or extension of time to the notifier and the Biosafety Clearing House
- Review of decisions by the importing party

AIA procedure does not apply to certain categories of LMOs:

- LMOs in transit (Article 6);
- LMOs destined for contained use (Article 6);
- LMOs intended for direct use as food or feed or for processing (Article 7.3).

In addition, the Party of import may also specify in advance to the Biosafety Clearing-House that it will exempt certain imports of LMOs from the AIA procedure (Article 13). Also, the Conference of the Parties serving as the meeting of the Parties to the Protocol may in future decide to exempt additional LMOs from application of the AIA procedure (Article 7.4).

Export of Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET) Items

Export of dual-use items and technologies under India's Foreign Trade Policy is regulated. It is either prohibited or is permitted under a license. In the Foreign Trade Policy, Category 2 of the SCOMET items also includes microorganisms and toxins controlled under the guidelines and rules of the Foreign Trade (Development & Regulation) Act, 1992. Applications for licence for export of SCOMET items are considered on merits by an Inter-Ministerial Working Group (IMWG) and once the case is approved by the IMWG, permission letter is issued to the exporter for obtaining export authorization from the concerned Zonal/Regional office of the Directorate General of Foreign Trade.

<http://dgft.gov.in/exim/2000/scomet/scomet2011.pdf>



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