In India, the Ministry of Environment, Forest and Climate Change (MoEFCC) 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 UNEP-GEF Phase II Capacity Building Project on Biosafety being implemented by the MoEFCC.

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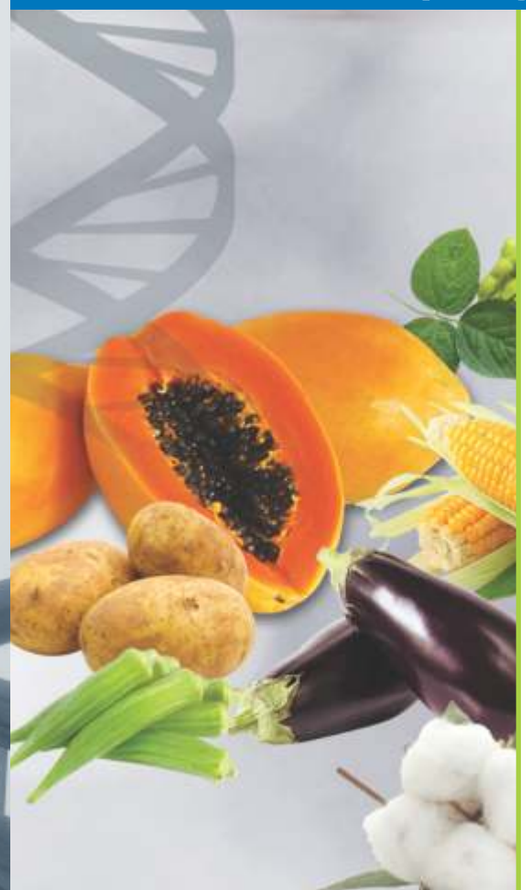


सत्यमेव जयते

REGULATORY FRAMEWORK
FOR GENETICALLY ENGINEERED PLANTS IN INDIA

Updated 2018

Phase-II Capacity Building Project on Biosafety

Ministry of Environment Forest and Climate Change

Ministry of Environment
Forest and Climate Change
Government of India

In association with

BCIL
Biotech Consortium India Limited
New Delhi

25 Convention on Biological Diversity

UNEP

gef

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 discussed on the need for regulating this technology in 1975 at a meeting in Asilomar, California and recommended voluntary guideline regarding cautious use.

In 1976, guidelines for laboratory work using genetic engineering (GE) techniques were issued by the US National Institute of Health followed by involvement of other regulatory offices to effectively regulate genetic engineering in USA.

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 that were useful as commercial products in healthcare and agriculture.

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.

Since 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.

Biosafety regulatory frameworks aim to ensure that safety of GE organisms is comparable to safety of conventional counterparts.

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 Environment (Protection) Act, (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 EPA, 1986.

In addition to these apex rules, provisions in other acts, rules and policies are also applicable to these organisms. These include:

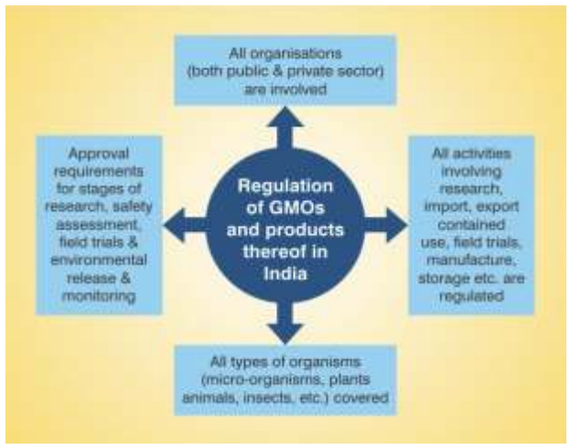
- Drugs and Cosmetics Rule (8th Amendment), 1988
- Biological Diversity Act, 2002
- Plant Quarantine Order, 2003
- Food Safety and Standards Act, 2006
- Directorate General of Foreign Trade (DGFT) Notification relating to inclusion of GM Policy in Foreign Trade Policy (2006-09)

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	• 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 Industries	• Enhance trade with other countries through export/import and 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

KEY FEATURES OF RULES 1989

1 Scope

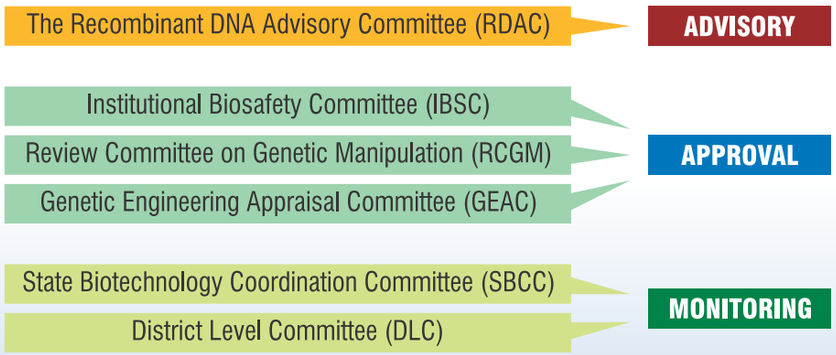
The Rules, 1989 are essentially cover entire spectrum
of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc. These
rules cover areas of research as well as large scale applications of GMOs and its products and apply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



- Manufacture, import and storage of micro-organisms and gene technological products
- Genetically engineered organisms/ microorganisms 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 (MoEFCC), 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.



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.

I Recombinant DNA Advisory Committee (RDAC)

- Functioning in DBT
- Reviews developments in biotechnology at national and international level and recommend suitable and appropriate safety regulations for India in recombinant DNA (rDNA) research, use and applications

II Institutional Biosafety Committee (IBSC)

- Mandatory for each organization involved in 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 regulatory manuals / guidelines.
- Serves as a nodal point for interfacing with other regulatory committees regarding ongoing research within the institutions.

III Review Committee on Genetic Manipulation (RCGM)

- Functioning in DBT
- Comprises of Members from DBT, Indian Council of Medical Research, Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR) 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 confined field trials at multi locations in an area of upto 1 acre per site.

IV Genetic Engineering Appraisal Committee (GEAC)

- Apex Regulatory Committee functioning in MoEFCC.
- Chaired by Special Secretary / Additional Secretary of MoEFCC 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 MoEFCC.
- Expert Members also include nominees of Director General, ICAR, 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 co-opts 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 experimental field trials.

V State Biotechnology Coordination Committee (SBCC)

- Set up in States wherever necessary
- Chaired by Chief Secretary of the State and comprises of Secretaries from the State Departments of Environment & Forest, Health, Agriculture, Industries and Commerce, Public Works, Chairman, State Pollution Control Board and Experts in the field of microbiology and pathology as Members. 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.
- Serves 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)

- Set up in districts wherever necessary
- 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 GM/ 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 MoEFCC 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.
- 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

MoEFCC 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:

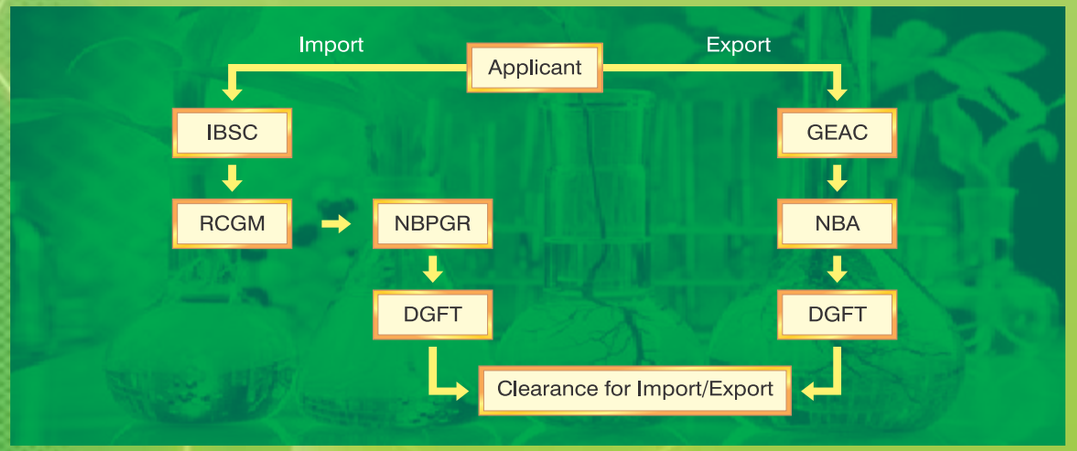
- Indigenous product development, manufacture and marketing of recombinant pharmaceuticals derived from organisms falling under Risk Group I & II.
- Import and marketing of products derived from LMOs as drugs/ pharmaceuticals in bulk and/ or finished formulations (therapeutic proteins) where the end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

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. 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://geacindia.gov.in/actf-and-rules.aspx

Procedure for Import/Export of GE Planting Material for Research Purpose



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

Grown in Bay of Containment

Laboratory Testing

Detection of transgene/Absence of terminator gene

Testing for seed transmitted viruses, fungi, bacteria EM/ELISA/RT-PCR/Incubation test

Joint Inspection
Entomology Nematology Pathology Virology Weed Science
Elimination of weeds, soil, plant debris, discoloured and deformed seeds, nematode galls, fungal fructifications, etc.

Polymerase Chain Reaction (PCR)

Harvest from Disease - free plants

Specialized Detection

Analysis and documentation of result

Released to indenters

Washing test Incubation test

Soaking Washing Staining

X ray radiography Seed transparency

Infested/ Infected material

Pest free material

Salveging hot water treatment X-ray radiography fumigation pestological treatment specialized treatment

Rejected and Inc Inerated

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

Applicant

IBSC
Forwarding applications for approval of RCGM

RCGM
Review of greenhouse/ lab research data, recommend conduct of confined field trials (event selection and BRL-I trials/ seed production) on the selected varieties/ hybrids and review and approve protocol for conducting biosafety studies

CCC
Visit field trial sites and inspect facilities to ensure compliance

GEAC
Approves conduct of confined field trials including BRL-II, seed production and review of safety of event in a given background

Stakeholder/ Expert consultation

Consideration for Environmental release or otherwise

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 received by ICAR 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. Guidelines have been issued for every step of development process of a GE plant.

Contained Research

rDNA Safety Guidelines, 2017 (updated from 1990)

- Provide guidance for R&D activities on GMOs, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research.
- The guidelines describe different categories of hazardous microorganisms, GE organisms or cells based on the level of associated risk.
- Appropriate containment measures necessary for safeguards in handling microorganisms, plants, animals, arthropods/insects and aquatic organism in various risk groups have been recommended.

Revised Guidelines for Research in Transgenic Plants, 1998

- Provide guidance for DNA research on plants including import and shipment of GE plants for research purpose.
- Include complete design of a contained green house suitable for conducting research with transgenic plants.
- For experiments on GE plants grouped under three categories
- Include appropriate containment measures.
- Also include information to be generated on biosafety aspects of the transgenic plants.

Confined Field Trials

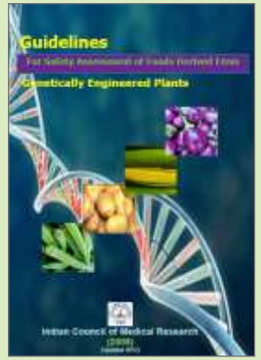
Guidelines & Standard Operating Procedures (SOPs) For Confined Field Trials (CFTs) of Regulated, Genetically Engineered (GE) Plants, 2008

- Provide guidance on conduct of CFTs 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.

Food Safety Assessment

Guidelines for the Safety Assessment of Foods Derived from 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.
- Protocols for Food and Feed Safety of GE plant 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



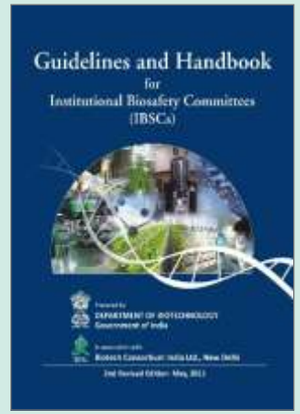
Environmental Safety Assessment

Guidelines for Environmental Risk Assessment of GE Plants, 2016

- Provide a comprehensive, transparent, and science-based framework by which regulators can identify potential harms and collect relevant scientific data pertaining to level of risk posed by GE plants.
- Scope of the guidelines has been defined and key definitions provided includes:
  - Instructions on data quality and sources of data.
  - Data requirements for ERA provided in detail.
  - Section on post release monitoring.

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.



BROAD INFORMATION REQUIREMENTS FOR SAFETY ASSESSMENT OF GE PLANTS*

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 CFTs with an objective to make a comparative assessment and determine if the GE plant is as safe as its conventional non-GM counterpart.

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 2003 : 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.
- 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, 2002 : 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.

Food Safety and Standards Act, 2006 : Food Safety and Standards Authority of India

- Regulates manufacture, storage, distribution, sale and import of food which includes GM food.
- The "genetically modified food" 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.

http://plantquarantineindia.nic.in/ http://www.nbaindia.org/ http://www.fssai.gov.in/

KEY FEATURES OF NATIONAL POLICIES

National Seeds Policy (2002): Ministry of Agriculture and Farmer's Welfare

- 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.
- 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) Research & Development (ii) Food (iii) Feed (iv) Processing in Bulk and (v) For Environment release will be governed by the provisions of the EPA, 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 (2015-2020): Department of Biotechnology

- Support regulatory system through process reforms.
- Facilitate safe processes by creation of infrastructure in the area of preclinical toxicology and clinical trial protocols
- Establish a toxicology centre for testing toxicity, safety and biological contaminants and adulterants in GM food
- Customized experimental resources in strategic locations across the country
- Efficient regulatory departments well versed with GCP, GMP and GLP.

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.

The forms for the following activities can be accessed at **http://geacindia.gov.in** and **http://dbtbiosafety.nic.in.**

- IBSC Registration and Reporting
- Import, Export, Transfer and Receive
- Activities involving Research and Safety Studies of GE Plants
- Conduct of Confined Field Trials of Regulated, GE Plants
- Environmental Release of GE Plants

GEAC has an e-application system for receiving and processing of applications under various categories. Applicants can submit the applications online, after registration.