

Regulatory Framework for Genetically Engineered (GE) Plants in India



Phase-II Capacity Building
Project on Biosafety



Ministry of Environment, Forest and Climate Change

Government of India

In association with



BCIL

Biotech Consortium India Limited

New Delhi

2015

DEVELOPMENT OF BIOSAFETY REGULATIONS FOR GENETIC ENGINEERING



- The first successful use of genetic engineering, also referred to as recombinant DNA (rDNA) technology was accomplished in 1973.
- Recognizing that this novel technology is beneficial but could also pose some risks, scientific community initiated discussions on the need for regulating this technology in 1975 at a meeting in Asilomar, California.
- A set of voluntary guidelines regarding the cautious use of recombinant technology and any products resulting from that technology were recommended at Asilomar.
- In 1976, guidelines for laboratory work using genetic engineering techniques were issued by the US National Institute of Health followed by involvement of other regulatory offices in USA to effectively regulate genetic engineering in USA.
- Initially, the regulations of rDNA technology focused on the technology and biosafety concerns were primarily towards safety procedures for recombinant DNA work within the laboratory. The objective was to ensure that researchers were taking proper steps to contain organisms that potentially posed a risk to themselves or human health. By the end of 1980s the focus shifted to the end products besides the technology as rDNA technology began to produce organisms and products thereof that were useful as commercial products in healthcare and agriculture.
- In 1982, the Organization for Economic Co-operation and Development (OECD) released a report on the potential hazards of releasing Genetically Modified Organisms (GMOs) into the environment as the first transgenic plant was being developed.
- A report on "Recombinant-DNA Safety Considerations" was published by the OECD in 1986 (also known as the "blue book"), which set out the first international safety guidelines for the use of recombinant DNA organisms in industry, agriculture and the environment.
- From 1986, biosafety regulations applicable to biotechnological products and activities have been developed in various countries as well as at international level.
- A national biosafety framework to regulate production and release of GMOs is considered essential in any country with a biotechnology programme.
- Regulatory frameworks aim to ensure that safety of genetically engineered (GE) plants is comparable to safety of conventionally produced plants.
- More recently, the establishment of biosafety regulatory framework was triggered in several developing countries, when Cartagena Protocol on Biosafety came into force.
- The regulatory framework in India was initiated in 1989 in response to commencement of research and development in biotechnology in India.

REGULATORY SYSTEM IN INDIA: AT A GLANCE

The **Environment (Protection) Act, 1986** is an umbrella legislation implemented by Ministry of Environment, Forest & Climate Change that provides a holistic framework for protection and improvement to the environment. Pursuant to sections 6,8 and 25 of the EPA, 1986 and with a view to protecting the environment, nature and health, in connection with the application of gene technology and microorganisms, the **Rules for the Manufacture/ Use/ Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (Rules, 1989)** have been notified under the Environment (Protection) Act, 1986. These rules are the apex rules for regulation of all activities related to genetically engineered organisms and products thereof. In addition, there are other acts, rules and policies which are also applicable to these organisms.

Applicable Acts and Rules

- Environment (Protection) Act, 1986 (EPA)
- Rules for the Manufacture/ Use/ Import/ Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (Rules, 1989) under the EPA
- Biological Diversity Act, 2002
- Plant Quarantine Order, 2003
- DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy (2006-09)
- Food Safety and Standards Act, 2006
- Drugs and Cosmetics Rule (8th Amendment), 1988

Mandate of Ministries/Departments

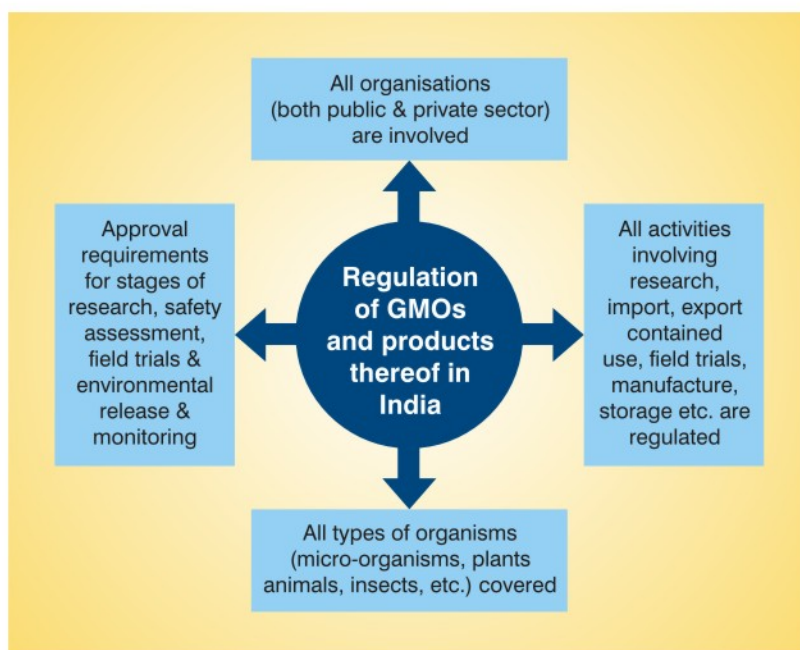
Ministry of Environment, Forest and Climate Change	<ul style="list-style-type: none"> • Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of GMOs / LMOs. • Nodal agency for implementing Rules, 1989 and the Cartagena Protocol on Biosafety
Department of Biotechnology (Ministry of Science & Technology)	<ul style="list-style-type: none"> • Nodal department for promoting biotechnology programs • Provides scientific support in implementation of biosafety regulations • Provide services in areas of research, infrastructure, generation of human resource
Ministry of Agriculture	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Policies aimed at protecting and monitoring human health. • Food Safety and Standards Authority of India responsible for regulating genetically engineered foods.
Ministry of Commerce and Industries	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Enforcement of regulation pertaining to transboundary movement of GMOs/LMOs at point of entry

KEY FEATURES OF RULES 1989

1 Scope

The Rules, 1989 are very broad in scope, essentially covering entire spectrum of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc. These rules cover areas of research as well as large scale applications of GMOs and its products and apply to:

- Manufacture, import and storage of microorganisms and gene technological products
- Genetically engineered organisms/ micro-organisms and cells and correspondingly to any substances and products and foodstuffs, etc., of which such cells, organisms or tissues hereof form part
- New gene technologies in addition to cell hybridization and genetic engineering



2 Competent Authorities

These rules are implemented by the Ministry of Environment, Forest & Climate Change (MoEF & CC), the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and State Governments. Six competent authorities and their composition and roles have been notified under the rules.

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

Various sub-committees and Expert committees are set up by RCGM and GEAC on a case by case basis and comprise of experts from various disciplines drawn from public sector institutions to prepare and review various guidelines and biosafety data. Central Compliance Committees are also set up for monitoring of confined field trials on case by case basis.

KEY FEATURES OF RULES 1989

I. Recombinant DNA Advisory Committee (RDAC)

- Is constituted by DBT
- Review developments in biotechnology at national and international level and recommend suitable and appropriate safety regulations for India in r-DNA research, use and applications
- Was set up in 1990 and prepared Recombinant DNA Safety Guidelines, 1990.

II. Institutional Biosafety Committee (IBSC)

- Is mandatory for each organization involved in Recombinant DNA (rDNA) activities.
- Comprises of the Head of Institute, three or more scientists engaged in rDNA work, a medical expert and a member nominated by DBT.
- Responsible for ensuring adherence to RDNA Safety Guidelines, experimentations carried out at designated locations as per approved protocols and prepare onsite emergency plans according to manuals / guidelines of RCGM.
- Serve as a nodal point for interfacing with other Regulatory Committees regarding ongoing research within the institutions.
- Review experiments falling in risk category III or above and recommend to RCGM.

III. Review Committee on Genetic Manipulation (RCGM)

- Is a Regulatory Body functioning in DBT
- Comprises of Members from DBT, Indian Council of Medical Research, Indian Council of Agricultural Research, Council of Scientific and Industrial Research and other experts from multi-disciplinary fields in their individual capacity.
- Responsible for bringing out manuals / guidelines specifying procedures for conduct of GMO research, use and industrial applications with a view to ensure environmental safety and lay down procedures restricting or prohibiting production, sale,

import and use of GMO as mentioned in the Schedule of Rules 1989.

- Authorized to review all ongoing rDNA projects and approve experiments falling in risk category III and above with appropriate containment and permit import of GMOs / transgene for research purpose.
- Authorized to recommend GM crop field experiments (BRL I) at multi locations in an area of upto 1 acre per site.

IV. Genetic Engineering Appraisal Committee (GEAC)

- Is the apex Regulatory Committee functioning in MoEF & CC.
- The Committee is chaired by Special Secretary / Additional Secretary of MoEF & CC and co-chaired by an Expert nominated by DBT and comprises of Members from Ministry of Industrial Development, DBT, Department of Atomic Energy. Member Secretary is an official of MoEF & CC.
- Expert Members also include nominees of Director General, Indian Council of Agriculture Research, Director General Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and Storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity. The Committee may co-opt other Members / Experts as necessary.
- Authorized to review, monitor and approve all activities involving large scale use of hazardous micro-organisms and recombinant research and industrial production including import, export, transport, manufacture, use or sale of GMOs and products thereof from environmental angle.
- Authorized to review, monitor and approve proposals relating to release of genetically engineered organisms and products into the environment including experimenting field trials with specific conditions for containment.

KEY FEATURES OF RULES 1989

V. State Biotechnology Coordination Committee (SBCC)

- Is a Regulatory Committee set up in each State where research and applications of GMOs are contemplated
- The Committee is chaired by Chief Secretary of the State and comprises of Secretaries from the State Department of Environment & Forest, State Department of Health, State Department of Agriculture, State Department of Industries and Commerce, State Department of Public Works, Chairman, State Pollution Control Board and Experts in the field of microbiology and pathology as Members. The Committee may co-opt other experts/ members as necessary.
- Empowered to inspect, investigate and to take punitive action in case of violations of statutory provisions through the nodal Department and the State Pollution Control Board or the Directorate of Health / Medical Services.
- Authorized to review periodically the safety and control measures in various industries/institutions handling genetically engineered/hazardous organisms.
- Serve as a nodal point at State level for coordinating activities related to GMOs in the State with the Central Ministries including monitoring of conditions stipulated by the RCGM/GEAC.

VI. District Level Committee (DLC)

- Is a Regulatory Committee set up in each District where research and applications of GMOs are contemplated
- The Committee is headed by District Collector of the District and comprises of Factory Inspector, Representative of State Pollution Control Board (SPCB), Chief Medical Officer, District Agriculture Officer, Representative of Public Health Engineering Department, Commissioner, Municipal Corporation and Technical Experts in the field of microbiology and pathology as Members. The Committee

may co-opt other experts/members as necessary.

- Authorized to monitor and inspect the safety regulations in installations engaged in the use of genetically modified/ hazardous organisms and its applications, formulate information chart, identify hazards and risks associated with each of these installation and coordinate activities with a view to meeting emergency.
- Serve as a nodal point at district level for coordinating activities related to GMOs in the District with the SBCC and GEAC including monitoring of conditions stipulated by the RCGM / GEAC.

3 Approvals and Prohibitions Under Rules, 1989

- No person shall import, export, transport, manufacture, store, process, use or sell any GMOs, substances or cells except with the approval of GEAC
- Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed in laboratories or inside laboratory areas notified by MoEF & CC for this purpose under the EPA, 1986.
- Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.
- Deliberate or unintentional release of GMOs shall not be allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC.
- All approvals shall be for a period of 4 years at first instance renewable for 2 years at a time.

KEY FEATURES OF RULES 1989

- GEAC shall have powers to revoke approvals in case of:
 - a. Any new information on harmful effects of GMOs.
 - b. GMOs cause such damage to the environment as could not be envisaged when approval was given.
 - c. Non-compliance of any conditions stipulated by GEAC.

4 Supervision and Penalties

- The GEAC has the authority to supervise the implementation of terms and conditions laid down in connection with the approvals accorded by it through the SBCC/DLC/SPCB or any person authorised by the GEAC.
- If an order is not complied with, there is provision for imposing penalties including immediate intervention by the SBCC/ DLC in order to prevent damage to the environment, nature and health without issuing any orders at the expense of the person responsible for such damage.
- The GEAC may fix fees to cover the expenses incurred by the authorities in connection with approvals, examinations, supervision and controls

5 Exemption

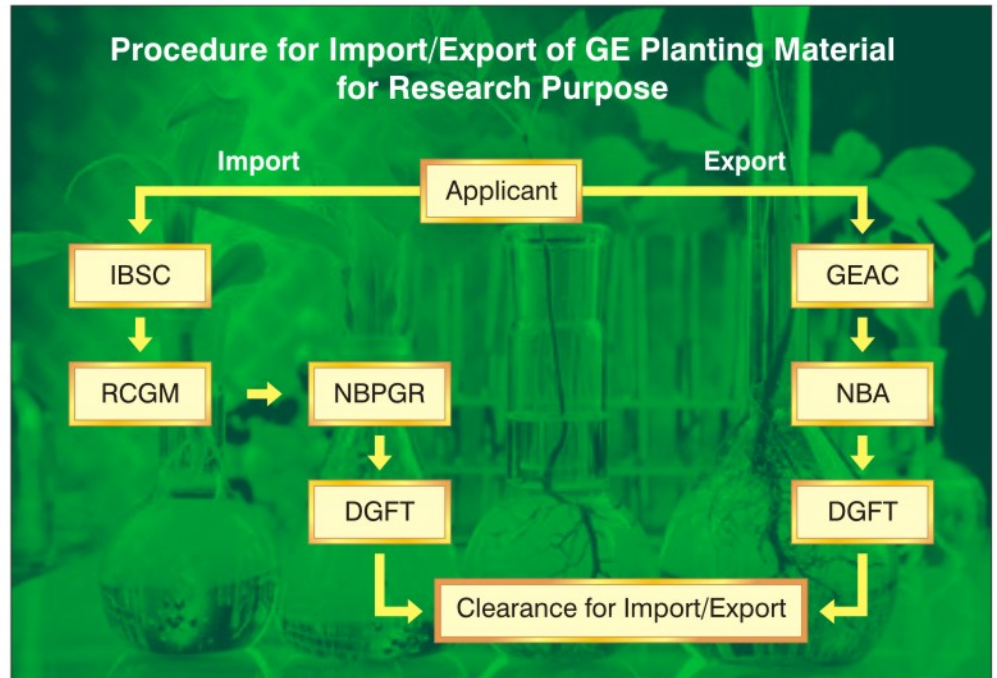
MoEF & CC has the authority to exempt an occupier handling a particular GMO from the provisions of Rules, 1989 (7-11). The following activities/products are exempted from the purview of Rules, 1989:

- Indigenous product development, manufacture and marketing of recombinant pharmaceuticals derived from organisms falling under Risk Group I & II.
- Import and marketing of products derived from LMOs as drugs/ pharmaceuticals in bulk and/ or finished formulations (therapeutic proteins) where the end product is not an LMO.
- Bt cotton hybrids containing approved events under the 'Event Based Approval Mechanism'.

Important Notifications issued under the Rules, 1989

1. Gazette Notification No. GSR 584(E) to GSR 589(E) dated 21st September, 2006 empowering Seed Inspectors/Seed Analysts/Laboratories notified under Seed Act, 1966 and Seed Control Order, 1983 under Environment(Protection) Act, 1986.
2. Gazette Notification No. GSR 616(E) dated 4th October, 2006 exempting certain categories of recombinant pharma from the purview of Rules, 1989, where the end product is not a LMO.
3. Gazette Notification No. S.O. 1519(E) dated 23rd August, 2007 exempting processed food derived from living modified organisms from the purview of Rules, 1989. This exemption has been kept in abeyance till 30.03.2016 or until issue of further notification.
4. Gazette Notification No. G.S.R. 613(E) dated 16th July, 2010 the name of the Genetic Engineering Approval Committee has been changed to Genetic Engineering Appraisal Committee.

<http://envfor.nic.in/sites/default/files/geac/notification.html>



Quarantine Processing of Transgenic Planting Material



Import clearance from RCGM through IBSC

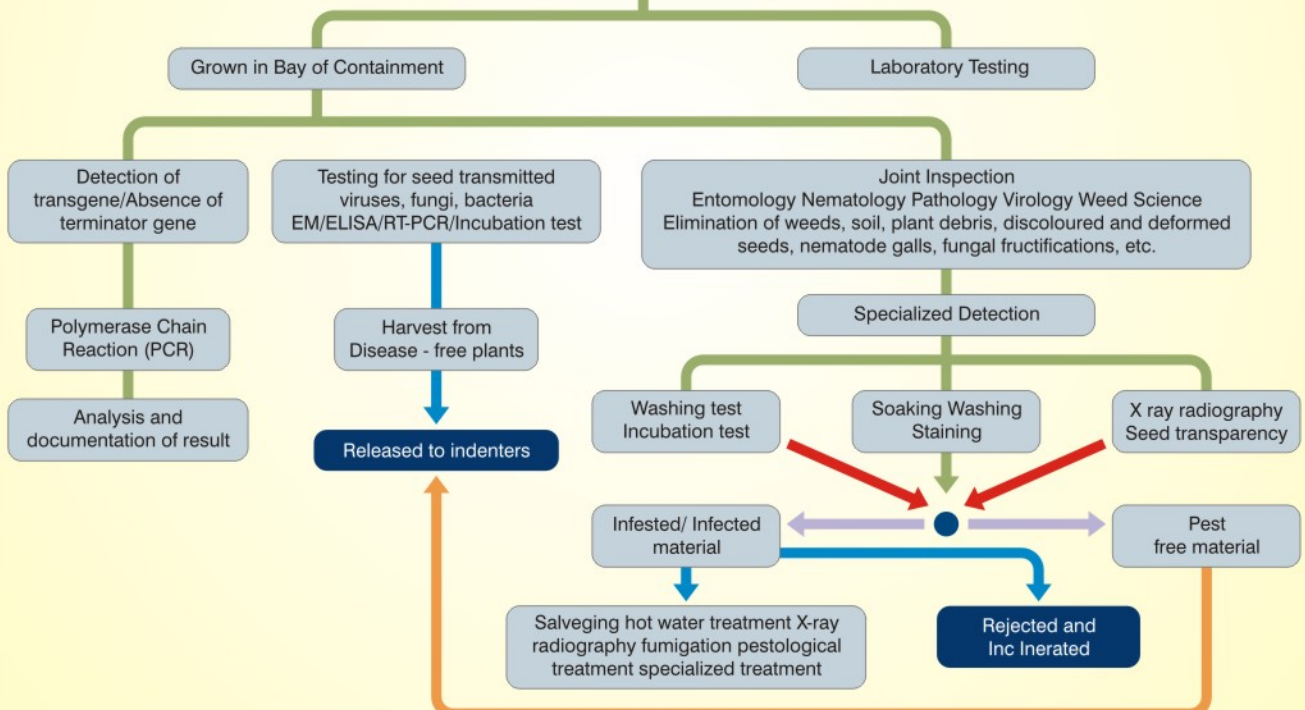
Application to NBPGR for Import Permit

Material with IP and PC received at NBPGR

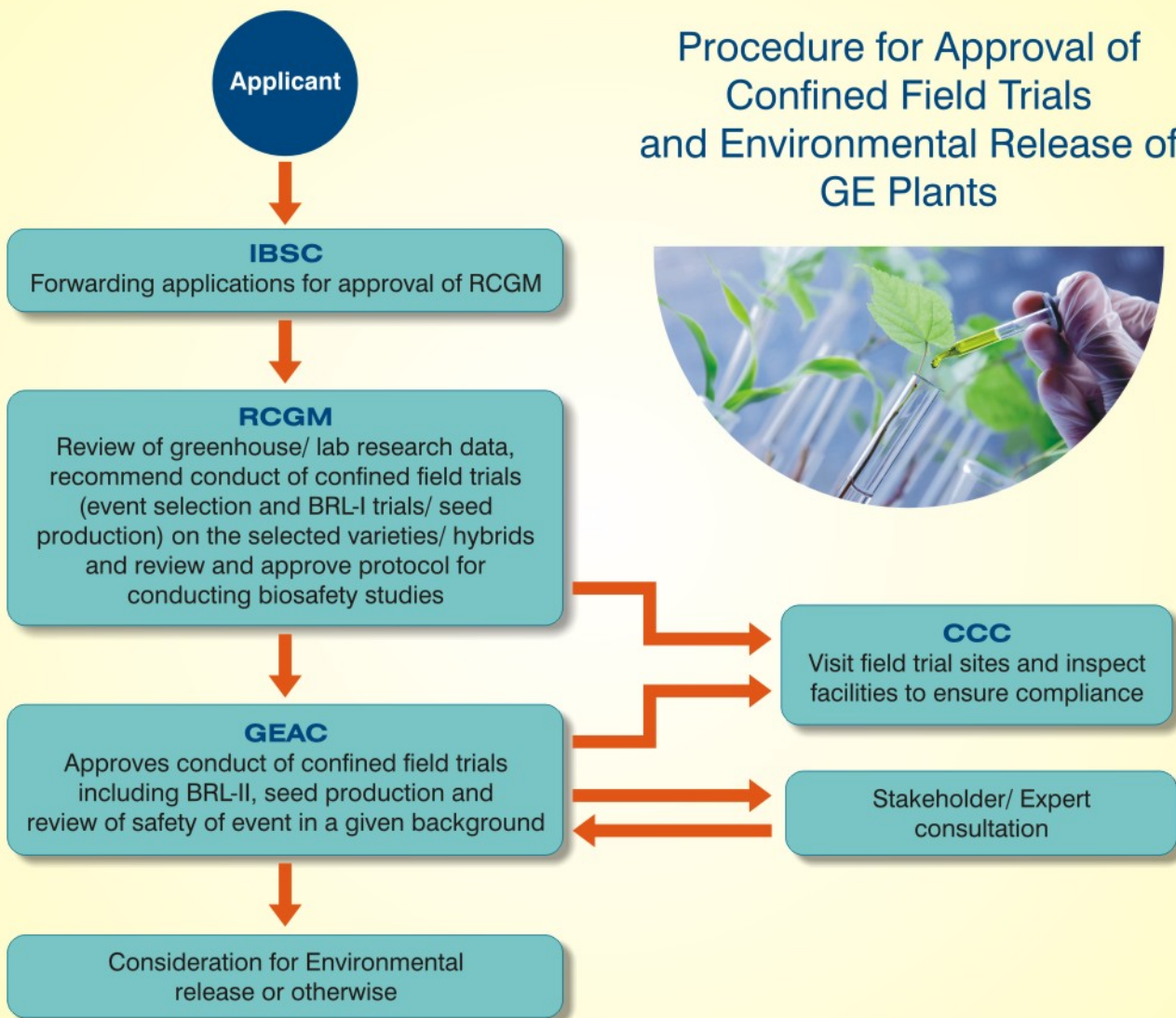
Containment Facility



CL-4 Containment Facility



Procedure for Approval of Confined Field Trials and Environmental Release of GE Plants



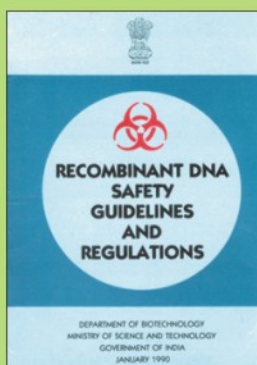
Event Based Approval Mechanism (EBAM) for Bt Cotton Hybrids

- GEAC adopted the EBAM mechanism in 2008. As per new procedure, Bt cotton hybrids expressing approved events and developed through conventional backcrossing are exempted from conduct of detailed biosafety studies as required for new events.
- All such cases are referred to a Standing Committee constituted by the GEAC. The Standing Committee is serviced by DBT.
- The new procedure lays down specific information to be submitted to the Standing Committee for taking a final view on the performance and suitability of a particular Bt Cotton hybrid/variety for a specific zone.

APPLICABLE GUIDANCE

Rules, 1989 are implemented by competent authorities through a series of biosafety guidelines with a view to minimise any adverse impact that the GMOs and product thereof would have on the environment as well as human and animal health.

RDNA Safety Guidelines, 1990



- Provide guidelines for R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research.
- The research activities classified into three categories based on the level of the associated risk.

Category-I : Experiments involving self cloning using strains and also inter-species cloning belonging to organism in the same exchanger group.

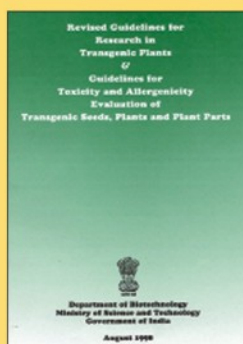
Category-II : Experiments falling under containment levels II, III and IV

Category-III : Experiments involving toxin gene cloning, cloning of genes for vaccine production, and other experiments

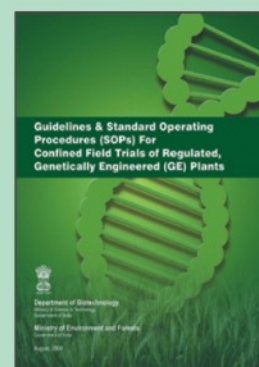
- The levels of risk and classification of the organisms within these categories have been defined in these guidelines.
- Appropriate practices, equipment and facilities necessary for safeguards in handling organisms, plants and animals in various risk groups have been recommended.

Revised Guidelines for Research in Transgenic Plants, 1998

- Provide guidance for recombinant DNA research on plants including the development of molecular and field evaluation of transgenic plant.
- Deal with import and shipment of GE plants for research purpose.
- Include complete design of a contained green house suitable for conducting research with transgenic plants.
- The GE experiments on plants have been grouped under three categories and appropriate containment measures have been prescribed.
- Also include information to be generated on biosafety aspects of the transgenic plants.

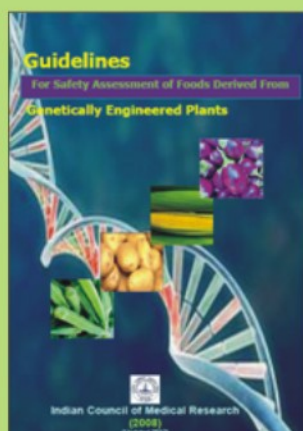


Guidelines & Standard Operating Procedures (SOPs) For Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008



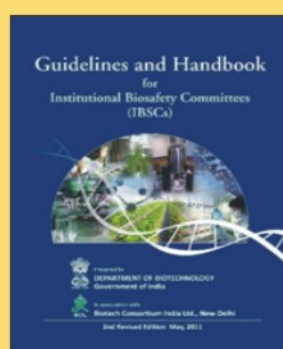
- Provide guidance on conduct of confined field trials of regulated GE plants
- Include procedures on filling the application form for seeking approval of CFTs from regulatory authorities.
- SOPs have been provided to ensure quality and safety at each stage of the CFT. These include SOPs for transport, storage, planting and harvest.
- Recording formats have been provided for proper and uniform documentation during the conduct of the trials.
- Provide guidance for the monitoring of confined field trials.
- Comprehensive glossary of terms used in the context of CFTs has also been provided.

Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered (GE) Plants, 2008



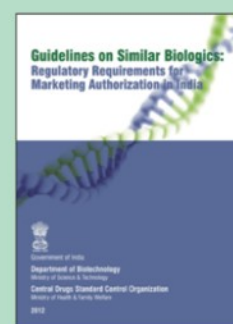
- Provide guidance on principles and steps on food safety assessment of GE plants
- Developed by Indian Council of Medical Research (ICMR) based on guidelines and principles of Codex Alimentarius Commission, 2003
- The guidelines include three appendices on Dossier Preparation Checklist, Codex Alimentarius Principles for the Risk Analysis of Foods derived from Modern Biotechnology and Annexes II & III to the Codex Alimentarius Guidelines on safety assessment of foods derived from GE plants modified for nutritional or health benefits and food safety assessment in situations of low level presence of GE plant material in food.
- Protocols for Food and Feed Safety of GE crops prepared by DBT in 2008 for undertaking the following studies:
 - Acute Oral Safety Limit Study In Rats and Mice
 - Sub-chronic Feeding Study In Rodents
 - Protein Thermal Stability
 - Pepsin Digestibility Assay
 - Livestock Feeding Study

Guidelines and Handbook for Institutional Biosafety Committees (IBSCs), 2011



- Includes Guidelines for IBSCs, checklists and application formats for use
- These guidelines describe the constitution, composition, role and functions of IBSC.
- Provide information for compliance requirements by IBSCs and processes to be followed while dealing with GMOs/LMOs and rDNA material in line with Rules, 1989
- An indicative checklist is included to assist IBSC members in reviewing the research proposals from investigators. Specific additions/deletions or modifications need to be made to suit the requirements of each proposal on a case by case basis.
- General guidance to the applicants for facilitating compliance and timely processing of their applications including the list of application forms for various activities has been included.

Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012



- Guidelines prepared by Central Drugs Standard Control Organization (CDSCO) and DBT to lay down the regulatory pathway for a similar biologic claiming to be similar to an already authorized reference biologic
- The guidelines address the regulatory pathway regarding manufacturing process and quality aspects for similar biologics
- These guidelines also address the pre-market regulatory requirements including comparability exercise for quality, preclinical and clinical studies and post-market regulatory requirements for similar biologics

<http://dbtbiosafety.nic.in/>

DATA GENERATION FOR SAFETY ASSESSMENT AT VARIOUS STAGES OF GE PLANT DEVELOPMENT

Safety assessment of a GE plant is the most important step in its development process. The data to be generated for safety assessment of a regulated GE plant involves research/experiments to be undertaken both under contained facilities as well as confined field trials with an objective to make a comparative assessment and determine if the GE plant is as safe as its conventional non-GM counterpart.

Laboratory Research

Green House Studies

Field Testing & Safety Assessment

Environmental Release & Commercial Cultivation

BROAD INFORMATION REQUIREMENTS FOR SAFETY ASSESSMENT OF GE PLANTS*

Effect of Genetic Modification and Protein Characterization

- Description of the GE plant
- Description of the biology of the non-modified host plant
- Description of the donor organism
- Description of the genetic modification
- Inheritance and stability of inserted gene(s)
- Molecular characterization
- Function/ specificity/ mode-of-action of expressed protein
- Protein expression levels
- History of safe use and consumption

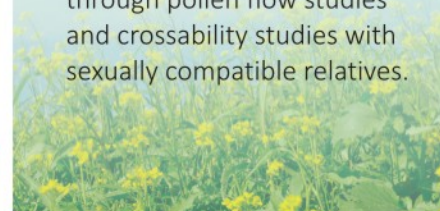
Food and Feed Safety

- Toxicity assessment by animal toxicity studies such as acute and sub-chronic studies.
- Assessment of allergenicity by comparing amino acid sequence homology of the newly expressed protein.
- Heat stability and susceptibility of the expressed protein to pepsin digestion.
- Compositional analysis by comparing changes in the level of key nutrients, natural toxicants or anti-nutrients, secondary metabolites, physiologically active (bioactive) substance etc.
- Livestock feeding studies.
- Effect of processing.



Environmental Safety

- Confirmation of expression level of new proteins: Quantify the expression level of the gene product associated with each introduced trait.
- Field trial locations and experimental designs.
- Description of the phenotype of the transformed plant.
- Plant growth and specific observations recorded during the field trials.
- Changes in weediness and aggressiveness potential.
- Susceptibility to diseases and pests.
- Impact on non-target and beneficial organisms like predators, soil micro flora etc.
- Changes in gene flow pattern through pollen flow studies and crossability studies with sexually compatible relatives.



* Govt. of India is following a case by case safety assessment of GE plants. The information requirement and analysis by regulatory authorities depends on the development stage of a particular product. Data requirement may also vary depending on the crop specific trait and intended use.

KEY FEATURES OF

OTHER APPLICABLE ACTS

Plant Quarantine (Regulation for Import into India) Order 2003¹ : Ministry of Agriculture

- Covers regulation of import of germplasm/ GMOs/ transgenic plant material for research purpose.
- National Bureau of Plant Genetic Resources (NBPGR) has been designated as the Competent Authority to issue import permits for import of seeds for research purposes after getting permission under Rules 1989 and to receive import material from customs authorities for quarantine inspection.
- All plant breeders and researchers intending to import seed/ planting material have to fulfill two mandatory requirements, i.e. (i) Import Permit before importing any material, and (ii) Phytosanitary certificate from country of origin.
- The suppliers of the transgenic material are required to certify that the transgenic material has the same genes as described in the permit and that these transgenic materials do not contain any embryogenesis deactivator gene sequence.

Biological Diversity Act, 2002² : National Biodiversity Authority

- Addresses issues of conservation, sustainable use of biological resources in the country, issue related to access to genetic resources and associated knowledge and fair and equitable sharing of benefits arising from utilization of biological resources to the country and its people.
- Regulates the use of biological resources including genes used for improving crops and livestock through genetic intervention.

- No person can obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization, without prior approval of National Biodiversity Authority.

The Food Safety and Standards Act, 2006³ : Food Safety and Standards Authority of India

- Regulates manufacture, storage, distribution, sale and import of food which includes GM food.
- The "genetically modified food" has been defined as the food, which is produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating or having adequate human intervention or both. Techniques of Genetic Engineering or modification include, but are not limited to recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion, addition and doubling.
- No person shall manufacture, process, export, import or sell genetically modified articles of food, organic foods, functional foods, nutraceuticals, health supplements etc. except in accordance with the regulations made there for under this Act.

The provisions of the Act relevant to GM foods are yet to be operationalized.

¹ <http://plantquarantineindia.nic.in/>

² <http://www.nbaindia.org/>

³ <http://www.fssai.gov.in/>

KEY FEATURES OF NATIONAL POLICIES

National Seeds Policy (2002): Ministry of Agriculture

- Transgenic crops/varieties are tested to determine their agronomic value for at least two seasons by ICAR before any variety is commercially released in the market.
- Performance of commercially release varieties are monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.
- Transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.
- All seeds imported into the country are required to be accompanied by a certificate from the Competent Authority of the exporting country regarding their transgenic character or otherwise.
- Packages containing transgenic seeds/planting materials carry a label indicating their transgenic nature including the agronomic/yield benefits, names of the transgenes and any relevant information.

Foreign Trade Policy (2006-09): Director General of Foreign Trade

- Import of GM Food, Feed, 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.
- 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.

National Environment Policy (2006): Ministry of Environment, Forest and Climate Change

- The regulatory processes for LMOs are reviewed so that all relevant scientific knowledge is taken into account, and ecological, health, and economic concerns are adequately addressed.
- The National Biosafety Guidelines, and Biosafety Operations Manual are reviewed to ensure that these are based on current scientific knowledge.
- Ensure the conservation of biodiversity and human health when dealing with LMOs in transboundary movement in a manner consistent with the Cartagena Protocol on Biosafety.
- Emphasizes on environmental education, awareness and information.

National Biotechnology Development Strategy (2014): Department of Biotechnology

- Establish Biotechnology Regulatory Authority of India through appropriate legislation.
- Improve existing Biotechnology Regulatory system based on RCGM and GEAC to make it scientifically strong, professionally competent, conflict free and transparent and backed by sound validation infrastructure.
- Provide training and re-training of regulatory professionals for regular and periodical skill up-gradation within the system.
- Strengthen guidelines and their implementation for commercialization decision by concerned Central/ State Ministries.
- Strengthen public communication through effective interface with print and electronic media.

RELEVANT APPLICATION FORMS FOR VARIOUS ACTIVITIES INVOLVING GE PLANTS

Specific application forms with information requirements have been prescribed by the regulatory committees for various activities and stages of the development process of GE plants. These forms can be accessed at <http://dbtbiosafety.nic.in> and <http://www.moef.gov.in>

IBSC Registration and Reporting

- Application for registration of an Institutional Biosafety Committee (IBSC) (Form A1).
- Application for renewal of IBSC (Form A2).
- Annual Report of the IBSC to RCGM (Form A3).
- Medical Surveillance Report (Form A4).
- Confidentiality agreement with IBSC members including DBT nominee (Form A5).

Import, Export, Transfer and Receive

- Application to RCGM for import of GMOs/LMOs and product(s) thereof for research and development purpose (Form B1).
- Application to RCGM for export of GMOs/LMOs and product(s) thereof for research and development purpose (Form B3).
- Application to RCGM for receiving GMOs/LMOs and product(s) thereof for research and development purpose within in India (Form B5).
- Application to RCGM for transfer of GMOs/LMOs and product(s) thereof for research and development purpose within India (Form B7).
- Application for Import of Food as LMO for Food/ Feed/Processing (Form III).
- Application for import of processed food/products derived from LMO/GMO (Form IV).

Activities involving Research and Safety Studies of GE Plants

- Information to RCGM to carry out research involving GMOs/LMOs for agricultural and environmental applications (Form D1).
- Application to RCGM for approval of biosafety protocols/studies for safety assessment of GMOs/LMOs for agricultural & environmental use (Form D3).
- Format for submission of safety studies of rDNA products of GMOs/LMOs for agricultural and environmental use (Form D5).

Conduct of Confined Field Trials of Regulated, GE Plants

- Application for confined field trial.

Environmental Release of GE Plants

- Application for Environmental Release of Transgenic Plants (Genetically Modified Plants) (Form IIB).



In India, the Ministry of Environment, Forest and Climate Change (MoEF & CC) promulgated the rules and procedures for the manufacture, import, use, research and release of GMOs as well as products made from such organisms in December, 1989 under the provisions of the Environment (Protection) Act, 1986. This umbrella legislation governing the GMO regulation is implemented through a series of biosafety guidelines and sectoral policies notified from time to time.

This brochure provides a comprehensive overview of the biosafety regulatory framework for GE plants in India with a view to facilitate easy understanding of the key provisions of various Acts, Rules, Guidelines and Sectoral Policies among various stakeholders.

This brochure is a part of the **Biosafety Resource Kit** prepared under the Phase II Capacity Building Project on Biosafety being implemented by the MoEF & CC.

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