

Subject : Procedure for clearance by GEAC for import of GM Products.

Detailed procedure for R&D (contained use), intentional release and GM Food are outlined below.

A. Procedure for import of GMOs/ LMOs for R & D.

The procedure to be followed and information to be submitted and the agency to accord approval (IBSC/RCGM/ NBPGR) have been well defined in the Rules 1989, Plant Quarantine (Regulation of Imports into India) – Order, 2004 issued by National Bureau for Plant Genetics & Resources (NBPGR), Recombinant DNA Safety Guidelines, 1990, Revised Guidelines For Research In Transgenic Plants & Guidelines For Toxicity And Allergenicity Evaluation Of Transgenic Seeds, Plants And Plant Parts, 1998 and Guidelines for import of germplasm, 2004 by NBPGR.

The information/proforma is available on MoEF website <http://envfor.nic.in>, <http://dbtindia.nic.in>, <http://nbpgr.delhi.nic.in> (**Form I**)

B. Procedure for import of GMOs/ LMOs for intentional Release (including field trials).

The procedure (including field trials) to be followed, information to be submitted and the agency to accord approval (IBSC/RCGM/GEAC/ICAR) have been well defined in the Rules 1989 and Biosafety guidelines of 1990 and 1998. The information/proforma is available on MoEF website <http://envfor.nic.in>. (**Form II A and II B**)

C. Procedure for import of GM Foods.

The GM food has been divided into three categories namely:

- a. LMO as Food Feed and Processing (FFP) (eg maize, Corn, Soybean, potato)
- b. GM processed food derived from LMOs (eg Corn flour, Soymeal, potato chips)
- c. Processed food containing ingredients derived from LMO (eg bread containing from non-GM flour but containing enzymes derived from GMO/LMO for increasing shelf life / non GM potato fried in GM soybean oil etc).

The following procedure shall apply for each of the above mentioned category:

i. GM food/feed as LMOS per se.

For import of LMO as FFP detailed environmental clearance of GEAC needs to be obtained for which detailed biosafety and food safety studies need to be furnished. The GEAC may stipulate additional studies taking into consideration the environmental risk in case of accidental release. The importer would also require compliance as per the provisions of Biosafety Protocol. The importer to submit detailed information as per the GEAC proforma for transgenic food. The prevailing Rules, and proforma for GEAC clearance may be viewed at MoEF website: <http://envfor.nic.in>. (**Form III**)

ii. GM processed food derived from LMOs.

In case of GM processed food, the GEAC follows an "event based approval" in a given crop. The importer is required to obtain one time approval of GEAC for which the following information may be furnished:

- List of gene/events approved in the crop species for commercial production in the country of export/ country of origin.

- Whether the product has been approved for consumption in countries other than producing countries
- Food safety study conducted in the country of origin.
- Analytical / compositional report from the country of export/ origin.
- Whether further processing is envisaged after import. If so details of the same.
- Whether the gene/events from which the product has been derived has been approved and is in commercial production, marketing, use for food/feed in the country of origin/export.

The proforma for GEAC clearance may be viewed at MoEF website: envfor@nic.in (**Form IV**)

iii. Processed food containing ingredients derived from GMO

If the processed food contains any ingredient derived from category i and ii mentioned above, and if the LMO / product thereof has been approved by the GEAC, no further approval is required except for declaration at the port of entry. In case it does not have the approval of GEAC, the procedure mentioned at ii above may be complied.

The proforma for GEAC clearance may be viewed at MoEF website: envfor@nic.in (**Form IV**)

D. The shipping documents that should accompany each consignment is as follows:

- i. In case of import of LMOs for R & D (contained use), intentional release and LMO as FFP, the shipping documentation prescribed under the Biosafety Protocol shall apply.
- ii. In case of processed food derived from LMOs/GMOs or food containing ingredients derived from LMOs/ GMOs shipping documentation as prescribed below shall apply:
 - Name of the importer and contact details.
 - The Country from where it is exported /origin.
 - Declaration/certification from the exporting country that the product contains/derived from gene/events approved by the GEAC
 - GEAC approval no and date.

The information may be furnished as a **stand alone document**.

E. The time frame for seeking the approval of GEAC:

The applicant is required to submit their proforma for importing the product along with the requisite information to the GEAC at least 90 days before the shipment leaves the shore of the country of export.

F. Requirement under PFA.

The GEAC clearance in no way obviates the requirement under Prevention of Food Adulteration Act.

The GEAC considers these applications and provides opportunity for making presentation by the applicant, if required.
